

## I. Biological arms control

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The principal legal instrument against biological warfare is the 1972 Biological and Toxin Weapons Convention (BTWC).<sup>1</sup> Andorra and Mauritania acceded to the BTWC in 2015. As of December 2015, the convention had 173 states parties and 9 signatory states.<sup>2</sup>

The main activity in 2015 in the biological arms control field was work carried out in connection with two meetings that formed part of the third intersessional process of the BTWC: the Meeting of Experts (10–14 August) and the Meeting of States Parties (14–18 December). The three standing agenda items for the third intersessional process meetings were: (a) cooperation and assistance (with a particular focus on Article X of the BTWC concerning economic and technological cooperation and development); (b) review of developments in science and technology; and (c) strengthening of national implementation.<sup>3</sup> The special biennial topic for 2015 was on implementation of Article VII of the BTWC (assistance to those threatened by biological weapons), including the consideration of ‘detailed procedures and mechanisms’ for the provision of assistance and cooperation among the states parties.<sup>4</sup>

In 2015 participation in the BTWC regime’s politically binding confidence-building measures (CBMs) improved. The Implementation Support Unit (ISU), which facilitates interaction among the states parties and other relevant actors, received 72 CBMs covering activities in 2014.<sup>5</sup> This was the highest number ever (by one) of CBMs submitted for a given year. Further additions were made to the ISU’s Cooperation and Assistance Database which contains offers and requests for assistance by the states parties.

<sup>1</sup> Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Biological and Toxin Weapons Convention, BTWC), opened for signature 10 Apr. 1972, entered into force 26 Mar. 1975, *United Nations Treaty Series*, vol. 1015 (1976).

<sup>2</sup> The signatories were: the Central African Republic, Côte d’Ivoire, Egypt, Haiti, Liberia, Nepal, Somalia, Syria and Tanzania. States that had neither signed nor acceded to the BTWC were: Angola, Chad, Comoros, Djibouti, Eritrea, Guinea, Israel, Kiribati, Micronesia, Namibia, Niue, Samoa, South Sudan and Tuvalu.

<sup>3</sup> Seventh BTWC Review Conference, Final document, BWC/CONF.VII/7, 13 Jan. 2012, para. 8, p. 21.

<sup>4</sup> BTWC, Meeting of States Parties, ‘Final report of the Meeting of States Parties’, BWC/MSP/2015/6, 22 Feb. 2016, paras 8–9.

<sup>5</sup> See the 2015 news section of the United Nations Office in Geneva’s website at: <[http://www.unog.ch/80256EE600585943/\(httpPages\)/87CF9BFD24A8D05FC1257574004B285B](http://www.unog.ch/80256EE600585943/(httpPages)/87CF9BFD24A8D05FC1257574004B285B)>.

## The preparations for the Eighth Review Conference

The 2015 meetings discussed and approved arrangements for the Eighth Review Conference, which will take place in November 2016, and the conference's Preparatory Committee. Various declarations, proposals and submissions relevant to the Eighth Review Conference were issued during the intersessional process.

### *The common position of the European Union*

The European Union (EU) adopted a common position on the Eighth Review Conference.<sup>6</sup> It underlined the importance of maintaining and strengthening the BTWC, and called for more effective national implementation and universal treaty membership. It supported a further intersessional programme of work between the Eighth and Ninth Review Conferences which, in turn, should comprise a 'substantive' work programme that 'addresses the limitations of previous intersessional programmes'.<sup>7</sup> The common position maintained that verification 'remains a central element of a complete and effective disarmament and non-proliferation regime'.<sup>8</sup> It also noted the importance of strengthening the operational capabilities of the UN Secretary-General's mechanism for investigating alleged chemical and/or biological weapon use by expanding the pool of qualified experts, as well as carrying out training, and tabletop and field exercises (see section II).<sup>9</sup>

The EU pledged to facilitate implementation of Article X of the BTWC by, among other things, supporting (a) the development of the Cooperation and Assistance Database, (b) the relevant actors involved in the implementation of the World Health Organization's 2005 International Health Regulations, and (c) the relevant goals of the Group of Seven (G7) Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.<sup>10</sup> The common position also noted that the EU supported putting in place 'more

<sup>6</sup> Council of the European Union, Council Decision (CFSP) 2015/2096 of 16 Nov. 2015 on the position of the European Union relating to the Eighth Review Conference of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC), *Official Journal of the European Union*, L303, 20 Nov. 2015.

<sup>7</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L303/15.

<sup>8</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L303/15.

<sup>9</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L303/16. For further details of the UN Secretary-General's investigative mechanism see United Nations Office for Disarmament Affairs (UNODA), 'Relating to the Secretary-General's mechanism for investigation of alleged use of chemical and biological weapons', Key documents, [n.d.].

<sup>10</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L303/16. On 18 Jan. 2016 the European Union adopted a decision to allocate €2.3 million to support the BTWC to (a) promote universality; (b) enhance interaction with non-governmental stakeholders in the field of science and technology; (c) support capacity building; (d) promote the Eighth Review Conference; (e) strengthen the UN Secretary-General's investigative mechanism; and (f) assist with awareness raising, education and engagement. Council of the European Union, Council Decision (CFSP) 2016/51 of 18 Jan. 2016 in support of the Biological and Toxin Weapons Convention (BTWC) in the framework of the

frequent and focused assessments' of relevant science and technology developments which could, in principle, incorporate 'a standing science and technology advisory function in the ISU'.<sup>11</sup> Finally, the EU expressed support for a comprehensive review of CBM formats, including moving the regime towards a position where annual CBMs act as 'the regular declaration tool' that informs consideration of the BTWC's 'implementation and compliance'.<sup>12</sup> This implies that the states parties to the convention should eventually make CBMs legally binding.

### *The meeting of Experts*

The Meeting of Experts in August 2015 discussed ways to maintain and strengthen treaty compliance. This included the lessons to be learned from a joint Belgium-Luxembourg-Netherlands (Benelux) peer-review system to assess national implementation of the BTWC, which was based on a December 2013 pilot-review exercise hosted by France.<sup>13</sup> The Benelux peer-review system is being implemented in two phases: (a) written consultation based on the 2015 CBM submissions of the Benelux states; and (b) an event at which this information is discussed, followed by on-site visits to declared installations.<sup>14</sup>

The Biosecurity Working Group of the Global Network of Science Academies consulted at the Meeting of Experts (and at other events in 2015) on BTWC-relevant trends in science and technology, outreach, and awareness-raising on dual-use issues and education on biosecurity.<sup>15</sup>

### *The meeting of States Parties*

Proposals for strengthening the BTWC regime to support the Eighth Review Conference were made at the Meeting of States Parties in December 2015. Russia expressed continued support for a reconsideration of compliance issues that takes into account the work of the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint (VEREX).<sup>16</sup> Armenia, Belarus, China and Russia tabled proposals for possible inclusion in the final document of

EU strategy against proliferation of weapons of mass destruction, *Official Journal of the European Union*, L12, 19 Jan. 2016.

<sup>11</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L303/16.

<sup>12</sup> Council of the European Union (CFSP) 2015/2096 (note 6), p. L 303/16.

<sup>13</sup> BTWC, Meeting of Experts, Belgium, Luxembourg and the Netherlands, 'Benelux BTWC peer review: outline of key features and objectives', BWC/MSP/2015/MX/WP.13, 6 Aug. 2015.

<sup>14</sup> BTWC, Meeting of Experts (note 13), p. 2.

<sup>15</sup> InterAcademy Panel, Global Network of Science Academies, Biosecurity Working Group, <<http://www.iapbwg.pan.pl/index.php>>.

<sup>16</sup> Hart, J. and Clevestig, P., 'Chemical and biological security threats', *SIPRI Yearbook 2015*, p. 571.

the Eighth Review Conference.<sup>17</sup> They proposed that an open-ended working group should elaborate on a consensus basis ‘appropriate measures and draft proposals’ to strengthen the BTWC as a legally binding instrument. The proposal stated that the working group could consider:

(a) the incorporation of existing and potentially further enhanced confidence building and transparency measures, as appropriate, into the regime; (b) measures to achieve effective national implementation of the Convention; (c) measures for considering the implications of developments in areas of science and technology relevant to the Convention and agreeing in that regard appropriate steps to enhance the effective implementation of the Convention; (d) measures for strengthening international co-operation for peaceful purposes in accordance with Article X of the Convention; (e) procedures and mechanisms for assistance and protection against biological weapons in accordance with Article VII of the Convention; (f) [a] mechanism for investigating alleged use of biological weapons (to be initiated by the affected State and conducted on its territory) pursuant to Article VI of the Convention.<sup>18</sup>

China proposed that the Eighth Review Conference develop a template for a biological scientist code of conduct.<sup>19</sup> China also recommended that the establishment of a non-proliferation export control regime under the framework of the BTWC be incorporated into the international cooperation agenda at the conference, and that the resources of existing international regimes and organizations, including the 1540 Committee and the Australia Group, be fully utilized.<sup>20</sup>

The United States proposed that the Eighth Review Conference establish a Steering Group consisting of the chairman, vice-chairmen and leaders of expert groups to liaise with the ISU in order to assist it to prepare for further annual intersessional meetings.<sup>21</sup> It also called for the parties to agree the parameters or guidelines for a fourth intersessional annual Meetings of States Parties, which should be authorized to take decisions (e.g. with respect to the implementation of the ISU’s Cooperation and Assistance Database).<sup>22</sup>

<sup>17</sup> The proposal does not include visits (i.e. routine inspections), which was one of the most difficult issues to resolve during efforts to negotiate a protocol to strengthen compliance with the BTWC between 1995 and 2001.

<sup>18</sup> BTWC, Meeting of States Parties, Armenia, Belarus, China and Russia, ‘Proposal for inclusion in the final document of the Eighth Review Conference of the Biological Weapons Convention’, BWC/MSP/2015/WP.4/Rev.1, 16 Dec. 2015, p. 2.

<sup>19</sup> BTWC, Meeting of States Parties, China, ‘Proposal for the development of the template of biological scientist code of conduct under the Biological Weapons Convention’, BWC/MSP/2015/WP.9, 15 Dec. 2015 (unofficial translation).

<sup>20</sup> BTWC, Meeting of States Parties, China, ‘Establishing a non-proliferation export control regime under the framework of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction’, BWC/MSP/2015/WP.8, 15 Dec. 2015, para. 8 (unofficial translation).

<sup>21</sup> BTWC, Meeting of States Parties, USA, ‘Strengthening the ability to take action: a realistic agenda for the Eighth Review Conference’, BWC/MSP/2015/WP.3, 14 Dec. 2015, p. 2.

<sup>22</sup> BTWC, Meeting of States Parties, USA (note 21), p. 2.

Eighteen states parties provided views and proposals concerning implications of the spread of technology and disease outbreak, including a proposal that the states parties should agree to discuss the role of the BTWC and the ISU in an investigation determining whether a disease outbreak is naturally occurring or deliberate.<sup>23</sup> Another grouping of states parties encouraged all the parties to submit comprehensive annual CBMs and to build ‘an operational capability (i.e. through generating a list of experts) that could be called upon to assist in responding to a biological incident, in the absence of a full-time inspectorate’.<sup>24</sup>

Finally, Switzerland outlined structural and cost elements employed at the international level for science and technology expert-led processes in order to facilitate understanding and possible future action on strengthening the institutional capacity of the treaty regime.<sup>25</sup>

### **Other biological security-related developments**

#### *Transfers of viable Bacillus anthracis by the US Army*

On 22 May 2015 a company informed the US Centers for Disease Control and Prevention (CDC) that it had found viable *Bacillus anthracis* (the causative agent for Anthrax) spores in a shipment from the US Army that should have contained only inactivated (i.e. non-viable) spores. This prompted a joint CDC–US Department of Defense investigation into the biosafety and biosecurity practices at the Dugway Proving Ground facility in Utah for the period 2004–15. On 17 December 2015 the US Government released an unclassified report detailing the individual and institutional accountability for the incident. The report also outlined a number of recommendations to improve policy and procedures at the facility.<sup>26</sup>

Russian authorities issued a statement that the inadvertent shipment of viable *Bacillus anthracis* constituted a ‘gross violation of biological safety

<sup>23</sup> BTWC, Meeting of States Parties, Australia, Canada, Chile, Colombia, Czech Republic, Finland, Germany, Hungary, Japan, Lithuania, Netherlands, Nigeria, Norway, Philippines, Republic of Korea, Slovakia, Sweden and Switzerland, ‘Addressing modern threats in the Biological Weapons Convention: follow-up and recommendations’, BWC/MSP/2015/WP.6/Rev.1, 14 Dec. 2015, para. 16(e).

<sup>24</sup> BTWC, Meeting of States Parties, Australia, Canada, Chile, Colombia, Costa Rica, Ecuador, Ghana, Japan, Malaysia, Norway, Philippines, Republic of Korea, Switzerland and Thailand, ‘Providing reassurance on Biological Weapons Convention (BWC) implementation’, BWC/MSP/2015/WP.11/Rev.1, 28 Dec. 2015, paras 4, 8.

<sup>25</sup> BTWC, Meeting of States Parties, Switzerland, ‘Reviewing developments in science and technology: examples of dedicated processes’, BWC/MSP/2015/WP.10, 16 Dec. 2015.

<sup>26</sup> US Army, Individual and Institutional Accountability for the Shipment of Viable *Bacillus Anthracis* from Dugway Proving Ground, AR 15-6 Investigation Report, unclassified (17 Dec. 2015). See also US Department of Defense, ‘Department of Defense press briefing by army officials in the Pentagon briefing room on the investigation into the inadvertent shipment from Dugway Proving Ground of live anthrax spores’, Press briefing, 15 Jan. 2016.

norms' and presented a danger to US and international populations.<sup>27</sup> Russia also criticised the 'US military international network of biological laboratories' in its revised 2015 national security strategy.<sup>28</sup>

The 2015 case had similarities to an incident in 2014 where a worker at a Bioterrorism Rapid Response and Advanced Technology laboratory operated by the CDC prepared eight bacterial 'select agents', including *Bacillus anthracis*, which were not properly sterilized.<sup>29</sup>

### *Gain-of-function research*

In October 2014 the US Government announced a pause on federally funded gain-of-function (GOF) research—which covers studies that increase the ability of a pathogen to cause disease—pending the crafting of clearer funding policy guidelines. The US Government simultaneously tasked the US National Institutes of Health's (NIH) National Science Advisory Board for Biosecurity (NSABB) with making recommendations on (a) the design, development and conduct of a risk-benefit assessment on GOF research to provide a framework for analysis to be undertaken by an independent contractor, and (b) a conceptual approach to the evaluation of proposed GOF research to guide future US policymaking in this area.<sup>30</sup>

In February 2015 two experts published an open letter to the NSABB underlining the need to take into account the views of vaccine developers, manufacturers and non-US actors.<sup>31</sup> In May 2015 the NSABB released its *Framework for Guiding the Conduct of Risk and Benefit Assessments of Gain-of-Function Research*, which supported the NIH in overseeing the independent contractor conducting the risk-benefit assessments.<sup>32</sup> On 23 December 2015 the NSABB issued a draft document outlining its initial findings on a conceptual approach to the evaluation of proposed GOF research. GOF oversight actions partly depend on how three key points are understood and whether some (or all) of them must be applicable before a given research

<sup>27</sup> Russian Ministry of Foreign Affairs, [Comment by the Information and Press Department of the Russian Ministry of Foreign Affairs regarding the US Department of Defense and anthrax] Press Release 1141, 9 June 2015 (in Russian).

<sup>28</sup> Russian Government, [National Security Strategy of the Russian Federation], Decree no. 683, 31 Dec. 2015, para. 19 (in Russian).

<sup>29</sup> US Centers for Disease Control and Prevention (CDC), *Report on the Potential Exposure to Anthrax* (CDC: Atlanta, GA, 11 July 2014).

<sup>30</sup> National Science Advisory Board for Biosecurity (NSABB), 'Working paper prepared by the NSABB working group on evaluating the risks and benefits of gain-of-function studies to formulate policy recommendations', 23 Dec. 2015 (draft).

<sup>31</sup> New England BioLabs Inc and Stanford University Medical Center, Open letter dated 24 Feb. 2015 by Sir Richard Roberts and Dr David Relman to Chairman and NSABB President Samuel L. Stanley.

<sup>32</sup> National Science Advisory Board for Biosecurity (NSABB), *Framework for Guiding the Conduct of Risk and Benefit Assessments of Gain-of-Function Research: Recommendations of the National Science Advisory Board for Biosecurity* (NSABB: May 2015).

activity is considered to be of GOF concern.<sup>33</sup> Such considerations will become more clear as a consequence of implementation practice. Finally, it should be noted that classified research remains outside the remit of the NSABB.

<sup>33</sup> The 3 key points are (a) the pathogen is highly-transmissible in relevant mammalian model; (b) the pathogen is highly virulent in a relevant mammalian model; and/or (c) the pathogen is more likely capable of being spread among humans than the currently circulating strains.