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EXPORT CONTROLS ON BIOLOGICAL AGENTS AND THEIR IMPACT ON VACCINE RESEARCH AND DEVELOPMENT: A FOCUS ON SARS-COV-2

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Abstract

This research focusses on export controls and the fight against epidemics and pandemics. Starting from a brief description of the complex network of treaty-law and soft-law instruments governing transfers of chemical, biological, radiological and nuclear weapons and dual-use items, this article describes how the uncertainty and regulatory burden surrounding the transfers of samples of SARS-CoV-2 is affecting the development of new vaccines, drug treatments and diagnostic tools. A coordinated global approach on this subject matter is therefore urgently needed. The approach to be taken however should not be limited to address the current state of emergency through one-time exceptions. We should not waste the COVID-19 crisis and use instead this opportunity to improve the international community preparedness to act in case of a new pandemic.

1. *Introduction*. — Export controls are national measures used to prevent the proliferation of chemical, biological, radiological and nuclear

(CBRN) weapons. These restrictive tools can take a variety of forms (like export bans, taxes, quotas and licence requirements) and have been used since the end of the second World War to limit international trade in a number of controlled items and materials.

The items subject to export controls are identified by national legislation through dedicated lists which are subject to a high degree of variation and converge only on a core group of weapons and sensitive dual-use items (*i.e.* agents, materials, equipment and technologies that can have both a civilian and a military application).

In fact, the international legal framework regulating this field consists in an intricate web of treaty-law obligations and soft-law commitments which do not guarantee a complete harmonisation of domestic legislations.

Most of the obligations on transfers arise from multilateral non-proliferation treaties — the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) [1], the Biological Weapons Convention (BWC) [2] and the Chemical Weapons Convention (CWC) [3] — which have an almost universal membership.

These treaties are complemented by the so-called 'informal export control regimes' in which, however, only a few States participate. With

[1] Treaty on the Non-Proliferation of Nuclear Weapons (1968), United Nations, *Treaty Series*, vol. 729, No. 10485, p. 161. The NPT entered into force in 1970 and currently counts 191 State Parties. The NPT has three goals: preventing the spread of nuclear weapons, promoting the peaceful uses of nuclear energy to the many applications it may have in medicine, industry and agriculture and promoting the reduction of nuclear weapons and disarmament.

[2] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1972), United Nations, *Treaty Series*, vol. 1015, No. 14860, p. 163. The BWC entered into force in 1975 and currently counts 183 State Parties. The treaty prohibits the development, production, stockpiling, acquisition or retention of biological weapons, equipment or means of delivery as well as of microbial or other biological agents, or toxins (Art. I BWC).

[3] Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993), United Nations, *Treaty Series*, vol. 1974, No. 33757, p. 45. The CWC entered into force in 1997 and currently counts 193 State Parties. State Parties undertake never under any circumstances to use, develop, produce, otherwise acquire, stockpile or retain chemical weapons, or transfer, directly or indirectly, chemical weapons to anyone (Art. I.1 CWC). The Annex on Chemicals contains three Schedules where toxic chemicals and precursors are grouped by relevance to chemical weapons production and potential legitimate peaceful use. Different conditions of supply apply to each category of chemicals. See in particular: W. Krutzsch and others (eds.), *The Chemical Weapons Convention: A Commentary*, Oxford, 2014; R. Trapp, *The Chemical Weapons Convention - Past Success, Current Challenges*, in M. Crowley and others (eds.), *Preventing Chemical Weapons: Arms Control and Disarmament as the Sciences Converge*, Royal Society of Chemistry, 2018, pp. 27-68.

this term we describe the fora in which groups of high-income countries convene to coordinate their trade policies over the export of CBRN weapons and, most importantly, dual-use agents, materials, equipment and technology [4].

Many of these informal regimes have been established to clarify the meaning of multilateral treaty provisions concerning transfers of controlled items and are therefore strictly connected to an existing treaty regime. To this end, informal regimes issue lists of items the export of which is subject to a license requirement (with the transfer of CBRN weapons being *per se* strictly prohibited).

For instance, in the field of nuclear materials and equipment to be used for peaceful purposes, the provisions of the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on transfers are complemented by the lists and guidelines adopted by two informal regimes: the Zangger Committee and the Nuclear Suppliers Group [5].

Similarly, the transfers provisions of the Biological Weapons Convention (BWC) and Chemical Weapons Convention (CWC) are complemented by the lists and guidelines adopted by the Australia Group [6].

Informal regimes are not treaty-based, they do not have international legal personality and their recommendations are not legally binding. In particular, participating countries have always reserved their right to apply export controls to additional items to those included in the lists

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[4] We are here referring to the Zangger Committee, the Nuclear Suppliers Group, the Australia Group, the Missile Technology Control Regime and the Wassenaar Arrangement. On these groups see SIPRI, *SIPRI Yearbook 2020: Armaments, Disarmament and International Security*, Oxford, 2020.

[5] Pursuant to Art. III.2 NPT, State Parties undertake not to supply *a*) 'source or special fissionable material' or *b*) 'equipment or material especially designed or prepared for the processing, use or production of special fissionable material' for peaceful purposes to any non-nuclear weapon State, unless the export is subject to the safeguards activities conducted by the International Atomic Energy Agency (IAEA). Since no clear definition is provided by the NPT, two informal regimes were established to ensure effective foreign policy coordination and to define a list of materials subject to export controls. Since 1971, the Zangger Committee gathers 15 supplier States, while 48 countries participate in the Nuclear Supplier Group (NSG) which was created in 1975. The Zangger Committee and the NSG issue two separate lists of materials. The Zangger Committee issues the so-called 'Trigger List' of nuclear materials and equipment the export of which 'triggers' IAEA safeguards pursuant to Art. III.2 NPT. The NSG adopts two set of guidelines, respectively on nuclear transfers and on transfers of dual-use equipment, materials, software and related technology, which could provide a major contribution to a nuclear explosive activity, an unsafeguarded nuclear fuel-cycle activity or acts of nuclear terrorism. Exports of such items are subject to various conditions of supply, among which license requirements and assurances on their peaceful use.

[6] On the Australia Group see *infra*, par. 2.

adopted by informal regimes and to apply further transfer conditions, according to national security concerns and economic interests.

This paper investigates the impact that export controls have on the capacity of researchers to study new viruses and fight epidemics and pandemics. To these ends, we will first briefly describe the international legal framework related to export controls in the field of biological weapons and dual-use agents, focussing on transfers of viruses. Then, we will describe how the European Union and the United States are regulating this field. Eventually, we will conclude by setting forward some proposals for the future.

2. *Export controls on biological weapons and dual-use agents*. — The BWC was the first multilateral treaty categorically banning an entire category of weapons of mass destruction [7]. It entered into force in 1975 and currently counts 183 State Parties.

The treaty prohibits the development, production, stockpiling, acquisition or retention of biological weapons, equipment or means of delivery as well as of microbial or other biological agents and toxins 'whatever their origin or method of production, of types and in quantities *that have no justification for prophylactic, protective or other peaceful purposes*' [emphasis added] (Art. I BWC).

In order to prevent the proliferation of biological weapons, Art. III BWC obliges States not to transfer to any recipient whatsoever, directly or indirectly, agents, toxins, weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. States are also prohibited from assisting, encouraging, or inducing any other State or group of States to manufacture or otherwise acquire such equipment and materials.

In parallel, Art. X BWC requires States: *a*) to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for the peaceful use of biological agents and cooperate for the prevention of diseases; and *b*) to implement the Convention in a

[7] J. Littlewood, *The Biological Weapons Convention: A Failed Revolution*, Aldershot, UK, 2004; J. Littlewood, 'The Biological and Toxin Weapons Convention' in M Crowley and others (eds.), *Preventing Chemical Weapons: Arms Control and Disarmament as the Sciences Converge*, (Royal Society of Chemistry 2018) 69-100; A Kelle, *Prohibiting Chemical and Biological Weapons: Multilateral Regimes and Their Evolution* (Lynne Rienner Publishers 2014).

manner designed to avoid hampering the economic or technological development of State parties and the international exchange of biological agents, toxins and equipment for peaceful purposes.

Unlike other multilateral non-proliferation treaties, the BWC lacks a verification regime [8]. Since the early phase of the BWC negotiations, it was recognised that the main reasons for the failure to introduce a verification and compliance mechanism are the inherent dual-use nature of bioagents, their importance for life sciences and the difficulty in determining whether they are used for prohibited purposes [9].

Notably, the BWC does not provide a definition of key terms, nor the Implementation Support Unit (ISU) [10] or the regular Review Conferences of the States Parties have ever adopted a list of biological agents, toxins and equipment the transfer of which is subject to export controls. True is that, thanks to the general-purpose definition adopted by Art. I BWC, the Convention can be interpreted in an evolutive way to keep up with scientific and technological advances. As we will see, however, the absence of legal clarity remains a major challenge both for non-proliferation purposes and to foster international cooperation in the field of peaceful activities with a view to implement Art. X BWC.

This important gap is to a certain extent addressed by the Australia Group (AG). This informal regime was established in 1985 among 15 countries willing to coordinate their national export controls on chemicals after the discovery that Iraq had used sarin, tabun and mustard gas during its war against Iran. The Group also played an important role in the negotiations of the CWC, which entered into force in 1997. By 1990, however, the Group had already broadened the scope of its activities to include, together with chemicals, also bioagents and toxins that can be used for the production of weapons of mass destruction.

The AG currently gathers 42 participating countries. All 27 EU

[8] Reference can be made to the safeguards activities carried out by the International Atomic Energy Agency and to the verification role of the Organization for the Prohibition of Chemical Weapons (OPCW).

[9] Negotiations on a Compliance Protocol to the BWC started in 1995. However, because of the 2001 United States rejection, the draft proposal issued by the *ad hoc* Group was ultimately shelved.

[10] The BWC Implementation Support Unit (ISU) regularly updates a document that provides information on the additional understandings and agreements reached by Review Conferences which interpret, define, elaborate the meaning or scope of a provision of the Convention or provide instructions, guidelines, recommendations on how a provision should be implemented.

Member States as well as the European Union itself, represented by the European Commission, participate in the Group.

Members commit to use licensing measures to ensure that the exports of certain chemicals, biological agents and toxins as well as dual-use biological and chemical equipment, technology and software are not diverted to CBW production.

To these ends, the AG issues five common control lists, which are adopted by consensus and revised annually [11]. In principle, national export control policies of AG members should be consistent with such lists (and therefore harmonised). However, participants have often used their discretion with regard to their implementation.

For the purposes of this research, the AG List of Human and Animal Pathogens and Toxins for Export Controls is particularly important [12]. It includes a number of viruses, among which notably the Severe Acute Respiratory Syndrome-related coronavirus (SARS-related coronavirus), the MERS-related coronavirus and the reconstructed 1918 influenza virus.

Any virus listed by the AG, whether natural, enhanced or modified, in the form of isolated live cultures or as material including living material which has been deliberately inoculated or contaminated with such cultures is subject to a licensing requirement, regardless of quantity or attenuation. The same applies to any genetically modified organism which contain (or genetic element that codes for) genes specific to listed viruses, synthetic DNA or RNA included [13].

Notably, the so-called 'release note' contained in the AG List of Human and Animal Pathogens and Toxins provides for a specific exception for vaccines, for which no license authorisation is required [14].

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[11] The five export control lists compiled by the AG are: the list of chemical weapons precursors (the nerve agent Novichok was added to this list at the end of 2020); the control list of dual-use chemical manufacturing facilities and equipment and related technology and software; the list of human and animal pathogens and toxins; the list of plant pathogens; and the control list of dual-use biological equipment and related technology and software.

[12] The list, as lastly amended, is available at: *https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/human_animal_pathogens.html* (last accessed 10 April 2021).

[13] See Australia Group, *Common Control List Handbook, Volume II: Biological Weapons-Related Common Control List*, revision 4, February 2018.

[14] A vaccine is defined by the AG as "a medicinal product in a pharmaceutical formulation licensed by, or having marketing or clinical trial authorisation from, the regulatory authorities of either the country of manufacture or of use, which is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered".

As clarified by the AG Plenary meeting held in Paris in June 2019, this exclusion applies not only to vaccines that are designed for use against listed biological agents (and may contain inactivated and live-attenuated viruses), but also to vaccines containing genes or partial sequences of viruses, bacteria, and toxins identified on the AG list and to vaccines containing their genetic elements or genetically modified organisms [15].

Such a timely decision was adopted taking into account recent scientific and medical developments concerning the modification of certain viruses "to express surface proteins of other target organisms or cells for stimulating immune response to the surface protein, thus acting as vaccines against those targets" [16] and is already proving its positive impact on the distribution of certain vaccines.

Prior to this clarification, in fact, a license was required to export chimeric vaccines which incorporates genetic elements of a virus included in the AG list (such as the Vesicular stomatitis virus, which is a common vector for vaccine development), but not for messenger RNA (mRNA) vaccines [17].

Even if vaccines are excluded from the scope of application of non-proliferation export controls [18], virus samples still need to be trans-

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[15] No information about this decision is published on the website of the Australia Group, but the US Bureau of Industry and Security refers to such a decision as a basis for issuing some clarifications about the scope of export controls that apply to certain vaccines. See US Department of Commerce, Bureau of Industry and Security, *Commerce Control List: Clarifications to the Scope of Export Control Classification Number 1C991 To Reflect Decisions Adopted at the June 2019 Australia Group Plenary Meeting*, 15 CFR Parts 742 and 774, US Federal Register vol. 86, n. 4, 7 January 2021, p. 944 ff.

[16] *Ibid*., p. 945.

[17] A chimeric virus is made by inserting the genetic material of one virus into the genome of another safe surrogate and these introduced sequences are passed on when the virus replicates. For example, the Ebola vaccine is a recombinant replication competent vaccine containing Vesicular stomatitis virus (VSV) as a vector in which one gene of VSV has been replaced with the gene that codes for the outer protein of the Zaire Ebola virus.

[18] Vaccines may be covered by export controls having another nature or purpose. See for example the European Commission Implementing Regulation (EU) 20217111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation, OJ L 311, 30.1.2021, p. 1. According to this regulation, for the exports of vaccines against SARS-CoV-2 and for a limited time period, a prior authorisation should be obtained from the Member State in which the vaccines are manufactured. This measure aims at limiting the risk of shortages that may be caused by the exportation of vaccines produced in the EU, with the Commission financial support, to non-vulnerable countries. Exports to 92 low- and middle-income countries in the COVAX Advance Market Commitment list are exempted.

ferred from one country to another for the purposes of studying their lethality, transmission, progression and variations.

In particular, access to samples of the SARS-CoV-2 virus, or portions of its genome, is vital for the development of vaccines, for finding new drug treatments and for testing the efficacy of diagnostic kits and protective equipment [19].

The procedures to obtain export authorisations are however time consuming and license applications usually require a costly legal support. They may delay transfers to the detriment of basic and applied scientific research. Moreover, regulations vary considerably among States.

The actual emergency situation may prompt the adoption of one-time exceptions or the application of expedited procedures. However, we should keep in mind that decisions adopted to cope with the COVID-19 crisis will inform our preparedness to address future epidemics and pandemics. In the interest of clarity, effectiveness and efficiency, an internationally coordinated approach needs to be adopted as soon as possible.

Unfortunately, as we will see in the following paragraph, States have reacted randomly, at least for the time being.

3. *Export controls on SARS-CoV-2 in the EU and in the United States*. — The aim of this paragraph is to briefly describes how the EU and the US legal frameworks on export controls apply to SARS-CoV-2 samples.

The departing point is that the last Intersessional Meeting of the Australia Group of February 2020 did not take any deliberation on the matter. No exemption or accelerated authorisation procedure was recommended by the Group.

For what concerns the EU legal framework, Regulation (EC) 428/2009 set up the EU regime for the control of exports, transfer, brokering

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[19] Interestingly, in March 2020, the European Commission adopted an implementing regulation making the exportation of certain personal protection equipment to countries outside the EU subject to an export authorisation in order to prevent and remedy the critical shortage situation within the EU. See European Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 amending Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation, OJ L 841, 20.3.2020, p. 1-2 (adopted on the basis of Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports).

and transit of dual-use items [20]. This regulation aims at ensuring that the EU and its Member States fully implement the obligations arising from relevant multilateral non-proliferation treaties and take into account commitments deriving from their participation in informal regimes, the Australia Group included.

The following basic principles are established: dual-use items subject to controls are listed in a common list (Annex I); listed items can be freely transferred within the EU territory, but an authorisation is required for their transfer to a destination outside the EU if they may be diverted to the development or use of CBRN weapons; common authorisation criteria are to be used by national export authorities (Art. 9); according to the so-called 'catch-all' principle, non-listed items are in any case subject to export controls if the importer might use them in a weapons of mass destruction programme or for a military end-use.

As lastly amended [21], the EU Dual-use Regulation keeps requiring an authorisation for the export of SARS-related coronavirus [22]. Exports of human pathogens, zoonoses and toxins require an export authorisa-

[20] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (OJ L 134, 29.5.2009, p. 1) (hereinafter 'the EU Dual-use Regulation'). Notably, the EU Dual-use Regulation is undergoing a review which started in 2016 with an ambitious Commission recast proposal adding cybersurveillance items to the regime and introducing serious violations of human rights and international humanitarian law as grounds for their export authorisation requirement. The legislative procedure is not concluded yet, but see the outcome of the European Parliament's first reading: Position of the European Parliament adopted at first reading on 25 March 2021 with a view to the adoption of Regulation (EU) 2021/... of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast), P9_TC1-COD(2016)0295.

[21] Commission Delegated Regulation (EU) 2020/1749 of 7 October 2020 amending Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, OJ L 412, 14.12.2020, p. 1-280.

[22] Pursuant to the so-called 'de-control' General Technology Note to Annex 1 of the EU Dual-use Regulation, controls on the transfer of 'technology' which is required for the use of controlled items (biological agents and toxins included) do not apply to information 'in the public domain', to 'basic scientific research' or to the minimum necessary information for patent applications. However, the regulation suffers from a lack of clarity on the meaning of 'basic scientific research' as opposed to 'applied research', especially at a time when the boundaries between the two concepts are blurred by increased cooperation between the academia and industry. Notably, these uncertainties have generated a heated controversy on whether export controls should apply in the field of academic publishing. On the recent dispute before Dutch courts concerning the publication of an academic paper on the gain-of-function of the H5N1 avian influenza in mammals, see C. Charatsis, *Setting the Publication of 'Dual-use Research' Under the Export Authorisation Process: the H5N1 Case*, in *Strategic Trade Review*, 2015, p. 56 ff.

tion even when directed to countries which are otherwise granted a 'general export authorisation' (Australia, Canada, Japan, New Zealand, Norway, Switzerland, including Liechtenstein, United Kingdom [23] and United States of America) [24]. The regulation will therefore affect also transfers to countries in which the biggest pharmaceutical companies are leading the race for vaccine development.

For what concerns the US legal framework, the Export Administration Regulations (EAR) administered by the Bureau of Industry and Security (BIS) of the Department of Commerce establish the conditions for exporting items outside the United States.

The EAR contain the Commerce Control List (CCL) of dual-use items of particular concern for which an export license is needed. The CCL includes the SARS-related coronavirus (ECCN 1C351.47) [25].

Already in February 2020, however, the BIS promptly issued a guidance update on the application of US export controls to the SARS-CoV-2 virus [26]. The BIS clarified that, since the "SARS-CoV-2 is a genetically distinct virus from SARS-CoV and causes a clinically distinct disease, COVID-19, from the severe acute respiratory syndrome-related coronavirus caused by SARS-CoV", the virus and its specific genetic elements will continue to be classified as items falling under the EAR entry for which an export license is not required (EAR99), at least for most of the destinations [27]. A license will instead still be necessary for

[23] After its withdrawal from the EU on 31 January 2020 (see Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7), the United Kingdom was granted a general export authorisation which applies from 1 January 2021. Since according to the terms of the Withdrawal Agreement, the United Kingdom is no longer a Member State of the European Union starting from 31 January 2020.

[24] See Regulation (EC) 428/2009, Annex IIa, Part 2.

[25] The ECCN is a five-digit alpha-numeric designation used by the Commerce Control List (CCL) to identify dual-use items for export control purposes. An ECCN categorizes items based on the nature of the product, *i.e.* type of commodity, software, or technology and its respective technical parameters; it also indicates reasons for the application of controls and available licences exceptions. ECCN 1C351 identifies human and animal pathogens and toxins. The list is consistent with the one agreed to in the Australia Group.

[26] US Department of Commerce, Bureau of Industry and Security, *Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) FAQ*, first published on 25 February 2020, last modified on 24 March 2021, available at *https://www.bis.doc.gov/index.php/documents/pdfs/2532-severe-acute-respiratory-syndrome-coronavirus-2-sars-cov-2-faq*.

[27] The EAR99 classification indicates that an item falls under the US Department of Commerce jurisdiction, but it is not listed on the Commerce Control List (CCL). EAR99 items generally consist of low-technology consumer goods and do not require a license in most circumstances. Exporters still need to perform careful due diligence to ensure the items are not

exports of MERS- and SARS-related coronavirus or of their genetic elements.

Interestingly, the BIS reached this conclusion despite the fact that the International Committee on Taxonomy of Viruses classified the SARS-CoV-2 virus as a variant belonging to the species 'SARS-related coronavirus'.

4. *Concluding remarks*. — The current pandemic has made it urgent a revision of the current legal framework on transfers of biological agents to be used for vaccine research and development. While the provisions of the BWC and the common control lists adopted by the AG have proved to be effective in preventing the proliferation of biological weapons, there is still a lot that can be made to improve the international community readiness to react to deadly virus outbreaks.

Strikingly, there is a gap that needs to be urgently addressed. While export controls on vaccines are being eased, there is no clarity on the regime applicable to transfers of virus samples for scientific research.

Even though the need to prevent the development of biological weapons programmes does not disappear during a pandemic or a local epidemic, export controls should not be overly restrictive and burdensome.

As a matter of fact, non-proliferation and global health are complementary goals that can be achieved through international cooperation (as required by Art. X BWC) and by strengthening the collaboration of BWC State Parties with the World Health Organisation (WHO), the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE).

As stressed by the Committee on Economic, Social and Cultural Rights, "Enhanced international cooperation could increase the preparedness of States and of international organizations to face future pandemics, for instance by sharing scientific information about potential pathogens. [...] If a pandemic develops, sharing the best scientific knowledge and its applications, especially in the medical field, becomes crucial

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going to an embargoed or sanctioned country, a prohibited end-user, or used in a prohibited end-use. For instance, however, exports to Cuba, which is subject to a comprehensive embargo under US law, will still require a license.

to mitigate the impact of the disease and to expedite the discovery of effective treatments and vaccines" [28].

To this end, we maintain that the impact of BWC obligations on vaccine research should be discussed at the Ninth BWC Review Conference which will convene at the end of 2021.

In fact, the guidance provided on this subject matter by the Australia Group is only a temporary solution, adopted by a restricted group of countries and subject to their voluntary implementation. The recommendation of the Australia Group needs to be further reinforced by a decision adopted by the BWC Review Conference.

Review conferences can in general be described as bodies mandated to periodically interpret, review and discuss practical ways to ensure the proper implementation of the obligations arising from a treaty. In this sense, they provide a useful framework for the cooperation of State parties on subsequent conduct with respect to the treaty.

In the framework of the BWC, State Parties hold Review Conferences every five years, while in the inter-sessional period a Meeting of Experts followed by a Meeting of the State Parties is convened every year [29].

Pursuant to Art. XII BWC, conferences of States parties are called "to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention [...] are being realised. Such review shall take into account any new scientific and technological developments relevant to the Convention" [30].

In particular, BWC Review Conferences can reach 'additional understandings and agreements' which are used to interpret, define or elaborate the meaning or scope of a provision of the Convention as well as to provide instructions, guidelines or recommendations on how a provision should be implemented [31].

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[28] Committee on Economic, Social and Cultural Rights, General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), 30 April 2020, E/C.12/GC/25, par. 82.

[29] The 2020 Meeting of States Parties has been postponed to November 2021 due to the COVID-19 pandemic.

[30] Art. XI BWC provides for a different procedure for the amendment of the treaty. Upon acceptance by the majority of the State parties, the amendment will enter into force for each State that has accepted it.

[31] The BWC Implementation Support Unit (ISU) regularly updates a document that provides information on the understandings and additional agreements reached by Review

Decisions of this kind have been adopted in relation to almost all the articles of the treaty "to address specific issues as and when they arose" [32], thus permitting the BWC to adapt to developments in science and technology. Of particular interest are those reached on Art. X BWC concerning international cooperation [33].

These additional understandings and agreements are considered by the International Law Commission (ILC) to embody a subsequent agreement — *i.e.* an authentic means of treaty interpretation — under Art. 31.3(a) of the Vienna Convention on the Law of Treaties (VCLT) [34], even when they are adopted by consensus [35].

Interestingly, during the 2019 Meeting of State Parties, some countries underlined that one of the central challenge to developing international cooperation, assistance and exchange in the biological sciences and technology was "the existence of multilateral export control regimes which impose restrictions on the legitimate trade in drugs, medicines, vaccines, diagnostics, biological agents, equipment and/or materials for peaceful purposes" and that the obligations established by Art. III BWC

Conferences which interpret, define, elaborate the meaning or scope of a provision of the Convention or provide instructions, guidelines, recommendations on how a provision should be implemented. The last Background Information Document on additional understandings and agreements was prepared by the Implementation and Support Unit in 2018 (BWC/MSP/2018/MX.1/2, Annex 1).

[32] P. Millett, *The Biological Weapons Convention: Securing Biology in the Twenty-first Century*, in *Journal of Conflict and Security Law*, vol. 15 (2010), pp. 25-43, at p. 33. See also N. Sims, *A simple treaty, a complex fulfillment: A short history of the Biological Weapons Convention Review Conferences*, in *Bulletin of the Atomic Scientists*, 2011, n. 3, p. 8-15, DOI: *10.1177/0096340211407400*.

[33] Meeting 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, *Background information document submitted by the Implementation Support Unit, Annex I: Additional understandings and agreements reached at previous review conferences relating to Article X*, 17 July 2018, BWC/MSP/2018/MX.1/2, in particular para. 121-124.

[34] See the commentary to draft conclusion n. 11 of the ILC concerning the decisions adopted within the framework of a Conference of States Parties in ILC, 'Draft conclusions on subsequent agreements and subsequent practice in relation to the interpretation of treaties', 2018, published in 'Report of the International Law Commission on the Work of its the 70th Session' (30 April-1 June and 2 July-10 August 2018) A/73/10, p. 85.

[35] Rule 28.2 of the Draft Rules of Procedure for the Eighth Review Conference establishes that "every effort should be made to reach agreement on substantive matters by means of consensus. There should be no voting on such matters until all efforts to achieve consensus have been exhausted". See the Draft Rules of Procedure of the Eighth Review Conference, Geneva, 19 August 2016, BWC/CONF.VIII/2. Pursuant to rule 28.6, in case a vote is called, "the relevant rules of procedure relating to voting of the General Assembly of the United Nations shall apply".

should not be used to impose restrictions and/or limitations on transfers and exchange of scientific knowledge, technology, equipment and materials for peaceful purposes [36].

This paper suggests that the next Review Conference should consider the issue of vaccine development while discussing the challenges and obstacles to developing international cooperation in the biological sciences and possible ways and means of overcoming such challenges (a topic which is also on the agenda of the forthcoming 2021 BWC Meetings of Experts).

The Ninth Review Conference can eventually adopt an additional understanding related to Art. X BWC (which, it has to be underlined, calls for the fullest possible exchange of equipment, materials and scientific and technological information for the use of biological agents and toxins for peaceful purposes) stressing that scientific research on vaccines falls within the concept of 'peaceful purposes' and that, therefore, the transfers of virus samples (those listed by the Australia Group and all those that can be turned in a biological weapon) for the purpose of vaccine development do not require a licence authorisation, but only a prior notification.

This *ouverture* can be balanced by maintaining a license authorisation requirement for transfers directed to certain countries, like those subject to UN sanctions, and when certain red flag indicators are present.

This additional understanding, establishing a presumption against the necessity of a license requirement for vaccine development, may also be complemented by a code of conduct for the community of scientists and companies working on vaccines on biosecurity measures to prevent diversion, unathorised use or possession, loss and theft of biological agents and toxins and their illicit acquisition by rogue States and terrorists.

In fact, as it has been recently affirmed, "compliance with the Biological Weapons Convention needs to be less about verifying a binary state — being 'in compliance' or 'not in compliance' — and more about

[36] Meeting 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, *Report of the 2019 Meeting of Experts on cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X*, 26 September 2019, BWC/MSP/2019/MX.1/2, para. 17.

analyzing justifications provided for the activities in question and managing dual use potential" [37].

Monitoring activities performed by researchers, private companies and civil society groups are becoming increasingly important, even more than the ones carried out by a centralised authority. Such monitoring activities may be conducted as a result of self-regulation, but they will be more effective if carried out following best practices or codes of conduct agreed upon under the umbrella of the BWC in cooperation with other international organisations and interested stakeholders.

We contend that, in so doing, BWC States Parties will contribute to the strengthening of international response capabilities for infectious disease outbreaks, whether natural or deliberate in origin.

The BWC framework can indeed be used to improve global health by facilitating (and securing) scientific research for peaceful purposes while still ensuring non-proliferation [38].

[37] F. Lentzos, *How to Protect the World from Ultra-targeted Biological Weapons*, in *Bulletin of the Atomic Scientists*, 2020, n. 6, pp. 302-308, at 306, DOI: *10.1080/00963402.2020.1846412*.

[38] For other recommendations, like revising the lists of pathogens covered by export controls to ensure they make taxonomic sense or listing the diseases caused by pathogens instead of pathogens, see P. Millett and P. Rutten, *COVID-19, SARS-CoV-2, and Export Controls*, in *Health Security*, 2020, pp. 329-334; J. Wolf et al., *The Impact of Export Regulations on Recombinant Viral Vaccine Development for Emerging Infectious Diseases*, in *Vaccine*, 2020, pp. 7198-7200. See also G. Cross and L. Klotz, *Twenty-first century perspectives on the Biological Weapon Convention: Continued relevance or toothless paper tiger*, in *Bulletin of the Atomic Scientists*, 2020, n. 4, p. 185-191.