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The Concepts of Biosafety and Biosecurity: The Need for a Coherent Approach

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Executive Summary

The risk of an accidental release or deliberate use of biological agents has been present for the past decades. Especially the COVID-19 pandemic has brought the issue once more to the attention of the international community showing that biohazards in general are real requiring adequate responses to avoid even greater harm to human health. Furthermore, scientific and technological developments may enhance the probability of biological hazards potentially having a substantial impact on the dual-use nature of many biological components, blurring the distinction between civilian and military purposes.

The prevention of deliberate misuse of biological weapons is usually labeled as “biosecurity”. Laboratory safety standards are equally important to prevent, for example, the (unintentional) spread of disease, but these standards and related practices and procedures are usually referred to as “biosafety”. Both concepts are thus somehow related but they also pursue different objectives. Various international institutions have created their definitions while also treating both terms differently, which has led to a lack of coherence.

Considering this challenging situation, some of the main ideas presented are the following:

- The lack of an agreed definition of ”biosafety” and ”biosecurity” makes it difficult to grasp the object and purpose of both concepts and to fully comprehend how they tackle contemporary challenges. Although biosecurity and biosafety are far from being identical, this paper suggests that both terms are interrelated and that they complement each other.
- The situation is further complicated by the increased attention to health preparedness. Various recent virus outbreaks have highlighted the limited response capabilities of states and the WHO, which certainly demand cooperation among states, but also among other relevant stakeholders in the biological industry. In light of these developments, especially within the context of International Health Regulations, the WHO framework is not well-equipped to deal with present risks on its own. A coherent and complementary approach that considers biosafety, biosecurity, and health preparedness together, might help overcome this impasse.
- The use of codes of conduct might serve as a common language for stakeholders to make safe and secure use of biology. The Tianjin Biosecurity Guidelines have gained wide support among States Parties to the BWC; also, the WHO has presented and updated non-binding recommendations for laboratory managers and national regulators. These initiatives might be a vital – though imperfect – tool to grasp the interrelationship between biosafety, biosecurity, and possibly health preparedness.
- Under these circumstances, a combination of recommendations and codes of conduct, and legally binding mechanisms – including standard-setting institutions and international institutions like the BWC itself – is suggested as a cooperative and transdisciplinary ‘One Biosecurity/Biosafety’ approach to effectively confront biosafety and biosecurity risks.

1 Introduction

Recent events, such as the COVID-19 pandemic, have raised alarms in the international community regarding prospective natural, accidental, or deliberate biological hazards. Despite lasting uncertainties of its origin,[1] the COVID-19 pandemic showed that the threat posed by biological weapons (BW) or natural disease outbreaks with potentially similar consequences is not merely hypothetical, and the potential human damage is enormous. The pandemic was certainly a turning point that revealed existing weaknesses and rekindled discussions on the need to enhance biosafety and biosecurity.

There is no generally agreed-upon definition of the terms "biosafety" and "biosecurity" respectively.[2] Generally speaking, biosafety denotes "the prevention of unintentional exposure to biological agents or their inadvertent release",[3] while biosecurity refers to "the prevention of unauthorized access, loss, theft, misuse, diversion or release to reduce the risks of accidents and of inadvertent and deliberate misuse of the life sciences"[4]. Both terms indicate a different kind of purpose: biosafety relates to accidental damage, including, but not limited to, natural disease outbreaks and measures to prevent them and prepare for them, and biosecurity primarily seeks to prevent intentional harm.[5] In a statement of 2006, Germany on behalf of the European Union highlighted the difference between biosafety and biosecurity. In the EU's view, biosafety stems from the premise that micro-organisms or toxins can cause disease, while biosecurity places its focus on a biological agent's potential to be misused as a weapon.[6] Even though both terms are slightly different, they ultimately require both safe and secure environments. In our view, this is the main overlap between biosecurity and biosafety, and the paper submits that both concepts complement and reinforce each other – at least in certain areas, which will be addressed in the following sections in more detail.

Even though the 1972 Biological Weapons Convention (BWC) primarily deals with biological disarmament, both biosecurity and biosafety have also ended up on the BWC agenda and many States Parties have addressed both issues simultaneously. In this context, it is important to take into account human health as a broad concept, also related to animal and plant health as potential sources of emerging diseases, and address resilience against intentional as well as unintentional biological hazards, which will, ultimately, help pursue the object and purpose of both biosecurity and biosafety. Thus, the paper submits that a 'One Biosafety/Biosecurity' approach should consider the diversity of existing mechanisms in the biosecurity and biosafety realms –mainly the BWC, the WHO instruments, and non-legally binding prominent guidelines – to create a coherent and complementary framework to be broadly, and more straightforwardly applied.

1 Laura H. Kahn, 'The origins of SARS-Cov-2: still to be determined', *Bulletin of the Atomic Scientists* (10 March 2022), available at: https://thebulletin.org/2022/03/the-origins-of-sars-cov-2-still-to-be-determined.

2 Kai Ilchmann and James Revill, 'Assessing the SecBio Platform Proposal for the Biological Weapons Convention', United Nations Institute for Disarmament Research (2022) 4, available at: https://unidir.org/sites/default/files/2022-12/UNIDIRAssessingSecBio%20V3.pdf.

3 Ibid. The choice of words is taken from the World Health Organization, 'Laboratory Biosafety Manual' (2020), available at: https://apps.who.int/iris/bitstream/handle/10665/337956/9789240011311-eng.pdf?sequence=1&isAllowed=y. See also Tatyana A. Novossiolova, Simon Whitby, Malcolm Dando and Graham S. Pearson, 'The vital importance of a web of prevention for effective biosafety and biosecurity in the twenty-first century' (2021) 17, 3 *One Health Outlook*, 2. See also Report of the Meeting of States Parties, 12 December 2008, BWC/MSP/2008/5 para 20.

4 Ibid.

5 Tatyana A. Novossiolova, Simon Whitby, Malcolm Dando and Graham S. Pearson, 'The vital importance of a web of prevention for effective biosafety and biosecurity in the twenty-first century', 4.

6 Statement submitted by Germany on behalf of the European Union, 'Biosafety and Biosecurity', 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 (20 October 2006) BWC/CONF./VI/WP.2, para 15.

2 Biosecurity and Biosafety and the BWC

It is important to note that the BWC neither refers explicitly to biosafety nor biosecurity. However, there are indicators that States Parties to the BWC are obliged to take concrete measures to enhance both biosafety and biosecurity at the national level to comply with their obligations under the BWC.[7] Indeed, the preamble of the BWC does neither refer to biosafety nor biosecurity but various paragraphs at least indicate the broad object and purpose of the BWC. According to preambular paragraph 7, BWC States Parties are "[c]onvinced of the importance and urgency of eliminating from the arsenals of States, through effective measures such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents". Furthermore, according to preambular paragraph 9, BWC States Parties are "[d]etermined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons". A concrete legal obligation to undertake measures with regard to biosafety and biosecurity could be derived from Articles I and IV BWC, whose terminology, alas, leaves significant room for interpretation. Since the treaty text itself does not provide sufficient answers, it is imperative to have a closer look at statements by States Parties and decisions taken at Review Conferences both from a historical and most importantly from a contemporary perspective. It will be demonstrated that even though the treaty text itself does not explicitly obligate States Parties to undertake measures with regard to biosafety and biosecurity, state practice seems to suggest that many States Parties indeed take the view that they are obliged to implement both biosafety and biosecurity and that both concepts are interrelated. This further supports our argument that only a coherent approach is ultimately able to deal with the various challenges relating to biosafety and biosecurity respectively.

2.1 The Role of Articles I and IV BWC

The implicit obligation to take concrete measures with regard to both biosafety and biosecurity could be derived from Article IV of the BWC, according to which "[e]ach State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention" within its own territory or territory under its jurisdiction or control. As the wording already indicates, Article IV is inextricably intertwined with Article I – the core provision of the Convention, prohibiting the development, production, stockpiling, acquisition or retention of *inter alia* biological agents, which have no justification for prophylactic, protective, or other peaceful purposes. By the same token, biological weapons for hostile purposes, including in armed conflicts, are prohibited. The terminology of both Articles I and IV indicates that the main object and purpose of "necessary measures" adopted should be the prevention of misuse of biological agents. Neither Article I nor Article IV seem to oblige States Parties to take concrete measures with regard to biosafety. It is important to note, however, that BWC States Parties have frequently referred to both biosafety and biosecurity in their written statements at Review Conferences and similar meetings. Thus, it seems that even though the BWC does not explicitly obligate States to adopt national legislation related to biosecurity *and* biosafety, state practice seems to suggest that States Parties acknowledge the interrelation of the concepts and that they should be addressed simultaneously.

2.2 The Historical dimension of biosecurity and biosafety

Biosecurity and biosafety have not always played a role in meetings of States Parties to the BWC. However, the topic of bioterrorism – a sub-category of biosecurity – became more prominent as a

[7] Statement submitted by Germany on behalf of the European Union, 'Biosafety and Biosecurity', 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 (20 October 2006) BWC/CONF./VI/WP.2, para 11.

point of discussion in the BWC when Aum Shinrikyo, a Japanese cult, released anthrax spores in Tokyo in 1994.[8] It was however especially the United States that brought biosecurity to the attention of the BWC in the aftermath of the terror attacks of 9/11 and the so-called "anthrax letters" which were dispersed to various US Senators, among others. Finally, in 2008, the Conference of the States Parties to the BWC *inter alia* decided to hold at least four annual meetings prior to the Seventh Review Conference "to promote a common understanding and effective action" on *inter alia* national measures relating to biosafety and biosecurity "including laboratory safety and security of pathogens and toxins".[9] Initially, substantial misunderstandings accompanied discussions on biosecurity and biosafety given the lack of familiarity with the concepts paired with linguistic differences. The concepts of biosecurity (and bioterrorism) as well as biosafety were officially acknowledged as an *integral* part of the discussion within the BWC and States Parties respectively by the Confidence-Building Measures (CBMs) as revised in 2011[10] and also by the Final Declaration of the Eight Review Conference in 2016.[11] In 2012, at a meeting of the States Parties, biosafety and biosecurity were largely discussed in the context of Article X BWC addressing the obligation of all States Parties to cooperate with a view to supporting those countries which do not have the same technical or financial resources.[12]

2.3 Current proposals to enhance biosafety and biosecurity in the BWC

In addition to the historical dimension, it is crucial to briefly address current proposals and developments to enhance both biosafety and biosecurity in the context of the BWC. In 2022, at the Ninth Review Conference, France, Senegal, and Togo proposed the establishment of an international platform that should solely be dedicated to matters relating to biosafety and biosecurity in the context of the BWC.[13] According to the proposal, the platform – SecBio – would be "a searchable repository for biosafety and biosecurity legal framework, treaties, laws regulations, case law, norms, standards and best practices, as well as scientific publications"[14]. At the same time, the platform should consist of "a learning module for users (…)"[15] and constitute "a forum for expert's networking (…)"[16]. The initiative was not the first of its kind[17] but it nevertheless adds value to the efforts taken to tackle the challenges lying ahead. On the one hand, it tries to bring all relevant stakeholders

8 Una Jakob, 'The Biological Weapons Convention' in *Research Handbook on Arms Control Law*, Thilo Marauhn and Eric Myjers (eds), Cheltenham: Edward Elgar (2022), 274. For more details see Marc E. Vargo, *The Weaponizing of Biology. Bioterrorism, Biocrime and Biohacking*, Mc Farland Publishers (2017) 140 – 164.

9 Ibid. For more details see Marc E. Vargo, The Weaponizing of Biology. Bioterrorism, Biocrime and Biohacking, 165 – 211.

10 Harald Müller, Una Becker-Jakob, and Tabea Seidler-Diekmann, 'Regime Conflicts and Norm Dynamics. Nuclear, Biological, and Chemical Weapons' in *Norm Dynamics in Multilateral Arms Control: Interests, Conflicts, and Justice*, Harald Müller and Carmen Wunderlich (eds), University of Georgia Press (2013), 61.

11 Final Document of the Seventh Review Conference, 13 January 2012, BWC/CONF.VII/7, 38 – 39. For more information see Una Jakob, 'The Biological Weapons Convention', 275.

12 Final Document of the Eighth Review Conference, 11 January 2017, BWC/CONF.VIII/4, 11-12. For more information see Una Jakob, 'The Biological Weapons Convention', 275.

13 France, Senegal, Togo, 'Proposal for establishment of an international platform dedicated to biosecurity and biosafety: SecBio', BWC/CONF.IX/WP.23, 16 November 2022.

14 Ibid. para 6 i).

15 Meetings 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, 8 September 2008, BWC/MSP/2008/MX/3, 1 a) iii).

16 Working Paper submitted by the United Kingdom, 'Challenges to developing international cooperation and assistance on biosafety and biosecurity: matching resources to reality', 12 July 2012, BWC/MSP/2012/MX/WP.2. The same was emphasized at a meeting of the States Parties in 2013 and 2014 respectively. See Report of the Meetings of the States Parties, 24 December 2013, BWC/MSP/2013/5; Report of the Meetings of the States Parties, 15 December 2014, BWC/MSP/2014/5.

17 Proposal for establishment of an international platform dedicate to biosecurity and biosafety: SecBio, submitted by France, Senegal and Togo, Ninth 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, 16 November 2022, BWC/CONF.IX/WP.23, para 1.

together and on the other, aims to support States in their individual efforts to implement measures related to biosafety and biosecurity at the national level.

The initiative is clearly laudable but its purpose is not to clarify what kind of common rules and procedures relating to biosafety and biosecurity should be implemented by BWC States Parties at the national level. Rather, the initiative should be considered as a starting point for further discussions and deliberations on the matter. Furthermore, Canada established the so-called "Analytical Approach for the Development of a National Biosafety and Biosecurity System"[18], which can be described as a tool to strengthen global biosafety and biosecurity by offering, *inter alia*, a free online course on biosecurity and biosafety, which is accessible for everyone registering. One of the main objectives of this voluntary initiative is to educate all stakeholders and to offer policy options on how to implement measures of biosafety and biosecurity. This initiative was also presented at the Ninth Review Conference with a view to encouraging States to actively engage in this process and make use of the online learning platform.[19]
In addition to these two proposals, the United States submitted a document at the Ninth Review Conference addressing the reinforcement of biosafety and biosecurity internationally.[20] Furthermore, States Parties addressed the issue of advancements in the field of science and technology. Switzerland, for example, suggested the establishment of a BWC Science and Technology Advisory Process. Even though the proposal does not mention biosafety or biosecurity explicitly, it certainly has relevance for both concepts.[21] Similar proposals have also been made by Russia[22], the United States,[23] Canada together with Germany,[24] and also Germany co-sponsored by the Netherlands and Sweden.[25] In addition, the EU in its working paper highlighted the need to consider technological developments when identifying common standards to increase both biosafety and biosecurity.[26]

Despite all these efforts and initiatives, especially SecBio and the Analytical Approach for the Development of a National Biosafety and Biosecurity System, states have hitherto failed at agreeing on common, all-encompassing and coherent standards on biosafety and biosecurity. The situation is further complicated by the fact that, especially in recent years, the BWC has become a forum to discuss another challenge: health preparedness.

3 From Biosecurity and Biosafety to Health Preparedness: Intersecting with the WHO

In relation to biosecurity and biosafety, health preparedness deals with disease threats more generally. It is thus a broader concept addressing all different forms of risks for the human body and society as a whole from infectious diseases – whether man-made or natural, deliberate or unintentional. Even though the concept of health preparedness has been primarily addressed by the WHO, it is also – at least by indication – reflected in the Final Document of the Eight Review Conference of the BWC, according to which "health and security issues are interrelated at both the

18 Ibid. para 6 lit i).
19 Ibid. para 6 lit ii).
20 United States of America, 'Report on Implementation of Article X of the Biological and Toxin Weapons Convention', BWC/CONF.IX/WP.24, 17 November 2022.
21 Ibid. para 6 lit iii).
22 Russian Federation, 'Proposals to Improve Biological Security and Enhance Confidence-Building Measures under the Biological and Toxin Weapons Convention', BWC/CONF.IX/WP.60, 12 December 2022.
23 United States of America, 'S&T Developments of Relevance to the Biological Weapons Convention', 12 September 2022
24 Canada together with Germany, 'Exploring Science and Technology Review Mechanisms under the Biological Weapons Convention', BWC/CONF.IX/WP.20, 15 November 2022.
25 Germany, co-sponsored by the Netherlands and Sweden, 'Rethinking the BTWC science and technology review: A renewed case for a BTWC Scientific and Technological Experts Advisory Forum (STEAF)', BWC/MSP/2019/MX.2/WP.1, 1 July 2019.
26 European Union, 'Support of the European Union and its Member States to Strengthening Biosafety and Biosecurity Globally', BWC/CONF.IX/WP.38, 29 November 2022. Other initiatives include inter alia the OPCW education and outreach program, the University of Bradford Educational Module Resource and the European Union Targeted Initiatives. For more information see Kai Ilchmann and James Revill, 'Assessing the SecBio Platform Proposal for the Biological Weapons Convention'.

national and international levels".[27] This ties in with the objective of the BWC to prevent the use of biological agents for hostile purposes, whereas the use for prophylactic or peaceful purposes is not prohibited.

One major aspect of health preparedness that is currently under discussion and being further developed is the response to epidemic outbreaks. The possibility of the WHO responding to a potential epidemic outbreak is limited, has historically revolved around the 1969 International Health Regulations (IHR), and has been under development for a long time.[28] Already during the SARS outbreak (2002-2004), there was some recognition that the WHO and the international community as a whole were unable to respond effectively in the case of outbreaks of international concern.[29] There has been some progress since, especially within the context of IHR. At the time, an updating process had already been started, but the difficulties in responding to SARS created an urgency to this process, ultimately leading to the process being concluded in 2005 and the revised IHR having entered into effect in 2007.[30]

Despite these developments, the limitations had also been pointed out in later health emergencies such as the Ebola outbreak in 2014, in which States imposed unilateral measures – like travel bans – instead of relying on the WHO, which declared the public health emergency with significant delay.[31] However, the failings of the system were even more visible and impactful during the COVID-19 pandemic, leading to the set up of an impartial review already in May 2020 covering experiences gained and lessons learned, as well as some recommendations.[32]

In the final report of the Independent Panel, some of the weaknesses in the system and the new IHR were put forth. These included the lack of the WHO acting immediately and independently.[33] Another important point from the Independent Panel was that states and the international system were not prepared to effectively respond to a pandemic and that such preparedness should be considered a core function of the international system.[34] The WHO was informed early about the outbreak in China and, although the Emergency Committee was split initially as to whether or not the outbreak constituted a Public Health Emergency of International Concern (PHEIC), the WHO Director-General declared a PHEIC on 30 January 2020. This was the loudest possible alarm that the WHO could sound under the 2005 Revised IHR.[35] While the WHO received the information at a reasonable speed and made its decisions at a considerable pace, the alert system as envisioned in the IHR was not fit to serve in the case of a fast-moving pathogen, and the IHR constrained rather than facilitated rapid action.[36] Also, although the decision was made to declare a PHEIC, this did not lead to immediate responses from states, and only in March 2020, when the disease was characterized as a pandemic, states started implementing measures, at a time when transmission was already rampant.[37] In order to be better capable of addressing a future pandemic, the Panel proposed the development of a pandemic preparedness treaty.

It is due to the recognition that the current framework cannot ensure an effective response that there have been ongoing discussions about a new international agreement for pandemic response,

[27] Final Document of the Eighth Review Conference, 11 January 2017, BWC/CONF.VIII/4, 16, para 45.
[28] The International Health Regulations are adopted by the WHO and seek to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade (Art. 2 IHR 2005).
[29] See for example: World Health Assembly Res No WHA56.28, Revision of the InternationalHealth Regulations 3(1) (2003).
[30] Caitriona McLeish, 'Evolving Biosecurity Frameworks' in *The Palgrave Handbook of Security, Risk and Intelligence,* Roberet Dover, Huw Dylan and Michael S. Goodman (eds.), Palgrave MacMillan (2017) 70.
[31] Ibid. 72-73.
[32] The Independent Panel for Pandemic Preparedness & Response, *Covid-19: Make it the Last Pandemic* (2021) 8.
[33] Ibid. 16.
[34] Ibid. 15-20, 50-51.
[35] Ibid. 22-24.
[36] Ibid. 25-26.
[37] Ibid 28-29.

originally referred to as the WHO Pandemic Preparedness Treaty but currently being developed as the Pandemic Prevention, Preparedness and Response Accord.

While the original intent of the treaty as foreseen by the Independent Panel was to strengthen the WHO and to allow it to function more effectively in the case of a pandemic,[38] the actual treaty draft does not really appear to do much to this extent.[39] The current working text does not alter the existing powers of the WHO in any significant manner, nor does it alter the current framework for international response to a possible pandemic. The current text mainly addresses steps states ought to take to improve their capabilities of preventing an epidemic or to respond to one. This includes many obligations for health preparedness, such as ensuring proper procedures and proper monitoring, as well as setting up cooperation with regard to necessary supplies and importantly obligations for states to ensure proper support for the nations' health care.[40] The WHO is mainly incorporated in a facilitating, supporting or organizing role to support the states in ensuring their preparedness.

Although the current draft text is certainly a step forward in that it obliges states to take certain steps to ensure that their national health systems are better equipped for a possible pandemic,[41] there is little in the text that would facilitate an improved international One Biosecurity/Biosafety approach response if a new pandemic occurs. What has instead been proposed is the analysis and potential amending of the IHRs, a process which is also currently ongoing. However, these regulations do not truly alter the existing process or provide new or expanded powers to the Director-General, or the WHO and it is certainly questionable whether the changes can make any difference in the case of an actual pandemic or if they are little more than minor alteration in the broader context. This raises the issue of whether a broader and more coherent approach that addresses the issue from more than just the WHO perspective and considers biosafety, biosecurity, and health preparedness together is necessary to effectively answer potential future challenges.

4 Non-Legally Binding Initiatives for Biosecurity and Biosafety Governance

Codes of conduct could be a helpful tool to address both issues related to biosecurity and biosafety under one umbrella framework. Codes of conduct can be defined as a "set of rules, responsibilities, norms, and expectations of appropriate behavior".[42] They could encompass a series of best practices in the realm of biosecurity and biosafety, guide procedures, and determine when and how biosecurity and biosafety evaluations are to be made and by whom. Thus, codes of conduct may contribute to biosafety and biosecurity by impacting on human behavior and avoiding human misuse or abuse.

State-level codes of conduct are characterized by the intrinsic qualities of non-legally binding tools, flexibility, and celerity: flexibility, because non-legally binding mechanisms can be more easily modified according to States' Parties needs; celerity, because non-legally binding mechanisms might be agreed faster, with a lower degree of accuracy. There are particular reasons that might encourage States to adhere and act according to these kinds of recommendations.[43] But, at the same time, stakeholders – such as industry, other practitioners, or academics – can work hand in hand with States towards the same endeavor while constantly improving and adjusting their institution or

[38] Ibid. 46-49.
[39] Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting, A/INB/4/3.
[40] Ibid. Chapter V.
[41] Ibid. Chapter IV.
[42] Yang Xue, Lijun Shang and Weiwen Zhang, 'Building and implementing a multi-level system of ethical code for biologists under the Biological and Toxin Weapons Convention (BTWC) of the United Nations', *Journal of Biosafety and Biosecurity* 3 (2021), 108 – 119, 110.
[43] The main reasons include the following: i) the willingness to avoid formal commitments; ii) the willingness to avoid the ratification process of treaties; iii) the capacity to renegotiate or amend international instruments in case of a change in circumstances; and iv) the need to quickly reach an agreement. See Charles Lipson, 'Why Are Some International Agreements Informal?', International Organization, vol 45 issue 4 (1991), 501.

company-wide guidelines.[44] The WHO itself affirmed in this sense that "a voluntary code of conduct can be more effective than one that is imposed provided it is understood and agreed among stakeholders".[45] However, codes of conduct in life sciences have been generally regarded as "difficult to implement because there is little empirical evidence to link them with positive changes in scientists' behaviors suggesting their effectiveness may be limited".[46] Notwithstanding, various State and institution-based initiatives might serve as a source of inspiration for States and stakeholders to agree on a legally non-binding document that would ultimately reconcile both biosecurity and biosafety and align both concepts accordingly to allow for cross-fertilization. In addition to that, different organizations – those primarily addressing issues related to biosecurity and those primarily addressing issues related to biosafety – should effectively work together, mutually endorse each other's work, and cooperate accordingly.

4.1 The scope of the Tianjin Biosecurity Guidelines

In the 2020 Meeting of States Parties to the BWC, which took place in November 2021 due to COVID-19 concerns, China and Pakistan, co-sponsored by Brazil, presented a Working Paper titled "The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists".[47] This document contained ten broad ethical principles precisely aimed at promoting responsible behavior and hence strengthening biosecurity, while always taking into account the articles and norms of the BWC.[48] It is worth recalling principle 2 regarding "Laws and Norms", as scientists are urged to "be aware of and observe applicable domestic laws and regulations, international legal instruments, and norms relating to biological research, including those on the prohibition of biological weapons", certainly referring to the BWC. However, the successful implementation of guidelines strongly depends on scientists' capabilities and the specificities of states' particular contexts. Guidelines on "Education and Training" (principle 6) have been highlighted in this sense,[49] which call scientists to "maintain a well-educated, fully trained scientific community". While these guidelines would not be legally binding, they would provide a good baseline framework to enhance biosecurity. They do so by setting standards concerning scientists' behavior but go beyond this by seeking to incorporate biosecurity into education and training. Besides, they describe a bottom-up approach to biosecurity governance.[50]

The Tianjin Biosecurity Guidelines have been equated to The Hague Ethical Guidelines, fostered by the Organization for the Prohibition of Chemical Weapons (OPCW), which deal with similar concerns in the context of chemical weapons.[51] Also, China, Pakistan, and Brazil in their Working Paper proposed that States Parties officially endorse these guidelines at the Ninth BWC Review Conference.

[44] Lijun Shang, Michael Mprah, Indrajitrakuraj Ravi and Malcolm Dando 'Key issues in the implementation of the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists: A survey of biosecurity education projects', *Biosafety and Health* 4 (2022) 345.

[45] Doc. WHO/CDS/EPR/2006.6, 'Biorisk management: Laboratory biosecurity guidance' (September 2006) 21.

[46] Ibid. 109.

[47] Regarding the development of the Tianjin Biosecurity Guidelines, see Leifan Wang, Jie Song and Weiwen Zhang, 'Tianjin Biosecurity Guidelines for codes of conduct for scientists: Promoting responsible sciences and strengthening biosecurity governance', *Journal for Biosafety and Biosecurity* 3 (2) (December 2021) 82 – 83.

[48] The Tianjin Biosecurity Guidelines include the following elements: Ethical Standards, Laws and Norms, Responsible Conduct of Research, Respect for Research Participants, Research Process Management, Education and Training, Research Findings Dissemination, Public Engagement on Science and Technology, Role of Institutions, and International Cooperation. See 'International Guidelines for Biosecurity Ethics', Johns Hopkins Center for Health Security, available at: https://centerforhealthsecurity.org/our-work/research-projects/international-guidelines-for-biosecurity-ethics.

[49] Lijun Shang, Michael Mprah, Indrajitrakuraj Ravi and Malcolm Dando, 'Key issues in the implementation of the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists: A survey of biosecurity education projects', 340.

[50] Kathryn Nixdorff, 'International Biosecurity Governance Evolution within the Biological Weapons Convention', CBWNet Working Paper No. 3 (2022) 8-9.

[51] Gigi K. Gronvall et al., 'The Biological Weapons Convention should endorse the Tianjin Biosecurity Guidelines for Codes of Conduct', *Trends in Microbiology* 30 (12) (December 2022), 1119 – 1120.

For most of the lead-up to the Review Conference it appeared likely that this would actually happen, as the Tianjin Guidelines had wide support among the States Parties to the BWC. However, the initiative ultimately failed due to the difficulties that arose in attaining consensus on the Final Document and the linking of the Tianjin Guidelines with other proposals that were not as universally supported.[52]

It is worth mentioning that, even though the Tianjin Guidelines have not been endorsed at state level, they have been adopted by the InterAcademy Partnership, which is a global network of civil society scientific institutions seeking to "advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals".[53]

4.2 The scope of the WHO Laboratory Biosafety Manual

Already in 2006, the WHO presented a set of recommendations and suggested voluntary codes of conduct to help laboratory managers and national regulators evaluate the peaceful and non-peaceful possibilities offered by scientific and technological developments.[54] These recommendations were attached to the WHO *Laboratory Biosafety Manual*, which has been constantly updated until its 4th edition in 2020.[55] This last edition includes guidelines to ensure laboratory biosafety and biosecurity policies and practices at the national level. More particularly, the Laboratory Biosafety Manual establishes a set of core requirements, in other words, "operational and physical elements that, when combined, should be sufficient to control the risks of most procedures with most biological agents in clinical and diagnostic laboratories",[56] which comprises biosafety and biosecurity, but also health preparedness in light of potential – deliberate or unintentional – epidemic outbreaks.

The WHO itself has recently emphasized the importance of combining stakeholders and governance tools and mechanisms to adapt biosafety and biosecurity measures to changing social needs and circumstances.[57] In this sense, it is worth recalling the WHO *Global Guidance Framework for the responsible use of the life sciences*, published in September 2022 to provide "the first global, technical and normative framework (…) to mitigate biorisks and govern dual-use research" among WHO Member States and key stakeholders.[58] This framework pursues "biorisk management", which covers both biosafety and biosecurity, against potential accidental releases or deliberate misuses arising from the health and security sectors.[59] Considering its reactive but also preventive character, the idea of health preparedness is also envisaged in the WHO framework, which calls for a coherent mechanism both in terms of stakeholders and risks involved.[60]

Besides the guidelines presented, the WHO also recalls the importance of codes of conduct such as the Tianjin Biosecurity Guidelines, standard-setting institutions like the International Organization for Standardization (ISO) or other international institutions like the BWC itself which assists States Parties through the Implementation Support Unit (ISU).[61]

[52] Jenifer Mackby and Sruthi Katakam, 'Biological Review Conference Dispatch: A Cliffhanger Conference Seeks to Strengthen Biological Weapons Convention', Arms Control Association (January/February 2023), available at: https://www.armscontrol.org/act/2023-01/arms-control-today/bwc-review-conference-dispatch-cliffhanger-conference-seeks.

[53] The InterAcademy Partnership, 'About us', available at: https://www.interacademies.org/iap/about.

[54] Doc. WHO/CDS/EPR/2006.6, 'Biorisk management: Laboratory biosecurity guidance' (September 2006).

[55] The first edition of the WHO Laboratory Biosafety Manual was published in 1983. Later, the second and third editions were published in 1993 and 2004, respectively.

[56] WHO, 'Laboratory Biosafety Manual Fourth Edition' (2020) 27.

[57] WHO, 'Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research' (September 2022), 56.

[58] Ibid. 6.

[59] Ibid. 8-9.

[60] Ibid. 53.

[61] Ibid. 67 and 69 respectively; WHO, 'Towards a global guidance framework for the responsible use of life sciences: summary report of consultations on the principles, gaps and challenges of biorisk management' (May 2022), 8 – 10.

Such cooperation between organizations and their various recommendations and codes of conduct are in line with the One Biosecurity/Biosafety approach suggested. Hence, guidelines must be appropriately combined with legally binding national and international mechanisms to effectively deal with biosecurity and biosafety.[62]

5 Conclusions

Recent events, such as the COVID-19 pandemic, have pointed out the importance and weaknesses of existing biosafety and biosecurity frameworks. While the topics and related concerns are not new, the new realization of the potential biological hazards arising from possible human misuse, abuse, or accident, has shown that the BWC or other existing instruments are not well suited to counter these threats if applied separately and inconsistently.

Initially, the BWC was a typical disarmament treaty obliging States Parties *inter alia* to take concrete measures at the national level to "prohibit and prevent the development, production, stockpiling, acquisition or retention" of biological weapons. After the 9/11 attacks, this also included measures in the realm of biosecurity. Over the course of time, however, it became clear to BWC States Parties that measures relating to biosafety were equally important and that in fact, biosecurity and biosafety should not be addressed separately. Thus, a significant number of States Parties addressed issues relating to both biosecurity and biosafety at meetings of BWC States Parties.

When it comes to the developments in other fora, such as the WHO, one of the organization's major achievements was to take concrete measures to foster health preparedness and to increase resilience. However, with the COVID-19 pandemic, the weaknesses of the system became more obvious. While the organization was already focused on the area of health preparedness, new attention has been given to the negotiation of other agreements, such as a Pandemic Prevention, Preparedness, and Response Accord, and to the potential amendment of the International Health Regulations.

One of the most effective ways to reconcile biosecurity and biosafety and to implement a 'One Biosecurity/Biosafety' approach would be the endorsement of new legally non-binding rules States can refer to and seek guidance from. Non-legally binding codes of conduct have already been developed in the fields of biosecurity – like The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists – and biosafety – like the WHO Laboratory Biosafety Manual –, which provide a set of guidelines and procedures to foster best practices among stakeholders. However, the diversity of different mechanisms and regimes shows to be a real challenge to enhance biosecurity and biosafety as the regulatory landscape seems to be rather fragmented than coherent.

To overcome these difficulties and prepare for future threats, both new and existing cooperation initiatives should be promoted providing states and other stakeholders with concrete and clear guidelines on how to implement measures at the national level with an aim at enhancing both biosecurity *and* biosafety. By further supporting states and other stakeholders, they are encouraged to work together, mutually endorse each other's work and openly cooperate and share information to allow for cross-fertilization.

The 'One Biosecurity/Biosafety' approach aims at interfacing with and complementing the current legal framework and institutional settings. In the end, it is the decision of states whether they aim for the adoption of legally or non-legally binding documents to specifically address the intersection of biosecurity and biosafety, and close the gap between the practical approaches in dealing with risks associated with these concepts. What is certainly needed, however, is that the different institutions working in the field of biosecurity and biosafety cooperate more openly so that issues can be addressed more coherently.

[62] Lijun Shang, Michael Mprah, Indrajitrakuraj Ravi and Malcolm Dando 'Key issues in the implementation of the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists: A survey of biosecurity education projects', 112-113.

The CBW network for the comprehensive strengthening of norms against chemical and biological weapons (CBWNet)

The research project CBWNet is carried out jointly by the Berlin office of the Institute for Peace Research and Security Policy at the University of Hamburg (IFSH), the Chair for Public Law and International Law at the University of Gießen, the Peace Research Institute Frankfurt (PRIF) and the Carl Friedrich Weizsäcker-Centre for Science and Peace Research (ZNF) at the University of Hamburg. The joint project aims to identify options to comprehensively strengthen the norms against chemical and biological weapons (CBW).

These norms have increasingly been challenged in recent years, *inter alia* by the repeated use of chemical weapons in Syria. The project scrutinizes the forms and consequences of norm contestations within the CBW prohibition regimes from an interdisciplinary perspective. This includes a comprehensive analysis of the normative order of the regimes as well as an investigation of the possible consequences which technological developments, international security dynamics or terrorist threats might yield for the CBW prohibition regimes. Wherever research results point to challenges for or a weakening of CBW norms, the project partners will develop options and proposals to uphold or strengthen these norms and to enhance their resilience.

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