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# A Dangerous Loophole: the Biological Weapons Convention's New Interpretation that Better Addresses Potentially Deadly Biological Research

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#### **Abstract**

There are three types of weapons of mass destruction (WMDs)—nuclear, chemical, and biological. Of the three WMDs, biological weapons are arguably the most dangerous as they are the most indiscriminate, the least controllable, and the least expensive to create. The seminal treaty for establishing legal constraints on this vital issue is the 1972 Biological Weapons Convention (BWC).<sup>2</sup> Article I of the BWC specifically outlaws State acquisition of "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..."<sup>3</sup>

The Vienna Convention on the Law of Treaties<sup>4</sup> (VCLT) provides the general rule for how to interpret treaty language: "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." Problematically, by reading the BWC in light of this general rule, because the BWC only prohibits acquisitions that have "no justification," the ordinary meaning of the text creates a wide loophole through which States may argue the acquisition of a potentially prohibited material has some justification, however minor, and therefore is not prohibited.

The Comment first reviews the background of biological weapons and regulation of their use. In this section, the Comment also describes the VCLT requirements for treaty interpretation and the evolutive approach to interpretation. Next, the Comment conducts a global analysis of State practice in regards to biosafety and biosecurity regulatory measures. It then analyzes the BWC using the various treaty interpretation methods—including addressing how subsequent state practice has affected this interpretation, and how an evolutive approach to interpretation changes the meaning of Article I of the BWC. Lastly, in recognition of this evolution in the law, this Comment recommends how to update enforcement mechanisms to accurately reflect the new state of the law.

#### Introduction

There are three types of weapons of mass destruction (WMDs)—nuclear, chemical, and biological. Of the three WMDs, biological weapons are the most dangerous, as they are the most indiscriminate, the least controllable, and the least expensive to create.<sup>6</sup> The 2019 coronavirus (SARS-CoV-2, also known as

<sup>&</sup>lt;sup>1</sup> © Lena Raxter 2021.

<sup>&</sup>lt;sup>2</sup> Emphasis added. Full text of the convention can be found at https://front.un-arm.org/wp-content/uploads/2020/12/BWC-text-English-1.pdf

³ Id

<sup>&</sup>lt;sup>4</sup> Full text of the Treaty can be found at https://legal.un.org/ilc/texts/instruments/english/conventions/1\_1\_1969.pdf

<sup>&</sup>lt;sup>5</sup> Id. at 12.

<sup>&</sup>lt;sup>6</sup> The Biological Threat: germs don't respect borders, so biological threats—manmade and naturally occurring—can quickly have global impacts, NTI (Dec. 30, 2015), https://www.nti.org/learn/biological; Richard G. Stearns, An Appropriate

COVID-19)<sup>7</sup> has brought the risk of a pandemic resulting from deadly disease research—whether by accident or intentional release—to the forefront of the international community's attention.<sup>8</sup>

This risk of dangerous research is even more acute due to the recent developments in science, which make research into deadly diseases easier. The discovery of a new, highly effective and accurate genome editing tool—CRISPR-cas9—has resulted in a genomics revolution, and has significantly decreased the time and resources necessary to engineer an extremely dangerous and deadly disease. For example, in 2016, a scientific paper drew attention to the risk of dangerous research by noting how the innocent testing of the 1918 Spanish flu virus, with the aim of bolstering disease surveillance, could actually be used to resurrect and disseminate the virus that killed an estimated fifty million people worldwide.

Legal Framework for Dealing with Modern Terrorism and WMD, in Intelligence and Human Rights in the Era of Global Terrorism 78, 83–84 (Steve Yui-Sang Tsang ed., 2006).

<sup>7</sup> It is important to note that the allegations that COVID-19 was created in a laboratory are unfounded. See Monique Brouillette & Rebecca Renner, Why misinformation about COVID-19's origins keeps going viral, Nat'l Geo. (Sept. 18, 2020), https://www.nationalgeographic.com/science/article/coronavirus-origins-misinformation-yan-report-fact-check-cvd.

<sup>8</sup> There are continual fears that non-state actors or adversarial States may obtain the technology necessary to create a biological weapon, and use such a weapon on their enemies. Willem Marx, COVID-19 has shown U.S., U.K. are vulnerable to biological terrorism, experts say, NBC News (May 18, 2020), https://www.nbcnews.com/politics/national-security/experts-covid-19-has-shown-u-s-u-k-are-n1207776. Compare States Must Step Up Efforts to Check Spread of Deadly Weapons as Non-State Actors Exploit Rapid Technology Advances, Speakers Tell Security Council (SC/12888), UN News (June 28, 2017), https://www.un.org/press/en/2017/sc12888.doc.htm (concluding that new technological advances pose a significant threat considering the developments regarding Da'esh and other such non-state actor groups) and Michael Moodie, Options and New Dynamics: Chemical and Biological Weapons Proliferation in 2020, in Over the Horizon Proliferation Threats 266 (James J. Wirtz & Peter R. Lavoy, eds., 2012) (concluding that the international regulatory framework for biological and chemical weapons should be revised considering the advances in science over the past decade), with Christian Enemark, Biological attacks and the non-state actor: a threat assessment, 21 INTEL. & NAT'L Sec. 911, 911 (2006) (concluding that a biological weapons attack by non-state actors is unlikely, but also that individual scientists conducting biological research should be closely monitored).

<sup>9</sup> James T. Areddy, Coronavirus Epidemic Draws Scrutiny to Labs Handling Deadly Pathogens, Wall St. J. (Mar. 5, 2020), https://www.wsj.com/articles/coronavirus-epidemic-draws-scrutiny-to-labs-handling-deadly-pathogens-11583349777; NTI, supra note 1.

<sup>10</sup> See Mark Shwartz, Target, delete, repair: CRISPR is a revolutionary gene-editing tool, but it's not without risk, Stan. Med. (Winter 2018), https://stanmed.stanford.edu/2018winter/CRISPR-for-gene-editing-is-revolutionary-but-it-comes-with-risks.html (elaborating on the revolution in genetic technology that has resulted from the discovery of CRISPR-cas9, and noting the risks posed by the technology unless regulations are implemented); see also Edith Brown Weiss, Establishing Norms in a Kaleidoscopic World 288–302 (2020) (describing CRISPR-cas9 and the related regulatory legal framework, both non-binding and binding).

<sup>11</sup> Elisa D. Harris, Dual-Use Threats: The Case of Biological Technology, in Governance of Dual-Use Technologies: THEORY AND PRACTICE \*1 (2016). Moreover, accidents while researching such deadly diseases may also pose a significant threat. See Stefan Riedel, Biological warfare and bioterrorism: a historical review, 17 BUMC PROCEEDINGS 400, 404 (2004) (explaining an incident in April 1979, where an anthrax epidemic in Sverdlovsk, Russia was attributed to an accident at a nearby USSR military microbiology facility); Alison Young & Jessica Blake, Here are Six Accidents UNC Researchers Had With Lab-Created Coronaviruses, ProPublica (Aug. 17, 2020), https://www.propublica.org/article/here-are-six-accidentsunc-researchers-had-with-lab-created-coronaviruses (reporting several incidents, from January 1, 2015 to June 1, 2020, of staff violating security measures while researching lab-created coronaviruses in a high-security lab at the University of North Carolina at Chapel Hill); Alison Young & Nick Penzenstadler, Inside America's secretive biolabs, USA Today (May 28, 2015), www.usatoday.com/story/news/2015/05/28/biolabs-pathogenslocation-incidents/26587505 (reporting an investigation which revealed "hundreds of accidents, safety violations, and near misses [which] put people at risk"); Cassandra Willyard, Biosafety bungle leads to bird flu contamination, 15 NATURE MED. 349, 349 (2009) (reporting a biosafety accident in the Czech Republic which involved ferrets being accidentally infected with avian influenza); Russian Scientist Russian Scientist Dies after Ebola Lab Accident, 304 Science 1225 (2004) (reporting the death of a Russian scientist after she was accidentally exposed to Ebola while researching the disease); CDC Lab Incident: Anthrax, CDC (July 19, 2014), https://www.cdc.gov/ anthrax/news-multimedia/lab-incident/index.html (reporting a lab accident involving Anthrax, which resulted in a moratorium on the transfer of any infectious agents—active or inactive—from any biosafety level 3 or 4 laboratories); cf. Lena H. Sun & Brady Dennis, Smallpox vials, decades old, found in room at NIH campus in Bethesda, WASH. POST (July 8, 2014), https://www. washingtonpost.com/national/health-science/smallpox-vials-found-in-storage-room-of-nih-campus-in-bethesda/2014/07/08/

The seminal treaty for establishing legal constraints on this vital issue is the 1972 Biological Weapons Convention (BWC). The BWC is a legally binding treaty that outlaws the development, stockpiling, acquisition, retention, or production of biological agents and toxins; weapons equipment, and delivery vehicles for such agents and toxins; and the transfer of any of the above. However, the BWC does not ban the use of biological agents and toxins, nor does it ban biodefense programs. Under Article I of the BWC, States are only prohibited from acquiring, developing, retaining, stockpiling, or producing "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 . . ."14

The Vienna Convention on the Law of Treaties (VCLT) governs how international law interprets treaty language, such as that found in the BWC. Specifically, the VCLT requires that a treaty is interpreted first based on the ordinary meaning of the treaty language, in light of the treaty's object and purpose. The interpreter must then take into account the subsequent rules of treaty interpretation, specifically the treaty's context, per Article 31(2) of the VCLT—meaning the treaty's preamble, other clauses, annexes, and any relevant agreements or instruments existing at the time of the treaty's creation; and the subsequent context, per Article 31(3) and 31(4) of the VCLT—meaning subsequent agreements, State practice, and relevant rules of international law. However, if interpretation using Article 31 creates an ambiguity or absurd result in the meaning of the treaty, the interpreter may reference Article 32 of the VCLT—which provides the supplemental means of interpretation.

Alternatively, in order to properly interpret a treaty, it is sometimes necessary to consider developments that occurred after the conclusion of the treaty—also known as "evolutive interpretation." Under this approach, a treaty is reinterpreted based on subsequent State practice, irrespective of the original interpretation.<sup>20</sup>

By only prohibiting acquisitions that have "no justification for prophylactic, protection or other peaceful purposes," the ordinary meaning of Article I of the BWC text creates a loophole allowing States to argue that acquisition of a potentially prohibited biological material has some justification, however minor, and therefore is not prohibited by the treaty. The result of this interpretation is a minimalist approach which allows for ready exploitation by States looking to acquire biological agents or toxins.

However, subsequent to the adoption of the BWC, and in consideration of scientific advancements since the 1970s, many States have implemented regulatory regimes which require extra laboratory safety measures based on the danger of the substance being tested.<sup>21</sup> Under this system, there is a four-tiered "safety scale": biosafety level 1 (BSL-1) is the least restrictive tier, requiring very few safety measures, whereas biosafety level 4 (BSL-4) is the most restrictive, requiring extensive safety measures.<sup>22</sup> As a result of implementing such systems, States are now weighing

bfdc284a-06d2-11e4-8a6a-19355c7e870a\_story.html (describing another serious incident, wherein government scientists unexpectedly found decades-old vials of smallpox in a storage room at the National Institute of Health Bethesda campus).

<sup>12</sup> The Biological Weapons Convention (BWC) At A Glance, https://www.armscontrol.org/factsheets/bwc (last visited Jan. 23, 2021).

<sup>13</sup> Id.

<sup>14</sup> Biological Weapons Convention art. I, open for signature Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. (entered into force Mar. 26, 1975) [hereinafter "BWC"].

<sup>15</sup> Georg Nolte, Treaties and Their Practice — Symptoms of Their Rise or Decline 219 (2019).

<sup>16</sup> Vienna Convention on the Law of Treaties art. 31(a), opened for signature May 23, 1969, 1155 U.N.T.S. 331 [hereinafter "VCLT"].

17 Id., art. 31(b)-(c); Anthony Aust, Modern Treaty Law and Practice 208 (3d ed. 2013).

<sup>18</sup> VCLT, supra note 11, at art. 32; Aust, supra note 12, at 208.

<sup>19</sup> Nolte, supra note 10, at 356.

<sup>20</sup> See VCLT, supra note 11, at art. 31(3)(b); see also Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, 1971 I.C.J. 16, ¶¶ 21–22 (June 21).

See generally Gigi Kwik Gronvall et al., High-containment biodefense research laboratories: meeting report and center recommendations, 5 BIOSECURITY BIOTERRORISM 75 (2007) (explaining the safety measures recommended for laboratories conducting high-risk research, due to the danger posed by the pathogens tested at the facilities).

<sup>22</sup> See generally Infographic: Biosafety Lab Levels, CDC (Dec. 21, 2020), https://www.cdc.gov/cpr/infographics/biosafety. htm (explaining the differences in protective measures, depending on lab level, as required by the CDC); Declan Butler, European biosafety labs set to grow, 462 NATURE 146 (2009) (explaining what requirements are necessary for each level of biosecurity).

the benefits of the research against the potential costs of accident or misuse and applying extra regulatory measures accordingly.

This Comment argues that the object and purpose of the BWC is to severely limit a State's ability to create or obtain biological weapons; further, the context of the treaty indicates that the drafters were conscious of the need to divert biological weapons to peaceful purposes and to implement "necessary safety precautions." Consequently, in light of the object and purpose and the context of the BWC, the minimalist interpretation of the BWC is not justified. Additionally, in accordance with both Article 31(3) of the VCLT and the "evolutive interpretation" approach, subsequent State practice has caused an evolution in the law, requiring States to implement more stringent regulatory measures based on the risks posed by the pathogen being tested. As a result, the minimalist interpretation of Article I of the BWC is removed, and States are now required to implement safety measures based on the risk posed by the pathogen being acquired, developed, produced, stockpiled, or retained—which can be classified as "Dual Use Research of Concern" (DURC)—to prove that the purpose of their use is in line with the allowances of the treaty.

The Comment will first review the background of biological weapons and regulation of their use. This section will also describe the VCLT requirements for treaty interpretation and the evolutive approach to interpretation. Next, the Comment will conduct a global analysis of State practice in regards to biosafety and biosecurity regulatory measures. It will then analyze the BWC using the various treaty interpretation methods—including addressing how subsequent state practice has affected this interpretation, and how an evolutive approach to interpretation changes the meaning of Article I of the BWC. Lastly, in recognition of this evolution in the law, this Comment will recommend how to update enforcement mechanisms to accurately reflect the new state of the law.

#### I. BACKGROUND

The spread of disease knows no borders. As demonstrated in the COVID-19 pandemic, the increase in globalization means disease outbreaks can spread rapidly throughout the global via our international transport networks. Further, no State, no matter how resourceful, can protect itself from the effects of a global pandemic. This section will first explain the history of disease. Second, it will address the history of biological weapons use. Third, it will introduce the regulatory measures that have been adopted to control biological agents. Lastly, it will address treaty interpretation by explaining the rules of treaty interpretation outlined in the VCLT and the "evolutive interpretation" approach.

#### A. History of biological weapons use

Since the beginning of time, pathogens—an organism that can cause disease, including bacteria<sup>25</sup> and viruses<sup>26</sup>—have made both human and animals sick, sometimes resulting in the death of those infected. As early as 600 B.C.E., humanity has recognized infectious pathogens for their devastating impact on humankind.<sup>27</sup> The pathogenic bacteria yersinia pestis caused the Black Death, also known as the bubonic plague, which is the deadliest

<sup>&</sup>lt;sup>23</sup> See BWC, supra note 9, at art. 2 ("Each State Party to this Convention undertakes to destroy, or to diver to peaceful purposes... all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention.... In implementing the provisions of this article, all necessary safety precautions shall be observed to protect populations and the environment.").

<sup>&</sup>lt;sup>24</sup> See Hussein H. Khachfe et al., An Epidemiological Study on COVID-19: A Rapidly Spreading Disease, 12 Cureus \*6–8 (2020) (examining the rapid spread of COVID-19).

<sup>&</sup>lt;sup>25</sup> Bacteria are microorganisms that live throughout nature—including in the human gut. They were first discovered in 1676 by Antoni van Leeuwenhoek, resulting in the development of the field "microbiology" that has transformed our understanding of the role of microbes in causing infectious diseases. Howard Gest, The discovery of microorganisms by Robert Hooke and Antoni Van Leeuwenhoek, fellows of the Royal Society, 58 Notes & Records Royal Soc'y London, 187, 188 (2004).

<sup>&</sup>lt;sup>26</sup> The first virus to be discovered was the tobacco mosaic virus in 1892. Less than ten years later, scientists discovered the first virus which was known to infect humans—yellow fever virus. Since then, scientists have discovered 219 virus species that are capable of infecting humans. Mark Woolhouse et al., Human viruses: discovery and emergence, 367 Philosophical Transactions Royal Soc'y London. Series B, Biological Sci., 2864, 2864 (2012).

<sup>&</sup>lt;sup>27</sup> Riedel, supra note 6, at 400.

pandemic in the history of the world, killing an estimated third of the world population in the fourteenth century.<sup>28</sup> Because of the deadly cost of pathogens, countless individuals throughout history have sought to discover the cause of, eradicate, or—in some cases—weaponize pathogens.<sup>29</sup>

Biological weapons are disease-causing pathogens,<sup>30</sup> bioregulators,<sup>31</sup> or biotoxins<sup>32</sup> that are produced and deliberately released to cause diseases in humans, animals, or plants.<sup>33</sup> Collectively referred to as "biological agents," they are typically divided into four subcategories: bacteria, viruses, rickettsia, and fungi.<sup>34</sup> Similar to chemical weapons, the value of biological weapons "lies in their ability to cause mass death without destroying infrastructure." However, unlike chemical weapons, biological agents are capable of reproducing on their own and therefore can infect vast populations without requiring large amounts of the agent.<sup>36</sup>

The earliest recorded use of pathogens for biological warfare was in 1346 when the Mongols catapulted the bodies of plague victims over the city walls of Caffa, in the Crimean Peninsula.<sup>37</sup> While biological weapons have never been used in traditional interstate warfare, in World War I, both sides of the conflict conducted biological weapons sabotage campaigns.<sup>38</sup> Further, in World War II the Japanese used the plague, anthrax, and other deadly diseases against prisoners of war.<sup>39</sup> Even during the inter-war period in the 1920s, a number of countries started biological weapons research and production programs, including Germany, France, Canada, the United Kingdom (UK), the United States (US), and the Union of Soviet Socialist Republics (USSR).<sup>40</sup> While some of these countries discontinued their biological weapons programs during the Cold War,<sup>41</sup> others restarted their pre-World War II program<sup>42</sup> or started a completely new program.<sup>43</sup>

The twenty-first century has also seen the rise of bioterrorism, which is the deliberate release of a biological agent.<sup>44</sup> One such example of an attack is the 2001 anthrax attacks in the US, wherein five people died after receiving

<sup>28</sup> Stearns, supra note 1, at 83.

<sup>29</sup> Friendrich Frischknecht, The history of biological warfare, 4 European Molecular Biology Org. Reports S47, S47 (2003) (explaining how pathogens have historically been used as means of assassination).

<sup>30</sup> Examples include the viruses that cause Ebola and Marburg, which have a lethality rate of nearly 100 percent; and small-pox, which has a lethality rate of around 30 percent or higher, depending on whether the population is vaccinated. While small-pox was eradicated from nature in the 1970s, "a successful smallpox attack in Europe or North America would almost certainly become a world-wide pandemic before running its course." Stearns, supra note 1, at 84.

<sup>31</sup> Bioregulators are "biochemical substances produced by the human body in tiny amounts for the regulation of physiological functions." Alexander Kelle, Kathryn Nixdorff, & Malcolm Dando, Preventing a Biochemical Arms Race 20 (2012).

<sup>32</sup> See also Stearns, supra note 1, at 83–84 (explaining that biotoxins are the most toxic known poisons, and are relatively easy to produce. Examples include ricin, which can be extracted from castor beans using a simple process—patented by the US army in 1952—that can be found on the internet. However, biotoxins are not infectious and are therefore more effective as an assassination tool than a method to cause mass death).

<sup>33</sup> See generally Biological Weapons, https://www.who.int/health-topics/biological-weapons#tab=tab\_1 (last visited Jan. 23, 2021); NTI, <u>supra</u> note 1; Dominika Švarc, Biological Weapons and Warfare, Max Planck Encyclopedias Int'l L. (2015); Hendrik A Strydom, Weapons of Mass Destruction, Max Planck Encyclopedia Int'l L. (2017).

<sup>34</sup> Kelle, Nixdorff, & Dando, supra note 26, at 20.

<sup>35</sup> Barry Kellman, Bridling the International Trade of Catastrophic Weaponry, 43 Am. U. L. Rev. 755 (1994).

<sup>36</sup> Michael A. Hayoun & Kevin C. King, Biological Warfare Agent Toxicity, StatPearls (May 5, 2020), https://www.ncbi.nlm.nih.gov/books/NBK441942/.

<sup>37</sup> Frischknecht, supra note 24, at 547; Riedel, supra note 6, at 400.

<sup>38</sup> Kelle, Nixdorff, & Dando, supra note 26, at 20–21; Riedel, supra note 6, at 401.

<sup>39</sup> Riedel, supra note 6, at 401; see also William V. O'Brien, The Jus in Bello in International Relations Studies, 31 Am. U. L. Rev. 1011, 1022 (1982) (describing false claims against the UN in Korea, claiming that forces used biological warfare agents); John Norton Moore, A Theoretical Overview of the Laws of War in a Post-Charter World, with Emphasis on the Challenge of Civil Wars, Wars of National Liberation, Mixed Civil-International Wars, and Terrorism, 31 Am. U. L. Rev. 841, 844 (1982) (also describing false claims against the UN in Korea, claiming that forces used biological warfare agents).

<sup>40</sup> Kelle, Nixdorff, & Dando, supra note 26, at 20–21.

<sup>41</sup> For example: Canada, the UK, the US, and the USSR. Id. at 21.

<sup>42</sup> For example: France. Id.

<sup>43</sup> For example: Iraq and South Africa. Id.

<sup>44</sup> H.J. Jansen et al., Biological warfare, bioterrorism, and biocrime, 20 CLINICAL MICROBIOLOGY & INFECTION 488, 488 (2014). However, scholars regularly debate whether terrorist organizations, such as al-Qaeda, are capable of creating, maintaining, and successfully releasing biological weapons. Compare Stearns, supra note 1, at 83–85 (concluding that it is unlikely al-

anthrax-laced letters. 45 Moreover, the Bush administration justified military action against Iraq based on evidence suggesting Iraq had the capability to produce WMDs—including biological weapons. 46

## B. Regulatory Measures, and the Non-proliferation Movement

Because of the danger biological weapons pose, the international community has long sought to regulate biological weapons.<sup>47</sup> The first effort to ban biological weapons was the 1925 Geneva "Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases, and of Bacteriological Methods of Warfare," which prohibits the use of chemical and biological agents during war.<sup>48</sup> However, due to the large number of States submitting reservations to the treaty—which, under international law, limits a State's responsibility for properly complying with the treaty—the Protocol is considered a non-first-use agreement for the States Parties to the agreement.<sup>49</sup> The next major effort to address biological weapons happened in 1972 with the creation of the BWC, which opened for signature in 1972 and entered into force in 1975.

# 1. Biological Weapons Convention

The BWC was the first multilateral disarmament treaty to ban an entire category of weapons and has since become the foundational treaty for the regulation of biological and toxin agents.<sup>50</sup> Through the BWC, States Parties are prohibited from developing, stockpiling, producing, or transferring biological agents and toxins unless there is a justification for protective, prophylactic, or peaceful use.<sup>51</sup> Further, States cannot develop weapons, equipment, or delivery systems to distribute these agents or toxins.<sup>52</sup> As of 2020, the

Qaeda maintains the technical capabilities required to produce a biological weapon capable of causing mass infection), with Moodie, supra note 3, at 280–281 ("Even if terrorists cannot exploit the most cutting edge scientific and technological capabilities, however, it does not mean they can do nothing. . . . Their science and technology have to be just 'good enough."").

- <sup>45</sup> John Lancaster & Susan Schmit, When anthrax-laced letters terrorized Washington and New York, Wash. Post (October 24, 2018), <a href="https://www.washingtonpost.com/history/2018/10/24/when-anthrax-laced-letters-terrorized-washington-new-york">https://www.washingtonpost.com/history/2018/10/24/when-anthrax-laced-letters-terrorized-washington-new-york see Ira P. Robbins, Anthrax hoaxes, 54 Am. U. L. Rev. 1 (2004) (describing a series of real and hoax biological weapons attacks post-9/11, and the regulations US law makers implemented to respond to them).
- <sup>46</sup> Michael Skopets, Battered Nation Syndrome: Relaxing the Imminence Requirements of Self-Defense in International Law, 55 Am. U. L. Rev. 753, 754–755, 776 n.104, 780 n.125 (2006); see Text of President Bush's 2003 State of the Union Address, Wash. Post (Jan. 28, 2003) ("We must assume that our enemies would use these diseases as weapons, and we must act before the dangers are upon us.").
- <sup>47</sup> U.S. Gov't Accountability Office, GAO-09-574, Report to congressional requesters. High containment laboratories: national strategy for oversight is needed (2009); U.S. Gov't Accountability Office, GAO-08-108T, Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives. High-containment biosafety laboratories: preliminary observations on the oversight of the proliferation of BSL-3 and BSL-4 laboratories in the United States (2007). But see Meredith Wadman, Booming biosafety labs probed, 461 NATURE 577 (2009) (reporting on the disagreement between scientists and US lawmakers on what regulatory security measures are necessary for high-containment laboratories). See generally Michael P. Scharf, Clear and Present Danger: Enforcing the International Ban on Biological and Chemical Weapons through Sanctions, Use of Force, and Criminalization, 20 Mich. J. Int'l L. 477 (1999).
- <sup>48</sup> Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571 [hereinafter "Geneva Protocol"].
- <sup>49</sup> "Non-first use" means that the State cannot be the initial party to use a biological weapon against another State; however, the State is permitted to use a biological weapon as a response to a similar attack by another State. Kelle, Nixdorff, & Dando, supra note 26, at 12.
- <sup>50</sup> Jenni Rissaen, The Biological Weapons Convention, NTI (March 1, 2003), https://www.nti.org/analysis/articles/biological-weapons-convention; About the Biological Weapons Convention, https://www.unog.ch/80256EE600585943/(httpPages)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument (last visited Jan. 23, 2021).
  - <sup>51</sup> Rissaen, supra note 45.
- <sup>52</sup> Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons (BTWC), https://www.nti.org/learn/treaties-and-regimes/convention-prohibition-development-production-and-stockpiling-bacteriological-biological-and-toxin-weapons-btwc/#:~:text=The%20Biological%20and%20Toxin%20Weapons, for%20protective%20or%20peaceful%20use (last visited Jan. 23, 2021) [hereinafter "NTI"].

treaty has 182 States Parties, including Palestine, and five signatory States.<sup>53</sup> Only ten States have neither signed nor ratified the treaty.<sup>54</sup>

Article I provides the rights and obligations for States under the BWC, and the following twenty-four articles provide support for the rights and obligations in Article I.<sup>55</sup> While the BWC does not explicitly ban the use of biological or toxin weapons, use is considered a violation of the treaty.<sup>56</sup> Moreover, unlike the Nuclear Non-Proliferation Treaty (NPT)—which divides States into two categories based on possession of nuclear weapons—all the States Parties to the BWC have the same rights and obligations, whether or not they have biological or toxin agents.<sup>57</sup> The BWC does not prohibit research into biological warfare agents.<sup>58</sup> For example, there was no violation of the BWC when, during the Cold War, the U.S. defense establishment implemented a policy to test not only those biological and toxin agents known to exist in the USSR stockpile, but also those "which might be produced in the future."

In order to evaluate the implementation of the BWC, States Parties agreed to hold review meetings every five years, starting when the treaty entered force. Since then, eight review conferences have occurred, resulting in many important updates to the BWC. For example, during the Sixth Review Conference for the BWC, the States Parties decided to establish the Implementation Support Unit (ISU). The ISU provides administrative support, assists with national implementation, supports and assists with confidence building measures, assists in obtaining a globalized biological weapons ban, and assists in increasing participation of developing States Parties' in the annual meetings. In ISU also submits annual reports on its work to the BWC's Meeting of States Parties. Though significantly smaller than its counterpart for the Chemical Weapons Convention—i.e., the Organization for the Prohibition of Chemical Weapons—the ISU plays an imperative role in monitoring compliance with the BWC.

## 2. Dual-Use Research of Concern

During the Review Conferences of the BWC in the first half of the 2010s, the US lobbied for inclusion of Dual-Use Research of Concern (DURC) in the discussions of the BWC.<sup>66</sup> DURC means research into certain high-consequence pathogens and toxins which could potentially be used as deadly weapons, meaning the possession of

<sup>&</sup>lt;sup>53</sup> <u>Id.</u>

<sup>&</sup>lt;sup>54</sup> <u>Id.</u>

<sup>55 &</sup>lt;u>Id.</u>

<sup>&</sup>lt;sup>56</sup> Id.

<sup>&</sup>lt;sup>57</sup> Rissaen, supra note 45.

<sup>&</sup>lt;sup>58</sup> Id

<sup>&</sup>lt;sup>59</sup> Kelle, Nixdorff, & Dando, supra note 26, at 4.

<sup>&</sup>lt;sup>60</sup> Get the Facts: The Biological and Toxic Weapons Convention, NTI (Nov. 2019), <a href="https://media.nti.org/documents/btwc\_fact\_sheet.pdf">https://media.nti.org/documents/btwc\_fact\_sheet.pdf</a>; Ayers, The Biological Weapons Convention: Creation and Problems with Enforcement, 2 J. BIOSECURITY BIOSAFETY & BIODEFENSE L. 1 (2012).

<sup>&</sup>lt;sup>61</sup> See NTI, supra note 47 (listing the developments from the review conferences).

<sup>&</sup>lt;sup>62</sup> Sixth 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: Draft Final Document, ¶ 36, U.N. Doc. BWC/CONF.VI/CRP.4 (Dec. 8, 2006).

<sup>&</sup>lt;sup>63</sup> Role of the Implementation Support Unit, https://www.unog.ch/80256EE600585943/(httpPages)/F8521A510F455706 C12573A6003F49F2?OpenDocument (last visited Jan. 23, 2021).

Implementation Support Unit, https://www.unog.ch/80256EE600585943/(httpPages)/16C37624830EDAE5C1 2572BC0044DFC1?OpenDocument (last visited Jan. 23, 2021).

<sup>&</sup>lt;sup>65</sup> Relevant Activities overseen by the BWC Implementation Support Unit, https://www.unog.ch/80256EE600585943/(httpPages)/1B69CE1F0B030DA0C1257F39003E9590?OpenDocument (last visited Jan. 23, 2021).

<sup>&</sup>lt;sup>66</sup> Piers Millett, The Biological Weapons Convention: Securing Biology in the Twenty-First Century, 15 J. Conflict & Sec. L. 25 (2010); see David R. Franz, The Dual Use Dilemma: Crying out for Leadership, 7 St. Louis U. J. Health L. & Poly 5 (2013); Carole R. Baskin & Todd J. Richardson, Dual Use Research Policy Implementation, 7 St. Louis U. J. Health L. & Poly 59 (2013); see also Victoria Sutton, Biodiplomacy: A Better Approach to Dual Use Concerns, 7 St. Louis U. J. Health L. & Poly 111 (2013). See generally Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies, Nat'l Acad. of Sci., Eng'g & Med. (2017).

the agent is the possession of a potential biological weapon.<sup>67</sup> DURC is often conducted for peaceful or prophylactic purposes and involves "gain of function" experiments, which are genetic experiments that add a new function to a tested virus, bacteria, or animal.<sup>68</sup> A classic conceptual example of a "gain of function" experiment is genetic experimentation that uses a viral vector to add the ability to glow in the dark to an animal, such as a mouse or a goldfish.<sup>69</sup> While many States were supportive of this inclusion, international discussion regarding this category of research dissipated in the second half of the 2010s, and is no longer a part of international discussion on the BWC.<sup>70</sup>

## 3. Regulation of Biological Research

In situations where scientists conduct extremely dangerous research, some States implemented regulations that provide for specific biosecurity measures, the strictness of which depends on how dangerous the research could be if an accident or misuse occurred.<sup>71</sup> However, governments and international organizations are not the sole bodies through which regulation may occur for DURC.<sup>72</sup> Because of the significant ethical dilemmas regarding what should be allowed in "gain of function" experiments,<sup>73</sup> the scientific community itself has imposed self-regulatory measures to ensure research is done in a safe and ethical manner.<sup>74</sup> Nevertheless, there is significant debate as to whether this regulation is sufficient.<sup>75</sup>

A key distinction should be made here: there is a difference between biosafety and biosecurity. Biosafety is "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release," whereas biosecurity is the "institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins." As a

<sup>&</sup>lt;sup>67</sup> Baskin & Richardson, supra note 61, at 59.

<sup>&</sup>lt;sup>68</sup> Michael J. Selgelid, Gain-of-Function Research: Ethical Analysis, 22 Sci. & Eng'g Ethics 924 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996883.

<sup>&</sup>lt;sup>69</sup> See Gain-of-Function Research: Background and Alternatives, in Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop (2015), <a href="https://pubmed.ncbi.nlm.nih.gov/25719185">https://pubmed.ncbi.nlm.nih.gov/25719185</a> (explaining different types of gain-of-function research and their application in scientific research).

<sup>&</sup>lt;sup>70</sup> Piers Millett, Gaps in the International Governance of Dual-Use Research of Concern \*2–4 (Jan. 17, 2017), https://www.nap.edu/resource/24761/Millett Paper 011717.pdf.

<sup>&</sup>lt;sup>71</sup> See Alexandra Peters, The global proliferation of high-containment biological laboratories: understanding the phenomenon and its implications, 37 Revue scientifique et technique (Int'l Office of Epizootics) 857 (2018), https://pubmed.ncbi.nlm.nih.gov/30964462 (conducting a review of global State practice regarding biosecurity measures); Barbara Johnson & Rocco Casagrande, Comparison of International Guidance for Biosafety Regarding Work Conducted at Biosafety Level 3 (BSL-3) and Gain-of-Function (GOF) Experiments, 21 Applied Biosafety: J. of ABSA Int'l 128 (2016), https://journals.sagepub.com/doi/full/10.1177/1535676016661772 (conducting a comparative review of biosecurity measures within the US, the World Health Organization, Great Britain, Australia and New Zealand, Singapore, and the European Union).

<sup>&</sup>lt;sup>72</sup> See Johnson & Casagrande, supra note 66, at 128–130.

<sup>&</sup>lt;sup>73</sup> See Michael J. Selgelid, Gain-of-Function Research: Ethical Analysis, 22 Sci. & Eng'g Ethics 923 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4996883 (analyzing the ethical debate regarding "gain of function" experiments); W. Ian Lipkin, Biocontainment in Gain-of-Function infectious disease research, 3 MBio 1 (2012), https://mbio.asm.org/content/mbio/3/5/e00290-12.full.pdf (stressing the need for the WHO to establish strict criteria for safety measures in BSL-3 and BSL-4 laboratories).

<sup>&</sup>lt;sup>74</sup> Major biosafety level 3 and 4 (BSL-3 and 4) facilities around the world, Fed'n of Am. Scientists (2009), www.fas.org/programs/bio/biolevel-old.html; Labs form a new front against deadly pathogens, 87 Bulletin of the World Health Org. 245 (2009), www.who.int/bulletin/volumes/87/4/09-010409/en.

<sup>75</sup> Jeffery Adamovicz, Select agent program impact on the IBC, Ensuring Nat'l Biosecurity 169 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7149598; Sabine Salloch, The dual use of research ethics committees: why professional self-governance falls short on preserving biosecurity, 19 BMC Med. Ethics 53 (2018); Engineering and Medicine, Developing Norms for the Provision of Biological Laboratories in Low-Research Contexts: Proceedings of a Workshop, Nat'l Acad. of Sci. (2019), https://doi.org/10.17226/25311.

<sup>&</sup>lt;sup>76</sup> World Health Organization, Laboratory Biosafety Manual 47 (3rd ed. 2004) [hereinafter "WHO Laboratory Safety"]. See generally Fact Sheet: Biosafety and Biosecurity, World Health Org. (March 20, 2018), https://www.who.int/influenza/pip/BiosecurityandBiosafety\_EN\_20Mar2018.pdf?ua=1 (providing information on the difference between the two); Marlon L. Bayot & Faten Limaiem, Biosafety Guidelines, StatPearls (March 25, 2020), https://www.ncbi.nlm.nih.gov/books/NBK537210 (providing detailed information regarding biosafety guidelines).

result of this distinction, regulations address both the biosafety for scientists who conduct experiments, as well as biosecurity for the general community around the laboratory in which the experiments take place.<sup>77</sup> Both types of regulation are relevant to the BWC as they each ensure the safe handling and research of dangerous pathogens.

# C. The Rules for Treaty Interpretation

Treaties are legally binding texts created through both a legal and political process. The Vienna Convention on the Law of Treaties (VCLT) provides the explicit rules for treaty creation and interpretation. States, international organizations, and individuals tasked with deciding how to apply a treaty face a specific legal dilemma: they must apply the treaty as correctly as possible, in a manner as uniform as possible. Further, the application of the provisions of a treaty inherently require States and other international institutions to interpret the treaty, regardless of whether or not the treaty terms are clear. St

Interpretation is the process of clarifying the rules created by a treaty. 82 Consequently, treaty interpretation is a legal technique that requires creating legal reasoning for why a treaty demands a certain action or omission. 83 In accordance with the rules set out in Article 31 of the VCLT, a treaty is interpreted using its terms, context, and object and purpose. 84 Consequently, treaty interpreters are faced with the difficult tasks of not only defining the ordinary meaning of a term within a treaty, and the term's context in light of the treaty's object and purpose, but also the way in which the treaty has been applied after its conclusion. 85 Additionally, if the rules set out in VCLT Article 31 are insufficient to clarify an ambiguity, or interpretation creates an absurd result, the treaty interpretation may be clarified using the methods provided in Article 32 of the VCLT. 86 The International Court of Justice (ICJ), the European Court of Justice, and multiple other international tribunals have repeatedly affirmed this process. 87 Further, although the US is not a State Party to the VCLT, the State Department and domestic courts recognize the VCLT as "a guide to international law and practice." 88

In sum, international law requires that a treaty be interpreted first by referencing Article 31(1)—which provides the general rule for interpretation of treaties—then Articles 31(2), 31(3), and 31(4)—which provide the

<sup>&</sup>lt;sup>77</sup> WHO Laboratory Safety, supra note 71, at 47.

<sup>&</sup>lt;sup>78</sup> Nolte, supra note 10, at 219.

<sup>&</sup>lt;sup>79</sup> Id. at 219, 332; cf. J. S. Stanford, The Vienna Convention on the Law of Treaties, 20 U. TORONTO L.J. 18 (1970) (explaining the drafting process and legal requirements under the treaty).

<sup>&</sup>lt;sup>80</sup> Georg Nolte, Introduction, in The Interpretation of International Law by Domestic Courts-Uniformity, Diversity, Convergence 3 (Helmut Aust & Georg Nolte, eds., 2016).

<sup>&</sup>lt;sup>81</sup> Anthony Nardi, Armored Plating and Aluminum Foil Are Not like Products: Consequences of the United States' Overbroad Interpretation of Article XXI of the GATT, 69 Am. U. L. Rev. 629, 647 (2019).

<sup>&</sup>lt;sup>82</sup> Int'l Law Comm'n, Rep. of the Seventieth Session, Official Records of the General Assembly, Supplement No. 10, "Subsequent Agreements and Subsequent Practice in Relations to the Interpretation of Treaties," U.N. Doc. A/73/10, art. 6 ¶ 3 (2018) [hereinafter "SASP draft conclusion"]; Aust, supra note 12, at 205; Nolte, supra note 10, at 331–32.

<sup>&</sup>lt;sup>83</sup> Nolte, supra note 10, at 331–32.

<sup>&</sup>lt;sup>84</sup> Id. at 220.

<sup>85</sup> Id. at 333.

<sup>&</sup>lt;sup>86</sup> VCLT, supra note 11, at art. 31, 32; Nardi, supra note 76, at 645.

<sup>&</sup>lt;sup>87</sup> Arbitral Award of 31 July 1989 (Guinea-Bissau v. Sen.), Judgment, 1991 I.C.J. 53, ¶ 48 (Nov. 12) ("[The principles of treaty interpretation] are reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties, which may in many respects be considered as a codification of existing customary law on the point."); Dispute Regarding Navigational and Related Rights (Costa Rica v. Nicar.), Judgment, 2009 I.C.J. 213, ¶ 47 (July 13); LaGrand (Ger. v. U.S.), Judgment, 2001 I.C.J. 466, ¶ 99 (June 27); Case C-386/08, Firma Brita CmbH v. Hauptzollamt Hamburg-Hafen, 2010 E.C.R. I-01289, ¶¶ 41, 43; Case C-63/09, Axel Walz v. Clickair SA, 2010 E.C.R. I-04239, ¶ 23; Responsibilities and Obligations of States Sponsoring Persons & Entities with Respect to Activities in the Area, Case No. 17, Advisory Opinion of Feb. 1, 2011, 15 ITLOS Rep. 10, ¶ 57; Demir & Baykara v. Turk., Judgment, App. No. 34503/97, ¶ 65 (Nov. 12, 2008); Al-Saadoon & Mufdhi v. U.K., App. No. 61498/08, 2010 Eur. Ct. H.R. 762, ¶ 126 (Mar. 2, 2010).

<sup>&</sup>lt;sup>88</sup> Christina A. Levesque, The International Covenant on Civil and Political Rights: A Primer for Raising a Defense against the Juvenile Death Penalty in Federal Courts, 50 Am. U. L. Rev. 755, 785 (2001); Louis B. Sohn, The Law of the Sea: Customary International Law Developments—The American University Washington College of Law Edwin A. Mooers Lecture—11 October 1984, 34 Am. U. L. Rev. 271, 276 (1985).

subsequent rules of interpretation.<sup>89</sup> If these are insufficient to clarify an ambiguity or absurd result, a treaty interpreter must then reference Article 32 of the VCLT—which provides the supplemental means of interpretation.<sup>90</sup> Lastly, in special circumstances, a term included within a treaty may be interpreted using an evolutive approach—meaning the term is interpreted in light of its changing connotation.<sup>91</sup>

# 1. Article 31 of the VCLT: the General rule of interpretation

Article 31(1) provides the general rule for interpretation of treaties: "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." Consequently, there are three elements to consider: the text of the treaty, its context, and its object and purpose. In accordance with Article 31(2), the context of a treaty means the text, preamble, and annexes of the treaty, as well as any relevant agreements or instruments existing at the time the treaty was created. 94

Contrary to widespread assumptions, there is no primacy given to any particular means of interpretation. Therefore, the text of the treaty—i.e., any ordinary or special meaning given to a term in the treaty—is not more important than the context, in light of the object and purpose of the treaty—i.e., subsequent practice or agreements. In practice, the ICJ will first examine the ordinary meaning of the terms of the treaty, and then examine the subsequent practice and agreements. 97

# 2. Article 31 of the VCLT: Subsequent rules of interpretation

Article 31(2) of the VCLT addresses the context element of treaty interpretation: a treaty must be interpreted in compliance with any agreements related to the treat at the time it was adopted, or any instruments made in connection with the treaty, provided that these instruments are "accepted by the other parties as an instrument related to the treaty." Further, Article 31(4) addresses the object and purpose requirement: a treaty must be interpreted using any special meaning intentionally given to a term within the treaty. <sup>99</sup> In the context of the BWC, there are no such agreements which address the loophole within the minimalist interpretation of Article I, nor is there a special meaning intentionally given to the phrase "no justification." Consequently, these rules of interpretation are not at issue in this Comment.

Article 31(3) of the VCLT provides that, in addition to considering the context, the interpretation and application of the treaty may be based on (a) any <u>subsequent</u> agreements between the parties or (b) any subsequent practice in the application of the treaty.<sup>101</sup> A subsequent agreement is "an agreement between the parties, reached after

<sup>&</sup>lt;sup>89</sup> Aust, supra note 12, at 208.

<sup>&</sup>lt;sup>90</sup> Id. at 208.

<sup>&</sup>lt;sup>91</sup> Nolte, supra note 10, at 356.

<sup>&</sup>lt;sup>92</sup> VCLT, supra note 11, at art. 31(1); Id. at 335.

<sup>&</sup>lt;sup>93</sup> Aust, supra note 12, at 208.

<sup>&</sup>lt;sup>94</sup> VCLT, supra note 11, at art. 31(2).

<sup>95</sup> SASP draft conclusion, supra note 77, at art. 2 commentary ¶ 6, 11−14.

<sup>&</sup>lt;sup>96</sup> Nolte, supra note 10, at 336; see Report of the International Law Commission covering the work of its sixteenth session, 11 May-24 July 1964, U.N. Doc. A/5809 (1964), 1964-II Y.B. INT'L L. COMM'N 173, 204 ("[T]he Commission's approach to treaty interpretation was on the basis that the text of the treaty must be presumed to be the authentic expression of the intentions of the parties, . . . making the ordinary meaning of the terms, the context of the treaty, its objects and purposes, and the general rules of international law, together with authentic interpretations by the parties, the primary criteria for interpreting a treaty.").

<sup>97</sup> See, e.g., Competence of the General Assembly for the Admission of a State to the United Nations, Advisory Opinion, 1950 I.C.J. 4, 7–8 (Mar. 3); Sovereignty over Pulau Ligitan and Pulau Sipadan (Indon./Malay.), Judgment, 2002 I.C.J. 625, ¶¶ 59–61, 80 (Dec. 17); Territorial Dispute (Libyan Arab Jamahiriya/Chad), Judgment, 1994 I.C.J. 6, ¶¶ 66–71; Dispute regarding Navigational and Related Rights (Costa Rica v. Nicar.), Judgment, 2009 I.C.J. 213, 290 (July 13) (declaration by Guillaume, J. ad hoc).

<sup>&</sup>lt;sup>98</sup> VCLT, supra note 11, at art. 31(2).

<sup>&</sup>lt;sup>99</sup> Id. at art. 31(4).

<sup>&</sup>lt;sup>100</sup> See NTI, supra note 47 (listing the developments from the review conferences).

<sup>&</sup>lt;sup>101</sup> VCLT, supra note 11, at art. 31(3); Nolte, supra note 10, at 220.

the conclusion of a treaty, regarding the interpretation of the treaty or the application of its provisions."<sup>102</sup> Subsequent practice, on the other hand, is more amorphous.

The International Law Commission defines subsequent practice as the "conduct in the application of a treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty." Subsequent practice also refers to any practice in relation to the treaty. Such practice can include the non-application of treaty provisions, or silence regarding another State's application of the treaty provisions. Further, subsequent practice "may consist of any conduct of a party in the application of a treaty whether in the exercise of its executive, legislative, judicial or other functions." Ultimately, subsequent practice "depends upon inferring subsequent agreement based on the conduct of parties in applying a treaty." <sup>107</sup>

Subsequent practice may help clarify the "ordinary meaning" of a term by "reinforcing one among several possible interpretations," meaning the interpreter will decide from one of several meanings for a term based on an analysis of subsequent State practice. <sup>108</sup> For example, in <u>Inter-Governmental Maritime Consultative Organization</u>, the ICJ used subsequent practice of parties to clarify that the phrase "eight...largest ship-owning nations" meant nations with the largest registered tonnage, not nations with the largest property of nationals. <sup>109</sup> Moreover, subsequent practice may support an interpretation in contradiction of the plain meaning of the text—or even the object and purpose—provided such practice is sufficiently compelling. <sup>110</sup> Subsequent practice and agreements may also help clarify the object and purpose of a treaty. <sup>111</sup>

Ultimately, subsequent practice is the most important element in interpreting a treaty since it is "objective evidence of the understanding of the parties as to the meaning of the treaty." This is because State application of the treaty is the best indicator for what obligations the parties intended the treaty to require. No matter how precise the language of a treaty may be, the way States actually apply the treaty is a vital indication of what States believe the treaty to mean—provided the State practice is commonly accepted, either expressly or implicitly, by all States Parties. As such, subsequent practice is only applicable where "there is a certain kind and degree of practice on the part of the parties evidencing their subsequent intention to interpret the treaty in a certain way." 115

 $<sup>^{102}</sup>$  SASP draft conclusion, supra note 77, at art. 4 ¶ 1.

 $<sup>^{103}</sup>$  Id. at art. 4 ¶ 2.

Nolte, supra note 10, at 222.

Interpretation: Techniques of Treaty Interpretation over Time and Their Diverse Consequences, 9 Law & Practice of Int'l Courts and Tribunals 443, 458 (2010) ("The principle of this mode of interpretation is that the practice of the parties in applying a treaty shall provide evidence for how they interpret, or have come to interpret, that treaty.") (emphasis in original); Int'l Law Comm'n, Rep. of the Eighteenth Session, 4 May-19 July 1966, Official Records of the General Assembly, Twenty-first Session, Supplement No. 9, "Draft Articles on the Law of Treaties with commentaries," U.N. Doc. A/CN.4/191, 1966-II Y. B. Int'l L. Comm'n 187, 222 [hereinafter "DALT"] (clarifying that State practice does not require all parties to engage in a practice; it is only necessary that non-engaging parties acquiesce to the practices of engaging States).

 $<sup>^{106}</sup>$  SASP draft conclusion, supra note 77, at art. 5 ¶ 1.

<sup>&</sup>lt;sup>107</sup> Arato, supra note 100, at 483.

<sup>&</sup>lt;sup>108</sup> Nolte, supra note 10, at 337.

<sup>&</sup>lt;sup>109</sup> Constitution of the Maritime Safety Committee of the Inter-Governmental Maritime Consultative Organization, Advisory Opinion, 1960 I.C.J. 150, 169 (June 8).

<sup>&</sup>lt;sup>110</sup> Arato, supra note 100, at 458, 462.

<sup>111</sup> See, e.g., Maritime Delimitation in the Area between Greenland and Jan Mayen (Den. v. Nor.), Judgment, 1993 I.C.J. 38, ¶ 27 (June 14); Oil Platforms (Islamic Republic of Iran v. U.S.), Judgment, 1996 I.C.J. 803, ¶¶ 27, 30 (Dec. 12); Land and Maritime Boundary between Cameroon and Nigeria (Cameroon v. Nigeria: Eq. Guinea intervening), Judgment, 1998 I.C.J. 275, ¶ 67 (June 11).

SASP draft conclusion, supra note 77, at art. 3; Aust, supra note 12, at 215; Nolte, supra note 10, at 222; see also Russian Claim for Interest on Indemnities (Russ. v. Turk.), 11 R.I.A.A. 421, 433 (Perm. Ct. Arb. 1912) ("the fulfillment of engagements between States, as between individuals, is the surest commentary on the meaning of those engagements."). But see DALT, supra note 100, at 222 ("[T]he value of subsequent practice varies accordingly as it shows the common understanding of the parties as to the meaning of the terms" which means that the value of subsequent practice depends on its clarity and consistency).

<sup>113</sup> SASP draft conclusion, supra note 77, at art. 5 commentary ¶ 10; Nolte, supra note 10, at 221.

<sup>&</sup>lt;sup>114</sup> Aust, supra note 12, at 215; Arato, supra note 100, at 460; DALT, supra note 100, at 222.

<sup>&</sup>lt;sup>115</sup> Arato, supra note 100, at 452.

It is not necessary, however, that all States participate in the practice; it is only necessary that States explicitly or implicitly assent to the practice. For example, in Loizidou v. Turkey, 117 the European Court of Human Rights confirmed the validity of interpretation based on "subsequent practice of the Contracting Parties" as "evidence of a practice denoting practically universal agreement amongst Contracting Parties." The International Covenant on Civil and Political Rights also allows arguments based on the participation of fewer than all States in the practice, 119 as does the International Tribunal on the Law of the Sea. 120 For example, in M/V "SAIGA" (No. 2), 121 the Tribunal relied on the "normal practice used to stop a ship" in accordance with the UN Convention on the Law of the Sea, therefore assuming a general State practice rather than specifically identifying State practice. 122

Lastly, subsequent practice is helpful when a treaty regime lacks an enforcement mechanism. <sup>123</sup> Treaties are similar to contracts under domestic law; however, unlike contract law, when a treaty lacks an enforcement mechanism, the continuing viability of a treaty depends on the parties' continued interpretation and implementation of the treaty. <sup>124</sup> Consequently, the existence of the treaty depends on the continued commitment of the parties, and the meaning of the treaty provisions can change accordingly. <sup>125</sup>

# 3. Article 32 of the VCLT: Supplemental means of interpretation

In some instances, interpretation using Article 31 of the VCLT creates an ambiguity or absurd result in treaty application. <sup>126</sup> In such a case, Article 32 of the VCLT provides that treaty interpretation may be based on "supplementary means of interpretation, including the preparatory work (<u>travaux preparatoires</u>, <u>travaux</u> for short) of the treaty and the circumstances of its conclusion." Despite what the ordinary meaning of a text may be, if the <u>travaux</u> suggests that this was not the intended meaning, the treaty should be interpreted using the intended meaning. However, the <u>travaux</u> must always be used with care; treaty interpretation using the <u>travaux</u> can be time consuming, while the material included can be misleading. Consequently, the usefulness of the <u>travaux</u> is often marginal and rarely decisive. <sup>130</sup>

For the BWC, because interpretation using the context and object and purpose of the treaty, as well as subsequent State practice, addresses the loophole within the minimalist interpretation of Article I, it is not necessary to

<sup>&</sup>lt;sup>116</sup> Aust, supra note 12, at 216; see Kasikili/Sedudu Island (Bots./Namib.), Judgment, 1999 I.C.J. 1045, ¶¶ 47−51, 63, 73, 75 (Dec. 13).

<sup>&</sup>lt;sup>117</sup> Judgment (Preliminary Objections), App. No. 15318/89 (Mar. 23, 1995).

<sup>118</sup> Id. at ¶¶ 79–80; see also Demir & Baykara v. Turk., Judgment, App. No. 34503/97, ¶ 52 (Nov. 12, 2008) ("[A]s to the practice of European States, it can be observed that, in the vast majority of them, the right for public servants to bargain collectively with the authorities has been recognized" and "[t]he remaining exceptions can be justified only by particular circumstances.").

<sup>&</sup>lt;sup>119</sup> See, e.g., Jong-Cheol v. The Republic of Korea, Views, Comm. No. 968/2001 (July 27, 2005), in Report of the Human Rights Committee, Official Records of the General Assembly Sixtieth Session, Supplement No. 40, U.N. Doc. A/60/40, Vol. II, Annex V, G,  $\P$  8.3; Yoon and Choi v. The Republic of Korea, Views, Comm. Nos. 1321/2004 & 1322/2004 (Nov. 3, 2006), in Report of the Human Rights Committee, Official Records of the General Assembly, Sixty-second Session, Supplement No. 40, U.N. Doc. A/62/40, Vol. II, Annex VII, V,  $\P$  8.4.

<sup>&</sup>lt;sup>120</sup> See, e.g., "Tomimaru" (Japan v. Russ. Fed.), Prompt Release, Case No. 15, Judgment of Aug. 6, 2007, 2005–2007 ITLOS Rep. 74, ¶ 72; Southern Bluefin Tuna (N.Z. v. Japan; Austl. v. Japan), Provisional Measures, Case No. 3 & 4, Order of Aug. 27, 1999, 1999 ITLOS Rep. 280, ¶¶ 45, 50.

<sup>&</sup>lt;sup>121</sup> M/V Saiga (No. 2) (St. Vincent v. Guinea), Case No. 2, Judgement of July 1, 1999, 1999 ITLOS Rep. 10.

 $<sup>^{122}</sup>$  Id. at ¶ 155.

<sup>&</sup>lt;sup>123</sup> Nolte, supra note 10, at 221.

<sup>&</sup>lt;sup>124</sup> Id.

<sup>&</sup>lt;sup>125</sup> Id.

<sup>&</sup>lt;sup>126</sup> Aust, supra note 12, at 217.

<sup>&</sup>lt;sup>127</sup> VCLT, supra note 11, at art. 32.

<sup>&</sup>lt;sup>128</sup> Aust, supra note 12, at 218.

<sup>&</sup>lt;sup>129</sup> Id. at 218–19.

<sup>&</sup>lt;sup>130</sup> Id. at 219.

use the traveaux to provide an unambiguous interpretation of the BWC. Consequently, this rule of interpretation is not at issue in this Comment.

## 4. Evolutive Interpretation

Sometimes, in order to properly interpret a treaty, an interpreter must consider developments that occurred after the conclusion of the treaty—also known as "evolutive interpretation." In such a situation, the treaty is reinterpreted, irrespective of the original interpretation. 132 However, the evolutive approach is only appropriate "where there are signs, in the text or elsewhere, that the parties intended the treaty to have an evolutive character linked to subsequent developments in law or facts."133 Further, such an approach must result from the ordinary process of treaty interpretation. 134

To determine the new meaning of a term, courts depend on the "international law applicable to the parties at the time of the application of the treaty," or "as enshrined in international law." 135 Further, the term should be given an evolutive meaning if such meaning is required by the object and purpose of the treaty. 136 A treaty term should only be considered evolutive where:

- (a) The concept is one which implied taking into account subsequent technical, economic or legal development;
- (b) the concept sets up an obligation for further progressive development for the parties; or (c) the concept has a very general nature or is expressed in such general terms that it must take into account changing circumstances. 137

In accordance with the above category (a), an evolutive character applies to treaty terms that are technical or highly general in nature. 138

The evolutive approach has been accepted in the jurisprudence of multiple international courts and tribunals. 139 For example, in the Namibia advisory opinion, 140 the ICJ found that the term "self-determination" had

<sup>&</sup>lt;sup>131</sup> Nolte, supra note 10, at 356.

<sup>132</sup> See VCLT, supra note 11, at art. 31(3)(b); see also Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, 1971 I.C.J. 16, ¶¶ 21–22 (June 21).

133 Arato, supra note 100, at 452.

SASP draft conclusion, supra note 77, at art. 8 commentary ¶ 8.

<sup>&</sup>lt;sup>135</sup> Arato, supra note 100, at 471 (emphasis added); Int'l Law Comm'n, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, U.N. Doc. A/CN.4/L.682, at ¶¶ 443, 478 (2006) [hereinafter "Fragmentation Report": Aegean Sea Continental Shelf (Greece v. Turk.), Judgment, 1978 I.C.J. 3, ¶ 77 (Dec. 19). But see Dispute Regarding Navigational and Related Rights (Costa Rica v. Nicar.), Judgment, 2009 I.C.J. 213, ¶ 64 (July 13) (finding that the meaning of the term "comercio" had evolved due to a change in factual circumstances).

See, e.g., Sergey Zolotukhin v. Russia, App. No. 14939/03, ¶¶ 78–80 (Feb. 10, 2009) ("Provisions of an international treaty such as the Convention must be construed in light of their object and purpose," and as such "a failure by the Court to maintain a dynamic and evolutive approach would risk rendering [the European Convention on Human Rights] a bar to reform or improvement" for human rights); cf. Scoppola v. Italy (no. 2), App. No. 10249/03, 2009 Eur. Ct. H.R. 1297, ¶ 104 (2009) ("It is of crucial importance that the Convention is interpreted and applied in a manner which renders its rights practical and effective, not theoretical and illusory. A failure by the Court to maintain a dynamic and evolutive approach would risk rendering it a bar to reform or improvement."). But see Award in Arbitration regarding the Iron Rhine ("Ijzeren Rijn") Railway between the Kingdom of Belgium and the Kingdom of the Netherlands (Belgium v. United Kingdom), 27 UNRIAA 35, ¶ 80-84 (Perm. Ct. Arb. 2005) (suggesting that a treaty should only be considered evolutive on the basis of a treaty's object and purpose if the new meaning is necessary to give effect to the treaty's object and purpose).

<sup>&</sup>lt;sup>137</sup> Int'l Law Comm'n, Conclusions of the Work of the Study Group on the Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, U.N. Doc. A/61/10, 2006-II Y.B. Int'l L. Comm'n 177, at 181 (2006) (internal citations deleted) [hereinafter "Fragmentation Conclusions"].

<sup>138</sup> Arato, supra note 100, at 469; see, e.g., Case Concerning the Gabčikovo-Nagymaros Project (Hung. v. Slovk.), 1997 I.C. J. 7, ¶ 112 (Sept. 25) (finding that a technical provision within the Treaty was not "static" and should therefore be interpreted using the evolutive approach); Appellate Body Report, United States — Import Prohibitions of Certain Shrimp and Shrimp Products, ¶ 130, WTO Doc. WT/DS58/AB/R (adopted Oct. 12, 1998) ("[T]he generic term 'natural resources' in Article XX (g) is not 'static' in its content or reference but is simply 'by definition, evolutionary.").

<sup>&</sup>lt;sup>139</sup> Aegean Sea Continental Shelf (Greece v. Turk.), Judgment, 1978 I.C.J. 3, ¶ 77 (Dec. 19); Arato, supra note 100, at 443. <sup>140</sup> Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, 1971 I.C.J. 16 (June 21).

evolved between the adoption of the UN Charter in 1945 and the case in 1971; consequently, it held that the treaty must be interpreted using the modern understanding, despite the fact that the new meaning was at odds with the original meaning. In re-interpreting the term "self-determination," the ICJ invoked practice "in relation to the treaty" as a means of interpreting the treaty. More generally, the ECHR has held "the Convention is a living instrument which must be interpreted in the light of present-day conditions." The evolutive approach was also followed in the Iron Rhine case, wherein the Permanent Court of Arbitration addressed Belgium's right of transit under a 1839 Treaty, in light of subsequent practice, and accepted that technical rules may need to be given an evolutive interpretation. I44

Courts and tribunals have frequently interpreted the VCLT as implicitly endorsing the evolutive approach to interpretation. <sup>145</sup> Further, the SASP draft conclusion 8—"[i]nterpretation of treaty terms as capable of evolving over time"—formalized this approach. <sup>146</sup> However, it also cautions that interpretation should not only be based on general developments related to the treaty, but also on the more immediate practice "in the application of the treaty." <sup>147</sup> Such caution is necessary because of potential conflict between the new meaning of the terms of the treaty and the parties' original understanding of the treaty terms. <sup>148</sup>

## D. Amendment or Modification of a Treaty

States Parties to a treaty may amend or modify the treaty via subsequent agreement, provided that such amendment does not violate preemptory norms of international law or the rights of third parties. However, the drafters of the VCLT rejected a proposed draft version of Article 38,150 which would have allowed subsequent practice to modify the provisions of a treaty. 151

Nevertheless, in <u>Temple of Preah Vihear</u>, <sup>152</sup> the ICJ found that Thailand's failure to object to French control of Thai territory constituted a subsequent practice that modified the meaning of the border treaty between Thailand and Cambodia (wherein France was the colonizing power of Cambodia at the time the border treaty was

<sup>&</sup>lt;sup>141</sup> Id. ¶¶ 21–22, 52.

<sup>&</sup>lt;sup>142</sup> Id. at ¶¶ 21–22, 53. But see Dispute Regarding Navigational and Related Rights (Costa Rica v. Nicar.), Judgment, 2009 I.C.J. 213, ¶ 47 (July 13) (concluding that, while subsequent agreements and practice can be interpreted as providing a term with a meaning capable of evolving over time, such agreements and practice do not always do so).

<sup>&</sup>lt;sup>143</sup> Leyla Sahin v. Turkey, App. No. 44774/98, 44 Eur. H.R. Rep. 99, ¶ 136 (2005); Tyrer v. United Kingdom, App. No. 5856/72, 1978 Eur. Ct. H.R. 2, ¶ 31 (1978). See also Öcalan v. Turkey, App. No. 46221/99, 2005-IV Eur. Ct. H.R. 12, ¶ 163 (2005) (using subsequent practice and evolutive interpretation to reinterpret the right not to be subject to inhuman and degrading treatment).

Award in Arbitration regarding the Iron Rhine ("Ijzeren Rijn") Railway between the Kingdom of Belgium and the Kingdom of the Netherlands (Belgium v. United Kingdom), 27 UNRIAA 35, ¶ 80 (Perm. Ct. Arb. 2005); see also Aegean Sea Continental Shelf (Greece v. Turk.), Judgment, 1978 I.C.J. 3, ¶ 77 (Dec. 19); Delimitation of Maritime Boundary between Guinea-Bissau and Senegal (Guinea-Bissau v. Sen.), 20 UNRIAA 119, ¶ 85 (Perm. Ct. Arb. 1989).

<sup>&</sup>lt;sup>145</sup> See, e.g., The Right to Information on Consular Assistance in the Framework of the Guarantees of the Due Process of Law, Advisory Opinion OC-16/99, Inter-Am. Ct. H.R., ¶ 114 (Oct. 1, 1999) ("[The] evolutive interpretation is consistent with the general rules of treaty interpretation established in the 1969 Vienna Convention."); see also United Nations Convention on the Law of the Sea annex III art. 153(4) & 154(4), 1833 U.N.T.S. 3 (noting that the ITLOS Seabed Disputes Chamber allows the an evolutive interpretation of the certain obligations to ensure environmental protection). See generally Fragmentation Conclusions, supra note 132, at ¶ 478(a); Richard Gardiner, Treaty Interpretation 225, 276 (2009).

<sup>&</sup>lt;sup>146</sup> SASP draft conclusion, supra note 77, at art. 8 ("Subsequent agreements and subsequent practice under articles 31 and 32 may assist in determining whether or not the presumed intentions of the parties upon the conclusion of the treaty was to give a term used a meaning which is capable of evolving over time.").

<sup>&</sup>lt;sup>147</sup> Id.; Nolte, supra note 10, at 360.

Nolte, supra note 10, at 360.

<sup>149</sup> Id.; see VCLT, supra note 11, at art. 39 (permitting the modification of treaties by agreement by the States parties).

<sup>&</sup>lt;sup>150</sup> "A treaty may be modified by subsequent practice in the application of the treaty establishing the agreement of the parties to modify its provisions." Y.B. Int'l Law Comm'n, U.N. Doc. A/6309/Rev.1, 236 (1966).

<sup>&</sup>lt;sup>151</sup> Arato, supra note 100, at 456.

<sup>&</sup>lt;sup>152</sup> Temple of Preah Vihear (Cambodia v. Thailand), Judgment, 1962 I.C.J. 6 (June 15).

concluded). 153 Further, in Dispute regarding Navigational and Related Rights, 154 the ICJ held that "subsequent practice of the parties, within the meaning of Article 31(3)(b) of the Vienna Convention, can result in a departure from the original intent on the basis of tacit agreement." 155 Most prominently, in both the Namibia advisory opinion 156 and the Wall advisory opinion, 157 the ICJ modified the ordinary meaning of the UN Charter based on subsequent practice of States, <sup>158</sup> Consequently, the decisions of the ICJ can be understood as explicitly or implicitly permitting amendment or modification of treaties. 159

Other tribunals have also adopted this approach, 160 leading one legal scholar to conclude that "the proliferation of cases on the basis of subsequent practice since the Vienna Convention dropped [Draft Articles on the Law of Treaties, Article 38" has resulted in a reinterpretation of the VCLT "on the basis of subsequent practice in its application," meaning that Article 31(3)(b) now allows "modification by subsequent practice." <sup>161</sup>

#### II. GLOBAL SURVEY OF STATE PRACTICE

Under international law, in order to establish State practice, an interpreter must conduct an survey of global State practice—including both the actions taken by States involved in the practice, and failure of States not involved in the practice to object to such actions. 162 For the BWC specifically, global State practice demonstrates the extensive application of extra safety measures for experimentation that could potentially be used as deadly weapons and therefore qualifies as DURC. 163 For instance, the World Health Organization (WHO) established non-binding guidelines that provide recommendations for how to regulate DURC. 164

In analyzing global State practice, this comment will address States by regions. It will first demonstrate whether the States are relevant to the global analysis by indicating how many BSL-3 or BSL-4 laboratories exist in the country or region. It will then provide a short overview of the regulatory regimes within the State, as a means of indicating whether the countries in the region are involved in the State practice. The analysis will also include relevant additional information that is helpful analyzing the global State practice.

<sup>153</sup> Id. at 23 ("[A]n acknowledgement by conduct was undoubtedly made in a very definite way . . . it is clear that the circumstances were such as called for some reaction."); see also Land and Maritime Boundary between Cameroon and Nigeria (Cameroon v. Nigeria: Eq. Guinea intervening), Judgment, 2002 I.C.J. 303, ¶ 68 (Oct. 1).

<sup>154</sup> Dispute Regarding Navigational and Related Rights (Costa Rica v. Nicar.), Judgment, 2009 I.C.J. 213 (July 13).

<sup>&</sup>lt;sup>155</sup> Id. at ¶ 64.

<sup>156</sup> Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, 1971 I.C.J. 16, ¶¶ 21–22 (June 21).

<sup>157</sup> Legal Consequence of the Construction of the Wall in the Occupied Palestinian Territory, Advisory Opinion, 2004 I.C.J. 136 (July 9).

158 1971 I.C.J. 16, at ¶ 22; 2004 I.C.J. 136, at ¶ 28.

<sup>&</sup>lt;sup>159</sup> Nolte, supra note 10, at 353; Arato, supra note 100, at 462. It should be noted that ILC SASP draft conclusion 7 explicitly denies that subsequent practice can modify a treaty; rather, the decisions of the ICJ simply provide for the reinterpretation of a treaty based on subsequent practice. SASP draft conclusion, supra note 77, at art. 7 commentary ¶ 31. However, this Comment disregards this distinction as both reinterpretation and modification have the same effect of changing the obligations required by

<sup>&</sup>lt;sup>160</sup> See, e.g., Soering v. United Kingdom, App. No. 14038/88, 11 Eur. H.R. Rep. 439, ¶ 103 (1989) ("Subsequent practice in national penal policy, in the form of a generalized abolition of capital punishment, could be taken as establishing the agreement of the Contracting states to abrogate the exception provided for under Article 2 § 1 (art. 2-1) and hence to remove a textual limit."); Öcalan v. Turkey, App. No. 46221/99, 2005-IV Eur. Ct. H.R. 12, ¶ 163 (2005) ("[subsequent] practice within the Member States could give rise to an amendment of the Convention.").

<sup>&</sup>lt;sup>161</sup> Arato, supra note 100, at 464 n.73.

<sup>&</sup>lt;sup>162</sup> See supra note 98 to 101, and accompanying text.

<sup>&</sup>lt;sup>163</sup> See supra note 61 to 65, and accompanying text.

<sup>164</sup> It is important to note that, because the guidelines created by the WHO are non-binding, States may choose whether or not to comply with them. Consequently, it is necessary to analyze each State specifically to determine whether or not the State has binding regulatory measures that govern DURC. See Johnson and Casagrande, supra note 66, at 128. See generally WHO Laboratory Safety, supra note 71, at 47 (providing non-binding guidelines for States in implementing biosafety measures).

#### A. North America

For the purposes of this Comment, this region includes the US and Canada. As of 2008, the US has at least fifteen BSL-4 facilities and 1,643 BSL-3 facilities, and maintains an extensive biosafety regime which heavily regulates DURC. Moreover, the practice of the US is arguably the catalyst for other State's subsequent change in practice. Moreover, the practice of the US is arguably the catalyst for other State's subsequent change in practice.

Similarly, Canada maintains an equally extensive biosafety regime that is enforced by the government.<sup>170</sup> However, Canada has a much less extensive network of laboratories, with only one BSL-4 facility and at least three BSL-3 facilities.<sup>171</sup> The Human Pathogens and Toxins Act (HPTA) of 2009, which is legally binding, governs these facilities.<sup>172</sup> The HPTA strengthens controls regarding access to human pathogens and toxins by facility licensing measures, security clearances for high-risk agents, and inspections.<sup>173</sup>

#### B. Latin America and the Caribbean

For the purposes of this Comment, this region includes Central America, the Caribbean, Mexico, and South America. Central America has no BSL-4 laboratories and only two BSL-3 laboratories; consequently, because the region has very few facilities in which the State practice would occur, the region is of limited relevance for the global

<sup>168</sup> See CDC, supra note 162 (providing the current US guidelines for biosafety); Historical Lab Safety Activities, https://www.cdc.gov/labs/safety-history.html (last visited Jan. 27, 2021) (providing the recent history of biosafety in the US).

<sup>&</sup>lt;sup>165</sup> For the purposes of this Comment, Mexico will be addressed in the "Latin America" section.

<sup>&</sup>lt;sup>166</sup> Peters, supra note 66, at 866–70.

<sup>167</sup> US National Research Council Staff, United States High-Containment Biological Labs and Regulations, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 193 (2012), https://www.nap.edu/read/13315/chapter/27. See generally Centers for Disease Control and Prevention (CDC), Biosafety in microbiological and biomedical laboratories (5th ed. 2009), www.cdc.gov/biosafety/publications/bmbl5 (providing the biosafety guidelines that the US laboratories must comply with, in accordance with the CDC's enforcement mechanisms); United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012), https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf (outlining the US government oversight of dual-use research of concern); Recommended Policy Guidance for Department Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO) (Jan. 9, 2017), https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf (providing recommendations for the safety measures implemented while researching "Potential Pandemic Pathogens"); Jocelyn Kaiser, White House announces review process for risky virus studies, Science (Jan. 9, 2017), https://www.sciencemag.org/news/2017/01/white-house-announces-review-process-risky-virus-studies.

<sup>169</sup> Harris, supra note 6, at \*10–15 (listing the US governance mechanisms for biological weapons development, biological research, and access and use to biological material); see Biosafety worldwide — Historical Background, https://www.biosafety.be/content/biosafety-worldwide-historical-background-0 (last visited Jan. 27, 2021) (explaining that the work of the Public Health Service of the US, in 1969, was adopted by the WHO in their regulatory measures of 1979—which "would afterwards serve as a basis for a large number of national reference documents."); see also, e.g., Ministry of Environment and Forest, Government of the People's Republic of Bangladesh, Biosafety Guidelines of Bangladesh (2005), http://extwprlegs1.fao.org/docs/pdf/bgd34267.pdf (providing the Bangladeshi guidelines for biosafety, which follow the same guidelines as those set by the CDC); Leila dos Santos Macedo, Overview of Biosafety and Biosecurity in High-containment Labs in Brazil: A report of the Brazilian Biosafety Association, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 143, 145 (2012) https://www.nap.edu/read/13315/chapter/19 (explaining that the Brazilian Ministry of Science and Technology uses the same definition of "selected agents" as the CDC).

<sup>&</sup>lt;sup>170</sup> Canadian Biosafety Standards and Guidelines, https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html (last visited Jan. 27, 2021); see Johnson and Casagrande, supra note 66, at 128 (analyzing the regulatory measures implemented in Canada).

<sup>&</sup>lt;sup>171</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>172</sup> Id.

<sup>&</sup>lt;sup>173</sup> Id.

survey of State practice. 174 Similarly, while the Caribbean—excluding Cuba—maintains no BSL-4 laboratories and only one known BSL-3 laboratory, 175 CARICOM—the regional group in the Caribbean—has implemented regulatory measures based on WHO recommendations. 176 However, it is relevant to note that neither region objects to the regulatory regimes existing in States with BSL-3 and BSL-4 laboratories. 177

Two countries of note are Mexico and Cuba. Mexico maintains eighteen BSL-3 laboratories, <sup>178</sup> which are regulated by a biological risk management system for public health laboratories that is promoted and evaluated by both a public initiative—InDRE<sup>179</sup>—and private initiative—AMEXBIO<sup>180</sup>. <sup>181</sup> Cuba, on the other hand, has at least one BSL-4 laboratory and at least five BSL-3 laboratories. 182 Cuba maintains a National Center for Biological Safety of the Ministry of Science, Technology, and Environment. 183 Moreover, in 2016, at the Eight Review Conference of the Biological Weapons Convention, Cuba offered to send technical experts to interested States in an effort to teach other States about "biosafety and biosecurity for biological agent controls."184

South America maintains three BSL-4 laboratories and approximately thirty-four BSL-3 laboratories, the majority of which are in Brazil and Argentina. 185 In Brazil, the Ministry of Health is responsible for all of the public health laboratories, which include twelve BSL-3 laboratories, whereas the Ministry of Agriculture is responsible for all agricultural laboratories, which include eight BSL-3 laboratories. 186 Each ministry has different protocols for biosafety; however, Brazil has only recently begun to address the issue of biosecurity, 187 Brazil began its first biosecurity course in 2007, with the support of the US Biosecurity Engagement Program. 188 Similarly, in 2001, with the assistance of the CDC, the Argentinian government created a biosafety course for laboratory workers, which provided advanced training in good laboratory practices. 189 Biosafety manuals were subsequently provided to every province; further, in 2004, government officials investigated biosafety in all public laboratories and provided any equipment necessary to modernize the tools and equipment to make them compliant with biosafety requirements. 190 The Ministry of Health and Environment also contributes greatly to the implementation of education and immunization programs in order to prevent laboratory accidents, and any outbreaks that could result from such accidents. 191

<sup>&</sup>lt;sup>174</sup> Id. While the lack of DURC in the region limits the relevance of the region for establishing State practice, it is notable in that there is no record of States within the region objecting to other State's DURC or the regulatory regimes created to oversee such research. See supra note 100, and accompanying text.

<sup>&</sup>lt;sup>175</sup> Peters, supra note 66, at 866–70.

<sup>176</sup> See World Health Organization, Extended Biosafety Advisory Group meeting: Meeting Report, 14, U.N. Doc. WHO/ HSE/GCR/2016.7 (Nov. 24–26, 2014) (providing a report of the efforts CARICOM has implemented).

<sup>&</sup>lt;sup>177</sup> See supra note 98 to 101, and accompanying text.

<sup>&</sup>lt;sup>178</sup> Mexico has no BSL-4 laboratories. Peters, supra note 66, at 868.

<sup>179</sup> Institute of Epidemiological Diagnosis and Reference Dr. Manuel Martínez Báez, https://www.gob.mx/salud/accionesy-programas/instituto-de-diagnostico-y-referencia-epidemiologicos-indre (in Spanish) (last visited Jan. 27, 2021).

180 AMEXBIO, http://amexbio.org/ (in Spanish) (last visited Jan. 27, 2021).

World Health Organization, supra note 171, at 13–14.

<sup>&</sup>lt;sup>182</sup> Cuba has a few BSL-4 laboratories in a single facility; however, they have never been used for BSL-4 research. Further, the country probably maintains an offensive research program. Peters, supra note 66, at 867.

<sup>&</sup>lt;sup>183</sup> Eighth Review Conference of Biological Weapons Convention, Non-official Translation; National Document Cuba, Cuban Offers and Requests to the International Cooperation Database under Article X of the BTWC, \*2, U.N. Doc. BWC/ CONF.VIII/WP.5 (2016).

<sup>&</sup>lt;sup>184</sup> Id. at \*1.

<sup>&</sup>lt;sup>185</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>186</sup> Macedo, supra note 164, at 144–45.

<sup>&</sup>lt;sup>187</sup> Id. at 147.

<sup>&</sup>lt;sup>188</sup> Id. at 148.

<sup>&</sup>lt;sup>189</sup> Nidia E. Lucero and Faustino Siñeriz, The Argentine experience in enhancing biosafety through good laboratory practices, 8 Asian Biotechnology & Dev. Rev. 99, 105 (2005), http://www.ris.org.in/images/RIS\_images/pdf/article4\_v8n1.pdf.

<sup>&</sup>lt;sup>190</sup> Id. at 105.

<sup>&</sup>lt;sup>191</sup> Id. at 108–10.

### C. Europe

For the purposes of this Comment, this region includes Eastern Europe, and Western Europe. Similar to North America, many States within Europe regulate DURC.<sup>192</sup> Overall, Western Europe maintains twelve BSL-4 and 161 BSL-3 laboratories.<sup>193</sup> Additionally, Eastern Europe maintains approximately six BSL-4 and four BSL-3 laboratories.<sup>194</sup> The European Union maintains the regulatory framework applicable for most States within Western Europe, and a handful of States within Eastern Europe.<sup>195</sup> One such regulatory framework is the "Chemical, Biological, Radiological, Nuclear Action Plan of 2009," which prevents unauthorized access to materials of concern.<sup>196</sup> While this plan is politically binding, it provides no information for State implementation.<sup>197</sup>

Despite having an applicable overarching regulatory framework, many States in Eastern and Western Europe have implemented State-specific regulatory measures. For example, Denmark implemented its own domestic legislation governing DURC—the 2008 "Act on Security for Biological Substances, Delivery Systems, Related Materials." This legally binding act implements control measures for access to biological substances, delivery systems, and related material; further, it requires oversight of dual-use research and imposes penalties for violation. Netherlands also implemented its own regulatory framework—the 2007 "Code of Conduct for Biosecurity." While not legally binding, the regulation calls for guidance in screening dual-use research and facility access. Moreover, the government of Netherlands ultimately deemed the regulation insufficient. Further States implementing domestic regulatory frameworks include Germany, France, Heriog. Ukraine, Lord U

Two States of particular note are the United Kingdom (UK) and the Russian Federation (Russia). The UK maintains nine BSL-4 laboratories and approximately 600 BSL-3 laboratories.<sup>207</sup> The government passed legally-binding legislation, the "Anti-Terrorism, Crime and Security Act of 2001 and 2007," which controls access to human pathogens and toxins, implements notification and security requirements, and requires background checks.<sup>208</sup> On the other hand, Russia has three BSL-4 laboratories and at least eighty-four BSL-3 laboratories.<sup>209</sup> Similar to the other powerful States in the international community, the Russian government maintains extensive regulations to control DURC, including Sanitary and Epidemiological Regulations SP 1.3.1285-03 on "[s]afe

<sup>&</sup>lt;sup>192</sup> Jordi Molas-Gallart, Coping with Dual-Use: A Challenge for European Research Policy, 40 J. Common Mkt. Studies 155 (2002), https://doi.org/10.1111/1468-5965.00348.

<sup>&</sup>lt;sup>193</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>194</sup> Id. at 866–70.

<sup>&</sup>lt;sup>195</sup> Ingegerd Kallings & Kathrin Summermatter, High-Containment Microbiology Laboratories in Europe, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 151 (2012), https://www.nap.edu/read/13315/chapter/20.

<sup>&</sup>lt;sup>196</sup> Harris, supra note 6, at \*28–29; see also id. at 151–55.

<sup>&</sup>lt;sup>197</sup> Johnson and Casagrande, supra note 66, at 128.

<sup>&</sup>lt;sup>198</sup> Harris, supra note 6, at \*27, \*29.

<sup>&</sup>lt;sup>199</sup> Id.

<sup>&</sup>lt;sup>200</sup> Id. at \*27, \*30.

<sup>&</sup>lt;sup>201</sup> Id.

<sup>&</sup>lt;sup>202</sup> Id.

<sup>&</sup>lt;sup>203</sup> Johnson & Casagrande, supra note 66, at 128; Id. at \*27, \*30–31.

<sup>&</sup>lt;sup>204</sup> Boris Pastorino, Xavier de Lamballerie & Rémi Charrel, Biosafety and Biosecurity in European Containment Level 3 Laboratories: Focus on French Recent Progress and Essential Requirements, 5 Frontiers in Public Health 1 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5449436/pdf/fpubh-05-00121.pdf.

<sup>&</sup>lt;sup>205</sup> Olena Kysil & Serhiy Komisarenko, High-Containment Laboratories in Ukraine: Local Resources and Regulations, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 171 (2012), https://www.nap.edu/read/13315/chapter/25.

<sup>&</sup>lt;sup>206</sup> Kallings & Summermatter, supra note 190, at 152.

Peters, supra note 66, at 870.

<sup>&</sup>lt;sup>208</sup> Johnson & Casagrande, supra note 66, at 128; Neild Davison & Filippa Lentzos, High-Containment Laboratories — UK Case Study, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 175 (2012), https://www.nap.edu/read/13315/chapter/26.

<sup>&</sup>lt;sup>209</sup> Peters, supra note 66, at 869.

handling of micro-organisms in pathogenic hazard groups I-II," which regulates biosafety in regard to testing infectious diseases.<sup>210</sup>

#### D. Middle East and North Africa

For the purposes of this Comment, this region includes Turkey, Libya, Sudan, Egypt, Iran, Afghanistan, North Africa, <sup>211</sup> and the countries on the Arab Peninsula. <sup>212</sup> Overall, the Middle East and North Africa maintain no BSL-4 laboratories, and approximately twelve BSL-3 laboratories.<sup>213</sup> This region contains a series of States of particular note. For one, the United Arab Emirates announced in 2005 that it would become the world's first "free trade zone" for biotechnology; consequently, the State maintains a National Committee on Biosecurity and regularly holds biosecurity conferences.<sup>214</sup> For another, Turkey has two ministries responsible for safety and security in high-level BSL laboratories: the Ministry of Agriculture and Rural Affairs, General Directorate of Protection and Control; and the Ministry of Health.<sup>215</sup> While there is no legislation which regulates the requirements for establishing a high-level BSL laboratory, Turkey extensively utilizes international standards and guidelines, such as those of the CDC's Office of Safety, Health and Environment, National Institute of Health, WHO's Center for Applied Biosafety, the Cartagena Protocol for Biosafety, as well as others.<sup>216</sup>

Unlike Turkey, Pakistan implemented the "Pakistan Biosafety Rules 2005," which established the National Biosafety Committee, the Technical Advisory Committee, and Institutional Biosafety Committees.<sup>217</sup> However, similar to Turkey, there are limited standard guidelines or regulations for biosafety. <sup>218</sup> Consequently, while Pakistan uses its 2005 National Biosafety Guidelines, it also uses the standards and guidelines from the WHO, the CDC's Biosafety in Microbiological Biomedical Laboratories, and the Canadian Association for Biological Safety.<sup>219</sup>

Two other countries are of note: Syria and Egypt. Both Syria and Egypt are only signatories to the BWC both having signed in 1972.<sup>220</sup> Under Article 18(a) of VCLT, a State that has signed a treaty must "refrain from acts which defeat the object and purpose of the treaty" until it is clear whether or not the State will become party to the treaty.<sup>221</sup> However, under Article 18(b) of the VCLT, States are exempted from this obligation if there has been "undue delay" in the treaty entering into force.<sup>222</sup> Syria has not made comments in support of the BWC and is

<sup>&</sup>lt;sup>210</sup> Michael V. Ugrumov & Sergey V. Netesov, Overview of High-Containment Biological Laboratories in Russia, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 161, 162–64 (2012), https://www.nap.edu/read/13315/chapter/22.

<sup>&</sup>lt;sup>211</sup> For the purposes of this Comment, countries in North Africa include Algeria, Egypt, Libya, Mauritania, Morocco, Western Sahara, and Tunisia.

<sup>&</sup>lt;sup>212</sup> See Erum Khan et al., Biosafety Initiatives in BMENA Region: Identification of Gaps and Advances, 4 Frontiers in Public Health 1 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4805608/pdf/fpubh-04-00044.pdf; Regional and National Biosafety and Biosecurity Strategies for the Middle East and North Africa (MENA), The International Council for the Life Sciences (2011), https://www.virtualbiosecuritycenter.org/wp-content/uploads/2011/04/Framework-English-Rev-May102.pdf.
<sup>213</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>214</sup> Biosecurity, United Arab Emirates Ministry of Climate Change & Environment, https://www.moccae.gov.ae/en/knowledge-and-statistics/biosecurity.aspx (last visited on Jan. 27, 2021); United Arab Emirates, https://www.nti.org/learn/countries/ united-arab-emirates (last visited on Jan. 27, 2021).

<sup>&</sup>lt;sup>215</sup> Hüseyin Avni Öktem, Country Overview for Turkey: Biosecurity Laws and Regulations in Turkey, in Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 169, 169 (2012), https://www.nap.edu/read/13315/chapter/24.

<sup>&</sup>lt;sup>216</sup> Id. at 169–70.

<sup>&</sup>lt;sup>217</sup> Anwar Nasim & Erum Khan, Biotechnology and Biosecurity Initiatives in Pakistan: A Country Report, Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop 159, 159 (2012), https://www.nap.edu/read/13315/chapter/21.

<sup>&</sup>lt;sup>219</sup> Id. at 160.

<sup>&</sup>lt;sup>220</sup> Arms Control Association, Biological Weapons Convention Signatories and States-Parties, https://www.armscontrol. org/factsheets/bwcsig (last visited Jan. 27, 2021).

<sup>&</sup>lt;sup>221</sup> VCLT, supra note 11, at art. 18(a).

<sup>&</sup>lt;sup>222</sup> Id. at art. 18(b).

not in compliance with the BWC.<sup>223</sup> There is limited information regarding whether Syria has either a BSL-3 or BSL-4 laboratory; however, there is evidence it has an offensive research program that is producing biological agents, and it may have assistance from Russia, North Korea, Iran, and possibly Iraq.<sup>224</sup> In Egypt, on the other hand, officials have regularly expressed their support for the BWC.<sup>225</sup> Further, when establishing the country's first BSL-3 laboratory, the Egyptian Ministry of Health and Population worked with the WHO to establish a regulatory framework for biosafety in the laboratory.<sup>226</sup>

Lastly, Israel is one of the ten States who are not party to the BWC.<sup>227</sup> It has no declared BSL-4 laboratories; however, such laboratories are probably associated with the Israel Institute for Biological Research.<sup>228</sup> Further, the country likely has an offensive research program which possibly has produced biological weapons.<sup>229</sup> Nevertheless, Israel has legally binding domestic regulation—the 2008 "Regulation of Research into Biological Disease Agents Act"—which controls access to biological agents by facility authorization; provides oversight of dual-use research; and is implemented at a national level.<sup>230</sup>

## E. Africa

For the purposes of this Comment, this region includes the countries in Eastern,<sup>231</sup> Western,<sup>232</sup> Central,<sup>233</sup> and Southern<sup>234</sup> Africa. Overall, the region maintains two BSL-4 laboratories and approximately twenty-four BSL-3 laboratories.<sup>235</sup> Moreover, the region includes six of the ten States that have neither ratified nor signed the BWC, as well as one of the States that has only signed the BWC.<sup>236</sup> This region is therefore of limited application to our analysis of state practice.<sup>237</sup> However two States may be beneficial: Kenya, which maintains six BSL-3 laboratories; and South Africa, which maintains one BSL-4 laboratory and six BSL-3 laboratories.<sup>238</sup> Using the WHO biosafety guidelines and local biosafety standards, Nigeria created the NUITM-KEMRI biosafety education program to teach laboratory workers the recommended WHO practices, in order to increase biosafety and biosecurity in BSL-3 laboratory research.<sup>239</sup> This demonstrates a State commitment to comply with global regulatory standards for biosafety and biosecurity. Further, in South Africa, policymakers mandated the Academy of Science of South Africa to conduct an analysis of biosafety and biosecurity in the State.<sup>240</sup>

<sup>&</sup>lt;sup>223</sup> Peters, supra note 66, at 870.

<sup>224</sup> Id

<sup>&</sup>lt;sup>225</sup> Egypt: Biological, https://www.nti.org/learn/countries/egypt/biological (last visited Jan. 27, 2021).

First biosafety level 3 (BSL-3) laboratory in Egypt, http://www.emro.who.int/blood-safety/blood-news/biosafety-labegypt.html (last visited Jan. 27, 2021).

<sup>&</sup>lt;sup>227</sup> Arms Control Association, supra note 215.

<sup>&</sup>lt;sup>228</sup> Peters, supra note 66, at 868.

<sup>&</sup>lt;sup>229</sup> Id.

<sup>&</sup>lt;sup>230</sup> Harris, supra note 6, at \*28.

For the purposes of this Comment, this region includes Comoros, Djibouti, Ethiopia, Eritrea, Kenya, Madagascar, Mauritius, Rwanda, Seychelles, Somalia, South Sudan, Sudan, Tanzania, and Uganda.

<sup>&</sup>lt;sup>232</sup> For the purposes of this Comment, this region includes Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire, Gambia, Ghana, Guinea-Bissau, Guinea, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

<sup>&</sup>lt;sup>233</sup> For the purposes of this Comment, this region includes Burundi, Cameroon, Central African Republic, Chad, Congo, Democratic Republic of Congo, Equatorial Guinea, Gabon, and São Tomé-and-Príncipe.

<sup>&</sup>lt;sup>234</sup> For the purposes of this Comment, this region includes Angola, Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, and Zimbabwe.

<sup>&</sup>lt;sup>235</sup> Peters, supra note 66, at 866–70.

Somalia is only a signatory to the BWC; Chad, Comoros, Djibouti, Eritrea, Namibia, and South Sudan have neither signed nor ratified the BWC. Arms Control Association, supra note 215.

<sup>&</sup>lt;sup>237</sup> See generally World Health Organization, Report on the Status of EDPLN BSL-3 in Select Countries in the African Region (Dec. 31, 2016) (analyzing the region's response to biosafety in BSL-3 laboratories).

<sup>&</sup>lt;sup>238</sup> Peters, supra note 66, at 866–70.

Betty Muriithi et al., Biosafety and biosecurity capacity building: insights from implementation of the NUITM-KEMRI biosafety training model, 46 Tropical Med. & Health \*1–3 (2018), https://doi.org/10.1186/s41182-018-0108-7.

Academy of Science of South Africa, The State of Biosafety and Biosecurity in South Africa 13 (May 2015), https://www.assaf.org.za/files/2017%20reports/The%20State%20of%20Biosafety%20%20Biosecurity%20Report%20FINAL.pdf.

Ultimately, the review concluded that, while the existing system is comprehensive, there are several weaknesses that must be addressed.<sup>241</sup>

# F. Asia

For the purposes of this Comment, this region encompasses Central Asia,<sup>242</sup> East Asia,<sup>243</sup> South Asia,<sup>244</sup> and Southeast Asia.<sup>245</sup> East Asia, which includes many of the developed States in Asia, maintains at least four BSL-4 laboratories and approximately 231 BSL-3 laboratories.<sup>246</sup> The other three regions, on the other hand, maintain one BSL-4 laboratory and approximately thirty-nine BSL-3 laboratories collectively.<sup>247</sup>

China has at least one BSL-4 laboratory, and is planning on building five to seven more by 2025.<sup>248</sup> Further, the country expanded from ten BSL-3 laboratories to at least thirty after the SARS outbreak of 2003.<sup>249</sup> In regards to biosecurity, prior to the COVID-19 pandemic, the State did not have any regulations; however, in the wake of the COVID-19 pandemic, China passed its first biosecurity law.<sup>250</sup> Conversely, in regards to biosafety, China has long maintained biosafety legislation.<sup>251</sup>

Japan, on the other hand, has two BSL-4 laboratories which do not conduct BSL-4 level research due to public opposition, and approximately 200 BSL-3 laboratories.<sup>252</sup> As with the other countries in East Asia, it maintains extensive regulation over DURC.<sup>253</sup> Other countries of note include India;<sup>254</sup> Philippines;<sup>255</sup> South Korea;<sup>256</sup> and Thailand<sup>257</sup>—all of which maintain extensive regulatory regimes for DURC.

<sup>&</sup>lt;sup>241</sup> Academy of Science of South Africa, supra note 235, at 14.

<sup>&</sup>lt;sup>242</sup> For the purposes of this Comment, this region includes Tajikistan, Uzbekistan, Kazakhstan, Turkmenistan, and Kyrgyzstan.

<sup>&</sup>lt;sup>243</sup> For the purposes of this Comment, this region includes China, Mongolia, North Korea, South Korea, Japan, Hong Kong, Taiwan, and Macau.

<sup>&</sup>lt;sup>244</sup> For the purposes of this Comment, this region includes Sri Lanka, Bangladesh, India, Afghanistan, Pakistan, Bhutan, Nepal, and the Maldives.

For the purposes of this Comment, this region includes Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Timor Leste, and Vietnam.

<sup>&</sup>lt;sup>246</sup> Peters, supra note 66, at 866–70; see also Christian Enemark, Preventing accidental disease outbreaks: biosafety in East Asia, APSNet Policy Forum (September 2006), http://nautilus.org/apsnet/0631a-enemark-html/.

Peters, supra note 66, at 866–70; cf. Togzhan Kassenova, Policy analysis brief. 1540 in PRACTICE: CHALLENGES AND OPPORTUNITIES FOR SOUTHEAST ASIA, Stanley Found. (May 2011), https://stanleycenter.org/publications/pab/KassenovaPAB611.pdf. Peters, supra note 66, at 867.

<sup>&</sup>lt;sup>249</sup> Id.; cf. David Cyranoski, Inside China's pathogen lab, 542 Nature 399 (2017), https://www.nature.com/news/inside-the-chinese-lab-poised-to-study-world-s-most-dangerous-pathogens-1.21487.

Guo Rui, China passes first biosecurity law in wake of Covid-19 pandemic, S. China Morning Post (Oct. 20, 2020), https://www.scmp.com/news/china/society/article/3106174/china-passes-first-biosecurity-law-wake-covid-19-pandemic.

<sup>&</sup>lt;sup>251</sup> Huigang Liang et al., History of and suggestions for China's biosafety legislation, 1 J. Biosafety Biosecurity 134, 134 (2019), https://doi.org/10.1016/j.jobb.2019.08.002; Guizhen Wu, Laboratory biosafety in China: past, present, and future, 1 Biosafety & Health 56 (2019), https://doi.org/10.1016/j.bsheal.2019.10.003.

<sup>&</sup>lt;sup>252</sup> Peters, supra note 66, at 868.

<sup>&</sup>lt;sup>253</sup> Tomohiko Makino, Japanese Regulatory Space on Biosecurity and Dual-Use Research of Concern, 8 J. DISASTER RESEARCH 686 (2013).

<sup>&</sup>lt;sup>254</sup> See Government of India, Ministry of Science and Technology, Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017); India gets high-security lab for human diseases, 449 Nature 649 (2007), https://doi.org/10.1038/449649e.

<sup>&</sup>lt;sup>255</sup> See National Committee on Biosafety of the Philippines, Philippine Biosafety Guidelines (1990) (providing the biosecurity framework for the Philippines, created by the National Committee on Biosafety which was created by President Corazon C. Aquino in Executive Order No. 430); Designation of the National Training Center for Biosafety and Biosecurity of the National Institutes of Health, University of the Philippines Manila as a Training Provider for Biosafety and Biosecurity, <a href="https://hfsrb.doh.gov.ph/?p=1673">https://hfsrb.doh.gov.ph/?p=1673</a> (last visited on Jan. 27, 2021) (noting that, in order for laboratories to test COVID-19, the laboratory must train all of its personnel in biosafety and biosecurity).

<sup>&</sup>lt;sup>256</sup> National Institute of Health, South Korea, Division of Biosafety Evaluation and Control, http://www.cdc.go.kr/contents.es?mid=a50101060200 (last visited Jan. 27, 2021).

<sup>&</sup>lt;sup>257</sup> BIOTEC, Regulatory frameworks to prevent the misuse of Science and Technology: Thailand (November 2018), https://www.unog.ch/80256EDD006B8954/(httpAssets)/350A301455C21AAFC12583B000491CDB/\$file/SIRAS\_Regulatory +frameworks+to+prevent+S&T+misuse.pdf.

#### G. Oceania

For the purposes of this Comment, this region includes Australia, New Zealand, Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, and Vanuatu. Overall, Oceania maintains three BSL-4 laboratories and forty-one BSL-3 laboratories. All of the BSL-4 laboratories and forty of the BSL-3 laboratories are located in Australia, and the final BSL-3 laboratory is located in New Zealand. Moreover, the region includes three of the ten States that have neither ratified nor signed the BWC. Consequently, while the region's general acceptance of other State's regulatory practice in regards to biosafety and biosecurity is relevant, only the regulatory practice of New Zealand and Australia are relevant to this Comment's analysis of global State practice.

Australia and New Zealand maintain a collaborative regulatory regime, which is extensive and robust. Regulation includes the 2000 Gene Technology Act, regulating research on genetically modified organisms; and the Australia and New Zealand Standard for Safety in Laboratories: Microbiological Aspects, which provides extensive regulation for BSL-3 and BSL-4 laboratory research.<sup>262</sup> The latter is regularly updated, and the most recent update was released for public comment in 2019.<sup>263</sup>

In conclusion, the global analysis of State practice in regards to regulation of DURC demonstrates that a vast majority of States with BSL-3 and BSL-4 laboratories maintain regulatory regimes for these laboratories. Further, States that do not participate in the State practice have not to date objected to the regulatory regimes of the other States. This subsequent practice and acquiescence is useful for interpreting the requirements of the BWC, in light of its context and object and purpose, as this Comment will address below.

#### III. ANALYSIS

Under Article I of the BWC, States parties are prohibited from acquiring, developing, retaining, stockpiling, or producing "microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have <u>no</u> justification for <u>prophylactic</u>, <u>protective or other peaceful purposes</u> . . ."<sup>264</sup> A plain text reading of this provision results in a minimalist interpretation, wherein a loophole exists allowing States to obtain potentially prohibited agents provided there is some justification, however minimal.

Subsequent to the adoption of the BWC, and in consideration of recent scientific advancements, a vast majority of States implemented regulatory regimes that weigh the benefits of the research against the potential costs of accident or misuse, and apply extra regulatory measures accordingly.<sup>265</sup> Consequently, subsequent State practice has addressed the loophole in the minimalist interpretation of Article I of the BWC by requiring safety measures, commiserate with the potential risks of the pathogen, in order to provide evidence that there is justification for the creation or acquisition of the pathogen.

This section will address the interpretation of the BWC using the rules set by the VCLT, as well as the potential application of an evolutive approach to interpretation. First, the section will address the ordinary meaning of Article I, in light of the treaty's object and purpose and its context. Next, the section will analyze the meaning based on subsequent State practice by referencing the global survey of State practice conducted above. Lastly, the section will address the evolutive interpretation of "no justification for prophylactic, protective or other peaceful purposes."

<sup>&</sup>lt;sup>258</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>259</sup> Id.

<sup>&</sup>lt;sup>260</sup> Kiribati, Micronesia, and Tuvalu have neither signed nor ratified the BWC. Arms Control Association, supra note 215.

<sup>&</sup>lt;sup>261</sup> Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>262</sup> Australian / New Zealand Standard, Safety in Laboratories: Microbiological safety and containment, AS/NZS 2243.3 (2010).

<sup>&</sup>lt;sup>263</sup> Australian / New Zealand Standard, Draft: Safety in Laboratories: Microbiological safety and containment, AS/NZS 2243.3 (2019), revising AS/NZS 2243.3:2010.

<sup>&</sup>lt;sup>264</sup> BWC, supra note 9, at art. I.

<sup>&</sup>lt;sup>265</sup> See supra "Global Survey of State Practice."

## A. Interpretation of the BWC—the General Rule of Treaty Interpretation

In accordance with the general rule of treaty interpretation, interpretation of the BWC must start with analyzing the ordinary meaning of the text—in light of the treaty's context, and object and purpose. <sup>266</sup> Under Article I of the BWC, States are prohibited from acquiring, developing, retaining, stockpiling, or producing "microbial or other biological agents, or toxins . . . of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes." Under the ordinary meaning of this clause, a minimalist interpretation allows a State to acquire potentially prohibited agents provided there is at least some justification for protective or peaceful use, however minor. However, this minimalist approach is inconsistent with both the object and purpose of the treaty, and its context—as explained below—because it allows a greater amount of access to biological weapons than the object and purpose and the context of the treaty allow.

### 1. Object and Purpose

The preamble of the BWC contributes to identifying the object and purpose of the treaty. The relevant portions of which provide:

"Determined to act with a view to achieving effective progress towards general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective international control, . . .

Convinced of the <u>importance and urgency</u> of eliminating from the arsenals of States, through effective measures, such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents, . . .

Determined, for the sake of all mankind, to <u>exclude completely</u> the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk."<sup>267</sup>

These provisions indicate that the drafters of the BWC intended the treaty to act as a mechanism to severely limit a State's ability to create or obtain biological weapons. This conclusion is further supported by the explicit provisions, included in the BWC, that indicate the treaty is intended to be read in connection with the 1925 Geneva Convention, which bans the use of chemical and biological weaponry in warfare. Since the BWC severely inhibits the ability of a State to obtain or create biological weapons, the "minimalist" interpretation of the treaty, that does not require biosafety or biosecurity regulation of DURC, allows a greater amount of access to biological weapons and therefore is in contravention to the object and purpose of the treaty.

## 2. Context

Under the rule set in Article 31(2) of the VCLT, the "context" of a treaty—which must be used when interpreting the treaty—has a special meaning: the treaty's preambles and annexes; any agreements "made between all the parties in connection with the conclusion of the treaty;" and any instruments "made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty."<sup>269</sup>

An analysis of the text, including the preamble, indicates that the drafters of the BWC were conscious that there was a need to strictly limit the acquisition of biological weapons, as well as a need to divert existing weapons to peaceful purposes.<sup>270</sup> First, the preamble states,

<sup>&</sup>lt;sup>266</sup> VCLT, supra note 11, at art. 31(1); Nolte, supra note 10, at 220.

<sup>&</sup>lt;sup>267</sup> BWC, supra note 9, at preamble  $\P 1$ , 7, 9–10 (emphasis added).

Id. at preamble ¶2, art. VIII; 1972 Convention on the Prohibition of Bacteriological Weapons and their Destruction, Int'l Comm. Red Cross 1 (2014).

<sup>&</sup>lt;sup>269</sup> VCLT, supra note 11, at art. 31(2).

<sup>&</sup>lt;sup>270</sup> BWC, supra note 9, at preamble ¶ art. 2.

"[C]onvinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective control."

The underlined portions of this clause indicate that the drafters were intending to achieve the "general and complete" disarmament of biological weapons stockpiles; further, they were aware of the need for strict and effective regulatory control in this effort. Further, the inclusion of the phrase "general and complete disarmament" provides evidence that the drafters did not support the loophole minimalist interpretation, as it allows more access to biological weapons than the drafters intended.

Additionally, Article II of the BWC includes a short provision—"[i]n implementing the provisions of this article all <u>necessary safety precautions</u> shall be observed to protect populations and the environment"—which indicates that the drafters were conscious of importance of safety precautions, as well as the risk biological weapons pose to humanity and the environment.<sup>271</sup> Further, the inclusion of the phrase "necessary" provides evidence that the drafters supported the implementation of regulatory regimes to oversee and control the possession of, and destruction of, biological agents. Additionally, the subsequent State practice highlights that States interpret this clause to require such regulatory regimes—as discussed further below.

Consequently, interpreting the BWC using the minimalist approach, which includes a loophole that allows States to obtain otherwise banned biological materials based on minimal justification, would be contrary to the object and purpose of the treaty. Furthermore, in analyzing the context of the treaty, it is evident that the drafters were supportive of regulatory regimes to oversee and control the possession of biological weapons. As a result, the general rule of treaty interpretation does not support the minimalist interpretation of Article I of the BWC. This is further confirmed by the analysis that follows.

# B. Interpretation of the BWC—VCLT, Article 31(3): Subsequent Agreements and State Practice

Whether or not the general rule of treaty interpretation provides a clear understanding of the obligations required under a treaty, an interpreter must next address the subsequent rules of treaty interpretation.<sup>272</sup> As noted previously, the relevant subsequent rules of treaty interpretation for the BWC are provided in Article 31(3) of the VCLT—i.e., a treaty must be interpreted in light of (a) any subsequent agreements between the parties, or (b) any subsequent practice in the application of the treaty.<sup>273</sup>

In regards to Article 31(3)(a), subsequent Agreements, an interpreter may reference the developments from the BWC review conferences. Specifically, the interpreter may note the discussion of "dual-use research of concern (DURC)."<sup>274</sup> During discussions, States were open to the inclusion of this phrase in the final conference documents; however, ultimately the phrase was never included in an official agreement between the parties.<sup>275</sup> While these discussions provide context to the parties' intentions, these discussions are not a conclusive method to interpret the treaty because DURC was never included in official agreements.

On the other hand, Article 31(3)(b), subsequent State practice, provides an abundance of evidence which would assist an interpreter in understanding the current obligations required under Article I of the BWC. As outlined by the analysis of global State practice, there is significant evidence that States consistently and extensively regulate BSL-3 and BSL-4 laboratories, which are responsible for conducting DURC. For North America, the large number of BSL-3 and 4 facilities and the existence of legally binding statutes—as well as the presence of large regulatory bodies in both Canada and the US—provide strong evidence of State practice regulating DURC.<sup>276</sup> Further, for Europe, the existence of multiple regulatory regimes—both within the framework of the EU and within specific States—provide evidence of a global State practice regulating DURC.<sup>277</sup> This is further supported by the

<sup>&</sup>lt;sup>271</sup> BWC, supra note 9, at art. II.

<sup>&</sup>lt;sup>272</sup> See supra note 92, and accompanying text.

<sup>&</sup>lt;sup>273</sup> VCLT, supra note 11, at art. 31(3).

See supra note 61 to 65, and accompanying text.

<sup>&</sup>lt;sup>275</sup> Millett, supra note 65, at \*2–4.

<sup>&</sup>lt;sup>276</sup> See supra note 161 to 168, and accompanying text.

<sup>&</sup>lt;sup>277</sup> See supra note 187 to 205, and accompanying text.

Netherland's conclusion that the non-legally binding 2007 "Code of Conduct for Biosecurity" was insufficient, suggesting that the Netherlands believes more extensive, legally binding regulation is necessary.<sup>278</sup>

For Latin America and the Caribbean, Central American and the Caribbean's acquiescence to global State practice supports the acceptance of State regulation of DURC—as well as CARICOM's regulatory regime, which is based off of the WHO guidelines.<sup>279</sup> A similar logic applies to Africa and Oceania: while there are limited BSL-3 and BSL-4 facilities that could conduct DURC—and therefore limited State practice—the general acquiescence by States to the regulatory regimes of other States provides evidence for the State practice.<sup>280</sup>

For specific States of note, the presence of multiple BSL-3 laboratories and the existence of regulatory regimes for both biosafety and biosecurity provides strong evidence of State practice in Nigeria and Cuba, as does Cuba's offer to conduct educational campaigns on biosafety and biosecurity for interested States.<sup>281</sup> Similarly, Nigeria maintains a domestic biosafety education program—providing support for the existence of regulatory State practice in Nigeria. 282 For Brazil and Argentina, the existence of multiple BSL-3 and BSL-4 laboratories, and regulatory regimes to govern biosafety and biosecurity in these facilities, supports the conclusion that both States participate in the State practice of regulating biosafety and biosecurity.<sup>283</sup> Additionally, the United Arab Emirates conducts extensive DURC, and consequently maintains a National Committee on Biosecurity.<sup>284</sup> Lastly, the review of biosafety and biosecurity in South Africa demonstrates an effort in that State to best implement biosafety and biosecurity, which is evidence of State practice in favor of implementing biosecurity and biosafety regulatory measures.<sup>285</sup> Consequently, the existence of extensive regulatory measures by the vast majority of States where BSL-3 and BSL-4 laboratories operate supports the conclusion that there is a global State practice of regulating DURC.

While a few States do not regulate DURC, which could work towards the detriment of interpreting the BWC based on Article 31(3)—State practice—of the VCLT, the VCLT does not require State practice to be universal.<sup>286</sup> Moreover, many States adopt the regulatory framework of non-binding international conventions when the State lacks adequate domestic legislation.<sup>287</sup> This is demonstrated in both Turkey and Pakistan. While Turkey has no binding domestic legislation regulating DURC, it extensively utilizes international standards and guidelines.<sup>288</sup> In contrast, unlike Turkey, Pakistan has domestic legislation regulating DURC; nevertheless, Pakistan supplements this regulation by also extensively utilizing international standards and guidelines.<sup>289</sup>

Moreover, we can compare two countries: Egypt and Syria, both of whom are only signatories to the BWC.<sup>290</sup> Article 18(a) of the VCLT requires that a State that has signed a treaty must "refrain from acts which defeat the object and purpose of the treaty" until it is clear whether or not the State will become party to the treaty.<sup>291</sup> For Syria, there is limited information whether the country maintains any BSL-3 or BSL-4 laboratories; however, the country maintains an offensive research program and has yet to adopt any regulatory measures for biosecurity or biosafety.<sup>292</sup> Two conclusions may be drawn from this: Syrian officials may not believe that it is

<sup>&</sup>lt;sup>278</sup> Harris, supra note 6, at \*27, \*29–30.

<sup>&</sup>lt;sup>279</sup> See supra note 169 to 171, and accompanying text.

<sup>&</sup>lt;sup>280</sup> See supra note 230 to 232 & 253 to 255, and accompanying text.

<sup>&</sup>lt;sup>281</sup> See supra note 171 to 179, and accompanying text.

<sup>&</sup>lt;sup>282</sup> See Peters, supra note 66, at 866–70.

<sup>&</sup>lt;sup>283</sup> See supra note 180 to 186, and accompanying text.

<sup>&</sup>lt;sup>284</sup> See supra note 209, and accompanying text.

<sup>&</sup>lt;sup>285</sup> See supra note 235, and accompanying text.

<sup>&</sup>lt;sup>286</sup> See supra note 98 to 103, and accompanying text.

<sup>&</sup>lt;sup>287</sup> See supra note 210 to 214, and accompanying text.

<sup>&</sup>lt;sup>288</sup> See supra note 210 to 211, and accompanying text.

<sup>&</sup>lt;sup>289</sup> See supra note 212 to 214, and accompanying text.

<sup>&</sup>lt;sup>290</sup> It should also be noted that even non-State Parties, such as Israel, have implemented regulatory frameworks for DURC. This could be evidence of an obligation under customary international law, which requires both state practice and opinio juris. Opinio juris is the belief that State is conducting a practice because the practice is required under international law. However, in Israel's case, there is no evidence of opinio juris; therefore, the elements necessary for customary international law are not present. See International Law Commission, Draft Conclusions on identification of customary international law, with commentary (2018).

291 VCLT, supra note 11, at art. 18(a).

<sup>&</sup>lt;sup>292</sup> Peters, supra note 66, at 870.

necessary to implement biosafety measures under the BWC, or—alternatively—Syria may consider the forty-eight year gap between the present day and when the treaty was signed an "undue delay," which therefore exempts the State from the requirement to comply with the object and purpose of the BWC.<sup>293</sup> Conversely, Egypt—which become a signatory State in the same year as Syria—has consistently expressed support for the BWC, and has implemented regulatory measures for biosafety and biosecurity. The creation of this framework could be due to the belief that it is required under the "object and purpose" of the BWC. Unlike Syria, "undue delay" would not be applicable because Egypt has repeatedly reiterated its support for the treaty—though it has yet to become a State Party.<sup>294</sup>

Considering the widespread existence of State practice requiring a higher level of regulation for BSL-3 and BSL-4 laboratories that conduct DURC, and in compliance with the VCLT rules of treaty interpretation, it can be concluded that the subsequent State Practice has altered the meaning of "no justification for prophylactic, protective or other peaceful purposes" to reflect a necessity for both biosafety and biosecurity regulation when DURC is conducted at a laboratory.

## C. Evolutive Interpretation of the BWC

In accordance with the ICJ precedent set in the <u>Namibia</u> advisory opinion, treaties may be reinterpreted, irrespective of the original interpretation, provided the interpretation is necessary to the object and purpose of the treaty. As noted above, the object and purpose of the BWC is to severely limit a State's ability to create or obtain biological weapons. Consequently, reinterpretation of the BWC to limit biological research beyond simply that with "no justification for prophylactic, protective or other peaceful purposes" is in compliance with the object and purpose of the BWC.

An evolutive approach to interpretation can be utilized in a series of situations, including—but not limited to —when (1) a concept within the treaty implies the need to consider subsequent technical, economic, or legal developments; or (2) a concept in the treaty is of such a general nature that interpretation requires consideration of changing circumstances.<sup>297</sup> For Article I of the BWC, both of these categories apply.

Modern day scientific developments allow for the safe experimentation of even the most dangerous pathogens, in an effort to develop responses should the pathogens be released into the general public.<sup>298</sup> With the recent developments in genetic manipulation—namely, CRISPR-cas9—it has become exponentially easier to conduct justified experiments on biological materials that would otherwise be prohibited by the BWC under Article I.<sup>299</sup> Consequently, it is necessary to interpret the BWC in a manner consistent with the modern state of scientific technology. In this vein, States must interpret the BWC using the evaluative process in which States implement regulatory regimes that subject DURC to higher biosafety and biosecurity standards than other pathogens, in order to fulfill the "some justification" standard.

Moreover, similar to the Court's interpretation of "territorial status" as generic in the <u>Aegean Sea</u> case, the BWC does not clarify what form of "justification" is necessary under Article I; consequently, the term is generic. 300 According to the ordinary meaning of the term, justification is an "acceptable reason for doing something." Under this definition, a State must have an acceptable reason for precuring an otherwise prohibited agent. Such justification would inherently derive from the possibility of scientific research on the pathogen for peaceful or prophylactic purposes. However, given the ability to justify experimentation on even the deadliest pathogens, the result from this

<sup>&</sup>lt;sup>293</sup> See VCLT, supra note 11, at art. 18(a)-(b).

 $<sup>^{294}</sup>$  Id

<sup>&</sup>lt;sup>295</sup> Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970), Advisory Opinion, 1971 I.C.J. 16, ¶¶ 21–22 (June 21).

<sup>&</sup>lt;sup>296</sup> See supra note 261 to 263, and accompanying text.

Arato, supra note 100, at 452; Fragmentation Report, supra note 130, at ¶ 23.

<sup>&</sup>lt;sup>298</sup> See Shailendra Kumar Verma & Urmil Tuteja, Plague Vaccine Development: Current Research and Future Trends, 7 Frontiers Immunology 602 (2016) (describing research on the deadly disease *y. pestis*, also known as the Black Death—the deadliest pandemic in world history, in an effort to develop a vaccine to the disease).

<sup>&</sup>lt;sup>299</sup> Jennifer A. Doudna & Samuel H. Sternberg, A Crack in Creation: Gene Editing and the Unthinkable Power to Control Evolution 117–153 (2018).

<sup>&</sup>lt;sup>300</sup> Aegean Sea Continental Shelf (Greece v. Turk.), Judgment, 1978 I.C.J. 3, ¶ 74 (Dec. 19).

Merriam-Webster, Justification, https://www.merriam-webster.com/dictionary/justification (last visited Jan. 28, 2021).

interpretation would be contrary to the object and purpose of the BWC. Consequently, it is necessary to interpret "justification" using the changing circumstances of modern science. Under the modern system, as demonstrated through State practice, current circumstances mandate that States implement more stringent biosafety and biosecurity measures based on the risk of the pathogen. This requirement is necessary to show that the State is meeting the "some justification" standard, as such regulation demonstrates that the creation or acquisition of the pathogen is not for nefarious purposes.

#### IV. POLICY RECOMMENDATIONS

While subsequent practice may cause the re-interpretation of a treaty, it does not officially amend or modify said treaty. <sup>302</sup> Consequently, in light of the evolution of science since the adoption of the BWC in 1972 and the lived experience of the COVID-19 pandemic, this Comment recommends that the international community reflect the evolution in the law by adopting the provision proposed below. While such modification is not necessary, <sup>303</sup> it is advisable because—by adopting this provision—the international community would clearly codify the current meaning of Article I of the BWC.

The mandate of the ISU expires in 2021.<sup>304</sup> Therefore, the Ninth Review Conference of the BWC—scheduled for November 8th to 26th of 2021—must extend the mandate of the ISU.<sup>305</sup> As noted earlier, review conferences for the BWC occur every five years, and are responsible for "reviewing the operations of the Convention, including clarifying States Parties' understanding about its provisions, strengthening its implementation, and charting next steps."<sup>306</sup> An example of this is found in the final outcome document of the Sixth Review Conference, which originally created the ISU.<sup>307</sup>

Consequently, considering the evolution of the law based on State practice, the Ninth Review Conference should include a provision within this resolution which codifies the change in the enforcement mechanism for biological weapons. The potential clause which could reflect this framework could be:

Each State Party to this Convention to undertake never, in any circumstance, to develop, produce, stockpile or otherwise acquire or retain:

Microbial or other biological agents, or toxins—whatever their origin or method of production—of types and in quantities that fall within the category of "dual-use research of concern," unless the State has implemented a regulatory regime(s) that weighs the benefits of the research against the potential costs of accident or misuse, and accordingly applies extra regulatory measures to maintain biosafety and biosecurity; . . .

As a result, by adopting this provision within the final outcome document of the Ninth Review Conference, the evolution of law would be codified within international law.<sup>308</sup>

#### Conclusion

Article I of the BWC prohibits the acquisition of microbial or other biological agents or toxins when there is "<u>no</u> justification <u>for prophylactic, protective or other peaceful purposes.</u>" However, the ordinary meaning of "<u>no</u> justification" implies that States may obtain otherwise prohibited biological materials, provided there is <u>some</u> justification, no matter how minimal. Such an interpretation is against the object and purpose, and the context, of the BWC.

<sup>&</sup>lt;sup>302</sup> See supra "Amendment or Modification."

<sup>&</sup>lt;sup>303</sup> DALT, supra note 100, at 235.

<sup>&</sup>lt;sup>304</sup> Implementation Support Unit, https://www.un.org/disarmament/biological-weapons/implementation-support-unit (last visited Apr. 2, 2021).

<sup>&</sup>lt;sup>305</sup> Id.; Events (2021), https://www.un.org/disarmament/events/ (last visited Apr. 2, 2021).

About the Biological Weapons Convention, https://www.state.gov/about-the-biological-weapons-convention (last visited Apr. 2, 2021); see also supra note 55 to 60, and accompanying text.

<sup>&</sup>lt;sup>307</sup> See supra note 57, and accompanying text.

<sup>&</sup>lt;sup>308</sup> See generally H. Lauterpacht, Codification and Development of International Law, 49 Am. J. Int'l L. 16 (1955) (explaining the concept of codification of international law, and the author's experiences with it through his work as a member of the International Law Commission).

Consequently, this minimalist approach is not supported by the norms of interpretation laid down in the VCLT. This is further confirmed by global State practice.

Subsequent to the adoption of the BWC, States adopted regulatory regimes which weigh the benefits of the research against the potential costs of accident or misuse, and apply extra biosafety and biosecurity regulatory measures accordingly. Accordingly, interpretation of the BWC using subsequent State practice—in compliance with VCLT, Article 31(3)(b)—also does not support the minimalist interpretation of the phrase "no justification for prophylactic, protective or other peaceful purposes." Instead, based on subsequent State practice and the context of the treaty, the law has evolved to require States to implement stringent biosafety and biosecurity regulatory measures based on the risk posed by the pathogen being tested.

Moreover, interpretation of the BWC using the evolutive approach requires that the phrase "prophylactic, protective or other peaceful purposes" be interpreted in light of the evolution of scientific research. Consequently, under this new interpretation of Article I of the BWC, States are required to apply extra biosafety and biosecurity measures to experimentation involving dangerous pathogens, bioregulators, or biotoxins—i.e., DURC. Finally, in consideration of the evolution in the law, this Comment recommends that the United Nations Security Council—the only committee of the U.N. whose resolutions are binding—should codify the law to accurately reflect its current requirements.