Chapter 16
The Biological Weapons Convention in the Age of Synthetic Nucleic Acids

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Abstract This chapter examines whether and how the Biological Weapons Convention, UN Security Council Resolution 1540, and the Chemical Weapons Convention govern synthetic nucleic acids. Building on the rules of treaty interpretation, we demonstrate that synthetic nucleic acids fall within the scope of these international non-proliferation laws. We further argue that member states are obliged to adopt control measures, including with respect to synthetic nucleic acid. To this end, member states should adopt and implement synthesis screening procedures. This procedure requires synthetic nucleic acid providers to screen the sequences being ordered and the customers who are making the order. Synthesis screening as a method for preventing the proliferation of bioweapons is widely endorsed by the biosecurity community, including BWC member states. Moreover, it is compliant with BWC obligations as it enables effective control of transfers of, and access to, prohibited nucleic acids, without hampering peaceful uses. Finally, we make three recommendations regarding the implementation of synthesis screening under the BWC. First, explicit recognition that nucleic acid screening is consistent with BWC obligations. Second, integrating the topic into future BWC work through establishing a multi-stakeholder initiative for developing screening best practices. Third, harmonising international and domestic control measures governing synthetic nucleic acids.

Keywords Biological Weapons Convention · Synthetic Biology · Biosecurity · Nucleic Acid Synthesis · Gene Synthesis · Export Controls · Treaty Interpretation · Dual-Use Research · Biosafety · International Law · Nonproliferation

16.1 Introduction

Biological and toxin weapons are governed by three main international non-proliferation instruments: the 1975 Biological Weapons Convention (BWC),[1] the 1997 Chemical Weapons Convention (CWC),[2] and 2004 Security Council Resolution 1540 (SCR 1540),[3] (hereinafter referred to jointly as the "international non-proliferation instruments" or the "international instruments"). Scientific and technological developments have opened the door to the potential development of new types of, or new ways to produce, biological and toxin weapons (hereinafter referred to jointly as biological weapons) that were not envisaged when these instruments were adopted. Nucleic acid synthesis, often referred to as gene synthesis, is one such technology. It allows for the production of synthetic nucleic acid from digital sequence data and has become much more accessible and affordable in recent years, facilitating the acquisition of prohibited synthetic pathogens and toxins and the enhancement of biological agents to make them more suitable for use as weapons.[4] Thus, the urgent question that arises in the age of engineering biology is whether the international non-proliferation instruments are limited to "traditional" agents, or whether they also govern biological agents made from, or altered using, synthetic nucleic acids (synthetic agents).[5] If so, then core obligations from these instruments extend to include access to, and transfer and use of, synthetic nucleic acids.

Against this background, the purpose of this chapter is to determine whether and how gene synthesis falls within the scope of the international non-proliferation instruments, and what safeguarding obligations member states have in this respect. It concentrates primarily on the BWC and SCR 1540, and just briefly mentions the CWC.

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[1] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, opened for signature 10 April 1972, entered into force 26 March 1975, 1015 UNTS 163.

[2] Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, opened for signature 13 January 1993, entered into force 29 April 1997, 1974 UNTS 45. The Biological Weapons Convention and UN Security Council Resolution 1540 both cover biological and toxin weapons. The Chemical Weapons Convention explicitly covers toxins, which are also explicitly referenced in the title of the BWC. In this chapter we *do* consider the use of synthetic nucleic acids to make toxin weapons, we *do not* consider the use of biologically-mediated production of toxic chemicals (chemical weapons). This issue has been examined in the context of the CWC and further academic exploration and policy clarifications may be useful.

[3] There is also the 1925 Geneva Protocol which prohibits their use in war. We have not examined this treaty in depth as it would not be possible to use these weapons if they have not already been developed, produced, stockpiled or otherwise acquired—which are all effectively prohibited under the three instruments considered in this chapter.

[4] InterAcademy Partnership 2016, p. 15.

[5] National Academies of Sciences, Engineering, and Medicine 2018, p. 9.

16.2 International Non-Proliferation Instruments Govern Synthetic Nucleic Acids

In this section, building on international law on treaty interpretation, and other general principles of international law, we argue that synthetic nucleic acids fall within the scope of the international non-proliferation instruments and are governed by them.

Articles 31–32 of the Vienna Convention of the Law of Treaties (VCLT) set out the international rules on treaty interpretation. Article 31(1) determines that: "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." Thus, the BWC and CWC, both being international treaties, should be interpreted in accordance with their terms, in their context, and in light of their purpose. As we demonstrate next, the instruments' terms and purpose clearly indicate that synthetic nucleic acid falls within their scope.

Article 32 of the VCLT also establishes state practice as a supplementary means of interpretation. We show that the biosecurity community, which comprises stakeholders from a variety of sectors including governments, international organizations, non-governmental organizations, industry and scientific organizations, largely supports and endorses a screening procedure for synthetic gene providers (Sect. 16.5). Also, at BWC meetings, member states have frequently proposed screening as a desirable tool (Sect. 16.2). Many states have also embedded a need to control access to synthetic nucleic acids within their export controls and some in their domestic controls (Sect. 16.4). The broad endorsement of screening by the biosecurity community and member states may reflect state practice.

16.2.1 Application Regardless of "Origin or Method of Production"

Article I of the BWC and Article II (2) CWC expressly specify that the treaty's obligations apply to biological agents and toxins intended to be used as weapons, regardless of their "origin or method of production".[6,7] The text is open-ended and not limited to specific development, production, or acquisition pathways. This indicates

[6] Article I BWC: Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (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 conflict.

[7] Article II, Para 2 CWC: "Toxic Chemical" means: Any chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, *regardless of their origin or of their method of production*, and regardless of whether they are produced in facilities, in munitions or elsewhere. (For the purpose of implementing this Convention, toxic chemicals which have been identified for the application of verification measures are listed in Schedules contained in the Annex on Chemicals.).

that synthetic agents fall within the scope of the treaties. Moreover, the purpose of the treaties, as reflected in their preambles, is to "exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons."[8,9] Given this absolute goal, excluding synthetic agents from the treaty would contradict the treaty's purpose.

16.2.2 Review in Line with Scientific and Technological Developments

The international instruments provide that they must be evaluated on a regular basis to reflect scientific and technological advances. These requirements were included because the parties were aware of the impending biotechnology revolution when the treaties were negotiated.[10]

16.2.2.1 The Provisions

Article XII of the BWC determines that parties shall:

> review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention…such Review shall take into account any new scientific and technological developments….

Similarly, the CWC empowers the Annual Conference of States Parties to "[r]eview scientific and technological developments that could affect the operation of this Convention."[11]

Further, in their review of SCR 1540, Security Council Resolutions 2325 (2016) and 2633 (2022) called upon states to "take into account developments on the evolving nature of risk of proliferation and rapid advances in science and technology".[12,13]

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[8] Preamble Para 10 BWC: Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapon.

[9] Preamble Para 7 CWC: Determined for the sake of all mankind, to exclude completely the possibility of the use of chemical weapons, through the implementation of the provisions of this Convention, thereby complementing the obligations assumed under the Geneva Protocol of 1925.

[10] Sutton 2015, p. 697.

[11] Article VIII Part B Para 21(h) CWC: The Conference shall: (h) Review scientific and technological developments that could affect the operation of this Convention and, in this context, direct the Director-General to establish a Scientific Advisory Board to enable him, in the performance of his functions, to render specialized advice in areas of science and technology relevant to this Convention, to the Conference, the Executive Council or States Parties. The Scientific Advisory Board shall be composed of independent experts appointed in accordance with terms of reference adopted by the Conference

[12] UN Security Council Resolution 2325 2016, p. 4.

[13] UN Security Council Resolution 2663 2022, p. 4.

16.2.2.2 Review Conferences

Accordingly, during review conferences, member states have recognized that Article I of the BWC applies to scientific developments, including synthetic nucleic acid. In 2014, at the 7th BWC Review Conference, the Final Declaration expressly determined that "Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention."[14] During the Ninth BWC Review Conference in 2022, the BWC Implementation Support Unit provided a summary of understandings and agreements reached at previous review conferences which expressly noted that the BWC covered "biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production", including "synthetically produced analogues" of toxins.[15] Further, the necessity for screening has been explicitly addressed during other official meetings of the BWC, which we will address in Sect. 16.5.1.3.

Likewise, under the CWC, member states have addressed the relevance of biological synthesis of toxins, bioregulators, and replicating systems, including from synthetic nucleic acids. In 2011, the OPCW Director-General established a Technical Working Group on the Convergence of Chemistry and Biology. The group's mandate included "the use of biologically mediated techniques for the synthesis of toxic chemicals" and "chemical synthesis of agents of biological origin".[16] This group met four times between 2011 and 2013, discussing nucleic acid synthesis and its use in synthetic genomics, and concluding that "biomediated processes might still be effective for producing weaponisable quantities of toxins that are lethal to adult humans in microgram or lower dosage".[17]

Regarding the meaning of the term "production by synthesis" (under subparagraph 1(a) of Part IX of the CWC Verification Annex), the group concluded that the term should cover "any process designed for the formation of a chemical substance",[18] under which 'any process' would include nucleic acid synthesis and 'chemical substance' would include toxins. A similar statement was made by the OPCW Scientific Advisory Board, and the assertion was repeated when the Chair of the Scientific Advisory Board briefed the subsequent CWC review conference in 2018.[19]

[14] BWC 2012a, Part II Final Declaration, Article I, p. 10.

[15] BWC 2022, Part III Article I, Section B Additional Understandings and Agreements, p. 3.

[16] Organization for the Prohibition of Chemical Weapons 2014, pp. 13–17.

[17] Ibid, p. 3.

[18] Ibid, p. 4.

[19] Organization for the Prohibition of Chemical Weapons 2018, p. 2.

16.2.3 The Principle of Evolutionary Interpretation

The principle of evolutionary interpretation of treaties also indicates that synthetic nucleic acids fall within the scope of BWC Article I and the instruments more generally. This principle determines that international instruments often need to be interpreted in a way that is consistent with later technical developments. Evolutionary interpretations are particularly relevant when a term falls into one of the following categories: (1) the concept implies taking into account subsequent technical developments, (2) the concept sets up an obligation for further progressive development for the parties; or (3) the concept is expressed in such general terms that it must take into account changing circumstances.[20] All of these clearly apply to the term "microbial or other biological agents … whatever their origin or method of production".[21] The term implies the method for producing the relevant biological materials may change over time as technology evolves and is expressed in very broad terms.

16.2.4 The General Principle of Tech-Neutrality

Finally, a general principle of international law—the principle that international law is "technology neutral"—lends weight to our conclusion. The questions of whether and how international law applies to emerging technologies have been studied in a variety of other circumstances. International law is recognized as a technology-neutral system,[22] and adaptable to emerging technologies (unless expressly excluded). In other words, unless expressly excluded, international laws apply to both past and present technologies. The International Court of Justice (ICJ), in its Nuclear Weapons Advisory Opinion, recognizes this principle. It determined that international law on the use of force and international humanitarian law apply to all types of weapons, regardless of the technology underlying them.[23] In the case of biological or chemical weapons, the international non-proliferation instruments do not exclude certain technologies, and have expressly acknowledged the need for updates to reflect scientific and technological developments.

16.2.5 Conclusion to Sect. 16.2

Building on the general principle of tech-neutrality, as well as the principles and rules of treaty interpretation, synthetic nucleic acids are subject to and are governed by the international non-proliferation instruments. As SCR 1540's role is primarily

[20] International Law Commission 2006, p. 181.

[21] Article I BWC.

[22] Akande et al. 2022, p. 24.

[23] International Court of Justice 1996, pp. 38–39.

to expand the prohibitions of the BWC and CWC to prevent acquisition of these weapons by non-state actors, the same conclusion should logically follow.

16.3 State Obligations to Adopt Effective Control Measures

Above we have established that synthetic nucleic acids fall within the scope of the international instruments and that they are governed by them. In this section, we argue that, in accordance with specific obligations of the BWC (Articles III, IV, X), CWC (Articles I and VI) and SCR 1540 (Article XX), states have committed themselves to adopt and implement effective control measures to prevent the development, use, sale, and transfer of biological weapons by states and non-state actors. Accordingly, effective control measures to prohibit and prevent synthetic nucleic acids from being misused to make such weapons are consistent with a state's obligations under these international instruments. We outline these obligations in the following sections.

16.3.1 States Are Prohibited from Transferring Synthetic Nucleic Acids Destined to Be Used to Make Biological Weapons

Article III of the BWC determines that every state undertakes not to transfer biological weapons. It determines that member states:

> …undertakes *not to transfer to any recipient* whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I…

The 2022 compilation of past understandings and agreements included examples of "appropriate measures" for implementing Article III, including "effective national export controls" (called for by the Sixth, Seventh and Eighth Review Conferences) and "measures to control access to and handling" to "ensure that biological agents and toxins relevant to the Convention are protected and safeguarded" (Sixth Review Conference)."[24]

Similar obligations are found in the CWC. Article I contains an obligation "never under any circumstances… [t]o develop, produce, otherwise acquire, stockpile or retain chemical weapons, or transfer, directly or indirectly, chemical weapons to anyone".[25]

[24] BWC 2022, Part V Article III, Section B Additional Understandings and Agreements, p. 6.

[25] Article I Para 1(a) CWC: Each State Party to this Convention undertakes never under any circumstances: (a) To develop, produce, otherwise acquire, stockpile or retain chemical weapons, or transfer, directly or indirectly, chemical weapons to anyone.

Accordingly, states are under an obligation not to transfer to any recipient synthetic nucleic acid destined to be used to make biological weapons. In pursuit of these obligations, many states opt to control access to, and handling of, certain biological materials.

16.3.2 States Must Adopt "Any Necessary Measures"

BWC Article IV determines that in order to implement their obligations under the treaty, states must adopt "any necessary measures":

> each state party shall... take *any necessary measures* to prohibit and *prevent the development, production, stockpiling, acquisition, or retention* of agents, toxins, weapons, equipment and means of delivery specified in Article I…within the territory of such State, under its jurisdiction or under its control anywhere.

BWC States Parties have agreed that it is necessary to implement national measures "to exclude use of biological and toxin weapons in terrorist or criminal activity" (Fourth Review Conference) and, more generally, to prevent *anyone* from carrying out activities prohibited by the BWC (Seventh and Eighth Review Conferences). These include the adoption of "legislative, administrative, judicial and other measures, including penal legislation, designed to … ensure the prohibition and prevention of" prohibited activities (Sixth, Seventh and Eighth Review Conferences).[26] Accordingly, states should be considered as obligated to adopt any necessary measures to prevent the use of synthetic nucleic acids to make biological weapons by terrorists, criminals, or anyone else.

BWC meetings also acknowledged the need for synthetic nucleic acid control measures. For example, at a 2011 BWC meeting, the Implementation Support Unit wrote a Background Paper on relevant developments in science and technology. It highlighted that nucleic acid synthesis could potentially enable malicious actors to circumvent existing control mechanisms.[27] At that same meeting, the United Kingdom submission also highlighted that nucleic acid synthesis screening was relevant to implementing Article IV.[28]

Similar obligations are to be found in the CWC. Article VI includes an obligation to:

> adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, otherwise acquired, retained, transferred, or used within its territory or in any other place under its jurisdiction or control for purposes not prohibited under this Convention.[29]

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[26] BWC 2022, Part VI Article IV, Section B Additional Understandings and Agreements, p. 7.

[27] BWC 2011a, p. 4.

[28] BWC 2011b, pp. 21–38.

[29] Article VI Para 2 CWC: Each State Party shall adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, otherwise acquired, retained,

16.3.3 Principle of "Effective Measures" in the Preamble

The preamble of the BWC also highlights the role of control measures, stating that states are "determined to act…towards general and complete disarmament…through effective measures".[30]

Similarly, the preamble of the CWC states that Member States are "[d]etermined to act with a view to achieving effective progress towards general and complete disarmament under strict and effective international control, including the prohibition and elimination of all types of weapons of mass destruction".[31]

16.3.4 SCR 1540

Security Council Resolution 1540 more explicitly expands state obligations to activities by non-state actors. Article 2 determines that:

> ...all States, in accordance with their national procedures, shall adopt and enforce appropriate *effective laws which prohibit any non-State actor* to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery.[32]

Article 3 of the SCR1540 then lays out an obligation to adopt control measures, stating:

> ...all States *shall take and enforce effective measures to establish domestic controls* to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing *appropriate controls over related materials*…[33]

SCR 1540 lists specific control measures that states must adopt, though they are not limited to these controls. These include measures "to account for and secure such items in production, use, storage or transport", "develop effective border controls and law enforcement", and "effective national export and trans-shipment controls".[34] Article 6 also encourages states to develop effective national control lists.[35]

Accordingly, states must adopt control measures to prevent non-state actors from using synthetic nucleic acids for prohibited purposes.

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transferred, or used within its territory or in any other place under its jurisdiction or control for purposes not prohibited under this Convention.

[30] Preamble Para 2 BWC.

[31] Preamble Para 2 CWC.

[32] UN Security Council Resolution 1540 2004, p. 2.

[33] Ibid, p. 3.

[34] Ibid.

[35] Ibid.

16.3.5 Control Measures Must Not Hinder Peaceful Uses of Biology

While states have an obligation to implement control mechanisms, they also have a commitment to not unduly hinder the use of biological agents for peaceful purposes. This requirement is set out in all of the non-proliferation instruments: BWC Article X determines that the Convention shall be implemented in a "manner designed to *avoid hampering* the economic and technological development of State Parties… or international cooperation in the field of peaceful biological activities….including the international exchange of biological agents and toxins….for… use or production of biological agents and toxins for *peaceful purposes*…"[36] Likewise, CWC Article VI contains explicit obligations to avoid unnecessarily hampering the peaceful use of science and technology,[37] and UN Security Council Resolution 2663 (2022), reauthorizing SCR 1540, reaffirmed that "prevention of proliferation … should not hamper international cooperation in materials, equipment and technology for peaceful purposes".[38]

Thus, we conclude that effective control measures should be *designed* to make a reasonable distinction between prohibited and peaceful uses. Section 16.5 explains how and why synthesis screening meets this condition.

16.3.6 Conclusion to Sect. 16.3

To conclude, the BWC and SCR 1540 require states to restrict the transfer of synthetic agents destined to be used as weapons, as well as to prohibit and prevent the manufacture, development, sale, etc. of synthetic agents destined to be used as weapons. To this end, states adopt and implement control measures. Such control measures include, but are not limited to, export controls, access controls, handling controls, or any other necessary measures designed to prohibit and prevent use as a weapon. As previously stated, synthetic nucleic acids fall within the scope of the international instruments. As a result, we conclude that the control measures implemented by States Parties should also cover synthetic nucleic acids. However, such control measures should not hinder peaceful uses of the technology. As a result, control measures should be designed to reasonably distinguish between peaceful and non-peaceful usage. In Sect. 16.5, we explain how and why synthesis screening is an optimal procedure or tool for meeting these criteria.

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[36] Article X Para 2 BWC.

[37] Article VI Para 1 CWC: Each State Party has the right, subject to the provisions of this Convention, to develop, produce, otherwise acquire, retain, transfer and use toxic chemicals and their precursors for purposes not prohibited under this Convention.

[38] UN Security Council Resolution 2663 2022, p. 2.

16.4 State Practice Controlling Nucleic Acids

We have outlined the obligations of states to adopt and implement control measures. In this section, we examine whether and how states have implemented this obligation with respect to synthetic nucleic acids. The evidence for state practice comes from diverse sources, including reports from the SCR 1540 Committee,[39] and the Biological Weapons Convention National Implementation Measures Database maintained by UN Institute for Disarmament Research in partnership with the Verification Research, Training and Information Centre.[40]

Most relevant to the prevention of the misuse of synthetic nucleic acids are regulations regarding the transfer of biological materials. They include export controls, governing transfers of biological materials across borders, and domestic controls, governing transfers within a state's borders. Export controls are implemented through lists of controlled organisms and biological agents and toxins. Some states have opted to work collectively to harmonise their export controls, for example, through the Australia Group. As we demonstrate below, export control lists frequently include some forms of nucleic acids, whereas domestic transfer controls tend to be much more diverse in structure, and it is rarer for them to apply to nucleic acids. Thus, we argue that in accordance with their international obligations, this disparity should be corrected, with domestic controls extending to nucleic acids.

16.4.1 Export Controls and Synthetic Nucleic Acids

From our review of export regulations in states which we know have synthesis companies operating within their borders, *all* such states include nucleic acids in their export control lists. These include Australia,[41] Canada,[42] China,[43] all of the

[39] United Nations Security Council 1540 Committee. National Reports. https://www.un.org/en/sc/1540/national-implementation/national-reports.shtml. Accessed 19 November 2024.

[40] United Nations Institute for Disarmament Research, Verification Research, Training and Information Centre. Biological Weapons Convention National Implementation Measures Database. https://bwcimplementation.org/. Accessed 19 November 2024.

[41] Defence and Strategic Goods List 2024 (Commonwealth of Australia) Part 1, Category 1 at 1C351–1C354, 2B32(i) and 2D352.

[42] Export and Imports Permits Act RSC 1985 (Canada) c E-19, s 3(1); and A Guide to Canada's Export Controls 2023 at 5505, 7–12(10) and 7–13.

[43] Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies 2002 (China), Annex, Part I(1)-(3) and (5), and Part II(1)-(5) and (7).

European Union,[44] India,[45] Japan,[46] Singapore,[47] South Africa,[48] South Korea,[49] the United Kingdom,[50] and the United States.[51]

Most of these states, excluding China and South Africa, use identical wording to define the nucleic acid sequences that they govern:

> Any … genetic element that codes for, any of the following:
>
> (a) any gene or genes … specific to any listed virus; or
>
> (b) any gene or genes specific to any listed bacterium or fungus, and which
>
> (i) in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health, or
>
> (ii) could endow or enhance pathogenicity; or
>
> (c) any listed toxins or their sub-units.

The export control lists in China and South Africa, as well as other states such as Brazil and the United Arab Emirates, for example, each instead use wording that refers to "genetic elements that contain nucleic acid sequences associated with the pathogenicity" of the listed microorganisms".[52]

Regardless of whether they are members of the Australia Group or not, the 2022 Comprehensive Review of the implementation of SCR 1540 found that 40% of United Nations members have export control lists for biological materials.[53] It is therefore possible that up to 40% of BWC members already control the export of synthetic

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[44] Regulation 2021/821 of the European Parliament and of the Council [2021] OJ L206/1, art 4 and Annex I at 1C351, 1C353–1C354 and 2B352(i).

[45] India Trade Classification (ITC(HS)) Based Import and Export Policy 2018, Schedule 2, Appendix 3, Category 2 at 2H and 3D014–3D015.

[46] 輸出貿易管理令別表第一及び外国為替令別表の規定に基づき貨物又は技術を定める省令 1991 (Japan), art 2-2 [Ordinance of the Ministry Specifying Goods and Technologies Pursuant to Provisions of the Appended Table 1 of the Export Control Order and Appended Table of the Foreign Exchange Order].

[47] Strategic Goods (Control) Order 2023 (Singapore), Part 2, Division 1, Subdivision 7, cl 10 and Schedule at 1C351–1C354 and 2B352(i).

[48] Government Gazette No. R. 4978 of 14 June 2024 (South Africa), cl 3(b) and Annex A(IV).

[49] Foreign Trade Act 1996 (South Korea), arts 11, 19 and 23; and 전략물자수출입고시 2024 (South Korea), Appendix 2 at 1C353 [Public Notice on Trade of Strategic Items].

[50] Retained Dual-Use Regulation (EC) No 428/2009 (UK), art 3 and Annex 1 at 1C351–1C354.

[51] Code of Federal Regulations Title 15, chapter VII, subchapter C § 774.1 (Supp 1) at 1C351 and 1C353–1C354.

[52] Exact quote from Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies 2002, Annex, Part I(3). The wording for South Africa's export control list is almost identical, however, see: Government Gazette No. R. 4978 of 14 June 2024, Annex A(IV). As is the wording used for Brazil in Decreto nº 4.214, de 30.04.2002, from the Ministry of Science, Technology and Innovation which approves the update of the List of Goods Related to the Biological Area and Directly Linked Services. Similar wording for the United Arab Emirates is included in the list mentioned in the Cabinet Resolution No. 50 for 2020 concerning the control list annexed to Federal Law No. 13 for 2007 relating to commodities subjected to import and export control.

[53] UN Security Council 2022, p. 13.

nucleic acids. Although not the majority of states, this is a high proportion.[54] It is noteworthy that all states which we believe have operating synthetic nucleic acid producers within their borders already control the export of genetic materials. This practice indicates that synthetic nucleic acid export regulations are a common and important way to implement BWC Article IV and SCR 1540 Article 3(d) obligations.

16.4.2 Domestic Controls and Synthetic Nucleic Acids

Many states have domestic control lists as part of their biosafety and biosecurity regulations, which are intended to safeguard and preserve biosafety and biosecurity inside their jurisdiction. Some of these domestic control lists were developed to protect worker safety, while others were designed to fulfil disarmament obligations. Frequently, these regulations explicitly impose requirements on entities which transfer, manufacture, possess, use, handle, or transport regulated biological agents.

Domestic control lists differ from export control lists in that they often only include entire pathogens and do not specify nucleic acids. For example, synthetic nucleic acids are *not* explicitly included in the relevant lists in Australia,[55] China,[56] India,[57] Japan,[58] or South Korea.[59] In other cases the definitions in the legislation appear broad enough to include synthetic nucleic acids, but the relevant control lists do not actually include nucleic acids. This appears to be the case, for example, in

[54] Conducting a detailed assessment of all national export controls could be useful but was beyond the scope of this chapter.

[55] National Health Security Act 2007 (Commonwealth of Australia), ss 3, 31(1) and 35(1); and Security Sensitive Biological Agents Regulatory Scheme—Fact sheet 5—List of Security Sensitive Biological Agents 2016 (Commonwealth of Australia) at 2. In this footnote and all others addressing domestic controls, legislative provisions referenced include key obligations that might have applied to nucleic acid synthesis companies if the legislation covered synthetic nucleic acids, as well as the provisions that define the type of biological agent that the legislation covers.

[56] Ministry of Health (China) "Directory of Pathogenic Microorganisms Transmissible Between Humans" (11 January 2006), as cited in Longfei et al. 2007, pp. 57–58.

[57] Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells Rules 1989 (India), ss 3(v) and 7 and Schedule.

[58] 感染症の予防及び感染症の患者に対する医療に関する法律 1998 (Japan), arts 6, 56–15, 56–16, 56–18, 56–19 and 56–20 [Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases].

[59] Act on the Control of the Manufacture, Export and Import of Specific Chemical Substances and Biological Agents for the Prohibition of Chemical and Biological Weapons 2006 (South Korea), arts 2(8), 5-2, 11, 12 and 13-2; 화학무기 · 생물무기의 금지와 특정화학물질 · 생물작용제 등의 제조 · 수출입 규제 등에 관한 법률 시행 령 2024 (South Korea), Appendix 1 [Enforcement Decree of the Act on the Control of the Manufacture, Export and Import of Specific Chemical Substances and Biological Agents for the Prohibition of Chemical and Biological Weapons]; Infectious Disease Control and Prevention Act 2009, arts 2(9), 2(19) and 21-23; and 감염병의 예방 및 관리에 관한 법률 시행 규칙 2024 (South Korea), Appendices 1 and 4 [Enforcement Rule of the Act on the Prevention and Management of Infectious Diseases].

Canada,[60] Singapore,[61] and (once we individually include European countries known to have nucleic acid synthesis companies within their borders) Austria,[62] Germany,[63] Luxembourg,[64] Norway,[65] Portugal,[66] and Switzerland.[67]

Few states have expressly adopted domestic controls for synthetic nucleic acids. Perhaps the most well-known is the Select Agents and Toxins List in the United States.[68] In addition to whole pathogens, the list includes nucleic acids that "can

[60] Human Pathogens and Toxins Act SC 2009 (Canada), c 24, ss 3(1) and 7 and schedules 1–4; and see discussion in Hagen 2016.

[61] Biological Agents and Toxins Act 2005 (Singapore), ss 2, 6(1), 11(1), 15(1) and 20(3) and the First Schedule and Second Schedule.

[62] Verordnung der Bundesministerin für Arbeit, Gesundheit und Soziales über den Schutz der Arbeitnehmer/innen gegen Gefährdung durch biologische Arbeitsstoffe (Verordnung biologische Arbeitsstoffe—VbA), BGBl. II Nr. 237/1998 (Austria), ss 1(2), 2, 11 and Appendix 2 [Ordinance of the Federal Minister of Labour, Health and Social Affairs on the protection of employees against risks posed by biological agents (Ordinance on Biological Agents—VbA), Federal Law Gazette No. 237/1998]; and Bundesgesetz über Sicherheit und Gesundheitsschutz bei der Arbeit (ArbeitnehmerInnenschutzgesetz—ASchG) BGBl. Nr. 450/1994 (Austria), ss 2(6), 40(5) and 41–43 [Federal Act on Safety and Health at Work (Employee Protection Act—ASchG), Federal Law Gazette No. 450/1994].

[63] Infektionsschutzgesetz (IfSG) 2000 (Germany), ss 2(1) and 44 [Protection Against Infection Act]; and Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit Biologischen Arbeitsstoffen (Biostoffverordnung - BioStoffV) 2013 (Germany), ss 2(1)–(3), 15–16 and Annex II [Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (Biological Agents Ordinance—BioStoffV)]. However, note Annex II of the Ordinance references 1C353 (defining controlled genetic elements for export purposes) of Annex I of Regulation (EU) No. 388/2012 of the European Parliament and of the Council of 19 April 2012 for the purposes of some required protective measures.

[64] Règlement grand-ducal du 4 novembre 1994 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents biologiques au travail (Luxembourg), ss 2(a)–(b), 2(d), 13(1) and Annex III [Grand Ducal Regulation of November 4, 1994 concerning the protection of workers against the risks linked to exposure to biological agents at work]; and Règlement grand-ducal du 17 mars 2021 modifiant le règlement grand-ducal modifié du 4 novembre 1994 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents biologiques au travail (Luxembourg), art 2 [Grand-Ducal Regulation of 17 March 2021 amending the amended Grand-Ducal Regulation of 4 November 1994 concerning the protection of workers against risks related to exposure to biological agents at work].

[65] Work Environment Act of 2005 (Norway), s 5–4(1)(c) and (e); and Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents 2013 (Norway), ss 1–7, 6-1 and Annex 2.

[66] Decreto-Lei nº 84/97 de 16 de Abril 1997 (Portugal), ss 3(a)–(b) and 5 [Decree-Law No. 84/97, of 16 April 1997]; and Portaria nº 405/98, de 11 de julho, Annexes II–V [Decree No. 405/98, of July 11].

[67] Ordinance on the handling of organisms in contained systems 2012 (Switzerland), arts 3–5, 8–11, 15 and 26; Verordnung über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen 1999, arts 2–3, 4.6, 5–6 and 15 [Ordinance on the Protection of Workers against Microbiological Risks]; and Swiss Expert Committee for Biosafety (SECB). List of Officially Classified Organisms. https://www.ecogen.admin.ch/public/#/organisms. Accessed 11 January 2026.

[68] Federal Register Vol. 70:52, p. 13316.

produce infectious forms of any of the select agent viruses",[69] or "encode for the toxic form(s) of any of the toxins listed".[70] The U.S. Center for Disease Control and Prevention has clarified the meaning of the first phrase, stating that the list only covers sequences which are "inherently infectious and are immediate precursors to virus production", specifically those which can generate infectious virus within a host without assistance from "exogenous factors".[71]

Examples of other states whose domestic control lists also include synthetic nucleic acids are Denmark, Hungary, the United Kingdom, France, and South Africa.

Denmark and Hungary directly implement their export control lists (which cover nucleic acids) in their domestic control lists. Both countries' export controls come from the European Union Regulation 2021/821, which includes synthetic nucleic acids through the wording covered in Sect. 16.4.1.[72]

Denmark's 2008 "Act on Securing Specific Biological Substances, Delivery Systems and Related Materials" allows regulation of the "possession, production, storage, purchase, sale and any other form of transfer … of biological substances …" included any European Union dual-use regulation.[73] The regulation created under this Act, the 2009 "Executive Order on securing specific biological substances, delivery systems and related materials", requires a permit for actions specified in the Act.[74] However, the Order appears to use different wording than the new EU dual-use regulation, referring to sequences "associated with the pathogenicity" of the listed organisms.[75]

Similarly, Hungary's amended Government Decree 21/2013 on the "Implementation of Reporting Obligations and Control Procedures under the Convention on the Prohibition of the Development, Production, and Storage of Bacteriological (Biological) and Toxin Weapons and on Their Destruction" directly incorporates the EU 2021 regulation's organism lists, including its definition of controlled nucleic acids.[76] This

[69] Ibid § 73.3(c)(1).

[70] Ibid § 73.3(c)(2).

[71] US Centers for Disease Control and Prevention, US Animal and Plant Health Inspection Service 2020, p. 6.

[72] Regulation 2021/821 of the European Parliament and of the Council [2021] OJ L206/1, art 4 and Annex I at 1C351, 1C353-1C354 and 2B352(i).

[73] Lov om sikring af visse biologiske stoffer, fremføringsmidler og relateret materiale (LOV nr 474 af 17/06/2008) (Denmark), s 1 [Act on Securing Specific Biological Substances, Delivery Systems and Related Materials (Act No. 474 of 17 June 2008)].

[74] Bekendtgørelse om sikring af visse biologiske stoffer, fremføringsmidler og relateret materiale (BEK nr 981 af 15/10/2009), s 4 [Executive Order on the security of certain biological substances, delivery vehicles and related material (Executive Order No. 981 of 15 October 2009)].

[75] Ibid, Annex 1.

[76] 21/2013 (I. 30.) Korm. rendelet a bakteriológiai (biológiai) és toxin-fegyverek kifejlesztésének, előállításának és tárolásának megtiltásáról és e fegyverek megsemmisítéséről szóló egyezményből eredő nyilatkozattételi kötelezettségek végrehajtásáról és az ellenőrzés rendjéről (Hungary), s 1(1) [Government Decree 21/2013 on the Implementation of Reporting Obligations and Control Procedures under the Convention on the Prohibition of the Development, Production, and Storage of Bacteriological (Biological) and Toxin Weapons and on Their Destruction].

Decree requires entities that manufacture, store, use or transfer within the EU any controlled organism to notify the Government Office of this fact.[77]

Further, the United Kingdom's Anti-terrorism, Crime and Security Act 2001 creates a duty to notify the Secretary of State before "keeping or using" any pathogen or toxin included in the Schedule 5 list of "dangerous substances".[78] Schedule 5 of the Act clearly includes synthetic nucleic acids, stating that:

> Any reference in this Schedule to a micro-organism includes:
>
> (c) any nucleic acid deriving from a micro-organism listed in this Schedule (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious or replication competent forms of any of the listed micro-organisms;
>
> (d) any nucleic acid sequence derived from the micro-organism which when inserted into any other living organism alters or enhances that organism's ability to cause serious harm to human health.
>
> …
>
> Any reference in this Schedule to a toxin includes:
>
> (a) any nucleic acid sequence coding for the toxin, and …

In France, the Public Health Code, article L5139-2 prohibits the production and transport (as well as the export and import) of listed pathogens without permission. The Order of April 26, 2023 sets out the pathogen lists, and states that where the list includes viruses it also includes sequences from that virus above 800 base pairs in length or which encode over 75% of the amino acid sequence of a protein of that virus. Sequences above 800 base pairs which form part of a short list of identified dangerous or toxin-encoding bacterial genes are also regulated.[79]

In South Africa the 1993 "Non-Proliferation of Weapons of Mass Destruction Act" permits the Minister of Trade, Industry and Competition to require a declaration to the South African Council for the Non-Proliferation of Weapons of Mass Destruction before the "manufacture, …, use, … transport, import, export, transit or re-export" of listed controlled goods.[80] The regulation created under this Act creates such a declaration requirement for the "transport" of listed controlled goods.[81] Nucleic acids are covered by the control list under the definition of "genetically modified micro-organisms", which is the same control list referenced in Sect. 16.4.1 that governs South Africa's export controls.[82]

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[77] Ibid, s 3(1).

[78] Anti-terrorism, Crime and Security Act 2001 (UK), ss 58 and 59(1).

[79] Arrêté du 26 avril 2023 fixant la liste des micro-organismes et toxines prévue à l'article L. 5139-1 du code de la santé publique (France), Annex A, 2° [Order of April 26, 2023 establishing the list of microorganisms and toxins provided for in article L. 5139-1 of the public health code].

[80] Non-Proliferation of Weapons of Mass Destruction Act 1993 (South Africa), s 13(2)(d).

[81] Government Gazette No. R. 4978 of 14 June 2024 (South Africa), cl 3(d).

[82] Ibid, Annex A(IV).

16.4.3 Conclusion to Sect. 16.4

Our review of state practice indicates that many states have adopted export control regulations whose control lists cover synthetic nucleic acids, although most domestic control lists remain limited to "traditional" agents and have not been updated to reflect the developments of synthetic biology. There are a few exceptions, particularly in the US and other European countries. This disparity is unjustified, given that synthetic nucleic acids can be misused within and outside a country's borders. States should adapt and amend their domestic control regulations and lists to include synthetic nucleic acids.

16.5 Synthesis Screening as an Effective Control Measure

Given the obligations discussed above, to be effective control measures must manage the risks of synthetic nucleic acids being used to make weapons while not hampering their use for peaceful and other permitted purposes.

As it is unlikely that a malicious actor will openly state that synthetic nucleic acids being acquired are destined for use in a weapon, and it is the specific use that is prohibited under international law and not the material itself, some proxy for malign intent is needed. Use of a proxy for intent is consistent with the export and domestic controls discussed in the last section. In practice, these controls effectively use a combination of what is being accessed and who is accessing it as a proxy for intent.

Use of a proxy for intent may be inconsistent with a possible narrow interpretation of BWC Article I, which refers to biological agents that have "no justification for … peaceful purposes". Such a 'minimalist' interpretation would hold that if there is any such justification, however minor, for acquiring the material then it is not a biological weapon under Article I, and so is not governed by Article IV obligations to prevent access but rather Article X obligations to promote access. Raxter's analysis of how dual-use research of concern is regulated by BWC member states shows that states in fact "weigh the benefits of the research against the potential costs of accident or misuse, and apply extra regulatory measures accordingly".[83]

State practice, such as that identified by Raxter and the access controls identified in Sect. 16.4 of this chapter, is a key source for treaty interpretation under Articles 31(3)(b) and 32 of the VCLT. In our view, it demonstrates that the correct interpretation of BWC Article I allows states to use a proxy for malign intent in their regulations of biological materials, rather than the 'minimalist' interpretation.

Returning to control of synthetic nucleic acids, it has become common practice to consider what is being ordered and by whom. By considering what is being ordered, it is possible to identify orders that might be more readily misused to make weapons. By considering who is doing the ordering, it is possible to identify customers that might be more likely to misuse these materials to make weapons. Screening procedures

[83] Raxter 2021, p. 129.

triage the large number of orders for synthetic nucleic acids and allow a small subset to be subjected to more careful review. By reducing the number of orders subjected to such scrutiny, gene synthesis screening helps limit any hampering of peaceful uses.

Commonly, a more detailed review of flagged orders will help reassure those responsible for making such decisions, that the order is not likely to be destined for use in making weapons. In most cases, it will become clear that there is a likely permitted use for the materials. These orders will be completed without delay. By providing a structured approach to resolve concerns over orders that might be destined for prohibited uses, or not, gene synthesis screening helps bring into alignment non-proliferation and peaceful use obligations.

In a few cases, there will be orders that should be legitimately denied. Such orders might not be consistent with international law. There are materials which should not be widely accessible, for example, smallpox research is highly regulated with strict international oversight and access to large fragments of its genome is restricted. Equally, there are individuals and groups that would not be permitted to access hazardous biological materials, for example, those subject to certain measures imposed by the United Nations Security Council. In other cases, orders may be inconsistent with national law, for example, sensitive materials subject to export restrictions, or in line with national sanction regimes. In some cases, it is the gene synthesis provider themselves left to decide whether the order is legitimate and whether they are prepared to accept it. In effect, these service providers decide what they are permitted to sell and to whom. By identifying a small subset of orders to subject to greater scrutiny, gene synthesis screening helps raise obstacles in the path of those intent on using these materials to cause harm.

In the absence of a screening procedure to triage orders, acquisition of synthetic nucleic acids either proceeds without due consideration as to the risk they are destined to be used to make weapons (which would be inconsistent with the obligation to prohibit and prevent such activities), or on the assumption that all orders of synthetic nucleic acids are destined to be used to make weapons and are prohibited, restricted, or controlled (which would be inconsistent with the obligation not to unduly hamper access for peaceful purposes). In effect, gene synthesis screening is how to manage the competing obligations discussed in Sect. 16.3.

16.5.1 Emerging Synthesis Screening Practices

16.5.1.1 International Voluntary Industry Standards

There is a long history of voluntary standards within the international industry that has established practices for synthesis screening, resulting in international voluntary private standards. In 2009, two industry groups released screening practices. The International Association Synthetic Biology (IASB) released a “Code of Conduct for

Best Practices in Gene Synthesis",[84] and the International Gene Synthesis Consortium (IGSC) released a "Harmonized Screening Protocol".[85] Both included provisions for sequence screening, customer screening, record-keeping, and cooperation with national authorities if suspicious activity was suspected. The number of synthesis providers operating under the IASB code of conduct is unknown, though several were interviewed in a 2015 report.[86] The IGSC maintains a formal roster that currently includes 34 members in 9 countries, though not all members are synthesis companies bound by the screening protocol.

16.5.1.2 National Frameworks

As previously stated, export and some domestic controls limit the transfer of listed synthetic nucleic acids. To comply with the restrictions in practice, providers of synthetic nucleic acid would have to screen orders. For example, to determine whether an export license is required, orders must be screened to determine whether they contain a controlled sequence (i.e. sequence screening) and customer data must be collected to determine whether they are in a different country from the synthesis company (i.e. customer screening). However, with the exception of the United States (which we address next), most governments have not issued screening guidelines that specify how to screen orders.

In 2010, the U.S. Department of Health and Human Services (HHS) issued a "Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids".[87] It was designed to assist companies in conforming with U.S. regulations of nucleic acid transfers, specifically the Commerce Control List and Select Agents and Toxins List. With increased concerns about the risks associated with this technology, there has been a renewed emphasis on the necessity of screening. Thus, in 2023 the HHS released an updated version,[88] setting forth updated screening practices that addressed some of the shortcomings of the earlier guidelines.

Moreover, in 2023, the White House issued the "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence". It includes provisions for establishing a framework under Section 4.4(b)(ii) to "encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms".[89]

The resulting U.S. Framework for Nucleic Acid Synthesis Screening[90] requires that researchers receiving funds from the U.S. government only order synthetic nucleic acids from providers who perform synthesis screening. Being limited to

[84] International Association for Synthetic Biology 2009.

[85] International Gene Synthesis Consortium 2017.

[86] Carter and Friedman 2015, p. 13.

[87] U.S. Department of Health & Human Services 2010.

[88] U.S. Department of Health & Human Services 2023.

[89] White House 2023.

[90] White House 2024.

those who receive federal funding, this is not a comprehensive legal requirement, but it does create a strong economic incentive to implement screening systems,[91] for two reasons. First, U.S. government funds are not only issued to researchers located in the United States. Second, synthesis companies around the world supply synthetic nucleic acids to U.S.-funded researchers.

Other recent screening initiatives include a report by the National Security Commission on Emerging Biotechnology,[92] and a Securing Gene Synthesis Bill which has been brought before Congress.[93]

Other countries are increasingly recognizing the need to issue screening guidance. In the United Kingdom, the Department for Science, Innovation and Technology published screening guidance on synthetic nucleic acids for users and providers in October 2024.[94] Also in 2024, reports in Norway,[95] and the EU,[96] recommended expansion of synthesis screening through regulation or liability incentives.

16.5.1.3 BWC Meetings

The BWC has included nucleic acid synthesis screening in its official work schedule, and member nations have discussed the issue at various BWC meetings since 2009.

A background document for the 2009 Meeting of Experts mentions two presentations related to the development of screening protocols for synthesis companies.[97] It argues, "[w]hilst there seems to be an almost industry wide acceptance that screening of orders will be necessary, there emerged two competing views over how to approach screening." The document summarises approaches by the International Association of Synthetic Biology (IASB) and the International Gene Synthesis Consortium (IGSC), which both included sequence and customer screening, but differed as to whether screening could be a fully automated process or required expert human review.

At the 7th BWC Review Conference in 2011, which addressed scientific and technological developments, Germany made a submission regarding screening practices, stating that they were adopted to prevent development of biological weapons. It described IASB and IGSC screening practices and noted that US screening guidance was "in line with the IASB Code and the IGSC Protocol". It concluded that existing German legislation on genetic engineering, based on Directive 2009/41/EC of the European Parliament, was already sufficient to deter actors seeking to develop biological weapons.[98]

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[91] Diggans and Leproust 2019.

[92] US National Security Commission on Emerging Biotechnology 2024.

[93] Markey 2023.

[94] UK Department for Science, Innovation and Technology 2024.

[95] Langsikt 2024.

[96] Graabak et al. 2024.

[97] BWC 2009, p. 4.

[98] BWC 2011b, pp. 9–10.

BWC states collectively reached by consensus a common understanding on the need to balance access to nucleic acid synthesis for peaceful purposes, while also controlling it to prevent prohibited activities. The Report of the 2012 Meeting of States Parties noted:

> States Parties identified opportunities for maximising benefits from these enabling technologies while minimizing risks of their application for prohibited purposes, including, for example, supporting … the beneficial applications of gene synthesis technologies while ensuring their use is fully consistent with the peaceful object and purpose of the Convention.[99]

At the same meeting, a Working Paper from the Non-Aligned Movement, representing 127 States Parties to the treaty, noted with regards to synthetic biology, and its underlying technologies:

> There is a need to regulate these activities, to ensure that they do not lead to any concerns related to ethics, safety and security as well as any uses contrary to the Convention… Such regulation must, however, be undertaken in a manner that does not hamper scientific and technological developments that are in keeping with the spirit and letter of the Convention, which are of benefit, more especially to developing countries.[100]

During the 2015 BWC Meeting of Experts, the Islamic Republic of Iran recalled "developments in enabling technologies including high throughput systems for sequencing, synthesizing and analyzing DNA … should provide opportunities for enhanced cooperation and making vaccines, medicines and diagnostics production simpler, faster, cheaper and more efficient in developing countries".[101] They further emphasised that "new developments in the field of science and technology related to the Convention shall, in no way, be the pretext to impose any trade limitations (sanctions) or hamper the economic or technological development of the States Parties".[102]

Several states picked up the issue of risks from nucleic acid synthesis and how to govern them during the sessions of the 2018 Meeting of Experts dedicated to reviewing advances in science and technology. For example, Australia noted in its Working Paper on advances in genome editing that risks from synthetic biology might be managed "by careful regulation of materials, including the distribution of synthetic DNA and methods for generating novel organisms".[103]

In its Working Paper on gene editing, the United States noted:

> The capability to chemically synthesize or genetically engineer viruses poses biosecurity risks and should serve as a strategic warning to BWC States Parties that biosecurity controls and preparedness—that rely primarily on controlling access to dangerous, existing pathogens—may be insufficient… Given that gene synthesis is performed by an array of international companies, and benefits legitimate research in many BWC State Parties, achieving greater safety and security around it will require discussions at international fora.[104]

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[99] BWC 2012b, p. 7.

[100] BWC 2018b, p. 3.

[101] BWC 2015, p. 2.

[102] Ibid.

[103] BWC 2018a, p. 4.

[104] United States of America 2018, pp. 5–6.

Also, the submission from the United Kingdom reviewed technical progress in peptide synthesis and considered parallels with nucleic acid synthesis screening.[105]

16.5.1.4 Other International Guidelines

Beyond the BWC, several other international groups and bodies have developed and promoted guidance around synthesis screening. Notable examples are the:

- 2022 WHO Guidance Framework for the Responsible Use of the Life Sciences. It includes a scenario in which synthetic nucleic acids, ordered from a provider who is not a member of the IGSC, are used to produce a chimeric virus, and highlights how biosafety and biosecurity risks could have been avoided if the synthesis company had screened the order.[106]
- 2024 Responsible Development of AI for Protein Design Principles. These scientist-led community principles include a commitment from signatories to obtain synthesis services only from providers with industry-standard screening practices.[107]
- ISO 20688-2 Biotechnology—Nucleic Acid Synthesis Standard. In March 2024 ISO issued this standard. While it focuses on product quality control for synthetic nucleic acids, a section on biosafety and biosecurity states that "all DNA producers should use a sequence screening mechanism to evaluate ordered sequences".[108] If the sequence screening mechanism flags an order, the standard outlines what a DNA producer should do before fulfilling it, including obtaining a written description of how the customer intends to use pathogen or toxin sequences, confirming that the customer has appropriate biosafety and biosecurity controls, and reviewing the customer's institutional affiliation or research history to establish that the products will be used for legitimate purposes.

16.5.1.5 Nucleic Acid Synthesis Screening Tool Providers

According to the Center for Health Security at John Hopkins University there are six tools currently available for screening nucleic acid synthesis:[109]

- Aclid
- Batelle: UltraSEQ
- IBBIS: Common Mechanism

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[105] United Kingdom 2018, pp. 4–5, pp. 13–14.

[106] World Health Organization 2022, pp. 131–141.

[107] Acevedo-Rocha et al. 2024.

[108] ISO 2024.

[109] Center for Health Security. List of Companies and Available Tools to Assist Providers and Manufacturers in Screening Orders. https://genesynthesisscreening.centerforhealthsecurity.org/for-providers-benchtop-manufacturers/list-of-companies-and-available-tools-to-assist-in-screening-orders. Accessed 19 November 2024.

- NCBI: BLAST
- RTX BBN Technologies: FAST-NA Scanner
- SecureDNA

For example, the International Biosecurity and Biosafety Initiative for Science (IBBIS) launched the Common Mechanism in 2004. This is a free tool intended to act as a globally accessible baseline for sequence screening,[110] and additional tools to support customer screening are being developed.[111] IBBIS intends to act as a home for international efforts to update screening practices as science advances, and to facilitate the inclusion of international stakeholders in standards development efforts.

16.5.2 Conclusion to Sect. 16.5

To conclude, nucleic acid synthesis screening is broadly supported by the biosecurity community, which includes many BWC member states. In fact, member states have highlighted this tool at BWC meetings. This suggests that synthesis screening can be an important control measure for preventing the production and use of bioweapons. Furthermore, screening is a technique that allows for the distinction between peaceful and forbidden applications, and so is consistent with the BWC, including the need to adopt control measures which do not hinder peaceful uses of the technology. Thus, to meet their commitments under the BWC, governments should adopt or implement screening guidelines for both export and domestic control.

16.6 Implementing Synthesis Screening Under the Biological Weapons Convention

Three key findings from this chapter provide foundations for further action under the BWC. First, States Parties have reached additional agreements on implementing treaty obligations, but none have specifically addressed nucleic acid synthesis screening. This should be corrected at the next review conference. Second, States Parties need to build a common understanding of how synthesis screening can be implemented as an effective control measure. Such technical work could be included in the next intersessional BWC work programme. Third, we highlighted how international transfers of synthetic nucleic acids are often governed differently than domestic transfers. These rules should be harmonised.

[110] Wheeler et al. 2024.

[111] Alexanian and Carter 2024.

16.6.1 Make a Statement Under the BWC on Synthetic Nucleic Acids

BWC States Parties have used past review conferences to capture additional understandings on obligations in the treaty text. For example, above we showed how review conference agreements provided additional context for Articles I, III, IV, and X.

We have also recalled important collective and individual contributions made by States Parties to recognise that the BWC covers nucleic acid synthesis and that screening can be a useful tool in implementing treaty obligations. These statements, made during official BWC work, come from a variety of states with different backgrounds, views, and priorities. These views enjoy support in the biosecurity community. This suggests a broad consensus already exists and the next review conference only needs to capture it.

At the next review conference, States Parties should capture a consensus agreement on nucleic acid synthesis and screening. If States Parties return to past practice and include a Final Declaration, such an agreement could be captured in sections on Article IV and Article X, perhaps repeating the same text in both places.

There are examples of additional agreements on specific approaches and measures useful for implementing the BWC, including on biosafety and biosecurity,[112] education and awareness raising,[113] and disease surveillance and detection.[114] Using these past examples, States Parties could, for example, agree that:

> The Conference calls upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to ensure those developing, producing, transferring domestically or internationally, or stockpiling synthetic nucleic acids which could be used for purposes prohibited by the Convention screen such orders to prohibit and prevent the development, production, stockpiling, acquisition, or retention of agents, toxins, weapons, equipment and means of delivery specified in Article I, while avoiding restrictions and/or limitations on transfers for purposes consistent with the objectives and provisions of the Convention of scientific knowledge, technology, equipment and materials under Article X.

To reduce potential confusion, it is important for States Parties to capture this agreement within the report from the next review conference. If States Parties adopt the approach from the Ninth Review Conference and do not include a Final Declaration, an additional agreement similar to the one proposed should be included somewhere, perhaps to introduce how this issue will be addressed in the next intersessional work program.

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[112] BWC 2022, paras 40–41.

[113] Ibid, paras 42–48.

[114] Ibid, para 49.

16.6.2 Provide a Forum for International Collaboration on Synthesis Screening

While there seems to be broad consensus that the BWC covers synthetically-produced biological agents, and on the value of screening orders and customers for Article IV and X obligations, there is likely less agreement as to what screening measures should look like in practice. Additional consideration under the BWC will be needed to find existing common understandings on details associated with these control measures. These might be included in any work programme agreed at the next review conference:

- If states agree on specific topics for consideration in a given year, nucleic acid synthesis and screening should be included as a stand-alone topic;
- If states agree on clusters of activities around different obligations under the BWC, such areas as developments in science and technology, national implementation, cooperation and assistance, then facets of nucleic acid synthesis and screening could be integrated into each theme;
- If states agree on individual working groups to tackle specific issues, then nucleic acid synthesis and screening could be the focus of one such working group as it is comprehensive in scope (given it inherently requires balancing Article IV and Article X obligations); and

If states establish new standing bodies, such as on cooperation and assistance or developments in science and technology, these bodies could be tasked with considering relevant facets of nucleic acid synthesis and screening.

Whichever model States Parties adopt, it is important that the BWC takes an inclusive approach, enabling a multistakeholder partnership among states, industry, NGOs, and the science and technology community to capture good practice and develop standards.

16.6.3 Harmonize Control Measures to Cover Synthetic Nucleic Acids

The potential misuse of synthetic nucleic acids can happen both across and within borders. Consequently, both export and domestic controls of biological agents and toxins should cover nucleic acids. Screening what is being ordered and by whom is useful for all orders, regardless of whether they are being transferred domestically or internationally.

Above we showed that states with export controls for biological agents and toxins often include ‘genetic elements’. However, domestic transfer controls for similar agents and toxins often do not cover ‘genetic elements’, or might be interpreted to include nucleic acids, but make no explicit mention of them. We further noted that many companies that provide synthetic nucleic acids, such as members of the

IGSC, are already screening all orders and could readily comply with rules requiring synthesis screening.

If BWC States Parties were to reach an agreement on nucleic acid synthesis and screening:

- At minimum, they should capture the need to cover both international and domestic transfers. For example, in the text we proposed in Sect. 16.6.1, we specifically reference both domestic and international transfers.
- A more ambitious approach would recognize the value of expanding domestic transfer controls to capture synthetic nucleic acids using terms similar to those found in export controls, for example, by including "genetic elements that contain nucleic acid sequences associated with the pathogenicity" or "Any genetic element that codes for any of the following: (1) any gene or genes specific to any listed virus; or (2) any gene or genes specific to any listed bacterium or fungus, and which: (a) in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health, or (b) could endow or enhance pathogenicity; or (3) any listed toxins or their sub-units."
- Ideally, States Parties would go beyond simply adding genetic elements to current pathogen-based control lists, which have well-documented shortcomings.[115] Instead, they could begin working on systems which capture biological functions of concern. While more technically demanding initially, such an approach could help futureproof sequence screening and build robustness against AI-led circumvention.

Rules governing international and domestic transfers of relevant biological agents and toxins are traditionally a national prerogative. National measures can be more readily tailored to specific needs and adapted for national contexts. As a result, we are not proposing that the BWC develop a model for national nucleic acid synthesis screening requirements. Rather, we propose that states collectively agree to work nationally to harmonise relevant control measures, and that the BWC provide a forum to exchange information on national experiences. States Parties could share questions they needed to answer, challenges faced, and how they overcame them. Such an exchange could lead, in the future, to a common understanding on which approaches are most likely to result in effective action. It could also lay foundations for technical discussions, for example, on how to describe what is being controlled to avoid unduly hampering the peaceful use of synthetic nucleic acids.

16.7 Conclusion

In the age of biological engineering, the question arises as to whether and how international non-proliferation instruments apply to synthetic nucleic acid. The purpose of this chapter has been to answer this question.

[115] Millett et al. 2023

Based on international treaty interpretation rules, we have demonstrated that synthetic nucleic acid falls within the scope of the Biological Weapons Convention, Chemical Weapons Convention, and UN Security Council Resolution 1540. States must adopt and implement control measures to prevent the transfer, development, use or manufacture of synthetic nucleic acids for prohibited purposes by governments or non-state actors. Drawing on state practice and member state positions at BWC and at other meetings and processes, the majority of member states endorse the necessity of governing synthesized nucleic acids. Accordingly, to comply with their international obligations, states should require screening and adopt screening procedures for both export and domestic controls. Synthesis screening, if adequately designed and implemented, is entirely consistent with the BWC, as it does not intrinsically prevent peaceful uses.

To further screening of nucleic acid synthesis, we recommend that states (1) explicitly agree that adopting nucleic acid screening requirements is consistent with BWC obligations and integrate the topic into the future work of the BWC, (2) establish a multistakeholder initiative for developing screening best practice, potentially under the auspices of a BWC working group, and (3) ensure that rules governing the production, transfer, and use of synthetic nucleic acids are the same domestically and internationally.

Post Scriptum Since this chapter was drafted in 2024, additional national frameworks have been developed, or are under development, which reinforce the view that state practice is moving towards controlling the transfer of synthetic nucleic acids. The clearest example of this is New Zealand's 2024 Gene Technology Bill, which if enacted would mandate screening by nucleic acid synthesis companies, third party vendors and benchtop synthesis providers.[116] The current (as of January 2026) official proposal for the European Union Biotech Act also contains references to nucleic acid synthesis screening and sets out draft provisions regarding benchtop synthesisers.[117] In the United States, the White House in 2025 issued the "Executive Order on Improving the Safety and Security of Biological Research". This Executive Order contains provisions providing for a new nucleic acid synthesis framework, enforcement through federal funding procurement contracts, and the development of measures to promote synthesis screening in non-federally funded settings.[118] In 2025 in South Korea legislation was enacted explicitly addressing synthetic biology,[119] and a report was issued recommending that South Korea adopt its own nucleic acid synthesis screening system.[120] In December 2025, the International Biosecurity and Biosafety Initiative for Science launched the Global DNA Synthesis Map which shows where synthesis providers are located, how providers screen their orders, and what policies apply. See: https://globalsynthesismap.bio/.

[116] Gene Technology Bill 2024 (New Zealand), cls 7, 13A, 83, 100–102, 149, and 157.

[117] Proposal for a Regulation of the European Parliament and of the Council on Establishing a Framework of Measures for Strengthening the Union's Biotechnology and Biomanufacturing Sectors, Particularly in the Area of Health, and Amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act), Explanatory Memorandum, art 45 and Annex I.

[118] White House 2025, ss 4(b), 5 and 7.

[119] 합성생물학 육성법 2025 (South Korea) [Synthetic Biology Promotion Act].

[120] Kim 2025.

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