Eighth 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

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English only

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Item 10 (b) of the provisional agenda
Review of the operation of the Convention as provided for in its Article XII: Articles I-XV

Compliance by States Parties with their obligations under the Convention

Background information document submitted by the Implementation Support Unit

Summary

The Preparatory Committee decided to request the Implementation Support Unit (ISU) to prepare a background information document on compliance by States Parties with all their obligations under the Convention, to be compiled from information submitted by States Parties (see BWC/CONF.VIII/PC/9, paragraph 26(f)). The ISU duly requested submissions from States Parties, and all submissions provided to the ISU by 27 September 2016 are included in this document. Any further submissions from States Parties will be included in an addendum to this document. The information in this document is reproduced as submitted by States Parties, in some cases with minor editing. Information submitted in official languages other than English has been translated into English.

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Contents

Australia

1. Australia provides the following information to the Biological Weapons Convention (BWC) Implementation Support Unit (ISU) on its compliance with obligations under key provisions of the Convention, as requested by the ISU in a letter dated 23 May 2016.

2. Information is provided under subheadings relating to key provisions of the Convention and draws on Australia's submission of Confidence Building Measures covering the 2015 calendar year, which is available publicly at www.unog.ch/bwc/cbms.

A. Article I

3. Australia has never had an offensive biological research, development or production program or obtained biological weapons through transfer and has never acquired or retained biological weapons. We have implemented legislative and regulatory measures that give effect to the prohibitions of this Article, and have initiated a variety of other actions to raise awareness in the biotechnological sector of the threat posed by biological weapons, including the need to enhance the security of hazardous biological substances.

B. Article II

4. Australia has never had an offensive biological research, development or production program or obtained biological weapons through transfer, and, accordingly, has had no need to destroy or divert to peaceful purposes any biological weapons, as required under the provisions of this Article.

C. Article III

5. Australia's compliance with this Article with respect to international transfers is demonstrated by our implementation of effective export control legislation, a summary of which is provided in our recent Confidence Building Measures (CBM) return Form E.

6. Our commitment to the principles of the Article is underscored by our permanent chairing of the Australia Group and our regional outreach program with respect to the Australia Group, the BWC, the Chemical Weapons Convention (CWC) and UN Security Council Resolution 1540.

7. Since the last BWC Review Conference in 2011, Australia has reviewed the security of hazardous biological materials in Australia. The Review *of Biological Agents of Security Concern* was completed in December 2015 to determine if any changes should be made to the biological agents regulated under the National Health Security Act 2007 (NHS Act) with public consultation held in late 2015.

8. The NHS Act was passed by the Australian Parliament in September 2007. It has two main operative parts: Part 2 of the Act enacts Australia's responsibilities under the International Health Regulations 2005 and formalised surveillance systems in Australia, while Part 3 established a regulatory scheme for biological agents of security concern.

9. Part 3 of the NHS Act enabled a national regulatory scheme (based in the Department of Health) to regulate the handling of Security Sensitive Biological Agents (SSBAs) and agents suspected of being SSBAs. The NHS Act established: a list of SSBAs to be regulated; a National Register that is informed by mandatory reporting; purposes for which the SSBAs may be handled; security (physical, personnel, information management,

disposal and transport) mandatory standards that must be met while handling SSBAs (including storage); exemptions from regulation; and an inspection scheme to monitor compliance with the regulatory scheme.

10. Further information is provided in our CBM return.

D. Article IV

11. Australia has implemented a number of legislative enactments to satisfy our BWC obligations to counter biological weapons proliferation and prevent bio-terrorism, as outlined in our recent CBM return.

12. Through the Defence Trade Controls Amendment Bill 2015 (DTC Amendment Bill) the offence provisions of the Defence Trade Controls Act 2012 for supplying, publishing and brokering Defence and Strategic Goods and technology came into force from 1 April 2016. The Biosecurity Act 2015 replaced the Quarantine Act 1908 from 16 June 2015. It provides broad powers to the Director of Biosecurity and Director of Human Biosecurity to control the importation and use of biological materials in Australia with the aim of preventing or controlling the introduction, establishment or spread of diseases or pests that will (or could) cause significant damage to humans, animals, plants and/or other aspects of the environment or economic activities.

13. Australia has implemented effective plant, animal and human disease surveillance systems, coordinated respectively through the Department of Agriculture and Water Resources and the Department of Health. These systems have been implemented in the context of protecting humans and agriculture from inadvertent disease establishment and spread. But equally, they comprise part of the national strategy to detect deliberate/suspicious disease outbreaks – whether by state or non-state actors. These surveillance systems relate to compliance with Articles VI, VII, X and, thereby, implementation of IV.

E. Article V

14. Australia considers that an objective of Article V is to provide a mechanism that gives States Parties confidence that other States Parties are compliant with the Convention. A key means of providing such confidence is the submission of Confidence Building Measures (CBM). Australia has submitted CBMs every year and makes its CBM return available publicly at www.unog.ch/bwc/cbms.

15. Australia has consistently participated in and contributed to BWC meetings of the last intersessional period, both formal Meetings of Experts and Meetings of States Parties and in informal workshops and seminars which aim to solve any problems with implementation of the Convention. Australia's commitment to encouraging engagement in the BWC is also demonstrated by its coordination of the BWC Western Group.

16. Ahead of the 8th Review Conference, Australia, in conjunction with other States Parties, has prepared proposals which seek to enhance participation in the CBM process – "Working Paper on providing reassurance on BWC implementation", and "Step-by-step approach in CBM participation".

F. Articles VI and VII

17. Australia has complied with Articles VI and VII, most notably through our on-going support for the UN Secretary General's investigative mechanism (UNSGM), as set out in General Assembly Resolution 42/37 of 30 November 1987.

18. Australia continues to nominate experts and laboratories for the UNSGM roster of qualified experts (most recently in August 2016), whose services could be called upon to assist in the event of alleged use of chemical, biological or toxin weapons. In October 2016 Australia will host with the UN Office of Disarmament Affairs (UNODA), a skills training course to strengthen capacity in the Asia-Pacific region to support the UNSGM's operational capabilities.

19. Australia stands ready to assist States that have been exposed to inadvertent or deliberate disease outbreaks. We have shared our experience in developing and implementing disease surveillance strategies and have provided practical assistance to countries affected by natural outbreaks of human, animal and plant diseases, as we have noted in our Article X reports.

20. In addition, we have assisted States Parties in the South East Asian region, by convening workshops to share Australian experience of developing national policies and practices that raise awareness of the security threat posed by hazardous biological materials, and that enhance the security of such materials.

21. Australia has prepared a separate Article VII report.

G. Article VIII

22. Australia acceded to the Geneva Protocol of 1925 on 24 May 1930 and withdrew its reservations on 9 December 1986.

H. Article IX

23. Australia ratified the Chemical Weapons Convention (CWC) on 6 May 1994 before its entry into force on 29 April 1997. The Australian Safeguards and Non-Proliferation Office (ASNO), in the Department of Foreign Affairs and Trade, is the National Authority responsible for implementation of the CWC in Australia. Amongst other responsibilities, ASNO is the focal point in Australia for liaison between stakeholders, such as operators of facilities regulated under the CWC, the OPCW, and the national authorities of other member countries on issues relating to implementation of the Convention.

I. Article X

24. Australia places great importance on the implementation of Article X of the BWC. We consider that implementation of Article X reinforces the security objectives of the BWC, as well as encouraging peaceful uses of biological science and technology. As part of our commitment to strengthening assistance and cooperation under the BWC, Australia strives to submit an annual report on national implementation of Article X of the BWC. This is in keeping with the agreement by States Parties at the Seventh Review Conference - and subsequent MSP and MXP meetings- on the importance of submitting clear, specific and timely national reports on implementation of Article X.

25. Further information may be found in Australia's separate Article X report.

J. Article XIV

26. Australia continues to encourage all States outside the BWC to ratify or accede to the Convention. Australia supported the 2016 BWC ISU sponsorship programme which enabled experts from 25 States Parties to attend the August 2016 BWC Preparatory Committee meeting, and the 8th BWC Review Conference.

27. Australia also supported participation by Pacific and Asian delegations in the 2015 Global Parliamentary Campaign for Universality and National Implementation of the BWC, organised by the Parliamentarians for Global Action (PGA).

Canada

28. Canada views the request emanating from the Preparatory Committee meeting in April 2016 (BWC/CONF.VIII/PC/2), and the subsequent letter from the Chair dated 25 May 2016, as embracing not only national observance of legally binding obligations established by the Biological and Toxin Weapons Convention (BTWC), but also the political commitments resulting from undertakings by States Parties as reflected in the Final Documents of past Review Conferences (i.e. obligations relating to the submission of annual declarations under the agreed Confidence Building Measures (CBMs)). This Canadian submission does not replicate all of the information that we have provided under the CBMs, and should be seen as complementary to those submissions.

A. Article I

29. Canada is in full compliance with its obligations under Article I. Furthermore, in keeping with the political commitment of the CBMs, we have reported on the nature of the former Canadian biological weapons programme as it existed historically and as terminated long before the entry into force of the BTWC. We continue to encourage other States Parties to report at an appropriate level of detail.

B. Article II

30. Canada is in full compliance with its obligations under Article II, and once again we refer States Parties to the text of our replies under the CBMs for other related information.

C. Article III

31. Since the BTWC entered into force in 1975, Canada has fully complied with its obligations under Article III. Over time, Canadian measures to implement its obligations have evolved with a view to preventing any transfer of materials, equipment or technical expertise that might contribute to a biological weapons program. This we have done through legislative and regulatory measures, *inter alia*, the *Export and Import Permits Act* and related regulations establishing a national licensing regime for controlled dual-use biological equipment, materials, and related software and technology, with concomitant penalties for violations thereof.. Canada is also a member of the Australia Group (AG); all goods on the AG Common Control List are part of Canada's national *Export Control List*, and as such are subject to the aforementioned licensing regime. Canada remains committed to adopting additional appropriate measures with a view to preventing the transfer of any material, equipment or expertise that could contribute to the proliferation of biological weapons. From January 1, 2011 to August 10, 2016, Canada's Export Controls Division

processed eight (8) applications for permits to export controlled dual-use equipment, biological weapons and related software and technology (i.e., goods, materials or technologies controlled under items 7-11 through 7-15 of the Export Control List). None of these were denied.

32. To ensure that Canadian companies meet their obligations, Canada conducts awareness-raising activities routinely in the export controls field, providing informational briefings to companies engaged in the export of all controlled goods and technology, including biological materials, equipment, software and technology. Such outreach activities take place on a one-to-one basis with companies and with industry groups. Canada also supports such activities by conducting outreach to companies and providing presentations on counter-proliferation and enforcement at appropriate domestic and international fora.

33. The *Human Pathogens and Toxins Act* (HPTA) is another key piece of legislation that implements Canada's obligations under the BTWC, through the establishment of national requirements for the safe and secure handling of human pathogens and toxins. The key components of the HPTA that support Canada's implementation of Article III include: oversight of imported and domestically acquired human pathogens and toxins; personnel security clearances for access to prescribed human pathogens or toxins; oversight of transfers; requirements for recording and maintenance of inventories; a requirement for reporting of inadvertent releases or production, and of laboratory acquired infections; compliance verification and enforcement; and penalties.

34. Canada is also fully committed to assisting BTWC States Parties to more fully implement their Article III obligations. Through its Global Partnership Program (GPP), Canada delivers concrete programming in support of the following Article III-relevant Global Partnership "Principles to prevent terrorists, or those that harbour them, from gaining access to weapons or materials of mass destruction", which were adopted by G8 Leaders at their Kananaskis Summit in 2002:

> (a) Develop and maintain effective border controls, law enforcement efforts and international cooperation to detect, deter and interdict in cases of illicit trafficking in [biological] items, for example through installation of detection systems, training of customs and law enforcement personnel and cooperation in tracking these items; provide assistance to states lacking sufficient expertise or resources to strengthen their capacity to detect, deter and interdict in cases of illicit trafficking in these items.
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> (b) Develop, review and maintain effective national export and transshipment controls over items on multilateral export control lists, as well as items that are not identified on such lists but which may nevertheless contribute to the development, production or use of nuclear, chemical and biological weapons and missiles, with particular consideration of end-user, catch-all and brokering aspects; provide assistance to states lacking the legal and regulatory infrastructure, implementation experience and/or resources to develop their export and transshipment control systems in this regard

35. Examples of Article III-relevant GPP programming in 2016 include: a $5.9M Project to strengthen export controls and border security in Latin America and the Caribbean; co-sponsorship with the United States of a Global Export Control Workshop (November 2016 in Prague); convening a conference on "Strengthening Strategic Trade Controls in the Caribbean: Preventing WMD Proliferation and Safeguarding Borders" (Barbados, 4-6 October 2016); and $6.25M to the joint United Nations Office on Drugs and Crime (UNODC) World Customs Organisation (WCO) Container Control Program (CCP) in South east Asia and the Caucasus (which aim to better enable partner countries to

undertake container profiling and interdict illicit trade, including chemical, biological, radiological & nuclear weapons and related dual-use materials)

D. Article IV

36. Canada has a broad range of laws and processes to implement our obligations under Article IV of the BTWC. It is the Canadian view that the fulfilment of obligations under the Convention is important, and that it is necessary to go even further than adhering to the strict requirements of the Convention in order to exclude use of biological and toxin weapons in terrorist or criminal activity.

37. On 1 December 2015, the HPTA and the *Human Pathogens and Toxins Regulations* (HPTR) came fully into force. These grant the Public Health Agency of Canada (PHAC) jurisdiction over individuals who are knowingly conducting controlled activities with Risk Groups 2, 3, and 4 human pathogens and toxins, ensuring that they meet appropriate biosafety and biosecurity standards. The new federal oversight also provides assurance that individuals with access to a prescribed list of security sensitive human pathogens and toxins have an appropriate security clearance. Additional pieces of legislation, including the *Health of Animals Act* and *Plant Protection Act*, control importation and reporting of animal pathogens and plant pests. Additional information on Canada's implementing legislation, as of August 2011, can be found in the joint Canadian/Swiss paper "National implementation of the BTWC: Compliance Assessment", tabled informally at the Seventh Review Conference and formally at the 2012 Meeting of Experts as document BWC/MSP/2012/MX/WP.17.

38. Compliance with the applicable portions of the *Canadian Biosafety Standard* (CBS) 2nd Edition, 2015 is a key condition of licence issuance under the HPTR. The CBS is the national standard for the safe handling and storing of human and terrestrial animal pathogens and toxins in Canada. The CBS is used by PHAC and the Canadian Food Inspection Agency to verify the ongoing compliance of facilities regulated under the HPTR and the *Health of Animals Regulations* (HAR).

39. In addition to domestic actions, Canada actively supports other BTWC States Parties to meet their Article IV obligations. Through its Global Partnership Program, Canada supports VERTIC to assist member countries in the Americas, Africa, Asia and the Middle East to develop national legislation and regulations to ensure full and effective implementation of the Convention.

E. Article V

40. Canada has not invoked Article V. We fully support Article V, and we do not interpret it as being a prior stage that needs be invoked before proceeding to Article VI of the Convention, should circumstances so warrant. Canada fully supports the political commitments reached at the Second, Third, and Seventh Review Conferences concerning the exchange of information under the heading of Confidence Building Measures, and we have consistently participated in every one of these exchanges, with the 2011-2016 CBM submissions being made publicly available.

F. Article VI

41. Canada has not invoked the provisions of Article VI nor has any other State Party invoked the provisions of Article VI against Canada.

G. Article VII

42. Canada has not been requested to provide assistance under Article VII. Further information on the measures Canada has taken to facilitate the provision of assistance in case of alleged use can be found in Canada's contribution to the background document on the implementation of Article VII.

H. Article VIII

43. Canada strongly supports the *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare*, and is in full compliance with all of its obligations under this Treaty.

44. Canada is committed to working with BTWC States Parties and the United Nations Office for Disarmament Affairs (UNODA) to improve the Secretary-General's investigative mechanism (UNSGM). In this regard, in August 2016 Canada contributed US$367,250 to UNODA to support activities to improve the preparedness and capacity of the UNSGM to investigate allegations of the use of biological and toxin weapons.

I. Article IX

45. A State Party to the *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction* (CWC), Canada implements fully the Convention's obligations. National implementing legislation is in place (the *Chemical Weapons Convention Implementation Act*), regulations under the *Export and Imports Permit Act* were revised to reflect the Convention, and a National Authority, located within Global Affairs Canada, has been established. Canada was a member of the Executive Council from 2010-2014 and participates actively in the work of the Organisation for the Prohibition of Chemical Weapons (OPCW) towards the effective implementation of the Convention, and is active in encouraging and supporting its universalization.

46. Canada is a significant supporter of global chemical weapons destruction efforts and is one of the largest voluntary contributors to the OPCW. The GPP has provided $21 million to OPCW since 2011 to support destruction of chemical weapons in Libya and Syria and to investigate allegations of chemical weapons use in the Syrian conflict. Canada's 2016 contributions include ~€2.5 million to support the OPCW's verification and fact-finding work in Syria, US$2 million to the OPCW-UN Joint Investigative Mechanism (JIM) charged with identifying those responsible for chemical weapons use in Syria, and €500,000 to support the elimination of Libya's remaining chemical weapons stockpile. The GPP also contributed $702,000 to OPCW in 2016 to help Iraq address the threat posed by chemical weapons use by Daesh. These funds will support equipment and training for the treatment of chemical weapons casualties and strengthen the Iraqi government's ability to investigate and respond to chemical weapons use.

J. Article X

47. Canada contributes in many ways, bilaterally and multilaterally, to economic and technological development programs consistent with the Article X provisions of the Convention. These contributions take a wide variety of forms, including: student exchanges; professional exchanges; convening of conferences open to interested professionals; training courses such as in the fields of biosafety with respect to the handling

of human and animal pathogens; assistance in the provision, directly or indirectly, of expertise that contributes to the detection, diagnosis and treatment of disease; cooperative research projects; database creation and exchange, for example BIONET and GPHIN; and other activities, some of which are also represented in our CBM returns related to the encouragement of the publication of results and promotion of the use of knowledge (CBM "C")

48. Under the framework of the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP), Canada is at the forefront of international efforts to prevent biological terrorism and proliferation. Canada's GPP supports a wide range of activities designed to strengthen biological security (biosecurity) and biological safety (biosafety), and to enhance the capacity of partner countries to prevent, detect and respond to biological threats, whether naturally-occurring, accidental or deliberately caused (i.e. bioterrorism). Examples of recent and ongoing GPP activities include: support for security-relevant aspects of the 2014-15 West Africa Ebola outbreak, including identification and consolidation of all Ebola samples in Sierra Leone into a single, secure facility ($7M to date); support to the World Organisation for Animal Health (OIE) and the Food and Agriculture Organisation (FAO) of the United Nations for Rinderpest Post-Eradication activities (€2.5M); enhancing Jordanian capacities for detection, defence and response against CBRN incidents ($32M); mitigation of biological risks in ASEAN Countries ($7M); and counter-terrorism upgrades at biological laboratories in Ghana and Nigeria ($6.9M).

49. Consistent with the Final Declaration of the Seventh Review Conference, in which States Parties are encouraged to submit detailed information on their implementation of Article X at minimum once every second year, as well as the decisions of the Preparatory Committees of the Seventh and Eighth Review Conferences, in which the Implementation Support Unit was requested to compile information on States Parties' implementation of Article X, Canada has prepared Article X reports. Produced annually since 2011, these reports provide details on projects organized and/or funded by the Government of Canada that relate to, inter alia, improving disease surveillance, detection, diagnosis, containment, and outbreak response and providing training in biosafety, biosecurity, and bioethics. Canada's 2016 report can be found as part of our contribution to the background document on the implementation of Article X.

50. Canada is making significant contributions by co-leading the Global Health Security Agenda (GHSA) Biosafety and Biosecurity Action Package. Under the GHSA, partner countries and international organizations are engaged in a process to identify new or expanded work areas for the prevention, detection, and response to infectious disease globally, regardless of their origin (i.e. natural, intentional or accidental). Canada works in close collaboration with its GHSA partners and has made a commitment to help build biosafety and biosecurity capacity in the areas of national program development and legislative and regulatory development. To achieve the commitment Canada is developing and piloting policy guidance manual, sharing expertise and lessons learned, and expanding membership through leveraging affiliations with countries that belong to the GPP, BWC, and United Nations Security Council Resolution 1540.

51. Canada is committed to further building its public health infrastructure and strengthening the practice of public health across the nation and globally. Through the Canadian Field Epidemiology Program (CFEP), Canada is helping create and sustain a national public health workforce that is able to respond quickly to emerging and urgent domestic and international public health events. Canada also supports global public health capacity building through the development and delivery of applied epidemiology and surveillance training, and the provision of technical experts for outbreak response. For example, CFEP mobilized technical experts to Guinea from January to July 2016 to support

the public health response to Ebola through the World Health Organization's Global Outbreak Alert and Response Network.

China

52. As a country which has suffered the effects of biological weapons and as a State party to the Biological Weapons Convention, China has always attached importance to the complete prohibition and thorough eradication of weapons of mass destruction, including biological weapons, and is resolutely opposed to the proliferation of bioweapons and bioweapon technology. It has consistently supported the aims and objectives of the Convention and has fully and strictly complied with its obligations thereunder, taking a positive part in and supporting the multilateral process of strengthening the effectiveness of the Convention.

53. China hereby reports to the Eighth Review Conference on its compliance with the Convention since the seventh Conference, as follows:

A. Compliance with basic obligations under the Convention

54. China has never developed, manufactured, stockpiled or in any other way acquired or possessed the biological agents or toxins prohibited under the Convention, or the related weapons or means of producing or delivering them.

B. Establishment of national compliance machinery

55. For effective compliance with the Convention, China has established an interministerial coordination system encompassing the Ministry of Foreign Affairs, the Ministry of National Defence, the Ministry of Public Security, the Ministry of Science and Technology, the Ministry of Agriculture, the National Health and Family Planning Commission and the Chinese Academy of Sciences. In keeping with the requirement expressed at the Sixth Review Conference, the Ministry of Foreign Affairs has been designated the national liaison point for compliance.

C. National legislation in compliance with the Convention

56. With a view to full, effective compliance, China enacts and strictly enforces pertinent laws and regulations. The third revision of the Criminal Code makes the illegal manufacture of, trade in, transport, stockpiling and retention, theft, seizure or looting of infectious agents and other such biological material into criminal offences; organizing, leading and participating in terrorist activities of any kind, including bioterrorism, are also criminal offences, punishable to degrees varying with the gravity of the crime.

57. The Counterterrorism Law of the People's Republic of China, enacted in December 2015, stipulates that no entity or individual may illegally manufacture, produce, store, transport, import or export, sell, provide, purchase, use, possess, scrap or destroy any infectious pathogens or other such substances. The relevant entities must provide for the strict supervision and management of infectious pathogens and other substances, in accordance with the regulations. In the event of the theft, diversion, loss or other disappearance of infectious pathogens or related substances, the public security authorities are to launch an investigation without delay. The relevant authorities are to issue warnings or fines, as appropriate, to anyone who fails to provide for the strict supervision and management of infectious pathogens or other substances in accordance with the regulations.

58. Since 2012, China has issued and implemented a series of ministerial regulations — criteria for the approval of laboratory activities involving highly pathogenic microbes, a plan for contagious human bacterial pathogen (and toxin) storage facilities (2013-2018), rules for the construction and inspection of laboratories working with highly pathogenic microbes — and, in the light of changing circumstances, has amended the Law of the People's Republic of China on Animal Epidemic Prevention and is pushing forward the drafting of a law regulating the management of human genetic resources. These new enactments have made beneficial additions to the current system of laws, further standardizing and improving biosafety management in laboratories and offering a stronger response to infectious illness.

D. Non-proliferation export controls

59. China resolutely opposes the proliferation of bioweapons and bioweapon technology in any form by any State, and has never in any way assisted, encouraged or induced any State, group of States or international organization to engage in activities prohibited under the Convention. It is constantly tightening export controls on dual-use biological agents and technology.

60. China already has a fairly complete system of export control laws and regulations and has issued and implemented a series of related laws and regulations that includes the Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies, together with a detailed control list, and rules for issuing permits for the import and export of dual-use items and technologies. It has adopted the internationally used export permit certificate management system, end-user and end-use declaration, detailed-list methodology, and the principle of complete control.

61. Since the establishment of an interministerial non-proliferation export control emergency coordination apparatus in 2004, China has been constantly strengthening the structure of the non-proliferation export control system. It has steadily pushed forward a system for high-level planning and interministerial coordination. By running training courses in law enforcement, it is improving the skills and capabilities of its export-control law-enforcement personnel. Training courses, seminars and leaflets reinforce the message to business enterprises, increasing awareness of and respect for the law as well as awareness of the need for self-regulation.

E. Confidence-building measures

62. In response to requests from review conferences, China has announced a succession of confidence-building measures over the years since 1988, thereby giving full expression to the political will and sincerity of the Government fully to comply with the Convention.

63. The Chinese Ministry of Foreign Affairs takes the lead in instituting confidence-building measures, but the Ministry of National Defence, the Ministry of Science and Technology, the Ministry of Agriculture, the National Health and Family Planning Commission, the Ministry of Commerce, the State Food and Drug Administration and the Chinese Academy of Sciences are responsible for gathering and submitting information on their work to the Ministry of Foreign Affairs for consolidation and transmission. The measures China announces cover biosafety laboratories, the national biological control programme, outbreaks of infectious disease, the outcomes of biological research, national legislation for implementation of the Convention and vaccine production facilities.

F. Biosafety and security

64. China pays close attention to the questions of biosafety and security, complying strictly with the Convention provisions on the subject and Security Council resolution 1540.

65. As regards laboratory biosafety and security, China has issued many laws and regulations on the subject, such as the Measures for the Biosafety Management of Pathogenic Microbe Laboratories, the General Regulations on Veterinary Laboratory Biosafety, and the Measures for the Examination and Approval of the Biosafety Administration of Highly Pathogenic Animal Pathogenic Microbe Labs, and has established corresponding operating procedures. It manages the specialists who store and handle pathogenic microbes, preventing loss and leakage. It has issued ministerial regulations such as the Regulations for the Biosafety Inspection of Scientific Research Projects Involving Highly Pathogenic Microbes, and it strictly enforces certification for activities related to laboratory biosafety and has instituted a periodic reporting system on research activity. It has set up and is expanding periodic and unscheduled safety inspections and supervision activities so as to eradicate hidden hazards, and it has set up a multi-ministry laboratory biosafety liaison mechanism.

66. With regard to education and training for staff, the Ministries of Health, Agriculture and others have used training courses, working groups, educational videos and other methods to provide training on biosafety and security in laboratories and on the airborne transmission of pathogenic microbes, constantly improving the skills and vigilance of the professionals concerned. Since 2012, the National Health and Family Planning Commission has included nationwide laboratory biosafety training in its annual programme of work and has held training sessions and symposiums for province-level staff members involved in the management of laboratory biosafety. The Ministry of Agriculture has held five nationwide training courses on quality management and biosafety in veterinary laboratories and has for example held five workshops on biosafety management in level 3 laboratories, along with accompanying conferences on the subject. The Chinese Academy of Sciences commissioned the Wuhan Institute of Virology to conduct an annual training course on the management of laboratory biosafety and experimentation techniques with a view to strengthening biosafety management efforts in all units of the Chinese Academy of Sciences.

67. As for responding to bioterrorism, the Chinese Government has drafted and issued the “Citizens’ Handbook on the Prevention of Terrorist Attacks”, which includes specific recommendations on how to protect and defend against bioterrorism attacks, call for help and report such incidents to the police.

G. Epidemic monitoring and response

68. China attaches great importance to epidemic monitoring. It already has in operation a relatively complete system for epidemic prevention and control as well as for medical treatment, covering cities and rural areas. For instance, it effectively responded to the severe infectious epidemics of H7N9 avian influenza and Middle East respiratory syndrome.

69. As regards a system for monitoring epidemics, in accordance with the provisions of relevant laws and regulations, such as the Law of the People’s Republic of China on the Prevention and Treatment of Infectious Diseases, the Law of the People’s Republic of China on Animal Epidemic Prevention and the Regulations on Plant Quarantine, the National Health and Family Planning Commission and the Ministry of Agriculture

respectively manage epidemic prevention and control for the human population and for plant and animal life throughout the country. Constant work is being carried out to strengthen the mechanism for joint interministerial prevention and control efforts, upgrade the epidemic reporting network, set up epidemic monitoring units, gather information on epidemics in a timely fashion, scientifically study and ascertain the severity of epidemics, and actively carry out epidemic surveys and provide emergency medical treatment. China already has interministerial mechanisms for cooperatively countering infectious diseases common to humans and livestock, responding to public health incidents in ports and reporting on outbreaks of infectious disease at schools.

70. China is constantly perfecting its emergency response system at all levels and has drawn up an emergency response plan for coping with sudden epidemics. It has perfected its system of emergency response teams and emergency supply reserves and regularly conducts periodic training and drills.

71. With regard to capacity-building, China has continuously expanded laboratory construction, increased its capacity to detect pathogens and established and set up a technical network to prevent and respond to new epidemic outbreaks with nationwide coverage. The Ministry of Science and Technology has conducted specialized technical research and created products for vaccinations for and the diagnosis of infectious diseases common to humans and livestock.

H. International exchanges and cooperation

72. China has consistently attached great importance to and actively participated in international exchanges and cooperation in the field of biology. For details, see its tenth report on compliance with the Convention, submitted to the Eighth Review Conference.

I. Active participation in the multilateral process of increasing the effectiveness of the Convention

73. China has attended all the meetings of States Parties and expert meetings held since 2012. It has submitted many working papers providing comprehensive accounts of domestic measures taken in compliance with the Treaty and its practices with regard to biosafety, scientific and technological development, epidemic prevention and control, and international cooperation, and it has actively participated in the related discussions. In the 2015 Meeting of the States Parties, China put forward two major proposals in the framework of the Treaty: it proposed establishing an international cooperation regime to control exports and prevent the proliferation of biological weapons and drafting a model code of conduct for scientists engaged in the biological sciences.

74. China attaches great importance to the Eighth Review Conference and actively participated in the two sessions of the Preparatory Committee for the Review Conference. It worked with Canada and the Convention Implementation Support Unit to host an international workshop on “The Eighth Biological Weapons Convention Review Conference: Promoting the Implementation of the Biological Weapons Convention and Enhancing Global Biosecurity Governance” in Wuxi in September 2016, taking part in an extensive exchange of ideas.

75. China has consistently supported the multilateral process of increasing the effectiveness of the Convention and is approaching the eighth Review Conference and related discussions with a constructive attitude, improving links and cooperation with all parties and working together to improve the effectiveness of the Convention overall.

Colombia

76. Article 81 of the Constitution prohibits the manufacturing, importation and use of weapons of mass destruction (nuclear, biological and chemical weapons) as well as the introduction into the national territory of nuclear and toxic waste. Accordingly, Colombia, does not possess, manufacture, use or store biological or toxin weapons (arts. I and II of the Convention).

77. At the international level, Colombia is firmly committed to the regime of disarmament and non-proliferation of weapons of mass destruction and, consequently, is a State party to the relevant legally binding instruments.

78. For this reason, Colombia is a State Party to the Biological Weapons Convention, which was approved by Act No. 10 of 4 February 1980 (art. 3) and entered into force on 19 December 1983 (art. IX of the Convention).

79. Colombia recognizes the historical importance of the Convention to the disarmament and non-proliferation regime of weapons of mass destruction, as the Convention was the first multilateral treaty to ban an entire category of this kind of weaponry.

80. In accordance with this principle, since the ratification of the Convention in 1983, Colombia has staunchly supported the efforts of the international community to prohibit such weapons of mass destruction and stresses the importance of effective national implementation.

81. For Colombia, it is of crucial importance to encourage discussions in the framework of the Biological Weapons Convention with a view to controlling related or dual-use materials. The country's main concern is the control and responsible use of biological materials that may be used as a precursor to a biological weapon.

82. It must be emphasized that in order to implement the Convention effectively, it is essential to adopt measures at the national level that regulate related materials.

83. In view of the foregoing, it is important to strengthen or implement policies aimed at the control of imports, exports and trans-shipments of dangerous goods. Furthermore, States should promote national measures for the accounting of biological materials handled on their territory so that such materials are not diverted to actors that seek to use them for hostile purposes.

84. As a way of strengthening the national implementation of the Convention, (arts. V and X) Colombia has been submitting voluntarily and regularly since 2011 reports on confidence-building measures, the sixth report was submitted in 2016. These reports help to follow up on the implementation of the Convention at the national level, by monitoring relevant activities and promoting inter-agency cooperation.

A. Legislative measures

85. With regard to the legislative developments in the country that have led to the effective implementation of the Convention (art. IV), it is important to mention offences that Colombia has incorporated into its basic criminal legislation:

(a) Penalties for illegal experimentation with biological agents;

(b) Penalties for the possession, manufacturing or illegal trafficking of hazardous materials;

(c) Penalties for the use and launch of or attack with dangerous substances or objects;

(d) Penalties for the manufacturing, importation, trafficking or possession of weapons of mass destruction;

(e) Penalties for the manufacturing, transport, use, stockpiling and unauthorized sale of hazardous materials;

(f) Penalties for the introduction into national territory of nuclear or toxic waste;

(g) Penalties for the disruption of a radioactive or nuclear facility;

(h) Penalties for spread of an epidemic.

86. These penalties are applicable to persons who are complicit in such acts. They also apply when another person is used as an instrument or when there is an infringement of the aforementioned provisions by omission.

87. Colombia has taken steps to prevent, detect, investigate and punish the financing of terrorism.

88. The importation of biological, chemical and radioactive materials is subject to the issue of an import licence following the evaluation of certain criteria to be met by the applicant.

89. Any material used for medical, industrial, agricultural, commercial, research, veterinary, educational or other purposes shall be subject to clearance by the entities listed below:

(a) Vaccines: Ministry of Health and Social Protection — National Health Institute;

(b) Pesticides and pesticides or insecticides for agricultural use: the importation, production and use of biological agents in this field shall be subject to national registration by the Colombian Agricultural Institute;

(c) Pesticides: the importation, use and handling of pesticides for public health use shall be subject to prior approval by the Ministry of Health and Social Protection;

(d) Living modified organisms: the Ministry of Health, Ministry of Agriculture and Ministry of Environment shall authorize the transboundary movement, transit, handling and use of the living modified organisms that may have adverse effects on the environment and biodiversity, taking into account the risks to human health, productivity and agricultural production.

B. Accounting and physical protection of biological materials

Production and use

90. Resolution No. 000698 of 2011:

Article 4.1.3 contains a requirement for the granting of licences which describes each stage of the process flow areas.

Resolution No. 000698 of 2011:

91. When biological agents are imported, their taxonomic identification (genus and species) and technical information on the microorganism must be provided.

92. Upon completion of this procedure, the competent authority conducts a technical inspection to analyse and verify the data provided by the applicant in the form designed for that purpose. Following approval by the competent authority, the registration is granted.

93. Ministry of Health Decree No. 1843 of 1991:

Article 13 on toxicological classification and licence to use in the country.

94. Any individual or legal entity who imports or develops products for use on national territory, irrespective of the quantity to be imported or sold, must obtain the prior approval of the Ministry of Health or its delegated authority, for the toxicological classification and licence to use the products in the country, in compliance with the provisions of chapter X of the present Decree.

Storage

95. Resolution No. 000698 of 2011:

The producer wishing to obtain a licence must, under article 4.2.1.2.1, submit the procedures for the storage and preservation of raw materials.

Transport

96. Resolution No. 8430 of 1993, article 71:

During the conduct of the research referred to in this chapter, the chief research officer shall be responsible for:

(e) Ensuring the swift transport of infectious materials, in accordance with the technical standards issued by the Ministry.

97. Decree No. 1609 of 2002, article 6:

> "National registration card for the transport of dangerous goods. In addition to the documents required under existing regulations for the transport of cargo by road and the requirements of the National Land Transport Code, a national registration card for the transport of dangerous goods must be obtained in order to transport such goods."

Physical protection: production and use

98. Resolution No. 008430 of 4 October 1993, article 70:

Microorganisms that are classified in risk group IV should be handled in maximum security microbiological laboratories, with the authorization and under the supervision of the relevant health authorities.

Physical protection: transport

Decree 1609 of 2002, article 4:

"Cargo handling. 1. Marking and labelling of packaging and containers. The marking and labelling of the packaging and containers of dangerous goods must comply with requirements for each class of cargo, as set forth in Colombian Technical Regulation 1692 (…)

"F. Packaging and containers for the transport of class 6 dangerous goods, for a Toxic and infectious substances, are covered by National Technical Regulation 4702-6."

99. Thus, the registration of users of dangerous biological materials, as well as national verification measures are practices that prove effective.

100. In application of article V of the Convention, Colombia carried out a simulation exercise of a bioterrorist attack in Bogotá on 1 October 2015.

101. The exercise was carried out under a biosafety programme developed by the Inter-American Committee against Terrorism, whose purpose is to build the capacities of member States of the Organization of American States to respond in a coordinated manner to potential bioterrorist threats. The Colombian authorities are drawing on the lessons learned to draft a national protocol for an inter-agency response to a biological incident or bioterrorist attack.

National authority

102. Since 2013, Colombia has been making progress in this area through an informal working group composed of representatives from government entities, which was set up to discuss and establish a national authority to ensure the application and effective implementation of the Convention in the country. The draft decree on the establishment of the national authority is currently under review in the legal offices of the relevant national entities.

103. Lastly, it should be noted that, on 24 November 2015, Colombia deposited its instrument of ratification for the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925 (art. VIII of the Convention).

Cyprus

A. Articles I-II

104. Cyprus is in full compliance with its obligations under Article I as it has never developed, produced, stockpiled or otherwise acquired or retained biological weapons and related equipment and means of delivery or engaged in relevant scientific and research programs. Therefore provisions of Article II are not applicable in the case of Cyprus.

B. Article III

105. With respect to international transfers, Cyprus implements export controls according to national legislation, which is in full compliance with the EU Regulation No 428/2009 for the Control of Exports of Dual Use Items and Technologies. Cyprus, as a member of the Australian Group, is also committed to its principles.

C. Article IV

106. In 2010, Cyprus enacted the Combating Terrorism Act 110(I)/2010 which includes provisions for countering bio-terrorism.

D. Article V

107. Cyprus, supporting the objective of building confidence, submits regularly the Confidence Building Measures (CBM) Report.

E. Article VI

108. Cyprus has not invoked Article VI nor has any other State Party invoked the provisions of Article VI against Cyprus.

F. Article VII

109. Cyprus has not been requested to provide assistance under Article VII, nor has it invoked Article VII to receive assistance.

G. Article VIII

110. Cyprus as a State Party to the Geneva Protocol of 1925 (21st of November 1966) acknowledges its obligations under this Protocol.

H. Article IX

111. Cyprus ratified the Chemical Weapons Convention in 1998 and remains committed to the objective of effective prohibition of chemical weapons.

I. Article X

112. Cyprus supports the concrete implementation of Article X and as a member of the European Union (EU) contributes to the various assistance programmes undertaken by the EU.

Czech Republic

113. In line with the decision taken during the first Preparatory Committee meeting in April 2016 the Czech Republic provides information on national compliance with the BTWC obligations. As the Czech Republic has been providing information on national compliance on regular basis, the input should be considered as a technical update.

114. The former Czechoslovakia signed the Biological and Toxin Weapons Convention (BTWC) on 10 April 1972 and ratified Convention on 30 April 1973. After the split of Czechoslovakia in January 1993, the Czech Republic undertook commitments to international law and on the 24 March 1993 became the member state of the BTWC.

A. Article I

115. The Czech Republic has never developed, produced, stockpiled or otherwise acquired or retained microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

116. The Czech Republic has never led an offensive biological research, development or production programme and has never acquired biological weapons or their means of delivery. Therefore provisions of Article II did not impose any obligation upon the Czech Republic.

C. Article III

117. The Czech Republic adheres to the obligation of Article III. Export of dual use items is regulated through national legislation which is based on EU legislation [Regulation (EU) No. 388/2012 of the European Parliament and of the Council, 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]. Rules for export and import of selected biological agents and toxins are also specified in Act on some measures related to a ban on bacteriological (biological) and toxin weapons (Act No. 281/2002 Coll., as amended).

D. Article IV

118. The obligations of Article I have been fully incorporated into Czech legal system by way of the Act on Some Measures Related to Ban of Bacteriological (Biological) and Toxin Weapons in 2002. There are also a number of other legislative measures and regulations that are closely connected to objective of the Convention (area of biosafety, GMOs, dual-use items, export, import and transport of biological agents and toxins). This legislation specifies penalties in case of its violation and breaches are punishable under the Penal Code.

119. Detailed information on national implementation by the Czech Republic was supplied to States Parties in working paper to the intersessional meeting "National implementation of the BTWC: compliance assessment: update" - submitted by Canada, the Czech Republic and Switzerland (BWC/MSP/2012/WP.6).

E. Article V

120. The Czech Republic has not invoked Article V and this Article has not been invoked against it. The Czech Republic has never participated in consultations under Article V.

121. The Czech Republic fully supports the Confidence Building Measures (CBMs) to strengthen the Convention adopted by the Second and Third Review Conferences of the States Parties. Since 1993, when the Czech Republic became a member state of the Convention, it has regularly participated in the information exchange through CBMs. The Czech Republic has decided to make CBMs returns public available on the web site of the UN Office at Geneva.

F. Article VI

122. The Czech Republic has not lodged any complaints with the Security Council regarding any other States Parties acting in breach of obligations under the provisions of the Convention.

G. Article VII

123. See separate paper on Article VII.

H. Article VIII

124. The former Czechoslovakia has ratified the 1925 Geneva Protocol on 16 August 1938. Czechoslovakia has withdrawn its reservations to the Geneva Protocol on 25 September 1990. After the split of Czechoslovakia in January 1993, the Czech Republic has undertaken commitments to international law, and consequently to the Geneva Protocol.

I. Article IX

125. The Czech Republic has signed the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction on 14 January 1993 and ratified it on 6 March 1996.

J. Article X

126. See separate paper on Article X.

Finland

A. Articles I and II

127. Finland has never developed, produced, stockpiled or otherwise acquired or retained microbial or other biological agents, or toxins of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes. Neither has Finland ever developed, produced, stockpiled or otherwise acquired or retained weapons, equipment or means of delivery designed to such agents or toxins for hostile purposes or in armed conflict.

B. Article III

128. Finland's national report to the UNSC 1540 Committee (submitted on 28 October 2004 and amended 2005, 2006, 2007 and 2011) contains information on Finland's efforts to prevent transfers of prohibited agents and equipment. Finland is committed to providing assistance to other States for fulfilling the provisions of the resolution 1540. Finland is also working together with Stimson Center in relation to 1540 issues.

C. Article IV

129. Finland's legislation on biological weapons is based on the Biological Weapons Act 257/1975 and Decree 258/1975. Corresponding penal provisions have been included in the Penal Code and in its amendments. The amended Code criminalizes the use, development, preparation, procurement, storage, possession, transport and delivery of biological weapons or related equipment. A comprehensive chapter on terrorist offences was also added to the Penal Code in 2003 and since then this chapter has been amended on the basis of new relevant international obligations.

130. It should be noted that other parts of legislation, e.g. the Firearms Act and the Communicable Diseases Act contain provisions that can also relate to biological weapon and related material. Furthermore, concerning national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins, Finland is currently considering the need to revise its related legislation.

D. Article V

131. Finland has participated annually in the information exchange through the Confidence Building Measures (CBM). The 2016 submission has been posted on the Internet site of the United Nations Office at Geneva (http://www.unog.ch/bwc).

132. As a Member State of the European Union, Finland is committed to the EU BTWC Action Plan of 2016, which concerns, inter alia, improving the quality and quantity of declarations submitted under the Confidence-Building Measures system in order to enhance confidence in compliance with the BTWC.

E. Article VI

133. To reflect the understandings of the 2003 Meeting of States Parties on enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease, Finland submitted in February 2011 and in 2014 to the UN updated information of Finnish qualified experts and analytical laboratories which may be used by the UN Secretary-General for the purposes of investigations of the reports of use of chemical and biological weapons. As a Member State of the European Union, Finland is also committed to the EU BTWC Action Plan of 2016 which supports strengthening the United Nations Secretary-General's Mechanism for investigation of Alleged Use of Chemical, Biological and Toxin Weapons (SGM). Finland has also been involved in the SGM.

F. Article VII

134. See separate background information document submitted by Finland on the Implementation of Article VII.

G. Articles VIII and IX

135. Finland is a State Party to the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925 and to the Chemical Weapons Convention and fully recognizes the obligations under the Geneva Protocol and the objective of effective prohibition of chemical weapons as requested in Articles VIII and IX of the Convention.

H. Article X

136. See separate background information document submitted by Finland on the Implementation of Article VII.

I. Article XI

137. Finland has not tabled any proposals to amend the text of the Convention.

J. Article XII

138. Finland actively participates in Review Conferences and Meetings related to the Convention.

K. Article XIV

139. Finland shares the view of the European Union and the G7 Global Partnership that universal adherence to the Convention is crucial. Finland is therefore actively promoting accession to the BTWC both bilaterally and at EU level (see EU Council Decision 2016/51/CSFP in support of the BTWC).

Germany

140. The Preparatory Committee decided to request that the Implementation Support Unit prepare eight background information documents, including a background information document on compliance by States Parties with all their obligations under the Convention, to be compiled from information submitted by States Parties. With regard to this request, Germany wishes to provide the following information on its compliance with BTWC obligations. Germany understands this report to be a unilateral statement on how national implementation measures comply with the obligations under the Convention, but not as a replacement of matters that need to be established in a general compliance monitoring/control system.

141. The report follows the structure of the Convention, but also provides information on other issues identified in the intersessional process as being relevant to the national implementation of the BTWC.

A. Article I

142. Germany ratified the Convention with the Biological Weapons Implementation Act of 21 February 1983. At that time, German legislation fulfilling the obligations under Article I of the Convention prohibiting biological weapons activities had already been in place since 1955. In the context of accession to the Western European Union, Germany signed Protocol No. III on the Control of Armaments in 1954. The Protocol prohibits, inter alia, the production of biological weapons. The obligation under the Protocol was implemented with the Act Regarding the Accession of the Federal Republic of Germany to the Brussels Treaty and the North Atlantic Treaty.

143. Additional BW-related prohibitions were implemented by the War Weapons Control Act of 20 January 1961. The Act prohibits activities named in Article I of the BTWC and penalises any breach of these prohibitions. It also contains a clause on extraterritorial application. A War Weapons List is annexed to the Act listing, inter alia, human, animal, and plant pathogens and toxins, as well as genetic sequences related to listed agents, which are considered to possess biological weapons potential.

B. Article II

144. With regard to Article II, the Federal Republic of Germany declared with its submission of the Confidence-Building Measures declaration 1991 that it has never had an offensive biological weapons research and development programme or possessed biological weapons.

C. Articles III and IV

145. Legislation on prohibiting and preventing the proliferation of biological weapons and on materials that can be misused for such weapons purposes has been in place in Germany since 1961. The Außenwirtschaftsgesetz (Foreign Trade and Payments Act) of 6 June 2013 and the Außenwirtschaftsverordnung (Foreign Trade and Payments Regulation) of 2 August 2013 provide the legal foundation for export control of biological dual-use materials. Important elements in German export control legislation include export licensing, end-user certificates, a list of dual-use materials, a catch-all clause, intangible transfers, transit control, brokerage, administrative and criminal penalisation of breaches of law, and extraterritorial applicability. German export control legislation is in line with EU Regulation (EC) 428/2009 of 5 May 2009 and the list of goods provided in this regulation. Commission Delegated Regulation (EU) 2015/2420 of 25 December 2015 provides the recent update of the list of controlled commodities.

146. With regard to the prevention part of Article IV, States Parties developed a common understanding in the intersessional process and called upon States Parties at the Seventh Review Conference to apply legislative, administrative, judicial, and other measures, including penal legislation designed for actions taken anywhere by natural or legal persons and to ensure the safety and security of microbial or other biological agents or toxins in laboratories and facilities, as well as during transportation, to prevent unauthorised access to and removal of such agents or toxins. This call is understood as a means to prevent non-state actors from gaining access to dangerous biological materials for weapons purposes. In Germany, the review of national legislation and technical guidelines with regard to compliance with international biosafety and security standards is a continuous process. Germany provides the ISU with updated lists of relevant BTWC related legislation and guidelines on a regular basis. The most recent update was submitted to ISU in August 2016. Recent improvements to relevant biological safety and security-related legislation – besides the above-mentioned export control list – are listed under the Biostoffverordnung (Regulation on the Safety and Health Protection at Workplaces Involving Biological Agents) and the Gefahrgutverordnung Strasse, Eisenbahn und Binnenschifffahrt (Dangerous Goods Regulation Road, Rail and Inland Waterways). According to the 2013 revised Biostoffverordnung, employers now require a license before first starting activities of protection levels 3 or 4 rather than a simple notification process. In addition, higher standards of required professional expertise for risk assessment and work at protection levels 3 or 4 are now set by legal obligation. The Gefahrgutverordnung Strasse, Eisenbahn und Binnenschifffahrt of 2015 includes all regulations, which were previously divided into three separate regulations. German laboratories and other bio-facilities are regularly controlled by public health, veterinary and other relevant state agencies. All laws and regulations contain penal and administrative enforcement clauses.

147. In the wider context of prevention, German activities of raising awareness in academia, industry and professional organisations regarding the risks of possible misuse of agents as well as technologies in life sciences resulted in the adoption of codes of conducts and similar guidelines by research and industry organisations such as the Deutsche Forschungsgemeinschaft (German Research Foundation), Max-Planck-Gesellschaft,

Leibniz Gemeinschaft, Robert Koch Institut, International Association Synthetic Biology and BIO Deutschland. Bearing in mind the international discussions surrounding dual use research of concern (DURC), the German Government asked the German Ethikrat (Ethics Council) to assess DURC risks in a report published in May 2014 under the title "Biosicherheit – Freiheit und Verantwortung in der Wissenschaft" (Biosecurity – Freedom and Responsibility of Research). The Deutsche Forschungsgemeinschaft (DFG) and the Deutsche Nationale Akademie der Wissenschaften Leopoldina (German National Academy of Sciences) published the report "Wissenschaftsfreiheit und Wissenschaftsverantwortung – Empfehlungen zum Umgang mit sicherheitsrelevanter Forschung" (Scientific Freedom and Scientific Responsibility – Recommendations for Handling Security-Relevant Research) in May 2014 recommending, inter alia, the self-regulation of science, taking into account the ample number of existing laws, regulations and technical guidelines regulating biosafety, biosecurity and genetic engineering in Germany.

148. Furthermore, a government-funded research project conducted at the Carl Friedrich von Weizsäcker-Zentrum for Science and Peace Research (ZNF) at the University of Hamburg is currently exploring open-source methods and data for the investigation of compliance with the provisions of the Convention. The project was initiated in 2014 and will have received funds totalling 572,000 euros by the end of 2016.

D. Article V

149. In 1986 and 1991, States Parties agreed on Confidence-Building Measures (CBMs) under Article V BTWC. Germany belongs to the States Parties that submitted CBM declarations to the BWC Implementation Support Unit at the Office for Disarmament Affairs every year from the outset. Starting in 2007, Germany made its CBM declarations publicly available without any restrictions.

150. At the beginning of August 2016, Germany offered a compliance visit to all interested BTWC member states as a peer review exercise to increase transparency. A military defence research facility in Munich (the Bundeswehr Institute of Microbiology) served as a model facility to be visited. Delegations from 15 different countries participated in the two-day exercise. Germany is of the opinion that full national implementation of its provisions is vital for the functioning of the Convention. If implementation is carried out in a transparent manner, it can contribute to enhancing confidence in States Parties' compliance with and commitment to the BTWC. As stated in the Common Position of the European Union to the Eighth Review Conference, voluntary peer review exercises seek to improve national implementation and to provide reassurance of compliance by means of information exchanges and enhanced transparency regarding, for instance, capabilities, activities and actions for implementation, and intentions regarding compliance. Although peer review exercises neither serve as a substitute for verification nor equate to compliance, they can be an important step towards developing an understanding of how to demonstrate compliance until a further agreement on verification procedures can be reached.

E. Article VI

151. With regard to Article VI BTWC and in the absence of a detailed mechanism under the Convention for investigating alleged use of biological weapons, Germany supports the UN Secretary-General's investigative mechanism set out in the UN Secretary-General's report A/44/561 and endorsed by the General Assembly in its resolution A/RES/45/57C by regularly nominating experts and laboratories to UNODA. Updates of laboratories and experts named by Germany were provided to UNODA in 2011 and 2014.

152. As part of its contribution to peace and security, the German Government initiated a project aimed at sustainably strengthening the United Nations Secretary-General's Mechanism for the investigation of the alleged use of biological weapons. The project was conducted by the Robert Koch Institute on behalf of the German Federal Foreign Office. Within this framework, two events were organised in 2014: a workshop in January and a ten-day comprehensive training course and exercise in November. The aim of the overall project was to evaluate and investigate a new approach, the Functional Subunits Approach, proposed by Denmark in 2012. The project seeks to assess whether the Functional Subunits (FS) Approach is suitable for optimising investigations of the alleged use of biological weapons.

153. The German workshop on further evaluation of the "Functional Subunits Approach to investigating the alleged use of biological weapons" took place in January 2014 and aimed to provide results and information as a basis for the further planning and content development of the exercise in November. The participation of 55 experts from 20 countries and four international organisations ensured wide geographical diversity. Within this framework, the plan was to identify existing FS that were able and willing to make a practical contribution to the assessment of the working hypothesis.

154. The second German event in 2014 was the exercise and training on the investigation of the alleged use of biological weapons under special consideration of the Functional Subunits Approach, which took place in Berlin from 10 to 19 November 2014. It was determined by the scenario developed especially for this event and challenged the interaction between FS and Command & Control. The focus was on cooperation between FS with clearly defined specialised tasks and single experts in the C&C function. For the first time, the current single experts' approach was combined with the FS Approach in a comprehensive exercise. The aim was to establish whether and which FS are able to optimise and facilitate investigations in the case of an alleged use of biological weapons. 77. In addition, it was intended to identify technical and practical gaps that have to be closed. Some 57 experts from 20 countries and representatives of four international organisations (WHO, OIE, INTERPOL, OPCW) and ECDC took part.

F. Article VII

155. See separate paper on Article VII as requested by ISU.

G. Articles VIII and IX

156. Germany is a State Party to the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925 and to the Chemical Weapons Convention and fully recognises the obligations under the Geneva Protocol and the objective of effective prohibition of chemical weapons as requested in Articles VIII and IX of the Convention.

H. Article X

157. See separate paper on Article X as requested by ISU.

I. Article XI

158. Germany seeks to actively contribute to the development of strategies for taking the Convention forward and has submitted national and group statements as well as working papers in this regard.

J. Article XII

159. Germany actively participates in Review Conferences and Meetings related to the Convention.

K. Article XIV

160. Germany shares the view of the European Union and the G7 Global Partnership that universal adherence to the Convention is crucial. Germany is therefore actively promoting accession to the BTWC both bilaterally and at EU level (see EU Council Decision 2016/51/CSFP in support of the BTWC).

161. Demarches in 2015 included South Sudan, Tanzania, Eritrea, Namibia, Kiribati, Tuvalu, Samoa, Côte d'Ivoire and Micronesia.

India

162. In its interim report dated 18 May 2016 (BWC/CONF.VIII/PC/), the Preparatory Committee to the 8th BTWC Review Conference had requested the Implementation Support Unit to prepare a background information document on compliance by States Parties with all their obligations under the Convention, to be compiled from information submitted by States Parties.

163. The following information is submitted by India in this context:

(a) India attaches high importance to the BTWC as the first non-discriminatory disarmament treaty banning a complete category of weapons of mass destruction. India signed the Convention in 1973 and ratified it in 1974. India is in compliance with all its obligations under the Convention. India is committed to improving the effectiveness and strengthening the implementation of the BTWC and supports efforts for its universalization.

(b) India has a broad-based regulatory framework to prevent the misuse of biological Sciences and technology. The over-arching legislation "Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act of 2005" builds on the existing regulatory framework to prohibit unlawful activities in relation to weapons of mass destruction and their means of delivery. The Act defines biological weapons in the same manner as the BTWC and prohibits unlawful manufacture, acquisition, possession, storage, handling, development, transfer or transport of biological weapons or their means of delivery.

(c) India has strong and law-based national export controls and is committed to maintaining the highest international standards with reference to control of biological agents and toxins to ensure that transfers are authorised only when the intended use is for purposes not prohibited under the Convention. India believes that effective national export controls are important tools to prevent the misuse of biological agents and toxins for purposes prohibited by the Convention or falling into the hands of terrorists, which is a major concern for the international

community. The list of micro-organisms and toxins controlled under India's export control regulations is contained in Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET) List under the Foreign Trade (Development and Regulation) Act of 1992 (amended in 2010).

(d) India has also established national level standards for BSL-2, 3 and 4 facilities, which conform to high international standards, and these have been fully implemented. India is willing to share its experience in this regard. India has also put in place a comprehensive system of disease surveillance on par with international standards and has formulated national guidelines on biological disasters covering management of epidemics and pandemics and bioterrorism, including agro-terrorism. India is implementing IHR 2005 of the WHO.

(e) India has put in place comprehensive systems for disease surveillance matching international standards and has formulated national guidelines on biological disasters covering management of epidemics and pandemics and bioterrorism, including agro-terrorism.

(f) India attaches importance to full and effective implementation of Article X of the Convention. The BTWC State Parties must facilitate the fullest possible exchange of equipment, materials and technology related to the use of biological agents and toxins for peaceful purposes consistent with their obligations under the Convention. India is both a provider and recipient of assistance in the fields of biological sciences and technology.

(g) CBMs are an important measure to enhance trust and confidence amongst member states. CBMs must be seen as a commitment that ought be implemented by States Parties. India has submitted its national CBMs and encourages other member states to do so.

(h) India believes that a multilaterally agreed mechanism for verification of compliance can provide the assurance that all States Parties to the BTWC are in compliance with their obligations under the Convention.

Iraq

A. National measures adopted by the Republic of Iraq to implement the Biological Weapons Convention

164. The value and importance of national implementation measures is to ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery as specified in Article I of the BW Convention. It also facilitates the process of voluntary implementing of the Biorisk management standards to ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins, and promote awareness among workers in the field of biological sciences concerning the obligations under the BW Convention as well as the relevant national legislation and guidelines. It also encourages the development of training and educational programs to those who access to biological agents and toxins, in addition to enhancing the methods and capabilities to monitor and detect disease outbreaks at the national, regional and international level.

165. The Seventh Review Conference reaffirms the commitment of States Parties to take the necessary national measures under Article IV. The Conference also reaffirms that the enactment and implementation of necessary national measures under this Article, in

accordance with their constitutional processes, would strengthen the effectiveness of the Convention. In this context, the Conference calls upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to:

(a) enhance domestic implementation of the Convention and ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery as specified in Article I of the Convention;

(b) apply within their territory, under their jurisdiction or under their control anywhere and apply, if constitutionally possible and in conformity with international law, to actions taken anywhere by natural or legal persons possessing their nationality;

(c) ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins.

B. Policies, Strategies and Legislative Measures

166. The Iraqi government adopted legislation, laws, regulations, policies and strategies to prevent the proliferation of biological weapons and their means of delivery in order to meet its obligations to implement the BTWC at national level and to reduce the risks of the biological sciences and biotechnologies being deliberately or inadvertently misused for malign purposes. The Iraqi government establish appropriate domestic controls over biological related materials and effective border controls to prevent their illicit trafficking.

167. The Iraqi National Monitoring Authority for Non-proliferation (INMA) as a national point of contact and coordination for national implementation of the BWC, establishing mechanisms for regular communication amongst key stakeholders and ensuring regular and timely participation in the confidence building measures process, including by involving all relevant areas of government and related areas and promoting the BWC through related initiatives, such as outreach to industry, education and research sectors, and through the European Union CBRN Centres of Excellence.

168. The Constitution of the Republic of Iraq has a provision which prohibits weapons of mass destruction in the territory of Iraq, which stipulates in Article 9 / I / E to “The Iraqi government respects and implements the Iraq's international obligations for non-proliferation and development, production and use of nuclear, chemical and biological weapons, and prevents development, manufacture, production and use of related equipment, materials, technology and delivery systems”.

169. The main national legislation related to prevention of the proliferation of biological weapons, their means of delivery and to preparedness to biological threats are the following:

(a) Anti-money laundering Law No. (93) (2004).

(b) Anti-terrorism Law No. (13) (2005).

(c) National Monitoring Authority for non-proliferation Law No. 48 (2012).

(d) Instructions concerning the implementation of the international treaties and conventions related to non-proliferation (2014).

(e) Biorisk management policy in Iraq.

(f) Biorisk management strategy in Iraq.

(g) National Strategy for Countering WMD Threats.

(h) National Biological Emergency Plan.

(i) National Action Plan for Countering WMD Threats.

170. To adaptation of the legal framework to prohibit proliferation activities in accordance with non-proliferation conventions, treaties and resolution1540(2004), Iraqi National Monitoring Authority for Nonproliferation (INMA) established according to the act No.48 (2012), to ensure that not, design, development, production, use, transfer, storage, import or export, or shipping any nuclear or chemical or biological weapons and their means of delivery within the borders of the Republic of Iraq. INMA seeks to achieve its goals through the following means:

(a) Establishing and maintaining a national system of monitoring, investigation and inspection that shall enable the Republic of Iraq to comply with its obligations pertaining to non-proliferation of weapons of mass destruction's conventions and treaties.

(b) Developing regulations and mechanisms for submitting offers, issuing licenses and establishing a comprehensive mechanical process for monitoring exports and imports related to dual-use materials and equipment and technologies.

(c) Monitoring the related peaceful activities to ensure prevention of converting them into any of the prohibited activities pursuant to non-proliferation conventions, resolutions and treaties, including the production, possession, use, storage, exporting and importing, shipping, transporting the dual use materials, equipment, and technologies.

171. A number of secondary laws, regulations, instructions and guidance have been adopted in the relevant Ministries and institutions. Any other measures considered necessary to the prevention of the proliferation of biological weapons, their means of delivery and related materials, will also be taken.

C. Protection of BW Related Materials

172. The appropriate measures to account for, secure and physically protect dual-use biological materials, sites and facilities was identified or formulated and proposed in the areas identified by the BW Convention. The Iraqi government has taken a series measures and practical steps over the past years to secure and protection of high-risk biological dual-use materials and facilities to ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, and to prevent unauthorized access to and removal of such agents or toxins. The Iraqi government hereby undertakes to promote and facilitate establishing and maintaining procedures and measures to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological materials.

173. The relevant Ministries and Institutions develop and maintain appropriate, effective physical protection measures to account for and secure the biological dual use materials in production, use, storage or transport to prevent unauthorized access to biological related materials, loss, theft, misuse, diversion or release. Efforts continue in order to identify good practices concerning the security of high-risk biological facilities. Based on this work, the relevant security authorities develop instructions and standard operating procedures (SOPs) and elaborating the mechanisms for identifying and reporting suspicious 30ehaviour and transactions. The Ministries and Institutions Continuously working to develop procedures

for implementing appropriate control on facilities containing biological materials in order to prevent their illegal possession and misuse, as well as spread in the environment.

D. The National Biorisk Management Committee (NBMC)

174. Given the importance of biosecurity and biosafety (Biorisk management) in reducing the impact of biological risk and prevent the spread of dangerous microorganisms and their effects on society and the environment, Iraq was established the National bio risk management Committee which aims to strengthen the implementation of Iraq's international obligations under the Convention on the Prohibition of Biological and Toxin Weapons and Security Council resolution 1540 (2004) in the field of biological risk management and control and mitigate all biological risks and prevent unauthorized persons to access valuable biological material which could be used for prohibited purposes through the establishment of an effective Biorisk management System and maintenance in biological laboratories in accordance with international standards to control it or mitigated to acceptable levels for workers and the community and others, as well as the environment in which they may be exposed directly or indirectly to the biological agents or toxins. The committee priority tasks are to develop a National Biorisk Management policy and strategy, develop a National Biorisk Management law in Iraq and seek to raising a community awareness with regard to biological material use and storage, transportation, and waste treatment and limiting the spread of diseases, add to that the development of legislation and regulations relating to biosecurity and biosafety in the laboratories according to the international standards.

E. Standard Operating Procedures SOPs

175. The Iraqi National Monitoring Authority for Non-proliferation (INMA) in collaboration with Cooperative Biological Engagement Program (CBEP) was formulate the National Standard Operating Procedures SOPs of the Bio risk operations and procedures applied in the public and animal health labs (Sample Handling, Storage and Transportation and Shipping, Personnel Protection Equipment's, laboratory Spill Response, Biological Inventory management, Biological Safety Cabinet, Waste Handling and Disposal and Operational and maintenance). SOPs will be disseminated to all the concerned governmental facilities and the private sector.

176. The Iraqi National Monitoring Authority for Non-proliferation has worked to implement several programs for Health and environment, Agriculture, Higher Education and Science and Technology ministries with the support of international organization and agencies in order to face the threats and reduce biological materials risks and ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins. These programs included:

(a) Reduction of biological risk (Biosecurity and Biosafety) program.

(b) Export and import of dual-use materials and equipment program.

(c) National capacity-building programs in the relevant institutions to prevent the proliferation of weapons of mass destruction.

(d) EU Centers of Excellence programs to mitigate chemical, biological and nuclear materials risk.

(e) Disease surveillance and outbreak response capacity

177. To strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels, the Iraqi National Monitoring Authority for Non-proliferation (INMA) in collaboration with Cooperative Biological Engagement Program (CBEP) and the relevant Ministries and Institutions have completed establishing the National team for Disease surveillance, which aims to establishing a unified efficient disease bio surveillance system in Iraq through an assessment the existing surveillance system in Iraq by different levels at National, intermediate and peripheral and review Iraq communicable diseases guide line to identify the gaps and the solutions and recommendations according plan of action including Strengths and weaknesses of the existing system were identified as well as opportunities for the biohazard to effective and efficient surveillance and control. These related to core surveillance activities as data collection and transmission, data analysis, feedback and supervision, epidemic preparedness and response to outbreaks. Resources are necessary for effective surveillance such as training, communication, and guidelines. The mainly components of the bio surveillance that need to be addressed are, Reporting and Communication, Outbreak Investigation and Sample collection and transport.

F. Export/Import Controls of BW Related Materials

178. Measures for the control of high-risk WMD dual-use materials (including biological materials) that require the issuance of export, import, transit, trans-shipment and re-export licences, and for the prevention of illicit trafficking in weapons of mass destruction, their means of delivery and related materials was identified or formulated and proposed.

179. In this regard and in order to establish an export control regime in Iraq that is in compliance with international regulations; that provides for effective oversight of the handling of dual use materials and technologies related to WMD and their means of delivery; and that effectively bars non-State actors from gaining access to such weapons and related materials, Iraqi National Monitoring Authority (INMA) has prepared and issued effective national control regime to control the export and import of dual use items in the basis of the EU law no.2000/ 1334 to control illegible usage of these items . The regime establishes the principles for implementing state policy and the legal bases for export control activity carried out by state agencies of Iraq and individuals and entities engaged in international trade. In regard with the national control lists, the National Biorisk management committee accomplished the national dual use and high risk biological agents and toxins lists. Efforts continue in order to prepare a national list of dual-use biological equipment. INMA was distributed the WMD dual-use materials lists to all ministries with the instructions to implementation of Nonproliferation treaties and conventions.

180. INMA continue to work on the tracking program (Tracker) that manages the import licensing process or export of dual-use equipment and materials under international treaties and agreements related to non-proliferation, through electronic connectivity through the information network of circles (Ministry of Commerce, the General Administration of Customs and the National Monitoring Authority), the program provides base huge information most dual materials include use of equipment and the prohibited substances that may enter in the manufacture or production of weapons of mass destruction.

G. Measures for intervention and response in the event of an incident

181. In order to respond to the emerging biological threats and prepare to liquidate their consequences, the National Monitoring Authority for non-proliferation (INMA) has drafted the national biological emergency plan. The plan was approved and INMA is now working with other ministries to coordinate efforts with them to be implementing those plan after its

approval. The related ministries and institutions will prepare sub plans to ensure the full implementation of the National Emergency Plan and planning to develop and conduct, on the basis of risk assessments, regular exercises at local and national level. These exercises involve and test cooperation of all relevant organizations and institutions to assess their roles and responsibilities.

182. The Iraqi National Monitoring Authority (INMA) in collaboration with the civil defense and the relevant Ministries and Institutions have completed establishing the Weapons of mass destruction Incident Response Team under the responsibility of the MoE/civil defense consist of 17-20 specialists. The presence of a dedicated team of rapid response to incidents that fall within the concept of weapons of mass destruction incidents contribute to the speed of response to these accidents and mitigate their effects on humans and the environment. Usually this team covers all activities that fall within the concept of the fact that events or accidents associated non-traditional and non-recurring and are similar in terms of procedures.

183. The Iraqi National Monitoring Authority (INMA) stick to contribute to build and enhance the national capabilities in the preparedness and response to WMD dual use materials (including biological materials) incidents, through the involvement of specialists in training courses, workshops and exercises and will continue to improve public preparedness for WMD dual use materials incidents and elaborating necessary mechanisms to increase awareness of these incidents. The National Monitoring Authority (INMA) with the relevant Ministries and Institutions will continue to identify good practices on preparing and responding to incidents involving the facilities possessing any of the high risk WMD dual use materials.

H. Raising awareness

184. The value of raising awareness measures is to promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines; and encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct to prevent anyone from developing, producing, stockpiling, or otherwise acquiring or retaining, transporting or transferring and using under any circumstances, biological agents and toxins, equipment, or their means of delivery for non-peaceful purposes. However, it is not enough simply to raise awareness without effective measures and building a culture of security and responsibility amongst relevant national professionals in the private and public sectors and throughout relevant scientific and administrative activities.

185. The National Monitoring Authority (INMA) with the relevant Ministries and Institutions will continue to promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines; promote the development of education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins; encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct and organizing awareness-raising workshops and training for establishing of efficient communication and coordination between national stakeholders.

Japan

A. Article I

186. Since its ratification of the Convention on 8 June 1982, Japan has never developed, produced, stockpiled or otherwise acquired or retained:

(a) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

187. Since Japan did not possess any of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention at the time of its ratification, this article does not apply.

C. Article III

188. Japan complies with the obligations of Article III and, under strict supervision and control, inter alia, the Export Trade Control Ordinance (enacted in 1949), has never transferred to any recipient whatsoever any of the agents, toxins, weapons, equipment or means of delivery specified in Article I.

D. Article IV

189. To implement Article IV of the Convention, Japan enacted in 1982 the Law on the implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction.

190. The Law was revised in 2001 when Japan ratified the International Convention for the Suppression of Terrorist Bombings, to add an article regarding the prohibition and penalties against the use of biological weapons and the discharge of biological agents and toxins.

191. With the amendment of the Law concerning Prevention of Infectious Diseases and Medical Care for Patients with Infections (hereinafter referred to as the Law concerning Infectious Diseases) in 2006, appropriate control system has been established on pathogenic microbe etc. by restricting the possession, transfer, delivery, import of pathogens and on-the-spot inspection to the possessor of the specific pathogens by the staff of Ministry of Health, Labour and Welfare and National Police Agency from June 2007. Also the information reported by the sentinel medical institutions for syndromic surveillance has been gathered in order to grasp the situation of outbreak of an unknown infectious respiratory disease and unknown infectious skin patients from April 2008.

192. With the amendment of the Law concerning Infectious Diseases in May 2008, the Immigration Control and Refugee Recognition Act (Article 5, Paragraph 1, Clause 1) was amended which added the patients of infectious diseases such as H1N1 influenza, including Suspected Disease Carriers and Disease Carriers Who Have No Symptoms, to the ground for denial of landing (Date of Enforcement: May 12, 2008). In May 2012, Act on Special

Measure for Pandemic Influenza and New infectious diseases was enforced and amended in June 2015.

193. In July 2014, Act on Domestic Animal Infectious Diseases Control has been amended from the aspect of decreasing the risk of outbreak and expansion of animal infectious diseases by the spilt pathogens, and established the restriction according to the danger level of the pathogens on the possession and transfer etc. in the country.

194. Japan contributed to various seminars related to public health and countermeasures for biological weapon by giving presentation and sending experts as follows;

(a) ARF workshop on disease and surveillance and detention (Philippines 2011)

(b) ARF workshop on preparedness and response to a biological event (Philippines 2012)

(c) Chemical and Biological Defense Science and Technology Conference (U.S.A 2015)

(d) Global Conference on Biological Threat Reduction (France 2015)

(e) S&T Trends Symposium to support the Biological and Toxin Weapons Convention (Poland 2015)

195. In September 2015, Basic Guidelines for Strengthening Measures on Emerging Infectious Diseases was enforced to swiftly response to public health emergency in collaboration with international organization.

E. Article V

196. Japan has not invoked the provisions of Article V, nor has any other State Party invoked these provisions against Japan. Japan fully supports the Confidence Building Measures developed at previous Review Conferences and has consistently participated in the exchange of information.

F. Article VII

197. Under Article Ⅶ, all States Parties are required to provide assistance to any State Party exposed to danger as a result of violation of the Convention. Japan regards enhancement of own national capacity related to detection of pathogens and response to public health emergency maximizes our ability to respond and provide assistance in such cases.

Legislation

a) Act on Special Measure for Pandemic Influenza and New Infectious Diseases (Law No.31, 2012)

b) Order for Enforcement of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases (Cabinet Order No. 122, 2013)

c) The Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases (Law No.15, 2014)

d) Quarantine Act (Law No.15, 2014)

e) Rabies Prevention Law (Law No.15, 2014)

f) Act on Domestic Animal Infectious Disease Control (Law No.15, 2014)

Action Plan/Basic Guidelines

a) National Action Plan for Pandemic Influenza and New Infectious Diseases(Cabinet Decision, 2013)

b) Action Plan for Strengthening Measures on Emerging Infectious Diseases(Cabinet Decision, 2016)

c) National Action Plan on Antimicrobial Resistance (Cabinet Decision, 2016)

G. Article IX

198. Japan ratified the Chemical Weapons Convention in 1995 and is strongly committed to its effective implementation.

H. Article X

199. In light of the objectives and purposes of Article X, Japan is strongly committed to promoting international cooperation bilaterally or in conjunction with international organizations, in support of the development and application of scientific discoveries for peaceful purposes in the field of bacteriology (biology).

200. In the field of health care, Japan contributes, through both bilateral and multilateral cooperation (e.g. the WHO), to financial assistance, capacity building, and the holding of international conferences to deal with recent epidemics of emerging and reemerging infectious diseases, such as avian flu and H1N1 influenza. Examples of Japan's international cooperation related to the Convention are listed in the paper "".

Netherlands

200. In line with the request by the Preparatory Committee to the BWC Implementation Support Unit to prepare a background information document on compliance by States Parties with their obligations under the Convention, the Netherlands wishes to submit the following information.

201. The Netherlands signed the Biological and Toxin Weapons Convention on 10 April 1972 and ratified the Convention on 22 June 1981. The domestic Biological and Toxin Weapons Act was enacted on 25 March 1981. This legislation provides for the necessary measures to be taken under domestic law to enable the Netherlands to fulfil its obligations under the Convention. The Netherlands is in full compliance with all its obligations under the Convention.

A. Articles I and II

202. The Netherlands has never developed, produced, stockpiled or otherwise acquired or retained microbial or other biological agents or toxins of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes, nor has it ever developed, produced, stockpiled or otherwise acquired or retained weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article III

203. The Netherlands complies with the undertaking not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any state, group of states or international organization to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

204. Export and transit of dual-use items is regulated in the Netherlands in the Decree on Strategic Goods, and is based on Council Regulation No. 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. This regulation was adopted on 5 May 2009, replacing an earlier Council Regulation dating from 2000 (No. 1334/2000). The regulation stipulates that a license is required for the export of certain types of items and technology, lists of which are regularly updated in accordance with the development of science and technology. The most recent update of the list of dual-use items is incorporated in the Commission Delegated Regulation (EU) 2015/2420 of 12 October 2015. Regular updates are necessary to ensure full compliance with international security obligations, to guarantee transparency, and to maintain the competitiveness of exporters. The updates are automatically inserted in the Dutch relevant legislation through dynamic references.

C. Article IV

205. The implementation of Article IV of the Biological and Toxin Weapons Convention is covered by the Biological and Toxin Weapons Act of 25 March 1981. Furthermore, a number of other acts, decrees, regulations and measures are in place that serves the purpose of the Convention, even though not specifically adopted for that purpose (regulations for biosafety, transport of hazardous materials, GMO's). An overview of relevant legislation, regulations and measures can be found in the ANNEX at the end of the Netherlands' Compliance report.

206. The Netherlands wishes to outline several implementation measures under Article IV of which the value was noted by the 7th Review Conference, such as awareness promotion among relevant professionals of obligations under the Convention and national legislation and guidelines and the voluntary development of codes of conduct. Bottom-up capacity-building is an important component of the Dutch biosecurity regime, which works bottom-up rather than top down. Each stakeholder has its own responsibilities, which involves awareness, education, and risk management in the field of biosecurity and non-proliferation. The role of the government is to stimulate and facilitate the necessary awareness and capabilities. To raise awareness in the scientific community on dual-use issues, the Royal Netherlands Academy of Arts and Science (KNAW) developed a code of conduct for biosecurity, to help individual researchers in their assessment of risks and benefits. The aim of this Code of Conduct is to prevent life sciences research or its application from directly or indirectly contributing to the development, production or stockpiling of biological weapons, as described in the Convention, or to any other misuse of biological agents and toxins. Moreover, the Netherlands Biosecurity Office serves as national knowledge and information center for biosecurity and forms a linking pin between policy-makers and the field. Its main objectives are to develop tools to help organizations implement biosecurity and create awareness among biosecurity stakeholders. Its awareness raising and capacity building products include a biosecurity toolkit, which is an online questionnaire. By completing the questionnaire, the organization gets an insight in the strengths and weaknesses of its biosecurity management. The outcome of these self-

assessment tools includes recommendations and good practices to improve the biosecurity level of the organization.

207. In 2015, the Netherlands jointly conducted a peer review exercise with Belgium and Luxembourg to enhance national implementation through sharing best practices and to strengthen confidence-building amongst States parties through increasing transparency. The Benelux approach to the peer review concept involved declarations (in the form of the Confidence Building Measures), written and oral consultations and on-site visits to relevant facilities, as declared in CBM-form A. Conducted peer review exercises have moreover proven to be valuable to increase awareness amongst national stakeholders and provide for a mutual learning experience. Peer review exercises are not intended as a substitute for verification. Rather, they are a way to voluntarily take concrete steps towards enhanced national implementation, transparency and confidence in compliance.

D. Article V

208. The Netherlands has not invoked Article V, nor has any other State Party invoked Article V in order to engage the Netherlands in consultations. The Netherlands fully supports the Confidence Building Measures developed at previous BWC Review Conferences and has consistently participated in all rounds (on an annual basis) of information exchange in the framework of the Confidence Building Measures. Its declarations on Confidence Building Measures are available to the public since 2014. The Netherlands welcomes the additional transparency measures some States Parties have taken, including through conducting peer review exercises.

E. Article VI

209. The Netherlands has not invoked the provisions of Article VI, nor has any other State Party invoked these provisions against the Netherlands.

F. Article VII

210. The Netherlands has not been requested to provide assistance under Article VII, nor has it invoked the provision of Article VII to receive assistance. The Netherlands attaches great importance to assistance provision and capacity-building in the framework of the Convention and therefore contributes to this end both individually and in cooperation with other states, international organization, non-governmental organizations and other relevant partners.

211. For more elaborate information on compliance with Article VII, please see the separate background information document submitted by the Netherlands on its implementation of Article VII.

F. Article VIII

212. The Netherlands is a State Party to the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases, and of Bacteriological Methods of Warfare, signed in Geneva on 17 June 1925 and ratified on 31 October 1930, and fully recognizes the obligations under the Geneva Protocol.

G. Article IX

213. The Netherlands has signed the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction on 13 January 1993 and ratified it on 30 June 1995. The Netherlands, host country to the Organization for the Prohibition of Chemical Weapons (OPCW), is strongly committed to the effective implementation of the Chemical Weapons Convention.

H. Article X

214. The Netherlands attaches great importance to cooperation and assistance under Article X of the Biological and Toxin Weapons Convention and remains committed to facilitating and participating in the exchange of equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. The Netherlands fulfils its obligations under Article X through contributing individually and in cooperation with other states, international organizations, non-governmental organizations and other relevant partners.

215. For more elaborate information on compliance with Article X, please see the separate background information document submitted by the Netherlands on its implementation of Article X.

The Netherlands – ANNEX (Article IV)

I. National Implementing Legislation

216. Different Dutch acts, decrees, regulation and other measures relating to

(a) the development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I,

(b) exports of micro-organisms and toxins, or

(c) imports of micro-organisms and toxins,

were amended or replaced since the last full overview provided (CBM Form E, 2007). The changes mainly concern reorganization of the legislation apparatus and not the content.

217. For information purposes, the actual Dutch acts, decrees, regulations or other measures relevant in the context of the BTWC as well as information on the enforcement thereof is listed and partly summarized below.

II. List of relevant acts, decrees, regulations and other measures (per 24 August 2016)

(a) BTWC Implementation Act

(b) Weapons and Ammunition Act

(c) Criminal Code

(d) Economic Offences Act

(e) Act/Decree/Regulation regarding the transport of hazardous materials

(f) Plant Sickness Act

(g) General Customs Act

(h) Strategic Goods (Import and Export) Decree

(i) Strategic Services Act

(j) Foreign Financial Relations Act 1994

(k) Working Environment Act/Decree

(l) Decree/Regulation on genetically modified organisms 2013

(m) Decree on the fight against harmful organisms

(n) Environmental Permitting (general provisions) Act/Decree/Regulation

(o) Environmental Management Act, Decree on general rules governing the environmental management of sites or Activities Decree, Ministerial regulation governing the environmental management of sites.

(p) Animals Act

218. Besides this list of Dutch legislation, the following EU legislation or documents are relevant for the Dutch practice:

(a) Military goods list as listed in the EU list of military goods (Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defense related products within the Community (EU 2016, L 163)

(b) Guidelines of the Commission for Genetic Modification, 1998

III. Summary of relevant acts, decrees, regulations and other measures

A. General legislation related to biological and toxin weapons

Biological Weapons Convention (Implementation) Act

219. The biological Weapons Convention (Implementation) Act (Uitvoeringswet verdrag biologische Wapens, http://wetten.overheid.nl/BWBR0003385/2010-10-10) implements Article IV of the Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction, done on the 10th of April 1972 in London, Moscow and Washington, 25 March 1981.

220. It provides the framework for the prohibition of the development, production, stockpiling, acquisition and retention of biological agents not justified for peaceful purposes within the meaning of the BWC (Article 2), prohibits the manufacture, acquisition, possession, development and transfer of biological weapons (Articles 3-4). Also prohibits the manufacture, acquisition, possession, development and transfer of the means of delivery of biological weapons (Article 4).

221. It contains a definition of biological agents that also includes toxins. Under this act, it is prohibited for anyone to develop, produce, stockpile, acquire or possess biological agents, if one knows or should assume that these agents are or could be intended to be used as a means of warfare. The latter is assumed when the type or quantity of the biological agents have no justification for prophylactic, protective, or peaceful purposes. Agents have to be destroyed if someone is caught having them. The act also prohibits the development, production, stockpiling, acquisition, or possession of weapons, equipment, or means of delivery to be used for biological agents as a means of warfare. Violation of these

prohibitions is considered to be an economic crime punishable with a maximum of six (6) years imprisonment or a fine of the fifth category; materials are to be confiscated.

222. This Act was last amendment on the 27th of May 2010. Article 5 was amended and article 7a was added due to the administrative reorganization of Bonaire, Saint Eustatius and Saba.

Weapons and Ammunition Act

223. The Weapons and Ammunition Act (Wet Wapens en munitie, http://wetten.overheid.nl/BWBR0008804/2015-07-01) prohibits the manufacture, possession and transfer of hazardous substances. This includes biological and chemical agents and nuclear material (Section 2, category II sub b in combination with sections 9, 14, 26, 27).

Criminal Code

224. The use of biological weapons is prohibited by the provisions of the Criminal Code relating to the creation of hazards (Wetboek van strafrecht, Sections 172, 173, 173a, 173b, 287 and 289, http://wetten.overheid.nl/BWBR0001854/2016-07-01). The prohibition to possess biological weapons means that the transport of biological weapons is prohibited as well.

Economic Offences Act

225. If a terrorist purpose is established in case of the violation of the above-mentioned provisions of the Implementing Act of the Biological Weapons Convention (see Section 83a of the Criminal Code in combination with Article 6.4 of the Economic Offences Act) (Wet op de economische delicten, http://wetten.overheid.nl/BWBR0002063/2016-08-11) higher penalties are imposed. Attempts by non-state actors to engage in any of the activities mentioned in operative paragraph 2 prohibited under the above-mentioned provisions of the Biological Weapons Convention (Implementation) Act, to participate in them as an accomplice, or to assist or to finance them qualify as criminal offences. The relevant provisions can be found in the Criminal Code with respect to attempt (Article 45), participation, subornation and material support (Article 47), complicity (Article 48) and participation in a criminal organization (Articles 140 and 140a).

B. Legislation related to biological and toxin weapons and transport

226. Domestic laws requires the physical protection of dangerous goods, including biological agents, chemical agents and nuclear material, during transport and requires transport companies to develop and maintain a security plan.

Act, Decree and Regulation regarding the transport of hazardous materials

227. For the protection of dangerous goods during transport the Act regarding the transport of hazardous materials (Wet vervoer gevaarlijke stoffen, http://wetten.overheid.nl/BWBR0007606/2015-04-01), the Decree regarding the transport of hazardous materials (Besluit vervoer gevaarlijke stoffen, http://wetten.overheid.nl/BWBR0008080/2015-04-01) and the Ministerial regulation regarding the transport of hazardous materials (Regeling vervoer over land gevaarlijke stoffen, http://wetten.overheid.nl/BWBR0010054/2015-11-19) were enacted.

Plant Sickness Act

228. The Ministerial regulation on import, export and transport of plants (Regeling invoer, uitvoer en verkeer van planten, http://wetten.overheid.nl/BWBR0005997/2016-08-

20) is based on the Plant Sickness Act (Plantenziektewet, http://wetten.overheid.nl/BWBR0002075/2015-01-01). It itself derives from the EU directives 77/93/EEG and 95/44/EG. The first has been replaced by EU directive 2000/29/EC, the latter by EU directive 2008/61/EG.

C. Legislation related to biological and toxin weapons and Customs

229. Community customs legislation and provisions adopted at the national level endows customs authorities with powers to undertake actions in general with a view to ensuring that customs rules and, where appropriate, other provisions applicable to goods subject to customs supervision are observed. Customs authorities perform specific acts, such as examining goods, verifying the existence and authenticity of documents, examining the accounts of undertakings and other records, inspecting means of transport, inspecting luggage and other goods carried by or on persons and carrying out official inquiries and other similar acts with a view to ensuring rules and provisions mentioned. The Netherlands has concluded several mutual administrative assistance agreements with her main trading partners. With the aid of these agreements international cooperation with regard to detect and prevent the illicit trafficking.

230. To enhance the possibilities to detect, deter and prevent the illicit trafficking and to align all powers to be executed by customs authorities in the case of goods entering the territory of on the Netherlands new customs legislation has entered into force (General Customs Act). The Netherlands is in the process of establishing a contiguous zone for the purpose of inter alia, carrying out checks at an earlier stage in the logistic chain.

General Customs Act

231. The Import and Export Act was repealed and is now part of the General Customs Act (Algemene douane wet, http://wetten.overheid.nl/BWBR0023746/2016-07-01). This is mainly a procedural change.

D. Legislation related to biological and toxin weapons and Export Control

Strategic Goods (Import and Export) Decree

232. The Strategic Goods (Import and Export) Decree (Besluit strategische goederen, http://wetten.overheid.nl/BWBR0024139/2015-04-01) introduced a system of import, export and transit controls. These include checks on end-users, military materials, including military technology, and dual-use items. EC Dual-Use Export Control Regulation No 1504/2004, amending regulation No. 1334/2000, set up a Community regime for the control of exports of dual-use items and technology, applies to the export of dual-use items and technology from Community territory whereas national legislation (i.e. the Strategic Goods ((Import and Export)) Decree) provides for additional measures regarding the imposition of penalties for infringements, and gives national authorities powers to carry out controls and to investigate and prosecute criminal offences.

233. The Decree was last amended in 2015 following the ratification of the Arms Trade Treaty. Before that, the Decree was thoroughly amended following the entry into force of the 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 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:134:0001:0269). The regulation was furthermore implemented in a (temporary) Sanctions Decree on Brokering 2009. That Decree was repealed on the 1st of January 2012. It’s content was included in the Strategic Services Act and in the Strategic Services Regulation (Uitvoeringsregeling strategische diensten, http://wetten.overheid.nl/BWBR0030629/2012-01-01).

234. The Decree on Issuing Certificates for Strategic Goods 1986 (Besluit afgifte verklaringen strategische goederen) was repealed on the 1st of August 2008. The content of this Decree has been included in the General Customs Act.

235. The Decree on Financial Involvement concerning Strategic Goods 1996 (Besluit financieel verkeer strategische goederen 1996) was repealed on the 1st of January 2012. The content of this Decree has been included in the Strategic Services Act.

Strategic Services Act

236. On the 1st of January 2012 the Strategic Services Act (Wet strategische diensten, http://wetten.overheid.nl/BWBR0030545/2016-01-01) entered into force. This act regulates advanced brokering controls on military and dual-use goods. Brokers in animal or human pathogens, as defined by the Australia Group, have to notify the Dutch government of their intention 2 weeks in advance of every brokering activity. This notification should include the exporter, the end-user and the end-use of the pathogens. If necessary, the Dutch government can prohibit brokering activities of concern.

Foreign Financial Relations Act 1994

237. The Foreign Financial Relations Act 1994 (Wet financiële betrekkingen buitenland 1994, http://wetten.overheid.nl/BWBR0006547/2013-01-01) requires a license for financial transactions involving the transit and brokering of war materials.

E. Legislation related to biological and toxin weapons and the Working Environment/Working with GMO's (bio safety)

Working Environment Act/Decree

238. Requirements of the Biological Agents Directive (2000/54/EC) have been implemented in Dutch legislation by means of the Working environment act/decree (Arbeidsomstandighedenwet, Arbeidsomstandighedenbesluit, http://wetten.overheid.nl/ BWBR0010346/2016-01-01).

239. The Working Environment Act/Decree outlines requirements relating to the protection of workers from risks related to exposure to biological agents at work. Certain activities involving biological agents should be notified to the labour inspectorate. Notification is required if there is an intention to use a biological agent from the hazard group 2, 3 or 4 for the first time at the premises. Notification of each subsequent use of a new biological agent of group 3 and 4 is also required. The employer is required to keep a register of the employees who work of have worked with biological agents from group 3 or 4.

Decree/Regulation on Genetically Modified Organisms 2013

240. Decree on Genetically Modified Organisms 2013. The objective of the Decree on Genetically Modified Organisms 2013 (Besluit genetisch gemodificeerde organismen milieubeheer 2013, http://wetten.overheid.nl/BWBR0035090/2015-03-01) is to ensure an adequate level of protection in the field of the safe handling and use of genetically modified organisms (GMOs) that may have adverse effects on the environment and human health or the environment. It secures the safety of man and the environment in working with genetically modified organisms. For this, the Decree lays down provisions of a permit application system for activities with GMOs. It deals with both the contained use and introduction into the environment of GMOs.

241. The decree implements the European Directives 2009/41/EC and 2001/18/EC on the contained use and the deliberate release into the environment of GMO's, respectively.

Where appropriate, the decree requires advanced written consent from competent authorities before activities with GMOs may be conducted. On the basis of the information gathered by the government as a result of the procedures of the decree, it is possible to pinpoint which GMOs are being handled by research facilities and at which location. The level of detail varies for different categories, but for pathogenic micro-organisms comprehensive information is available to the competent authority.

242. The Decree on Genetically Modified Organisms 2013 replaced the Decree on genetically modified organisms from 1990 and is largely based on the newest European directives concerning the contained use of genetically modified micro-organisms (EU Directive 2009/41/EC) and the deliberate release of genetically modified organisms (2001/18/EC).

243. The Decree is furthermore based on the following European Regulations:

(a) Regulation 1829/2003/EC on genetically modified food and feed;

(b) Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified;

(c) organisms and the traceability of food and feed products produced from genetically modified;

(d) organisms, and amending Directive 2001/18/EC;

(e) Regulation 1946/2003 on trans boundary movements of genetically modified organisms.

244. The Inspectorate of Housing, Spatial Planning and the Environment supervises the compliance with the GMO Decree and enforces the Decree.

245. The contained use of genetically modified organisms is part of the Decree/ Ministerial Regulation on Genetically Modified Organisms 2013. The separate Ministerial Regulation on it was repealed.

246. Ministerial Regulation on Genetically Modified Organisms 2013. The Ministerial Regulation on Genetically Modified Organisms 2013 (Regeling genetisch gemodificeerde organismen milieubeheer 2013) contains the technical rules for working with GMO's, for example the risk assessment rules for contained use, the technical rules for each facility for transport and storage of GMO's and the storage of waste containing GMO's.

247. Decree on the fight against harmful organisms *(Besluit bestrijding schadelijke organismen, http://wetten.overheid.nl/ BWBR0005206/2015-01-01)*

F. Legislation related to biological and toxin weapons and the environment

Environmental Permitting (general provisions) Act/Decree/Regulation

(a) Environmental Permitting (general provisions) Act (Wet algemene bepalingen omgevingsrecht, http://wetten.overheid.nl/BWBR0024779/2016-07-01)

(b) Environmental Permitting Decree (Besluit omgevingsrecht, http://wetten.overheid.nl/BWBR0027464/2016-07-01). This decree replaces the Establishments and Licenses Decree (Inrichtingen- en vergunningenbesluit milieubeheer).

(c) Environmental Permitting Regulation (Ministeriële regeling omgevingsrecht, http://wetten.overheid.nl/BWBR0027471/2016-07-01)

Environmental Management Act, Decree on general rules governing the environmental management of sites, Ministerial regulation governing the environmental management of sites

(a) Environmental Management Act (Wet milieubeheer, http://wetten.overheid.nl/BWBR0003245/2016-07-01). The premises for contained use activities requires a separate permit, which is obtained through the Environmental Management Act. In this act the need for a license for laboratories, animal housing facilities, growth chambers, greenhouses, production facilities is laid down in case these buildings are used for work with GMO's. This license is issued by the local authorities (Municipal council, Province). The Inspectorate of Housing, Spatial Planning and the Environment supervises the compliance with the GMO Decree and enforces the Decree. Facilities in which activities with GMO's take place (contained use) are supervised by the local authorities (town or province) within the scope of the Environmental Management Act.

(b) Decree on general rules governing the environmental management of sites or Activities Decree, also called the Activities Decree (Besluit algemene regels voor inrichtingen milieubeheer (Barim), http://wetten.overheid.nl/BWBR0022762/2016-01-01).

(c) Ministerial regulation governing the environmental management of sites (Regeling algemene regels voor inrichtingen milieubeheer (Rarim), http://wetten.overheid.nl/BWBR0022830/2016-01-01)

Animals Act

248. The Animals Act (Wet dieren, http://wetten.overheid.nl/BWBR0030250/2015-02-01) in its article 2.12, that didn't enter into force yet, obliges to give notice of animal sicknesses and zoonosis.

Norway

249. Norway signed the Convention on 10 April 1972 and ratified it on 1 August 1973

A. Article I

250. Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

251. Norway has never developed, produced, stockpiled or otherwise acquired or retained microbial or other biological agents or toxins of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes, nor has it ever developed, produced, stockpiled or otherwise acquired or retained weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

252. Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in Article 1 of the Convention, which are in its possession or under its jurisdiction or control. In implementing the provisions of this Article all necessary safety precautions shall be observed to protect populations and the environment.

253. Norway has never had an offensive biological research, development or production programme or otherwise acquired biological weapons, and, accordingly, has had no need to destroy or divert to peaceful purposes any biological weapons, as required under this Article.

C. Article III

254. Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

255. Norway complies fully with the undertaking not to transfer or in any way assist, encourage or induce any other States or organisations to manufacture or otherwise acquire biological weapons. This is reflected in a number of Acts and Regulations, which are listed below.

256. All Acts and Regulations are available in Norwegian at www.lovdata.no. An English version of many Norwegian acts and regulations is available at https://lovdata.no/info/information_in_english, but these are not official translations, and in many cases they have not been updated to include the latest amendments.

(a) Act relating to control of the export of strategic goods, services, technology, etc., (Export Control Act) (LOV-1987-12-18-93, as amended 2015).

(b) Act relating to the regulation of imports and exports (LOV-1997-06-06-32, as amended 2015). Under this Act, a special licence is required to import or export certain goods.

(c) Act on Customs Duties and Movement of Goods (Customs Act) (LOV-2007-12-21-119, as amended 2016).

(d) Act relating to the control of communicable diseases (LOV-1994-08-05-55, as amended 2015; updated English translation not available). This Act sets out measures to prevent communicable diseases from being brought into the country or spread to other countries (quarantine measures), including measures in respect of persons, animals, means of transport, goods and objects that may conceivably transmit communicable diseases. The Act also contains provisions on measures such as compulsory medical examinations and disinfection, as well as documentation requirements in connection with entry into and departure from Norway and in connection with the import and export of goods.

(e) Act relating to food production and food safety etc. (Food Act) (LOV-2003-12-19-124, as amended 2015; updated English translation not available). Under the Food Act, the Norwegian Food Safety Authority is responsible for

ensuring compliance and may make the necessary decisions to ensure the implementation of the Act. This includes prohibiting imports, exports and trade in plants/animals/food, or ordering the withdrawal of such products from the market, the closure of premises, isolation, killing of animals, destruction, disinfecting, labelling/stamping or other special measures.

(f) The Norwegian Penal Code (LOV-2005-05-20-28, as amended 2016; English translation not available). Section 142 prohibits the acquisition, possession, transport, transfer, production, use, or other illegal involvement with biological weapons and any equipment meant for their production/use or delivery. Sections 107-108 make it a war crime to use or conspire to use biological weapons in armed conflicts. Sections 131-136 prohibit terrorist use of biological weapons, acting as an accomplice to acts of terrorism, participation in or recruitment to terrorist organisations, training and incitement to acts of terrorism, and the financing of terrorism. Sections 237-240 prohibit the spread of disease, the use of poison, and the pollution of air, water or the ground with a view to endangering life and the environment. Sections 355-357 make it illegal to expose or conspire to expose the public to any serious danger that could easily lead to the loss of human life.

(g) Regulations to the Act on Customs Duties and Movement of Goods (Customs Regulations) (FOR-2008-12-17-1502, as amended 2016), regulating the powers of the customs authorities to seize, destroy or dispose of any illegally imported substances and impose sanctions in connection with attempted illegal export; and Export Control Regulations (FOR-2013-06-19-718, as amended 2016) and legislation relating to control of the export of strategic goods, services and technology.

(h) Regulations relating to the export of defence-related products, dual-use items, technology and services – Implementing legislation. Laid down by the Ministry of Foreign Affairs on 19 June 2013 (FOR-2013-06-19-718).

(i) Regulations on the notification of, and measures to be taken in the event of, serious events of significance for international public health (the IHR Regulations) (FOR-2007-12-21-1573, as amended 2015).

(i) Regulations on the import, transport and other handling of materials that are infectious to humans (FOR-1996-09-12- 903, as amended 2013).

(j) Regulations amending the regulations on plant health (FOR-2016-03-29-327), which impose restrictions on the production, transport, packaging, import and export of plants.

(k) Regulations relating to trade in animals (FOR-2004-02-20-464, as amended 2016).

(l) Regulations on the veterinary control of products at border stations (FOR-2005-11-30-1347, as amended 2014, and FOR-2008-06-26-726, as amended 2015); and Regulations on the inspection and control of animal products in transit or for import (FOR-1999-10-27-1166, as amended 2015).

(m) The implementing agencies are Norwegian Customs Authorities, the Norwegian Food Safety Authority, the Ministry of Foreign Affairs and the Norwegian Police Security Service.

D. Article IV

257. Each 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 the territory of such State, under its jurisdiction or under its control anywhere.

258. Norway fulfils the requirements set out in Article IV on national implementation through a number of Acts and Regulations, which are directly or indirectly in compliance with the Convention. In addition to the Acts and Regulations mentioned under Article I, this includes:

(a) The Norwegian Penal Code (LOV-2005-05-20-28, as amended 2016). Section 142 prohibits the acquisition, possession, transport, transfer, production, use, or other illegal involvement with biological weapons and any equipment meant for their production, use or delivery. Sections 107-108 make it a war crime to use or conspire to use biological weapons in armed conflicts. Sections 131- 136 prohibit terrorist use of biological weapons, acting as an accomplice to acts of terrorism, participation in or recruitment to terrorist organisations, training and incitement to acts of terrorism, and the financing of terrorism. Sections 237-240 prohibit the spread of disease, the use of poison, and the pollution of air, water or the ground with a view to endangering life and the environment. Section 355-57 make it illegal to expose or conspire to expose the public to any serious danger that could easily lead to the loss of human life.

(b) Act relating to the Production and Use of Genetically Modified Organisms, etc. (Gene Technology Act) (LOV-1993-04-02-38, as amended 2015). This Act imposes strict controls on the production and use of genetically modified organisms.

(c) Act relating to the application of biotechnology in medicine (LOV-2003-12-05-100, as amended 2015). This Act imposes strict controls on the use of biotechnology.

(d) Act relating to the prevention of fire, explosion and accidents involving hazardous substances and to the tasks of the fire service (LOV-2002-06-14-20, as amended 2015). This Act imposes strict controls on the production and handling of hazardous substances and dangerous goods.

(e) Act relating to aviation (LOV-1993-06-11-101, as amended 2016). (f) Act relating to harbours and territorial waters (LOV-2009-04-17-19, as amended 2015).

(f) Regulations relating to impact assessment pursuant to the Gene Technology Act (FOR-2005-12-16-1495, as amended 2013).

(g) Regulations relating to the labelling, transport, import and export of genetically modified organisms (FOR-2005-09-02—1009, as amended 2013).

(h) Regulations concerning the declaration and labelling of microbiological products (FOR-1998-01-22- 93, as amended 2013).

(i) Regulations relating to the land transport of dangerous goods (FOR-2009-04-01-384, as amended 2016).

(j) Regulations relating to the air transport of goods (FOR-2003-01-11-41, as amended 2013).

(k) Regulations relating to environmental safety for ships (FOR-2012-05-30-488, as amended 2015).

(l) Regulations relating to the unloading, loading, storage and transport of dangerous goods in municipal coastal areas and harbours (FOR-2009-12-15-1543, as amended 2013).

(m) Regulations relating to the conduct of investigations to identify communicable diseases (FOR-1998-12-22-1432, as amended 2013).

(n) Regulations concerning infectious waste from the health sector and animal

(o) health sector (FOR-2005-10-11-1196, as amended 2013).

E. Article V

259. The States Parties to this Convention undertake to consult one another and to co-operate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and co-operation pursuant to this Article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.

260. In accordance with the relevant decisions of States Parties at the Second, Third, Sixth and Seventh Review Conferences of the Convention, Norway has annually submitted the declaration forms on Confidence-Building Measures to States Parties through the BWC Implementation Support Unit (ISU) under the UN Office for Disarmament Affairs. The Norwegian declarations on Confidence-Building Measures are available to the public.

F. Article VI

(a) Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.

(b) Each State Party to this Convention undertakes to co-operate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.

261. Norway has not lodged any complaints with the UN Security Council regarding any breaches of the obligations under the Convention by any other States Parties, nor has any other State Party lodged a complaint under Article VI against Norway.

262. The Norwegian Army has a Rapidly Deployable Outbreak Investigation Team (RDOIT). The team consists of doctors, veterinary surgeons and nurses from civilian medical institutions, who are trained and certified every year. RDOIT can provide assistance in investigating outbreaks of diseases where the origin is unknown, taking clinical samples, mapping epidemics and handling disease outbreaks. The team may, under certain circumstances, be put at the disposal of the United Nations Secretary-General's Mechanism (UNSGM) for a limited period of time, in which case the UN has to put forward a formal request to the Norwegian authorities.

G. Article VII

263. Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.

264. Norway has not received any requests for assistance under Article VII from other States Parties, nor has it requested assistance under Article VII from any other State Party.

288. Norway made a significant contribution to the international response to the Ebola outbreak, and provided over NOK 500 million (approx. USD 70 million) in funding. The funds were channelled through partners such as WHO, the UN, the African Union, Médecins Sans Frontières, the International Red Cross and others. Norway also sent 110 Norwegian health workers to West Africa and made a Hercules aircraft available for the transport of personnel and equipment. In addition, Norway has played a leading role in the work to develop a promising Ebola vaccine.

H. Article VIII

265. Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any State under the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925.

266. Norway ratified the 1925 Geneva Protocol on 27 July 1932.

267. The Norwegian Penal Code (LOV-2005-05-20-28, as amended 2016; English translation not available). Section 142 prohibits the use of or other illegal involvement with biological weapons. Sections 107-108 make it a war crime to use or conspire to use biological weapons in armed conflicts. Sections 131- 138 prohibit terrorist use of biological weapons, acting as an accomplice to acts of terrorism, participation in or recruitment to terrorist organisations, training and incitement to acts of terrorism, and the financing of terrorism. Section 141 prohibits the use of biological weapons on or against ships and the emission or release of biological weapons from ships. Sections 237-240 prohibit the spread of disease, the use of poison, and the pollution of air, water and the ground with a view to endangering life and the environment. Sections 355-357 make it illegal to expose or conspire to expose the public to any serious danger that could easily lead to the loss of human life.

I. Article IX

268. Each State Party to this Convention affirms the recognised objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

269. Norway ratified the Chemical Weapons Convention on 7 April 1994.

270. Norway and Denmark contributed to the elimination of Syria’s chemical weapons programme, in line with UNSCR 2118 and OPCW Executive Council decision EC-M-34/DEC-1, by transporting chemical weapons out of Syria. The Norwegian contribution

consisted of a civilian cargo ship, a military escort vessel, a Vessel Protection Team and a CBRN response team. Norway's total costs for the Norwegian operation were NOK 284 million (approx. USD 40 million). In addition, Norway provided NOK 17 million (approx. USD 2.4 million) to the OPCW Syria Trust Fund for the Destruction of Chemical Weapons.

J. Article X

271. The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also co-operate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.

272. This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international co-operation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

273. Norway has fulfilled its commitments under Article X, both by facilitating and participating in the fullest possible exchange of equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes, and by engaging in international cooperation. Norway's most important activities during the intersessional programme (2011-2016) are outlined below.

(a) The Norwegian Institute of Public Health has a Department for International Public Health and a large number of international cooperation projects. These range from basic (pure) research projects to capacity-building, development and networking activities. For more information, see the Institute website: www.fhi.no.

(b) Norwegian universities have extensive international cooperation programmes. The Universities of Oslo and Bergen also have a Centre for Global Health and a Centre for International Health, respectively (for more information on these centres, see http://www.med.uio.no/helsam/english/research/centres/global-health/index.html and http://www.uib.no/en/cih).

(c) The Ministry of Foreign Affairs, through the Norwegian Agency for Development Cooperation, Norad (a directorate under the Ministry), is funding a programme to strengthen the implementation of the International Health Regulations (IHR). The programme is being implemented by the Norwegian Institute of Public Health. The programme, which is associated with the Global Health Security Agenda, is being carried out in collaboration with partner institutions in Ghana, Malawi, Moldova and Palestine. The objective is to improve health preparedness and to build capacity in detecting and managing crises and disease outbreaks, on a daily basis as well as during emergencies. For more information on the project, see http://www.fhi.no/eway/default.aspx?pid=240&trg=MainContent_6898&Main_6664=6898:0:25,8158:1:0:0:::0:0&MainContent_6898=6706:0:25,8823:1:0:0:::0:0

(d) Since the Seventh Review Conference of the BTWC, Norway has supported a number of projects to strengthen the capacity of developing countries to participate in multilateral processes and to implement their commitments related to

controlling and eliminating weapons of mass destruction. Norway's support for projects of this kind has totalled NOK 38.8 million (around USD 5.7 million). This funding has been channelled through partners such as the United Nations Institute for Disarmament (UNIDIR), the United Nations Office for Disarmament Affairs (UNODA), the International Law and Policy Institute (ILPI), PIR Center Moscow and the BTWC Implementation Support Unit.

(e) Norway has also supported a project to strengthen Africa's regional capacity for diagnosis of emerging or re-emerging zoonotic diseases, including Ebola Virus Disease (EVD), and establishing early warning systems. The project was implemented by the International Atomic Energy Agency (IAEA).

(f) Norway has established guidelines to limit the risks of proliferation and terrorism involving biological weapons by controlling tangible and intangible transfers that could contribute to BW activities by states or non-state actors, consistent with Article III of the Biological Weapons Convention. In accordance with Article X of the Biological Weapons Convention, these Guidelines are not intended to impede biological trade or international cooperation for peaceful purposes. The guidelines form the basis for controlling transfers of materials, equipment, technology and software that could contribute to BW activities to any destination beyond the Government's national jurisdiction or control. Norway sees export licensing as a vital means of ensuring that the legitimate trade in biological agents and related equipment can proceed unfettered. Careful regulation of potentially sensitive exports helps to reduce the risk that companies will unwittingly export products for use in BW programmes, thereby incurring severe penalties. This gives companies greater confidence to trade in products that have the potential to be used in the production of BW. Licensing measures have a minimal impact on the total trade in biological agents and dual-use items and equipment. Export licences deter proliferation by increasing the visibility of trade in relevant materials, and provide authority to stop a sale if the product concerned is likely to contribute to a BW programme. The licensing measures only affect sales to a small number of countries where there is evidence of an interest in developing or maintaining a BW capacity or of a risk of diversion to terrorists groups. The activities are limited to non-proliferation measures, and are not intended to hinder legitimate economic development in other countries.

(g) Over the past 15 years, Norway has played a leading role in international efforts to promote global health, by making considerable financial investments and engaging in political and technical work. The Norwegian Government has over the past five years allocated approximately NOK 4-4.5 billion each year to global health efforts. These efforts have been aligned with the Millennium Development Goals, and are now aligned with the Sustainable Development Goals. Priorities have been maternal and child health, and the fight against AIDS, tuberculosis, malaria and other infectious diseases. Child mortality has been reduced by almost 50% in recent years. One important reason for this is the significant progress made in fighting HIV/AIDS, malaria and tuberculosis.

274. GAVI (the Vaccine Alliance), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Global Financing Facility in support of Every Woman Every Child are the main channels for the Norwegian Government's global health efforts. In addition, Norway continues to be among the biggest donors to WHO, UNAIDS, UNFPA, UNITAID and UNICEF.

275. It has become increasingly clear that weaknesses in national health systems also pose a significant threat to global health security. The Ebola outbreak was an important wake-up call, demonstrating major deficiencies in global preparedness and capacity to

handle health crises. Norway made a significant contribution to fighting the outbreak, providing NOK 500 million in funding, and sent 110 health workers to West Africa. Norway has also played a leading role the work to develop an Ebola vaccine. In the aftermath of the outbreak, Norwegian Prime Minister Erna Solberg, together with German Chancellor Angela Merkel and Ghanaian President John Dramani Mahama, advised UN Secretary-General Ban Ki-moon to establish a high-level panel to strengthen the global response to health crises. The high-level panel's report was published in January 2016. Norway will actively support the implementation of the Panel's 26 recommendations by supporting the newly-established Global Health Crises Task Force under the UN Secretary-General. Norway has also taken a lead role in establishing the new Coalition for Epidemic Preparedness Innovation, (CEPI), which aims to promote research and the development of new vaccines to stop outbreaks at an early stage with a view to preventing pandemics.

Qatar

276. With reference to preparations currently underway for the Eighth Review Conference of the Biological Weapons Convention, which is due to be held in Geneva from 7 to 25 November 2016, and in response to a request from the Implementation Support Unit for States parties to contribute information on their compliance with all their obligations under the Convention and on the implementation of articles 7 and 10 of the Convention, the information requested is given below.

277. Qatar was one of the first States to sign the Biological Weapons Convention. It issued the instrument of ratification on 17 March 1975 and the Convention was ratified pursuant to Royal Decree No. 32 of 2001. Qatar has also acceded to other disarmament treaties, which promote international peace and security.

278. Qatar believes in the importance of cooperation with the international community in the eradication of weapons of mass destruction and fulfils its own obligations under relevant treaties. In that context, Qatar established the National Committee for the Prohibition of Weapons pursuant to Decree of the Council of Ministers No. 26 of 2004, as amended by Decree No. 45 of 2007. The body is a standing committee of the Ministry of Defence and deals with all matters relating to international disarmament treaties.

279. In the face of the threat that biological weapons pose to national, regional and international security, the National Committee for the Prohibition of Weapons acted promptly to ensure that the Convention became operational at the national level. Its efforts resulted in Biological Weapons Act No. 4 of 2016, which brought the Convention into effect in accordance with article 4 of the Convention itself. Qatar fulfils its own obligations in the implementation of the Convention and duly submits the annual questionnaire of the Implementation Support Unit, as part of the confidence-building measures decreed by the five-yearly review conferences.

280. The National Committee for the Prohibition of Weapons, as the point of contact between Qatar and international disarmament organizations, seeks to implement those international resolutions that encourage States to set up programmes to raise awareness about disarmament treaties. The annual schedule of the National Committee for the Prohibition of Weapons includes provision for training courses and specialized awareness-raising workshops in which biological weapons and the Biological Weapons Convention feature prominently. The courses and workshops also cover other subjects such as biological security and safety and the moral questions biologists have to face. The workshops are attended by doctors, laboratory technicians, and officials and inspectors from the customs service, as well as by officers from the various branches of the armed forces and ministries of State, and representatives of the industrial sector. The aim is to

inform society and educate people about the dangers of biological weapons and how to deal with them.

281. The National Committee for the Prohibition of Weapons also works to raise awareness about the dangers of such weapons and the dual use of biological materials, organizing conferences and workshops to inform all relevant groups within society. This includes lectures on the dangers of biological weapons in annual awareness-raising workshops for high-school and university students.

282. As part of those efforts, the National Committee for the Prohibition of Weapons awards annual motivational prizes to high-school and university students for conducting research projects on disarmament treaties and for designing posters to raise awareness about weapons of mass destruction and internationally prohibited weapons;

283. The National Committee for the Prohibition of Weapons has prepared some concise information about weapons of mass destruction, including biological weapons, which will be incorporated into high-school curricula in Qatar.

284. A number of informative articles about disarmament, the history of biological wars, biological warfare and biological terrorism have been posted at the following website: www.ncpw.org.qa. Furthermore, a booklet on military operations other than war, which was published in 2014 and provides detailed information about treaties regulating weapons of mass destruction and relevant organizations, including the Biological Weapons Convention, has been distributed to the various units of the armed forces, ministries of State and high schools.

285. The Doha regional centre for training on treaties concerning weapons of mass destruction opened in November 2012 to provide training at all levels: national, regional and international. It is the first institution of its kind in the Middle East and Asia and its purpose is to develop capacity-building programmes and to promote the institutions that implement the country's international obligations in the field of security and non-proliferation.

Republic of Moldova

286. The Republic of Moldova has accepted all relevant arms control obligations of the former Soviet Union included those under the Biological Weapons Convention, signed on 10th April 1972. The Republic of Moldova acceded to the provisions of the Biological Weapons Convention on 5th December 2004, when the Parliament of the Republic of Moldova adopted the National Law No.360-XV, which entered into force on 28 January 2005, with the following reservation: "Until the full re-establishment of the territorial integrity of the Republic of Moldova, the provisions of the Convention shall be applied only on the territory effectively controlled by the authorities of the Republic of Moldova".

287. The Ministry of Defense of the Republic of Moldova is the national authorities for coordinating the domestic implementation of the Convention, according with Article 2 of the Law No.360-XV of 5 December 2004.

288. A National Point of Contact from the Ministry of Defense of the Republic of Moldova was nominated for communicating with other States Parties to the Convention and relevant international organizations, as well with national stakeholders.

A. Article I

289. The Republic of Moldova has never developed, produced, stockpiled or otherwise acquired or retained:

(a) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

290. The Republic of Moldova has never had any offensive biological research, development or production programs, nor has ever obtained biological weapons through transfer, and, accordingly, has had no need to destroy or to divert to peaceful purposes any biological weapons, as required under the provisions of this Article.

C. Article III

291. The Republic of Moldova complies fully with the undertaking not to transfer to any recipient whatsoever, directly or indirectly, and in any way to assist, encourage, or induce any state, group of states or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

292. The Republic of Moldova continues to fulfill its obligations through national legislation and administrative arrangements and guidelines.

293. The Republic of Moldova's national reports to the UNSC 1540 Committee contains information on the Moldavian efforts to prevent transfers of prohibited agents and equipment (http://www.un.org/en/sc/1540/national-implementation/pdf/RepublicOf MoldovaReport16jan08.pdf and https://documents-dds-ny.un.org/doc/UNDOC/GEN/ N13/297/34/PDF/ N1329734.pdf?OpenElement)

D. Article IV

294. In accordance with Article IV, the Republic of Moldova has taken the 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.

295. Such measures apply to the territory effectively controlled by the authorities of the Republic of Moldova, except Transnistrian region, which is not under the control of the constitutional authority of the Republic of Moldova.

296. A compilation of all relevant national legislation that is regularly updated is available online (http://www.vertic.org/pages/homepage/programmes/national-imple mentation-measures/biological-weapons-and-materials/bwc-legislation-database/m.php).

E. Article V

297. The Republic of Moldova supports fully the decisions of States Parties recorded in the Final Declaration of the Review Conferences with regard to consultation and co-operation mechanisms.

298. The Republic of Moldova has participated annually in the information exchange through the Confidence Building Measures, via the Implementation Support Unit (ISU) within the UN Office for Disarmament Affairs.

299. Since 2011, the CBM Returns are available in the public section of the United Nations Office for Disarmament Affairs web-page. Last CBM Return covering 2015 year is available on http://www.unog.ch/80256EDD006B8954/(httpAssets)/5F9159669398A403C1257F9B00437CFE/$file/BWC_CBM_2016_Moldova.pdf).

300. The Republic of Moldova remains committed to a strengthening and efficient use of the CBMs.

301. With a view to enhance the confidence building through active transparency; the Republic of Moldova invited in 2011 the Geneva disarmament community to visit the high containment facility (BSL3) of the National Center for Public Health of the Republic of Moldova.

F. Article VI

302. The Republic of Moldova has not lodged any complaints with the Security Council regarding any other States Parties acting in breach of obligations under the provisions of the Article I or Article II of the BTWC.

G. Article VII

303. No State Party has requested assistance from the Republic of Moldova under Article VII, nor has the Republic of Moldova invoked the provision of Article VII to receive assistance.

H. Article VIII

304. The Republic of Moldova ratified the 1925 Geneva Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare on 04 November 2010 (http://disarmament.un.org/treaties/s/republicofmoldova).

I. Article IX

305. The Republic of Moldova ratified the Chemical Weapons Convention (CWC) on 08 July 1996 (https://www.opcw.org/about-opcw/member-states/member-states-by-region/eastern-europe/member-state-moldova/ or http://disarmament.un.org/treaties/s/republicofmoldova).

306. A National Authority has been established under the lead of the Ministry of Economy of the Republic of Moldova, according with provision of the Law No.358 of 05 November 2004 on implementation of the CWC and Law No. 1163 of 26 July 2000 on control of export, re-export, import and transit of strategic goods.

J. Article XII

307. The Republic of Moldova is fully committed to continue to strengthen the implementation of the Convention.

Russian Federation

308. The Russian Federation reaffirms its commitment to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (referred to below as the Convention) and fully and unswervingly complies with its obligations under the Convention. One of the main priorities of Russian State policy is to strengthen the Convention and comply with international obligations regarding the prohibition and non-proliferation of biological and toxin weapons.

309. The Russian Federation considers that the Convention and the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, the latter signed in Geneva on 17 June 1925 (referred to below as the 1925 Geneva Protocol), are complementary international instruments for the prohibition and non-proliferation of biological and toxin weapons. In accordance with constitutional procedures, the necessary national measures have been taken in the Russian Federation to comply with these instruments.

310. The Russian Federation does not carry out activities incompatible with the objectives and provisions of Article I of the Convention.

311. The Russian Federation does not develop, produce, stockpile, acquire or retain:

(a) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

312. Article II of the Convention is therefore not applicable to the Russian Federation.

313. The Russian Federation has never transferred such material to any recipient whatsoever, directly or indirectly, nor has it in any way assisted, encouraged or induced any State, group of States, international organization or non-State entity to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

314. A system of export controls in line with international standards and regulations has been established and is in operation in the Russian Federation. This system is constantly being improved as new challenges and threats to humanity emerge. Legislation, regulations and export/import activities ensure full compliance with the obligations of the Russian Federation under Article III of the Convention.

315. A list of controlled goods, including biological agents, toxins, equipment and technologies, is approved by presidential decree. In order to defend national interests and ensure compliance with obligations stemming from the Convention, the procedure for export controls on products for biological use is governed by federal laws, government decisions and other legal enactments. Foreign trade involving controlled goods and technologies (including intangible transfers) is subject to licensing.

316. Non-observance of the requirements of Russian legislation relating to foreign trade (illegal export or transfer, failure to make a customs declaration or the submission of an invalid declaration, or the illegal provision of services relating to raw materials, other materials, equipment or technologies or of scientific or technical information) is both a criminal and administrative offence.

317. In accordance with its constitutional procedures, the Russian Federation has adopted and implemented (Article IV of the Convention) the necessary national 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.

318. A legislative and regulatory framework has been established to ensure compliance with the obligation to prohibit biological and toxin weapons. There is a designated national authority to monitor compliance with the Convention (the Ministry of Industry and Trade).

319. Federal laws, government decisions and other enactments establish safety measures for activities involving various biological agents and toxins and regulate the procedure for issuing authorizations to work with microorganisms and toxins, for accounting for them and for their storage, transport and transfer.

320. A licensing system for activities related to the use of infectious disease pathogens and a State registry for genetic engineering activities have been established. Pursuant to the Criminal Code, violation of the obligations stemming from the Convention is punishable by a prison sentence of between 5 and 10 years, and the use of prohibited substances is punishable by a sentence of between 10 and 20 years. The Criminal and Administrative Codes set out penalties for violation of the established rules on working with pathogenic microorganisms and toxins.

321. Measures to prevent the use of biological agents and toxins for terrorism or other criminal purposes have been adopted and are being improved.

322. The Russian Federation is open to consultation and cooperation with other States parties to the Convention to solve any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Between 2012 and 2016, the Russian Federation, as a Depositary of the Convention, received no communications from any States parties expressing concerns about compliance with the obligations under the Convention. Such communications would have had to be submitted in accordance with the procedures agreed upon at the Second and Third Review Conferences (Article V of the Convention).

323. The Russian Federation is in full compliance with the recommendations and resolutions of the review conferences of the Convention. Pursuant to the decisions taken at the Second, Third and Seventh Review Conferences, the Russian Federation, as part of confidence-building measures, presented the United Nations with information on facilities and biological activities in the established format by 15 April of every year between 2012 and 2016. We consider that the presentation of such information by all States parties to the Convention is one of the main factors in strengthening the Convention.

324. The Russian Federation remains committed to the need to develop and adopt a legally binding international mechanism for monitoring the Convention. In 2015, in the context of the meetings of experts and representatives of States parties, the Russian Federation, jointly with Armenia, Belarus and China, distributed a discussion paper, Strengthening the Convention, which included a draft decision of the Eighth Review Conference on the organization of new international negotiations to elaborate a legally binding instrument to develop the provisions of the Convention.

325. Proposals were also submitted for the adoption of decisions of the Eighth Review Conference on the establishment, in the framework of the Convention, of a scientific advisory committee to examine developments in the fields of science and technology related to the Convention and on the establishment, under the aegis of the Convention, of mobile medical and biological units to provide assistance in the event of a biological weapons attack.

326. The Russian Federation is in full compliance with the requirements of Security Council resolution 1540 (2004). The Security Council Committee established pursuant to that resolution is provided with information on the implementation of the measures called for by the resolution. The Russian Federation participates in consultations, workshops and meetings on its implementation.

327. The Russian Federation is prepared to cooperate in carrying out investigations initiated by the United Nations Security Council under Article VI of the Convention, on the basis of substantiated complaints lodged by States parties of breaches by other States of their obligations under the Convention or the 1925 Geneva Protocol.

328. The Russian Federation undertakes to provide or support assistance to any Party to the Convention, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention (Article VII of the Convention).

329. The Russian Federation is a signatory to the 1925 Geneva Protocol, maintains no reservations to that instrument and fully meets its requirements.

330. The Russian Federation is concerned that some States, among them States parties to the Convention, maintain reservations made at the time of their ratification of the 1925 Geneva Protocol and calls upon all States to withdraw such reservations without delay (Article VIII of the Convention).

331. The Russian Federation complies with its obligations under the Convention and considers Article X of the Convention to be an important factor in joint action by States parties to combat dangerous infectious diseases, whether they occur naturally or result from the intentional use of biological agents and toxins.

332. The Russian Federation has the resources and methods to combat infectious diseases of people, animals and plants. It actively cooperates with many States and international organizations in addressing problems in this field.

333. The scientific and technical activities of the Russian Federation in the field of biology and biotechnology are fully open to the international community, and Russian scientific institutions cooperate actively with scientific and technical centres in other States. Evidence of this cooperation includes the existence of many collaborative scientific programmes, the expansion of scientific networks, the openness of Russian scientific and biological laboratories to foreign specialists, and a large number of joint publications with foreign scientists in Russian and foreign scientific journals.

334. Addressing the challenges of combating infectious diseases remains a priority of the Russian Federation in terms of international cooperation in intergovernmental forums and organizations, including the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE), the Commonwealth of Independent States (CIS), the Shanghai Cooperation Organization (SCO), the Brazil, Russian Federation, India, China and South Africa (BRICS) group and other organizations. The Russian Federation has actively participated and continues to participate in the provision of practical assistance to other countries in combating dangerous infectious diseases. One example of such assistance is the work done by the Russian Federation to eliminate the outbreak of Ebola virus disease in West Africa.

335. To exchange the latest scientific knowledge, the Russian Federation has held international seminars and conferences on various aspects of biology and biotechnology in the period 2012-2016. Foreign specialists have received training in biosafety, veterinary epidemiology, and the diagnosis, prevention and control of dangerous infectious diseases.

336. Technical support has been provided to States that requested assistance in conducting foreign trade activities with microorganisms, toxins, equipment and technologies included on the lists of controlled goods. Strains of infectious disease pathogens have been exchanged, with due consideration for the requirements of Article III of the Convention and the national procedures applicable to foreign trade operations.

337. The Russian Federation advocates the strengthening of international cooperation and is prepared to provide assistance to other States as they combat dangerous infectious diseases, including through the conclusion of bilateral agreements and in compliance with international instruments.

338. The Russian Federation believes that there is currently no reason to introduce amendments to the text of the Convention (Article XI of the Convention).

339. The Russian Federation considers that the review conferences of the Convention are important international events for the strengthening of the instrument, and that they make it possible to assess the status of compliance with obligations stemming from the Convention and to identify further steps to strengthen the Convention and implement its provisions. We believe that the next review conference should be scheduled for 2021 (Article XII of the Convention).

340. The Russian Federation expresses satisfaction that not a single State party to the Convention has given notice of its intention to withdraw for any reason and hopes that this will not happen in the future (Article XIII of the Convention).

341. The Russian Federation calls for the Convention to be ratified by all States and welcomes those that became parties to it in the period 2012-2016. The Russian Federation will continue to assist States parties in successful implementation of the Convention and the decisions of its review conferences (Article XIV of the Convention).

342. We call on States that have not yet become parties to the Convention to accede to it as soon as possible.

343. The Russian Federation is in full compliance with its obligations as a Depositary of the Convention (Article XV of the Convention).

Serbia

344. The Republic of Serbia ratified the Convention in 1972, fully supporting BWC universalization, strict implementation and further strengthening of the Convention. The Republic of Serbia is firmly committed to fulfilling all of its obligations under BWC.

345. The Republic of Serbia participates in the exchange of information through Confidence Building Measures and regular submission of its national annual reports. In accordance with the Sixth Review Conference, we appointed the National Point of Contact for the BWC.

346. The Parliament of Serbia adopted in 2009 (Official Gazette of the Republic of Serbia – International Treaties No. 42/09 of 2 June 2009) the Law on the withdrawal of the reservation to the 1925 Geneva Protocol, i.e. the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare.

347. With the aim to improve the national legislation, the Parliament of the Republic of Serbia adopted in the year 2011 the Law on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction (Official Gazette of the Republic of Serbia No 87/11 of 21 November 2011). In this Law we reiterated again our commitments to full implementation of the obligations under the BTCW.

348. Besides the Law on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction, the following laws, regulatory/legislative instruments, guidelines and recommendations directly or indirectly have a bearing on the biosafety and biosecurity implementation: Law on Health Protection, 2005, as amended in 2010, 2011, 2012, and 2013 (Official Gazette of the Republic of Serbia nos. 107/2005, 72/2009, 88/2010, 99/2010, 57/2011, 119/2012 and 45/2013), Law on Public Health (Official Gazette of the Republic of Serbia no.72/2009), Law on the Protection of the Population from Contagious Diseases (Official Gazette of the Republic of Serbia no 125/2004), Law on Sanitary Surveillance (Official Gazette of the Republic of Serbia no 125/2004), Law on Chemicals (Official Gazette of the Republic of Serbia nos. 36/2009, 88/2010, 92/2011 and 93/2012), Law on Emergency Situations (Official Gazette of the Republic of Serbia nos. 111/09, 92/2011 and 93/2012), Law on Environmental Protection (Official Gazette of the Republic of Serbia nos. 135/2004, 36/2009 and 72/2009), Law on Waste Management (Official Gazette of the Republic of Serbia nos. 36/2009 and 88/2010), Law on Plant Health (Official Gazette of the Republic of Serbia no. 41/2009), Law on Veterinary (Official Gazette of the Republic of Serbia nos. 91/2005 and 30/2010), Law on Biocide products (Official Gazette of the Republic of Serbia nos. 36/2009, 88/2010 and 92/2011), Law on ratification of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Rotterdam 1998 (Official Gazette of the Republic of Serbia no. 38/2009), Law on Genetically Modified Organisms (GMO) (Official Gazette of the Republic of Serbia no. 41/2009), Regulations on Contained use of Genetically Modified Organisms (Official Gazette of the Federal Republic of Yugoslavia no. 62/2002, 15.11.2002, modified in the Official Gazette of Serbia and Montenegro no. 1/2003 and the Official Gazette of the Republic of Serbia no. 69/2012), Law on Health Protection (A list of about 70 different types of dangerous infections exists, which must be reported to the National Public Health Institute) (Official Gazette of the Republic of Serbia nos. 107/2005, 72/2009, 88/2010,99/2010, 57/2011, 119/2010 and 45/2013), Law on the transportation of dangerous goods and its connected by-law and sub-legal acts (Official Gazette of the Republic of Serbia no 88/2010), Law on State Border Protection (Official Gazette of the Republic of Serbia no. 97/2008), Law on the export and import of dual-use goods (Official Gazette of the Republic of Serbia no 95/2013), National Control List of Dual-Use Goods (Republic of Serbia regularly harmonizes/updates its control list with the latest EU "LIST OF DUAL-USE ITEMS AND TECHNOLOGY"), Law on the Export and Import of Weapons and Military Equipment (Official Gazette of the Republic of Serbia no. 107/2014), National Control List of Weapons and Military Equipment (Republic of Serbia regularly harmonizes/updates its control list with the EU Military Control List), Rulebook on preventive measures for safe and healthy work during exposure to biological hazards (Official Gazette of the Republic of Serbia no.96/2010 - Annex 3 contains “Classification of biological harmfulness” with lists of bacteria and similar organisms, viruses and fungi which can cause harm to humans), Rules of immunization and methods of protecting by medicines (Official Gazette of the Republic of Serbia nos. 11/2006, 25/2013, 63/2013, 99/2013, 118/2013 and 65/2014), Laboratory Biosafety Manual, 3rd ed., WHO 2004.

Seychelles

349. Seychelles has never in any circumstances developed, produce, stockpile or otherwise acquire or retain (a) microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, (b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

350. In view of Seychelles' status in regards to Article I, there have been no agents, toxins, weapons, equipment or means of delivery in its possession or under its jurisdiction or control to destroy or to divert to peaceful purposes.

351. Seychelles has not transferred to any recipient whatsoever, directly or indirectly, and in addition not in any way assists, encourages, or induces any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I.

352. Although there is no specific legislation yet nationalizing the BWC in Seychelles' laws, various other legislations exist which contributes to Seychelles' compliance with its obligations under the BWC.

353. This includes, but is not limited to, the:

(a) Environment Protection Act of 1995

(b) Pesticides Control Act of 1996

(c) Occupational Safety and Health Decree of 1978

(d) Food Act of 1990 and 2014

(e) Manufacture and Export of Produce (Regulation) Act of 1963

(f) Firearms and Ammunition Act of 1973

(g) Anti-Personnel Mines (Prohibition) Act of 2004

(h) Explosives Act of 1966

(i) Customs Management Act of 2011

354. Seychelles has also signed, ratified or acceded to various international treaties such as the Chemical Weapons Convention, the Convention on Cluster Munitions and most recently the Arms Trade Treaty.

355. In addition, Seychelles is also a party to different organizations including the Organization for the Prohibition of Chemical Weapons, the International Atomic Energy Agency, and is also an active participant in the CBRN Centres of Excellence initiative of the EU.

356. A CBRN Risk mitigation National Action Plan is currently being produced and near completion.

Slovakia

357. The former Czechoslovakia signed the Biological and Toxin Weapon Convention on 10 April 1972 and ratified Convention on 30 April 1973. After the split of Czechoslovakia in January 1993, the Slovak Republic ratified Biological Weapon Convention on 17 May 1993.

A. Article I

358. The Slovak Republic has never developed, produced, stockpiled or otherwise acquired or retained:

(a) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

359. The Slovak Republic has never had agents, toxins, weapons, equipment and means of delivery specified in Article I the Convention. Therefore provisions of Article II did not impose any obligation upon the Slovak Republic.

C. Article III

360. The Slovak Republic adheres to the obligation of Article III. Export of dual use items is regulated through national legislation [Decree of the National Council of the Slovak Republic No. 39 of 2 February 2011 on Dual –use Items] which is based on EU legislation [Council Regulation No. 428/2009 setting up a Community regime for the control of exports of dual use items and technology].

D. Article IV

361. The Slovak Republic adheres to the obligation of Article IV. The obligations of Article IV have been fully incorporated into Slovak legal system [Decree of the National Council of the Slovak Republic No. 217 of 28 March 2007 on Prohibition of Biological Weapon. During 2007 was amended Decree No. 644/2007 Coll. implementing the Act No. 217/2007Coll. on Prohibition of Biological Weapon].

E. Article V

362. The Slovak Republic has not invoked Article V. The Slovak Republic has never participated in consultations under Article V.

363. The Slovak Republic has regularly participated in the information exchange through the Confidence Building Measures (CBMs).

F. Article VI

364. The Slovak Republic has not lodged any complaints with the Security Council of the United Nations regarding any other States Parties acting in breach of obligations under the provisions of the Convention.

G. Article VII

365. The Slovak Republic has not been requested to provide or support assistance, in accordance with the United Nations Charter, to any State Parties to the Convention.

H. Article VIII

366. The former Czechoslovakia has ratified the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (signed at Geneva on 17 June 1925) on 16 August 1938.

I. Article IX

367. The Slovak Republic has signed the Convention on the prohibition of the Development, production, Stockpiling and Use of Chemical Weapons and on their Destruction on 14. January 1993 and ratified it on 17. October 1995.

J. Article X

368. The Slovak Republic has encouraged both bilateral and multilateral cooperation with the other State Parties to the Biological Weapon Convention or international organization to facilitate the exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.

369. During the last year the cooperation with the Robert Koch Institute (RKI) in Berlin (Germany) was initiated, related to the further molecular biology based analysis in a suspected case of botulism.

Switzerland

370. In line with the requested background information for 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, in particular the request for background information on compliance by all States Parties with all their obligations under the Convention as contained in document BWC/CONF.VIII/PC/2, Switzerland submits the following report to States Parties.

371. Switzerland is in full compliance with its obligations under the Convention, and offers the following information.

A. Articles I and II

372. Switzerland has never developed, produced, stockpiled or otherwise acquired or retained:

(i) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(ii) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[1]

373. Switzerland is party to the Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, adopted in Geneva on 17 June 1925 ("Geneva Protocol"), without any reservations.

374. International law, when it enters into force for Switzerland, automatically acquires validity and binding force under the Swiss legal system and does not require a constituting act of national law, adoption or transformation to give the international norm validity under the domestic system ("monism"):

- RS 0.515.07: Convention du 10 avril 1972 sur l'interdiction de la mise au point, de la fabrication et du stockage des armes bactériologiques (biologiques) ou à toxines et sur leur destruction http://www.admin.ch/opc/fr/classified-compilation/19720074.
- RS 0.515.105: Protocole du 17 juin 1925 concernant la prohibition d'emploi à la guerre de gaz asphyxiants, toxiques ou similaires et de moyens bactériologiques http://www.admin.ch/opc/fr/classified-compilation/19250020.

375. The prohibitions contained in Article I of the BWC as well as in the Geneva Protocol of 1925 are essentially prescribed and penalized in the three following Federal Acts:[2]

376. The Federal Act on War Material (RS 514.51: Loi fédérale du 13 décembre 1996 sur le materiel de guerre; http://www.admin.ch/opc/fr/classified-compilation/19960753) prohibits the possession, development, production, brokerage, acquisition, transfer, import, export, transit and stockpiling of nuclear, biological or chemical weapons under Article 7. It also prohibits the instigation of, or assistance to, any person to carry out an act mentioned above. The prohibition also applies to acts carried out abroad, irrespective of the law at the place of commission, if the acts violate international law agreements to which Switzerland is a party, and if the perpetrator is Swiss or is domiciled in Switzerland. Article 34 penalizes these offences.

377. The Swiss Criminal Code (RS 311.0: Code pénal suisse du 21 décembre 1937; http://www.admin.ch/opc/fr/classified-compilation/19370083) prohibits and penalizes felonies and misdemeanours against public health, including by causing danger by means of genetically modified or pathogenic organisms, the transmission of human diseases, the transmission of an epizootic disease, the propagation of a parasite or micro-organism that constitutes a danger to agriculture or forestry, and the contamination of drinking water (Articles 230bis-236). In the context of international and non-international armed conflicts, the use of biological or chemical weapons, including poisonous or asphyxiating gases, substances and liquids constitutes a war crime under Article 264h.

[1] On the latter point, Switzerland retains the following reservation: "Owing to the fact that the Convention also applies to weapons, equipment or means of delivery designed to use such biological agents or toxins, the delimitation of its scope of application can cause difficulties since there are scarcely any weapons, equipment or means of delivery peculiar to such use; therefore, Switzerland reserves the right to decide for itself what auxiliary means fall within that definition."

[2] Further information on national implementing legislation is provided under Article IV below. Titles and explanations in English are unofficial translations that are provided for information purposes only and have no legal force. To access legal documents, please consult the Swiss federal legislation in French (cf. provided URLs), German or Italian.

378. The Military Criminal Code (RS 321.0: Code pénal militaire du 13 juin 1927; http://www.admin.ch/opc/fr/classified-compilation/19270018) prohibits and penalizes the transmission of human diseases, the transmission of an epizootic disease, and the contamination of drinking water (Articles 167-169). In the context of international and non-international armed conflicts, the use of biological or chemical weapons, including poisonous or asphyxiating gases, substances and liquids constitutes a war crime under Article 112d.

B. Article III

379. Switzerland has extensive legislation in effect that covers exports of dual-use items and war materials and prohibits transfers of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

380. The majority of the relevant provisions are included in the Federal Act on the Control of Dual-Use Goods, Specific Military Goods and Strategic Goods (Goods Control Act; SR 946.202). The corresponding Ordinance on the Control of Dual-use Goods, Specific Military Goods and Strategic Goods (Goods Control Ordinance; SR 946.202.1) contains, in its annexes 2 and 3, the complete control lists of the four international export control regimes.

381. The catch-all clause contained in article 3 paragraph 4 of the Goods Control Ordinance is used extensively by the Swiss authorities. This clause states that planned exports of goods that are not listed in the annexes of the Ordinance are denied if the exporter or the Swiss authorities know or have reason to believe that the goods are intended for the development, production or use of nuclear, biological or chemical weapons or of related delivery systems. The legislation also requires exporters to apply for an export licence for the goods listed in the annexes to the Ordinance. Exports are denied if they might be contributing to WMD or missile programmes or if they violate international agreements or sanctions. They are further denied if there is reason to believe that the export would support terrorist groups or organized crime.

382. Individuals or legal entities who apply for an export licence have to provide all information to the authorities and submit the necessary documentation for a comprehensive evaluation and control. The requested documentation includes company profiles, confirmation of orders, sales contracts or customer bills, exporters' end-use statements, import certificates of the country of destination and consignees' end-use statements. Trading companies will generally not receive deliveries unless they can provide a viable statement of end-use by an industrial company. Switzerland uses all available sources to establish the legitimacy of a potential end-user. In particular, intelligence assessments and information from partners and other members of export control regimes are taken into account. In addition, the risk report and other open-source material is considered. Switzerland also requires a statement of end-use from the exporter detailing the latter's knowledge of the end-user. In cases where fixed equipment is installed, the export control authorities may require the exporter to provide an installation report. End-user statements are routinely required. If it cannot be determined, based on all available information, that the end-user conducts legitimate business, an export will be called into question and subsequently denied.

383. Pursuant to article 14 of the Goods Control Act, a prison sentence or a fine of up to 1 million Swiss francs shall be imposed on anyone who fails to comply with the legislation governing transfers of dual-use goods. End-use statements contain a clause prohibiting the re-export of goods to third countries without the consent of the Swiss export control authorities. According to article 14 of the Goods Control Act, a prison sentence or a fine of up to 1 million Swiss francs shall be imposed on anyone who "has goods delivered or

passed on to or brokered for a person other than the end purchaser or final destination stated in the licence".

384. Controlled dual-use goods may not be transported through Swiss customs territory if the shipment is not proven to be in accordance with the relevant regulations of the country of origin. If there is reason to believe that the transit violates international control measures adhered to by Switzerland, the transit is prohibited.

C. Article IV

385. In accordance with Article IV, Switzerland has taken the 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 territory and under its jurisdiction respectively.

386. In addition to the conventions and federal legislation mentioned above in relation to Articles I and II, the current status of the further implementation of the Convention into the Swiss legal system is as follows:[3]

- Federal Constitution of the Swiss Confederation (RS 101 Constitution fédérale de la Confédération suisse du 18 avril 1999) http://www.admin.ch/ opc/fr/classified-compilation/19995395
- Federal Act on Measures Ensuring Homeland Security (RS 120 Loi fédérale du 21 mars 1997 instituant des mesures visant au maintien de la sûreté intérieure) http://www.admin.ch/opc/fr/classified-compilation/19970117
- Ordinance on the Intelligence Service of the Confederation (RS 121.1 Ordonnance du 4 décembre 2009 sur le Service de renseignement de la Confédération) http://www.admin.ch/opc/fr/classified-compilation/20091819
- Ordinance on Information Systems of the Intelligence Service of the Confederation (RS 121.2 Ordonnance du 8 octobre 2014 sur les systèmes d'information du Service de renseignement de la Confédération) http://www.admin.ch/opc/fr/classified-compilation/20140980
- Federal Act on the Prohibition of « al-Qaeda » and « Islamic State » Groups and related Organizations (RS 122 Loi fédérale du 12 décembre 2014 interdisant les groupes « Al-Qaïda » et « État islamique » et les organisations apparentées) http://www.admin.ch/opc/fr/classified-compilation/20142993
- Ordinance on the Federal Expert Commission for Biosafety (RS 172.327.8 Ordonnance du 20 novembre 1996 sur la Commission fédérale d'experts pour la sécurité biologique) http://www.admin.ch/opc/fr/classified-compilation/19960584 Establishes the roles of the Federal Commission of Experts for Biological Security to ensure the protection of the Swiss population against transmissible diseases, the health of workers, and the protection of animals and plants and their environments.
- Swiss Criminal Code (RS 311.0 Code pénal suisse du 21 décembre 1937) http://www.admin.ch/opc/fr/classified-compilation/19370083 Prohibits and penalizes felonies and misdemeanours against public health, including by causing danger by means of genetically modified or pathogenic organisms, the transmission of human diseases, the transmission of an epizootic disease, the

[3] Titles and explanations in English are unofficial translations that are provided for information purposes only and have no legal force. To access legal documents, please consult the Swiss federal legislation in French (cf. provided URLs), German or Italian.

propagation of a parasite or micro-organism that constitutes a danger to agriculture or forestry, and the contamination of drinking water (Articles 230bis-236). In the context of international and non-international armed conflicts, the use of biological or chemical weapons, including poisonous or asphyxiating gases, substances and liquids constitutes a war crime under Article 264h.

- Swiss Code of Criminal Procedure (RS 312.0 Code de procédure pénale suisse du 5 octobre 2007) http://www.admin.ch/opc/fr/classified-compilation/ 20052319
- Ordinance on the Communication of Penal Decisions Taken by Cantonal Authorities (RS 312.3 Ordonnance du 10 novembre 2004 réglant la communication des décisions pénales prises par les autorités cantonales) http://www.admin.ch/opc/fr/classified-compilation/20041752
- Military Criminal Code (RS 321.0 Code pénal militaire du 13 juin 1927) http://www.admin.ch/opc/fr/classified-compilation/19270018 Prohibits and penalizes the transmission of human diseases, the transmission of an epizootic disease, and the contamination of drinking water (Articles 167-169). In the context of international and non-international armed conflicts, the use of biological or chemical weapons, including poisonous or asphyxiating gases, substances and liquids constitutes a war crime under Article 112d.
- Federal Act on International Legal Aid in Criminal Cases (RS 351.1 Loi fédérale du 20 mars 1981 sur l'entraide internationale en matière pénale) http://www.admin.ch/opc/fr/classified-compilation/19810037
- Federal Act on Main Offices of Criminal Investigation Departments of the Confederation (RS 360 Loi fédérale du 7 octobre 1994 sur les Offices centraux de police criminelle de la Confédération) http://www.admin.ch/opc/fr/classified-compilation/19940242
- Ordinance on the Information System of the Federal Criminal Police (RS 360.2 Ordonnance du 15 octobre 2008 sur le système informatisé de la Police judiciaire fédérale) http://www.admin.ch/opc/fr/classified-compilation/20081753
- Ordinance on the National Central Bureau Interpol Bern (RS 366.1 Ordonnance du 21 juin 2013 concernant le Bureau central national Interpol Bern) http://www.admin.ch/opc/fr/classified-compilation/20130208
- Ordinance on the Coordinated Medical Service (RS 501.31 Ordonnance du 27 avril 2005 sur le Service sanitaire coordonné) http://www.admin.ch/opc/fr/classified-compilation/20041336
- Federal Act on the Army and the Military Administration (RS 510.10 Loi fédérale du 3 février 1995 sur l'armée et l'administration militaire) http://www.admin.ch/opc/fr/classified-compilation/19950010
- Ordinance on Measures Taken by the Army against Human and Animal Epidemics (RS 510.35 Ordonnance du 25 octobre 1955 concernant les mesures à prendre par l'armée contre les épidémies et épizooties) http://www.admin.ch/opc/fr/classified-compilation/19550188
- Ordinance on Domestic Disaster Management by the Army (RS 513.75 Ordonnance du 29 octobre 2003 sur l'aide militaire en cas de catastrophe dans le pays) http://www.admin.ch/opc/fr/classified-compilation/20031556
- Federal Act on War Material (RS 514.51 Loi fédérale du 13 décembre 1996 sur le materiel de guerre) http://www.admin.ch/opc/fr/classified-compilation/19960753. Prohibits the possession, development, production, brokerage, acquisition,

transfer, import, export, transit and stockpiling of nuclear, biological or chemical weapons under Article 7. It also prohibits the instigation of, or assistance to, any person to carry out an act mentioned above. The prohibition also applies to acts carried out abroad, irrespective of the law at the place of commission, if the acts violate international law agreements to which Switzerland is a party, and if the perpetrator is Swiss or is domiciled in Switzerland. Article 34 penalizes these offences.

- Ordinance on War Material (RS 514.511 Ordonnance du 25 février 1998 sur le matériel de guerre) http://www.admin.ch/opc/fr/classified-compilation/ 19980112 Regulates the initial authorisation and the specific authorisations that are required for the manufacture, the brokerage, the import, the export and the transit of war materials, as well as the conclusion of contracts to transfer incorporeal property, including know-how and the concession of related rights. Applies in Switzerland customs area, to Swiss customs warehouses and Swiss customs enclaves.
- Federal Act on the Protection of the Population and Civil Protection (RS 520.1 Loi fédérale du 4 octobre 2002 sur la protection de la population et sur la protection civile) http://www.admin.ch/opc/fr/classified-compilation/20011872
- Ordinance on the Organization of Deployments in case of NBC Incidents and Natural Incidents (RS 520.17 Ordonnance du 20 octobre 2010 sur l'organisation des interventions en cas d'événement ABC et d'événement naturel) http://www.admin.ch/opc/fr/classified-compilation/20090306
- Ordinance on the National Emergency Operations Centre (RS 520.18 Ordonnance du 17 octobre 2007 sur la Centrale nationale d'alarme) http://www.admin.ch/opc/fr/classified-compilation/20063371
- Federal Act on Customs (RS 631.0 Loi du 18 mars 2005 sur les douanes) http://www.admin.ch/opc/fr/classified-compilation/20030370
- Ordinance on Customs (RS 631.01 Ordonnance du 1er novembre 2006 sur les douanes) http://www.admin.ch/opc/fr/classified-compilation/20052713
- Ordinance on Competencies of the Federal Customs Administration in Criminal Matters (RS 631.09 Ordonnance du 4 avril 2007 réglant les compétences de l'Administration fédérale des douanes en matière pénale) http://www.admin.ch/opc/fr/classified-compilation/20070458
- Ordinance on the Transportation of Hazardous Goods on the Road (RS 741.621 Ordonnance du 29 novembre 2002 relative au transport des marchandises dangereuses par route) http://www.admin.ch/opc/fr/classified-compilation/20022136 Regulates the transport of dangerous materials by automobiles or other mediums of transport on roads open to those same vehicles.
- Ordinance on Hazardous Goods Representatives for the Transportation of Hazardous Goods on the Road, by Air or by Sea (RS 741.622 Ordonnance du 15 juin 2001 sur les conseillers à la sécurité pour le transport de marchandises dangereuses par route, par rail ou par voie navigable) http://www.admin.ch/opc/fr/classified-compilation/20001699
  Determines the appointment, tasks, training and examination of persons charged with reducing risks to people, property and the environment during transportation of hazardous goods or packaging operations, shipment or loading and unloading associated with this transport.
- Ordinance on the Transportation of Hazardous Goods by Railway and Aerial Railway (RS 742.412 Ordonnance du 31 octobre 2012 sur le transport de

marchandises dangereuses par chemin de fer et par installation à câbles) http://www.admin.ch/opc/fr/classified-compilation/20121700

- Federal Act on Surveillance of Postal Mail and Telecommunications (RS 780.1 Loi fédérale du 6 octobre 2000 sur la surveillance de la correspondance par poste et télécommunication) http://www.admin.ch/opc/fr/classified-compilation/ 20002162
- Ordinance on Surveillance of Postal Mail and Telecommunications (RS 780.11 Ordonnance du 31 octobre 2001 sur la surveillance de la correspondance par poste et télécommunication) http://www.admin.ch/opc/fr/classified-compilation/20002506
- Ordinance on the Transplantation of Organs, Tissues and Cells of Animal Origin (RS 810.213 Ordonnance du 16 mars 2007 sur la transplantation d'organes, de tissus et de cellules d'origine animale) http://www.admin.ch/opc/fr/classified-compilation/20051808
- Ordinance on Clinical Trials with Therapeutic Products (RS 810.305 Ordonnance du 20 septembre 2013 sur les essais cliniques dans le cadre de la recherche sur l'être humain) http://www.admin.ch/opc/fr/classified-compilation/20121176
- Ordinance on Pharmaceuticals (RS 812.212.21 Ordonnance du 17 octobre 2001 sur les médicaments) http://www.admin.ch/opc/fr/classified-compilation/20011787 Regulates: a. authorization of medicines on the market ready for use, b. authorization processes of surface treatment of labile blood products, c. classification criteria for categories of delivery, d. distribution restrictions, e. authorization of mail order drugs, f. market surveillance and vigilance.
- Federal Act on the Protection against Dangerous Substances and Preparations (RS 813.1 Loi fédérale du 15 décembre 2000 sur la protection contre les substances et les préparations dangereuses) http://www.admin.ch/opc/fr/ classified-compilation/19995887. Protects the lives and health of human beings from the harmful effects of substances or preparations.
- Ordinance on Good Laboratory Practice (RS 813.112.1 Ordonnance du 18 mai 2005 sur les bonnes pratiques de laboratoire) http://www.admin.ch/ opc/fr/classified-compilation/20031589 Fixes the principles of good laboratory practices, guarantees the quality of studies and regulates the verification of these requirements.
- Ordinance on Marketing and Handling Biocidal Products (RS 813.12 Ordonnance du 18 mai 2005 concernant la mise sur le marché et l'utilisation des produits biocides) http://www.admin.ch/opc/fr/classified-compilation/ 20021524. Regulates marketing of biocidal products and their active substances, particularly the various types and licensing procedures, the use of data from previous requests for the benefit of new applicants, and the classification of packaging, labelling and safety data sheets.
- Federal Act on the Protection of the Environment (RS 814.01 Loi fédérale du 7 octobre 1983 sur la protection de l'environnement) http://www.admin.ch/ opc/fr/classified-compilation/19830267
- Ordinance on the Protection against Major Accidents (RS 814.012 Ordonnance du 27 février 1991 sur la protection contre les accidents majeurs) http://www.admin.ch/opc/fr/classified-compilation/19910033 Covers activities involving the contained use of genetically modified organisms and pathogenic

organisms in laboratories, production facilities, greenhouses and premises housing animals.

- Ordinance on Waste Management (RS 814.600 Ordonnance du 4 décembre 2015 sur la limitation et l'élimination des déchets) https://www.admin.ch/ opc/fr/classified-compilation/20141858
- Federal Act on non-Human Genetic Engineering (RS 814.91 Loi fédérale du 21 mars 2003 sur l'application du génie génétique au domaine non humain) http://www.admin.ch/opc/fr/classified-compilation/19996136 Protects humans, animals and the environment against the abuse of genetic engineering, and ensures that applications of genetic engineering serve humans, animals and the environment.
- Ordinance on the Release of Organisms into the Environment (RS 814.911 Ordonnance du 10 septembre 2008 sur l'utilisation d'organismes dans l'environnement) http://www.admin.ch/opc/fr/classified-compilation/ 20062651. Protects humans, animals and the environment, as well as biodiversity and sustainable use of its components against the dangers and outrages associated with the use of organisms, their metabolites and their waste.
- Ordinance on the Contained Use of Organisms (RS 814.912 Ordonnance du 9 mai 2012 sur l'utilisation des organismes en milieu confiné). http://www.admin.ch/opc/fr/classified-compilation/20100803 Protects people and the environment and in particular communities of animals and plants and their habitats, against harmful effects or nuisances of the contained use of organisms. Contributes to the maintenance of biodiversity and soil fertility. Regulates the contained use of organisms, in particular genetically modified or pathogenic organisms.
- Ordinance on Transborder Traffic of Genetically Modified Organisms (RS 814.912.21 Ordonnance du 3 novembre 2004 sur les mouvements transfrontières des organismes génétiquement modifiés) http://www.admin.ch/opc/fr/ classified-compilation/20031535. Regulates the transborder trasnport of GMOs. Does not apply to medicines for human use which contain GMOs.
- Federal Act on Foods and Commodities (RS 817.0 Loi fédérale du 9 octobre 1992 sur les denrées alimentaires et les objets usuels) http://www.admin.ch/opc /fr/classified-compilation/19920257
- Ordinance on Foods and Commodities (RS 817.02 Ordonnance du 23 novembre 2005 sur les denrées alimentaires et les objets usuels) http://www.admin.ch /opc/fr/classified-compilation/20050153
- Ordinance on Impurities and Ingredients in Foods (RS 817.021.23 Ordonnance du DFI du 26 juin 1995 sur les substances étrangères et les composants dans les denrées alimentaires) http://www.admin.ch/opc/fr/classified-compilation/ 19950193
- Ordinance on Genetically Modified Foods (RS 817.022.51 Ordonnance du DFI du 23 novembre 2005 sur les denrées alimentaires génétiquement modifiées) http://www.admin.ch/opc/fr/classified-compilation/20050176
- Ordinance on Hygiene (RS 817.024.1 Ordonnance du DFI du 23 novembre 2005 sur l'hygiène) http://www.admin.ch/opc/fr/classified-compilation/20050160
- Ordinance on the Enforcement of the Legislation on Foods (RS 817.025.21 Ordonnance du DFI du 23 novembre 2005 sur l'exécution de la législation sur les

denrées alimentaires) http://www.admin.ch/opc/fr/classified-compilation/20050163

- Ordinance on Animal Slaughter and Meat Control (RS 817.190 Ordonnance du 23 novembre 2005 concernant l'abattage d'animaux et le contrôle des viandes) http://www.admin.ch/opc/fr/classified-compilation/20051437
- Ordinance on Animal Slaughter Hygiene (RS 817.190.1 Ordonnance du DFI du 23 novembre 2005 concernant l'hygiène lors de l'abattage d'animaux) http://www.admin.ch/opc/fr/classified-compilation/20051438
- Federal Act on the Control of Communicable Human Diseases (RS 818.101 Loi fédérale du 28 septembre 2012 sur la lutte contre les maladies transmissibles de l'homme) https://www.admin.ch/opc/fr/classified-compilation/20071012. Regulates fight against diseases transmissible to man by stating that the Confederation and the cantons take the necessary measures, including biosafety precautions, to protect human beings against pathogens including those genetically modified. Regulates identification of laboratories through permits delivered by the Swiss Institute of Therapeutic Products. Regulates the trade in pathogenic agents and requires an authorisation from every person disseminating pathogens for research or commerce. Entitles the Federal Council to regulate the transport, importation, exportation and the transit of pathogens, to limit or to ban the use of certain pathogens, to fix the conditions for persons using pathogens. Outlines the provisions for quarantine, vaccination, and disease surveillance and reporting requirements. Provides for imprisonment or fines anyone who intentionally or by negligence does not respect the prescriptions of the Federal Act.
- Ordinance on the Control of Communicable Human Diseases (RS 818.101.1 Ordonnance du 29 avril 2015 sur la lutte contre les maladies transmissibles de l'homme) https://www.admin.ch/opc/fr/classified-compilation/20133212
- Ordinance on the Declaration of Observations of Communicable Human Diseases (RS 818.101.126 Ordonnance du DFI du 1 décembre 2015 sur la déclaration d'observations en rapport avec les maladies transmissibles de l'homme) https://www.admin.ch/opc/fr/classified-compilation/20151622
- Ordinance on Microbiological Laboratories (RS 818.101.32 Ordonnance du 29 avril 2015 sur les laboratoires de microbiologie) https://www.admin.ch/opc/fr/classified-compilation/20143116
- Ordinance Relating to the Act of Labour (RS 822.114 Ordonnance 4 du 18 août 1993 relative à la loi sur le travail) http://www.admin.ch/opc/fr/classified-compilation/19930255
- Ordinance on the Protection of Workforce against Microbiological Risks (RS 832.321 Ordonnance du 25 août 1999 sur la protection des travailleurs contre les risques liés aux micro-organismes) http://www.admin.ch/opc/fr/classified-compilation/19994946 Defines micro-organisms and genetically modified micro-organisms and techniques for genetic modification. Requires the regular identification and evaluation of the risks to which workers are exposed and the notification of the "Bureau de Biotechnologie de la Confédération" by employers. Defines general security measures for the protection of the workers by employers. Covers activities involving the contained use of genetically modified organisms and pathogenic organisms in laboratories, production facilities, greenhouses and premises housing animals.
- Federal Act on Agriculture (RS 910.1 Loi fédérale du 29 avril 1998 sur l'agriculture) http://www.admin.ch/opc/fr/classified-compilation/19983407

- Ordinance on the Coordination of Controls on Agricultural Farms (RS 910.15 Ordonnance du 23 octobre 2013 sur la coordination des contrôles dans les exploitations agricoles) http://www.admin.ch/opc/fr/classified-compilation/20130217
- Ordinance on Primary Production (RS 916.020 Ordonnance du 23 novembre 2005 sur la production primaire) http://www.admin.ch/opc/fr/classified-compilation/20051718
- Ordinance on the Release of Phytopharmaceutical Products (RS 916.161 Ordonnance du 12 mai 2010 sur la mise en circulation des produits phytosanitaires) http://www.admin.ch/opc/fr/classified-compilation/20100203 Ensures that plant protection products lend themselves well in their intended use and as those are used in accordance with the requirements preventing unacceptable side effects on the health of humans, animals and the environment.
- Ordinance on Plant Protection (RS 916.20 Ordonnance du 27 octobre 2010 sur la protection des végétaux) http://www.admin.ch/opc/fr/classified-compilation/20101847. Protects plants of all sorts against the nuisances of dangerous organisms, and protects agriculture and horticulture fields from the same organisms.
- Ordinance on the Control of Milk (RS 916.351.0 Ordonnance du 20 octobre 2010 sur le contrôle du lait) http://www.admin.ch/opc/fr/classified-compilation/20100941
- Ordinance on the Milk Production Hygiene (RS 916.351.021.1 Ordonnance du DFI du 23 novembre 2005 réglant l'hygiène dans la production laitière) http://www.admin.ch/opc/fr/classified-compilation/20051436
- Federal Act on Animal Diseases (RS 916.40 Loi du 1er juillet 1966 sur les épizooties) http://www.admin.ch/opc/fr/classified-compilation/19660145
- Ordinance on the Control of Animal Diseases (RS 916.401 Ordonnance du 27 juin 1995 sur les épizooties) http://www.admin.ch/opc/fr/classified-compilation/19950206 Designates new contagious animal diseases and defines the measures of control of and the organization of the fight against animal diseases, as well as the compensation of animal keepers.
- Ordinance on the Disposal of Animal Side Products (RS 916.441.22 Ordonnance du 25 mai 2011 concernant l'élimination des sous-produits animaux) http://www.admin.ch/opc/fr/classified-compilation/20101486. Ensures that animal by-products do not endanger human and animal health and do not harm the environment. Allows as much as possible the recovery of animal by-products. Ensures that the infrastructure for the disposal of animal by-products is available.
- Ordinance on Import, Transit and Export of Animals and Animal Products Exchanged with Third Countries (RS 916.443.10 Ordonnance du 18 novembre 2015 réglant les échanges d'importation, de transit et d'exportation d'animaux et de produits animaux avec les pays tiers) https://www.admin.ch/opc/fr/classified-compilation/20151237 Regulates the import, transit and export of animals, animal by-products and animal products.
- Ordinance on Import, Transit and Export of Animals and Animal Products Exchanged with EU Member States, Iceland and Norway (RS 916.443.11 Ordonnance du 18 novembre 2015 réglant les échanges d'importation, de transit et d'exportation d'animaux et de produits animaux avec les Etats membres de l'UE, l'Islande et la Norvège) https://www.admin.ch/opc/fr/classified-

compilation/20151238 Regulates the import, transit and export of animals, animal by-products and animal products.

- Federal Act on the Control of Dual-Use Goods, Specific Military Goods and Strategic Goods (RS 946.202 Loi fédérale du 13 décembre 1996 sur le contrôle des biens utilisables à des fins civiles et militaires, des biens militaires spécifiques et des biens stratégiques) http://www.admin.ch/opc/fr/classified-compilation/19960740 Regulates, inter alia, the import, export and transit of microorganisms and toxins. Applies to dual-use goods and specific military goods which are the subject of international agreements. Also outlines the responsibilities of the Federal Council in this regard including licensing and reporting requirements and surveillance measures for import, export, transit, production, storage, transfer and use of goods.
- Ordinance on the Control of Dual-Use Goods, Specific Military Goods and Strategic Goods (RS 946.202.1 Ordonnance du 3 juin 2016 sur le contrôle des biens utilisables à des fins civiles et militaires, des biens militaires spécifiques et des biens stratégiques) https://www.admin.ch/opc/fr/classified-compilation/20151950 Regulates the export, import and transit of dual-use goods and specific military goods which are the subject of international control measures not binding pursuant to international law. Applies in Swiss customs area to Swiss customs warehouses and Swiss customs enclaves.
- Ordinance on the Control of Chemicals Suitable for Civilian and Military Purposes (RS 946.202.21 Ordonnance du 21 août 2013 sur le contrôle des produits chimiques utilisables à des fins civiles et militaires) http://www.admin.ch/opc/fr/classified-compilation/20121582
- Ordinance Establishing Measures against Persons and Entities Linked to Osama bin Laden, the al-Qaeda Group or the Taliban (RS 946.203 Ordonnance du 2 octobre 2000 instituant des mesures à l'encontre de personnes et entités liées à Oussama ben Laden, au groupe «Al-Qaïda» ou aux Taliban) http://www.admin.ch/opc/fr/classified-compilation/19996052
- Federal Act on Sanctions on Trade with Foreign Countries (RS 946.231 Loi fédérale du 22 mars 2002 sur l'application de sanctions internationales) http://www.admin.ch/opc/fr/classified-compilation/20000358
- Ordinance on Measures against the Democratic People's Republic of Korea (RS 946.231.127.6 Ordonnance du 25 octobre 2006 instituant des mesures à l'encontre de la République populaire démocratique de Corée) http://www.admin.ch/opc/fr/classified-compilation/20062706
- Ordinance of the Swiss Financial Market Supervisory Authority on Combatting Money Laundering and Financing of Terrorism in the Financial Sector (RS 955.033.0 Ordonnance de l'Autorité fédérale de surveillance des marchés financiers du 3 juin 2015 sur la lutte contre le blanchiment d'argent et le financement du terrorisme dans le secteur financier) https://www.admin.ch/opc/fr/classified-compilation/20143112
- Ordinance on the Reporting Bureau in Matters of Money Laundering (RS 955.23 Ordonnance du 25 août 2004 sur le Bureau de communication en matière de blanchiment d'argent) http://www.admin.ch/opc/fr/classified-compilation/20031873

387. A compilation of all relevant national legislation is also available in Form E of the Annual Confidence Building Measures Reports of Switzerland that can be found on the public website of the BWC/United Nations Office in Geneva.

388. Further to the discussions held during the 2007-2010 Intersessional Process, Switzerland started to work on additional measures to promote education and awareness-raising among life scientists as outlined in Working Paper 20 submitted to the Seventh Review Conference (BWC/CONF.VII/WP.20/Rev.1). In the 2012-2015 Intersessional Process, Switzerland continued its efforts by conducting awareness-raising lectures at universities and scientific conferences. Furthermore, Spiez Laboratory, the Swiss Institute for NBC-Protection, introduced a code of conduct specifically addressing the dual use problem in science. Progress has also been made in terms of institutionalization of dual use awareness-raising in academia and dual use codes of conduct at scientific research institutions.

389. In 2016, the Swiss Academy of Sciences, funded by the Swiss Government, organized three discussion sessions at Swiss academic institutions addressing the misuse potential of biological research. Discussions involved the relevance of the topic for the research community as well as the necessity to establish a code of conduct.

D. Article V

390. Switzerland fully supports the provision of Article V and the decisions of States Parties as contained in the final declarations of previous Review Conferences with regard to consultation and co-operation mechanisms.

391. Switzerland participates annually in the information exchange through the Confidence Building Measures (CBMs). Since 2006, Switzerland has made its returns available on the public section of the website of the BWC/United Nations Office in Geneva. Switzerland remains fully committed to strengthening participation in this important mechanism and to an efficient use of the information contained in the CBMs. To this end, Switzerland has put forward several proposals during the 2012-2015 Intersessional Process and continues to do so.

392. With a view to demonstrate transparency and foster confidence building, Switzerland repeatedly invited the disarmament community to visit Spiez Laboratory, the home of Switzerland's only BSL4 facility (in June 2010, July 2012, June 2014 and September 2016).

393. Switzerland, together with Canada and the Czech Republic, actively engaged in the Compliance Assessment Initiative with the aim of demonstrating compliance with the BWC by assessing a country's implementation of the treaty through, for example, an examination of its national legislation. Switzerland also actively participated in the Peer-Review Exercises of France in 2013 and Germany in 2016 aimed at reinforcing assurances of compliance.

E. Articles VI and VII

394. Switzerland has not lodged any complaints with the Security Council under Article VI regarding any other State Party acting in breach of obligations deriving from the provisions of the Convention.

395. No State Party has requested assistance from Switzerland under Article VII, nor has Switzerland invoked the provisions of Article VII to receive assistance.

396. Switzerland is ready to provide or support assistance under Article VII, provided that its general reservation related to its status as a neutral State is respected, i.e. its assistance within the framework of the Convention cannot go beyond the terms prescribed

by that status.[4] Switzerland has personnel, expertise, equipment and infrastructure available that could provide capacities in case of specific requests, depending on their exact nature.

397. With regard to Articles VI and VII, Switzerland considers the United Nations Secretary-General's Mechanism for the Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM) to be an important operational instrument. Switzerland nominated experts and laboratories to the respective rosters of the UNSG and regularly updates the information provided. Swiss experts have engaged in numerous activities related to the UNSGM, e.g. specialized expert trainings, table-top exercises, field exercises as well as policy discussions to further develop and operationalize the mechanism. Furthermore, Switzerland is currently holding a series of three expert workshops geared towards the establishment of a functional laboratory network, composed of UNSGM designated laboratories on a voluntary basis, for investigations of alleged use of biological weapons and other pertinent purposes.

398. Regarding the outbreak of Ebola in Western Africa between 2013 and 2016, Switzerland supported Doctors without Borders (MSF-Suisse) in its work to combat the Ebola epidemic in Guinea, Liberia and Sierra Leone. Furthermore, the Swiss Humanitarian Assistance financed various direct actions of the Government of Liberia and sent personnel to the region. Also Spiez Laboratory contributed on site to the fight against the Ebola virus in Western Africa through its active participation in the European Mobile Laboratory (EMLab) project which is linked to WHO's Global Outbreak Alert and Response Network (GOARN). To fulfil its tasks, Spiez Laboratory relied on its expertise in quality assurance of specialized laboratories for the analysis and diagnosis of highly pathogenic agents (EQADeBa, QUANDHIP, EMERGE) and toxins (EQuATox, EuroBioTox).

F. Article VIII

399. Switzerland signed the 1925 Geneva Protocol on 17 June 1925 and ratified it on 12 July 1932 without any reservations (https://www.admin.ch/opc/fr/classified-compilation/19250020/201308150000/0.515.105.pdf).

G. Article IX

400. Switzerland ratified the Chemical Weapons Convention (CWC) on 10 March 1995; it entered into force for Switzerland on 29 April 1997 (https://www.admin.ch/opc/fr/classified-compilation/19980132/201306060000/0.515.08.pdf). A National Authority has been established under the lead of the Federal Department of Foreign Affairs. Further information on the national implementation of the CWC in Switzerland is available online (http://www.labor-spiez.ch/en/the/cw/index.htm).

H. Article X

401. Switzerland is fully committed to its obligations under Article X.

[4] To quote in full: "By reason of the obligations of its status as a perpetually neutral State, Switzerland is bound to make the general reservation that its collaboration within the framework of this Convention cannot go beyond the terms prescribed by that status. This reservation refers especially to Article VII of the Convention as well as to any similar clause that could replace or supplement that provision of the Convention (or any other arrangement)."

402. An example of our activities includes a Swiss-Iraqi cooperation project on laboratory biosafety-level 3 requirements and procedures, which was held in March 2011 in Switzerland. In January 2013, a delegation from Iraq visited Switzerland again in order to exchange expertise in the area of biosafety and biosecurity and discuss options for a legal framework in this domain. This cooperation project included officials from the Swiss Federal Office of Public Health and the Federal Department of Foreign Affairs as well as from the Iraqi Ministry of Science and Technology, the Central Public Health Laboratory of Iraq and the Iraqi National Monitoring Authority.

403. Switzerland supports initiatives aimed at enhancing cooperation across sectors in an international setting. In 2016, the Government of Switzerland assisted the Governments of Vietnam and Pakistan through WHO headquarters and the WHO country offices in the elaboration and establishment of national biosafety legislation.

404. Switzerland actively contributes to the Global Health Security Agenda (GHSA) in order to strengthen implementation of the International Health Regulations of the WHO. The Swiss engagement focuses on aspects of antimicrobial resistance (action package 'Prevent 1') and national laboratory systems (action package 'Detect 1').

405. Regarding the outbreak of Ebola in Western Africa between 2013 and 2016, Switzerland supported Doctors without Borders (MSF-Suisse) in its work to combat the Ebola epidemic in Guinea, Liberia and Sierra Leone. Furthermore, the Swiss Humanitarian Assistance financed various direct actions of the Government of Liberia and sent personnel to the region. Also Spiez Laboratory contributed on site to the fight against the Ebola virus in Western Africa through its active participation in the European Mobile Laboratory (EMLab) project which is linked to WHO's Global Outbreak Alert and Response Network (GOARN). To fulfil its tasks, Spiez Laboratory relied on its expertise in quality assurance of specialized laboratories for the analysis and diagnosis of highly pathogenic agents (EQADeBa, QUANDHIP, EMERGE) and toxins (EQuATox, EuroBioTox).

406. Switzerland intends to further its efforts in the field of assistance, in particular in the areas of training and education as well as implementation support.

I. Article XII

407. Switzerland is fully committed to continue reviewing the operation of the Convention in order to strengthen its implementation.

408. Switzerland is particularly engaged with regard to the provision of Article XII to conduct reviews that take "into account any new scientific and technological developments relevant to the Convention". In an effort to give effect to this provision and strengthen the Convention, Switzerland actively promoted the establishment of a systematic and dedicated science and technology review process during the 2012-2015 Intersessional Process and the Eighth Review Conference, which allows for a more thorough examination of S&T developments and their implications for the various provisions of the Convention, in particular Articles I, III, IV, V; VI, VII and X.

409. The Swiss delegation actively contributed to the science and technology exchanges in the framework of the Convention with several pertinent technical presentations and statements, including on gene editing technologies such as CRISPR, during Meetings of Experts of the 2012-2015 Intersessional Process.

410. In addition, Switzerland contributes to furthering the important issue of examining developments in science and technology with the organisation of a workshop series held biennially under the title 'Spiez Convergence' focusing on advances in chemical and biological sciences and their increasing convergence. The objective is to identify

developments in chemistry and biology which may at some point have implications for the BWC as well as the Chemical Weapons Convention. To date, workshops were held in 2014 and 2016.

Ukraine

A. Article I

411. Ukraine signed the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction on 10 April 1972 and ratified it on 21 February 1975.

412. Ukraine fully supports the principles and purposes of the Convention.

413. Ukraine has never developed, produced, stockpiled or otherwise acquired or retained:

(a) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) Weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

414. This article does not apply to Ukraine, as it does not possess any of the agents, toxins, weapons, equipment or means of delivery specified in article I.

C. Article III

415. Ukraine fully subscribes to article III of the Convention and, consequently, it has never transferred to any recipient whatsoever, directly or indirectly, nor has it in any way assisted, encouraged or induced any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in article I.

416. On 21 April 2005, Ukraine became a member of the Australia Group international export control regime, which aims to control the export of dual-use materials, equipment and technologies that may be used in the manufacture of chemical or biological weapons.

417. The legal framework for State export control consists of the Constitution, laws, presidential decrees and decisions of the Cabinet of Ministers, other laws and regulations and also international treaties by which the Verkhovna Rada, the parliament of Ukraine, has agreed to be bound.

418. The legislation on export control includes the following laws and regulations:

(a) Act No. 549-IV of 20 February 2003 on State control of international transfers of military and dual-use goods;

(b) Act No. 959-XII of 16 April 1991 on foreign trade activities;

(c) Criminal Code;

(d) Code of Administrative Offences;

(e) Presidential Decree No. 1265 of 27 December 2001 on the State Export Control Service;

(f) Presidential Decree No. 448 of 8 April 2011 on the State Export Control Service;

(g) Presidential Decree No. 861 of 15 July 1999 on the procedure for imposing (lifting) restrictions on the export of goods in accordance with the international obligations undertaken by Ukraine;

(h) Cabinet of Ministers Decision No. 767 of 15 July 1997 approving the regulations governing the procedure for carrying out expert appraisals in the area of export control;

(i) Cabinet of Ministers Decision No. 125 of 4 February 1998 approving the regulations governing the procedure for State monitoring of negotiations to conclude foreign trade agreements (contracts) for international transfers of military and dual-use goods;

(j) Cabinet of Ministers Decision No. 1807 of 20 November 2003 approving the procedure for State control of international transfers of military goods;

(k) Cabinet of Ministers Decision No. 86 of 28 January 2004 approving the procedure for State control of international transfers of dual-use goods;

(l) Cabinet of Ministers Decision No. 838 of 8 June 1998 approving the regulations governing the procedure for granting entities engaged in foreign trade the right to export and import military goods and goods containing information that constitutes a State secret;

(m) Cabinet of Ministers Decision No. 920 of 27 May 1999 approving the regulations governing the procedure for the provision of safeguards and State monitoring of obligations regarding the use, for declared purposes, of goods subject to State export control;

(n) Cabinet of Ministers Decision No. 500 of 6 June 2012 approving the procedure for State export control for negotiations involving foreign trade agreements (contracts) on the export of goods.

419. In the interests of national security and compliance with the international obligations undertaken by Ukraine as regards the non-proliferation of weapons of mass destruction and their means of delivery and restrictions on transfers of conventional weapons, the regulations on the State Export Control Service were approved by Cabinet of Ministers Decision No. 159 of 31 March 2015; the regulations give effect to State policy in the area of State controls on international transfers of military, dual-use and other goods that may be subject to State export control procedures under the Act on State Control of International Transfers of Military and Dual-Use Goods and contain proposals for formulating and facilitating such a policy.

420. Among the principles of State export control policy referred to in the Act on State Control of International Transfers of Military and Dual-Use Goods is the binding nature of the international obligations undertaken by Ukraine regarding the non-proliferation of weapons of mass destruction and their means of delivery, the establishment of State control of international transfers of military and dual-use goods and the implementation of measures to prevent such goods from being used for terrorist or other illegal purposes.

421. The preamble specifies that the Act regulates State control of international transfers of military and dual-use goods in order to protect the national interests of Ukraine and ensure that it complies with its international obligations regarding the non-proliferation of weapons of mass destruction and their means of delivery.

422. Article 4 notes that among the principles of State export control policy are the binding nature of the international obligations undertaken by Ukraine regarding the non-proliferation of weapons of mass destruction and their means of delivery, the implementation of measures to prevent such goods from being used for terrorist or other illegal purposes and cooperation with international organizations and foreign States in the sphere of State export control with the aim of strengthening international security and stability, including preventing the proliferation of weapons of mass destruction and their means of delivery.

423. Article 10 sets forth State export control procedures designed to prevent the proliferation of weapons of mass destruction and their means of delivery. According to this article, export control procedures may in some cases be applied even to goods that do not appear on the export control lists (the so-called catch-all principle).

424. For example, if the central authorities responsible for export controls receive information that there is an intention or likelihood that goods of any kind not appearing on the control lists will be used in States that are end users for the development, manufacture, stockpiling, testing, repair, servicing, modification, modernization, disposal, management, storage, detection, identification or proliferation of weapons of mass destruction or their means of delivery, those authorities must notify the State Export Control Service, which may apply State export control procedures to the goods in question.

425. State export controls are carried out on the export or temporary export of goods not appearing in the control lists if the goods are being exported or temporarily exported from Ukraine to a State against which a full or partial embargo on the supply of such goods has been imposed under a resolution of the Security Council or other international organizations or under national legislation and on imports of such goods if, at the request of the exporting State, an international import certificate is required for such goods to be imported into Ukraine.

426. As the national authority responsible for State export controls, the State Export Control Service is required under article 6 of the Act to assist with activities connected with international transfers of goods or to limit or ban such activities where there are grounds to believe that the goods are connected with weapons of mass destruction or are intended for the production of such weapons or their means of delivery, or where there are no adequate safeguards (obligations) regarding the end use of the goods.

427. By Cabinet of Ministers Decision No. 86 of 28 January 2004, the procedure for State control of international transfers of dual-use goods was adopted. This document defines the procedures for the exercise of State control of international transfers of dual-use goods, specifically goods that can be used to produce biological or toxin weapons, regardless of the circumstances of supply, the nature of the contracts, the customs regime or other aspects of the transfer.

428. The procedure applies to all business entities in Ukraine registered with the State Export Control Service as entities undertaking international transfers of goods and engaged in the export, import or temporary export or import of dual-use goods, including in connection with manufacturing and science and technology, and to business entities engaged in the transit of such goods through the territory of Ukraine.

429. The Procedure therefore excludes the possibility of international transfers of dual-use goods that could be used by non-State actors to produce weapons of mass destruction or their means of delivery.

430. In accordance with this procedure and also the procedure for State control of international transfers of military goods approved by Cabinet of Ministers Decision No. 1807 of 20 November 2003, the following rules apply:

431. It is prohibited to export individual goods to countries against which the Security Council of the United Nations has imposed an embargo on the export of such goods and also in the event that expert analyses in the area of State export control indicate that there are grounds to believe that they are intended for:

(a) The production of weapons of mass destruction or their means of delivery

(b) Use for terrorist or other illegal purposes

(c) Use in activities connected with the production of nuclear explosive devices or in activities connected with the nuclear fuel cycle that are not under International Atomic Energy Agency (IAEA) safeguards

(d) Use in activities connected with the acquisition, production, stockpiling or use of pathogenic agents (pathogens) and toxins as biological and toxin weapons or their components

Lists of dual-use goods

432. Lists of dual-use goods that may be used to produce a biological weapon are set forth in annex 5 of the procedure for State control of international transfers of dual-use goods.

433. Goods included in the lists that are transported across the customs borders of Ukraine are subject to mandatory customs clearance in accordance with the procedure established under the legislation of Ukraine.

D. Article IV

434. Ukrainian legislation prohibits individuals and legal entities from engaging in activities in violation of article I of the Convention.

Liability for the proliferation of weapons of mass destruction

435. Liability for violation of the laws concerning State control of the non-proliferation of weapons of mass destruction is governed by the Act on State Control of International Transfers of Military and Dual-Use Goods (sect. IV (Prevention of violations and liability in the area of State export control)), the Criminal Code (art. 333) and the Code of Administrative Offences (arts. 188-17 and 212-4).

436. In accordance with article 24 of the Act on State Control of International Transfers of Military and Dual-Use Goods, offences in the area of State export control include:

(a) International transfers of goods without obtaining a licence, safeguards conclusion or document under the established procedure or making of such transfers on the basis of licences, safeguards conclusions or documents obtained by providing counterfeit documents or documents containing false information;

(b) Conclusion of foreign trade agreements (contracts) concerning international transfers of any goods or participation in their implementation in any way other than as specified by the Act on State Control of International Transfers of Military and Dual-Use Goods if the exporter becomes aware that such goods may be used by a foreign State or foreign business for the purpose of producing weapons of mass destruction or their means of delivery;

(c) International transfer of goods even though the exporter has become aware that the goods will be used for purposes or by end users other than those specified in the foreign trade agreement (contract) or related documents on the basis of which the licence, safeguards conclusion or international import certificate was obtained;

(d) Deliberate concealment of information relevant to the decision on whether to grant licences, safeguards conclusions or international import certificates;

(e) International transfer of goods in violation of the conditions specified in the licences, safeguards conclusions or international import certificates, including after making changes to the foreign trade agreement (contract), without the consent of the designated export control authority, concerning the names and particulars of exporters, importers, brokers and end users and also the descriptions of goods, end-use requirements and submission of the relevant safeguards documents;

(f) Conduct of negotiations concerning the conclusion of foreign trade agreements (contracts) on the export of goods on which a partial embargo has been imposed against the foreign State concerned without obtaining the relevant approval of the designated export control authority;

(g) Failure to submit or late submission of reports and relevant documents to the designated export control authority concerning the outcome of the negotiations specified above, the export or import of goods actually carried out on the basis of licences, safeguards conclusions or international import certificates obtained or the use of such goods for their declared purposes;

(h) Obstruction of the performance of the official duties of staff of the designated export control authority and other State bodies involved in State export control during the performance of their official duties or failure to comply with legitimate requests by such persons;

(i) Unwarranted refusal to provide information and documents requested by the designated export control authority or other competent State bodies involved in State export control or the deliberate falsification or concealment of such information and documents;

(j) Deliberate destruction of documents relating to the conclusion or execution of foreign trade agreements (contracts) on the conduct of international transfers of goods on the basis of which licences, safeguards conclusions or international import certificates were received before the end of the period during which they are required to be retained.

437. Article 25 of the Act establishes the liability of legal entities involved in international transfers of goods for violation of the requirements of the law in the area of export control specified in article 24 (i)-(x).

438. The national export control authority imposes fines on legal entities involved in international transfers of goods for violations referred to under article 24, as follows:

(i) and (ii) — 150 per cent of the value of the goods that were involved in the relevant international transfer if the competent central authorities and other State bodies find that the interests of Ukraine (political, economic or military) have been harmed or its international obligations violated or 100 per cent of the value of the goods that were involved in the relevant international transfer if the competent central authorities and other State bodies find that there has been no harm to the

interests of Ukraine (political, economic or military) or violation of its international obligations;

(iii)-(v) — 100 per cent of the value of the goods that were involved in the relevant international transfer;

(vi) and (x) — 1,000 times the individual income tax exemption limit;

(vii) — 500 times the individual income tax exemption limit;

(viii)-(x) — 100 times the individual income tax exemption limit.

439. Article 25 also provides that the national export control authority, besides imposing the aforementioned fines, may revoke or suspend the licence, safeguards conclusion or international import certificate that it granted to such a business entity or revoke its registration with the authority as an entity authorized to conduct international transfers of goods, which has the effect of suspending any permit or safeguards document granted to such an entity and valid at the time of the deregistration.

Criminal liability for the proliferation of weapons of mass destruction

440. Any development, production, stockpiling or use of weapons of mass destruction stems from the decisions and actions of individuals, whether they are officials, private business persons, weapons experts or terrorists. However, the international conventions prohibiting such weapons have almost no provisions on individual liability. States are therefore faced with the need to introduce appropriate provisions in their legislation to establish criminal liability for activities linked with the proliferation of weapons of mass destruction.

441. Thus, the Criminal Code of Ukraine contains eight articles that in one way or another are concerned with criminal liability for activities involving the potential proliferation of weapons of mass destruction: article 258 (Terrorist acts); article 261 (Attacks on facilities that contain objects posing an increased risk to the surroundings); article 321 (Illegal production, manufacture, acquisition, transport, transfer or stockpiling for sales purposes, or sale, of toxic or potent substances and of toxic or potent medicines); article 326 (Infringement of the rules on handling microbiological or other biological agents or toxins); article 333 (Infringement of the procedure for conducting international transfers of goods subject to State export control); article 439 (Use of weapons of mass destruction); article 440 (Development, production, acquisition, stockpiling, sale and transport of weapons of mass destruction); and article 441 (Ecocide).

Article 258 (Terrorist acts)

442. A terrorist act — that is, the use of a weapon, carrying out of an explosion, arson or other acts endangering the life or health of people or causing substantial damage to property or other serious consequences, if such actions were committed for the purposes of undermining public security, intimidating the population, provoking a military conflict or aggravating the international situation, influencing decision-making or whether or not action is taken by State or local government bodies, officials of those bodies, citizens' associations or legal entities or drawing the attention of the public to certain political, religious or other views of the offender (terrorist), or the threat to commit such acts for the same purposes — is punishable by a term of imprisonment of between 5 and 10 years.

443. When the same actions are committed more than once or by prior conspiracy among a group of persons or result in substantial damage to property or other serious consequences, they are punishable by a term of imprisonment of between 7 and 12 years.

444. If the actions referred to in paragraphs 1 and 2 of article 258 result in the loss of human life, they are punishable by a term of imprisonment of between 10 and 15 years, or life imprisonment.

Article 261 (Attacks on facilities that contain objects posing an increased risk to the surroundings)

445. Attacks on facilities at which radioactive, chemical, biological or explosive materials, substances or items are produced, stored or used or in which they are transported, carried out with the aim of seizing, damaging or destroying such facilities, are punishable by a term of imprisonment of between 5 and 12 years.

Article 321 (Illegal production, manufacture, acquisition, transport, transfer or stockpiling for sales purposes or sale of toxic or potent substances and of toxic or potent medicines)

446. The illegal production, manufacture, acquisition, transport, transfer or stockpiling for sales purposes or the sale of toxic or potent substances other than narcotics, psychotropic substances or analogues of such substances, or of toxic or potent medicines, and also the illegal production, manufacture, acquisition, transport, transfer or stockpiling for sales purposes or the sale of equipment intended for the production or manufacture of toxic or potent substances, or of toxic or potent medicines, where these actions have not been specially authorized, is punishable by a fine of from 50 to 100 times the individual income tax exemption limit or a term of imprisonment of up to 3 years.

447. Violation of the rules governing the production, acquisition, storage, release, recording, transport or transfer of toxic or potent substances other than narcotics, psychotropic substances or their analogues, or of toxic or potent medicines, is punishable by a fine of up to 100 times the individual income tax exemption limit, or a term of imprisonment of up to 3 years.

Article 326 (Infringement of the rules on handling microbiological or other biological agents or toxins)

448. Infringement of the rules governing the storage, use, recording or transport of microbiological or other biological agents or toxins, and any other rules related to their handling, where it has presented a risk to human life or a risk of other grave consequences, or caused harm to the health of a victim, is punishable by a fine of up to 50 times the individual income tax exemption limit, or punitive deduction of earnings for up to 2 years or restriction of liberty for up to 3 years, with or without deprivation of the right to occupy certain positions or engage in certain activities for up to 3 years.

449. Where such actions have caused the loss of human life or other grave consequences, they are punishable by restriction of liberty for up to 5 years or imprisonment for the same period, with deprivation of the right to occupy certain positions or engage in certain activities for up to 3 years.

Article 333 (Infringement of the procedure for conducting international transfers of goods subject to State export control)

450. Infringement of the procedure for conducting international transfers of goods subject to State export control is punishable by a fine from 100 to 200 times the individual income tax exemption limit, or restriction of liberty for up to 3 years or imprisonment for the same period, with or without deprivation of the right to occupy certain positions or engage in certain activities for up to 3 years.

451. When the same actions are committed more than once or by an organized group, they are punishable by restriction of liberty for up to 5 years or imprisonment for the same period, with deprivation of the right to occupy certain positions or engage in certain activities for up to 3 years.

Article 439 (Use of weapons of mass destruction)

452. The use of weapons of mass destruction that are prohibited by international treaties ratified by the parliament of Ukraine is punishable by a term of imprisonment of between 8 and 12 years.

453. When the same action has caused loss of human life or other grave consequences, it is punishable by a term of imprisonment of between 8 and 15 years, or life imprisonment.

Article 440 (Development, production, acquisition, stockpiling, sale or transport of weapons of mass destruction)

454. The development, production, acquisition, stockpiling, sale or transport of weapons of mass destruction that are prohibited by international treaties ratified by the parliament of Ukraine is punishable by a term of imprisonment of between 3 and 10 years.

Article 441 (Ecocide)

455. The large-scale destruction of plant or animal life, the poisoning of the atmosphere or water resources and any other actions that may cause an environmental disaster are punishable by a term of imprisonment of between 8 and 15 years.

Code of Administrative Offences

454. Article 188-17 of the Code of Administrative Offences establishes administrative responsibility of individuals and legal entities for non-compliance with legitimate requests by staff of the designated export control authority. Such violations are punishable by a fine ranging from 15 to 20 times the individual income tax exemption limit for private citizens and 20 to 50 times the individual income tax exemption limit for officials.

455. Moreover, in accordance with article 212-14, the following violations of the legislation on State export control are punishable by a fine ranging from 15 to 20 times the individual income tax exemption limit for private citizens and 20 to 50 times the individual income tax exemption limit for officials, namely the:

(a) Conduct of negotiations concerning the conclusion of foreign trade agreements (contracts) on the export of military goods or dual-use goods on which a

partial embargo has been imposed against the foreign State concerned without obtaining the relevant approval of the designated export control authority;

(b) Failure to submit or late submission of reports and relevant documents to the designated export control authority concerning the outcome of the negotiations specified in paragraph 1 of this article, international transfers of military and dual-use goods actually carried out on the basis of licences or safeguards conclusions obtained and the use of such goods for their declared purposes;

(c) Deliberate destruction of documents relating to the conclusion or execution of foreign trade agreements (contracts) on the conduct of international transfers of military and dual-use goods on the basis of which licences, safeguards conclusions or international import certificates were received before the end of the period during which they are required by law to be retained.

E. Article V

456. Ukraine continuously engages in consultations and cooperation with other States parties in addressing any issues related to the implementation of the provisions of the Convention.

457. Ukraine submits to the Secretariat of the United Nations each year the requisite declarations on the implementation of the Convention as part of the confidence-building measures approved at the Second and Third Review Conferences of the States Parties to the Convention.

458. Ukraine favours the further development and upgrading of machinery for cooperation among States parties under the Convention, and particularly the strengthening of cooperation in such areas as enforcement and information exchange, and also cooperation between national export control authorities.

F. Article VI

459. Ukraine has not invoked the provisions of Article VI, nor has any other State party invoked its provisions against Ukraine.

G. Article VII

460. Ukraine has not received any requests for assistance under Article VII.

H. Article IX

461. Ukraine ratified the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction on 16 October 1998. Ukraine affirms its commitment to the effective implementation of the Chemical Weapons Convention.

I. Article X

462. Ukraine cooperates bilaterally and multilaterally with other States parties to the Biological Weapons Convention in order to promote the exchange of equipment, materials

and scientific and technological information for the use of biological agents and toxins for peaceful purposes.

United Kingdom of Great Britain and Northern Ireland

463. In line with the request for background information for 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 agreed at the first Preparatory Committee meeting on 26-27 April 2016, the United Kingdom (UK) provides the following report to States Parties to demonstrate its compliance with all its obligations under the Convention.

A. Article I

464. Since its ratification of the Convention the UK has not developed, produced, stockpiled, or otherwise acquired or retained microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes. The UK continues to hold biological or toxin agents of types and in quantities justified for prophylactic, protective or other peaceful purposes under appropriate supervision or control in accordance with UK national implementation measures under Article IV of the Convention, which includes legislation, regulation and other measures related to biosafety and biosecurity – see further discussion below on Article IV.

465. Since its ratification of the Convention the UK has not possessed or developed, produced, stockpiled or otherwise acquired or retained any weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

B. Article II

466. The provisions of Article II impose obligations only upon those States Parties that possess or have under their jurisdiction or control, microbial or other biological agents, or toxins, weapons, equipment, or means of delivery specified in Article I.

467. In its 1992 Form F submission under the annual information exchange (CBMs), the UK reported to States Parties the destruction of its only stockpile of biological weapons prior to entry into force of the Convention in 1975. In the interests of transparency the relevant extract is reproduced here[5]: '... the War Cabinet's requirement for a retaliatory capability in World War II was fulfilled by the development of a modest anti-livestock aircraft-delivered BW capability based on anthrax spores in cattle cakes. A stockpile of 5,000,000 cattle cakes was produced by the BDP in 1942-3 and was stored at Porton. The weapon was never employed. In the immediate post-war period the cattle cake stockpile was destroyed by autoclaving and burning; a few cardboard boxes each holding 400 cakes were retained as curiosities in the culture collection of the then Microbiological Research Establishment (MRE) at Porton until they were destroyed in 1972 at the time of the signature of the Biological Weapons Convention.'

5 Exact reproduction from UK CBM Form F – BDP was the Biology Department, Porton located within the then Chemical Defence Experimental Station.

C. Article III

468. The UK complies fully with the undertaking not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any state, group of states or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

469. The UK continues to fulfil its obligations under Article III through legislation and a number of administrative arrangements and guidelines. The following legislation is the principal means of implementation within the UK:

(a) The Biological Weapons Act 1974.

(b) The Chemical Weapons Act 1996 implements the provisions of the Chemical Weapons Convention. The Act prohibits the transfer of chemical weapons including those based on toxins.

(c) Council Regulation (EC) 428/2009 setting up a European Community regime for the control of exports, transfer, brokering and transit of dual-use items, including biological-related dual-use items and technology. The regulation was adopted in May 2009, replacing the earlier regulation 1334/2000, and is amended regularly, generally on an annual basis.

(d) The Anti-Terrorism, Crime and Security Act 2001 – see below under Article IV.

(e) The Export Control Act 2002 and the Export Control Order 2008.

470. UK legislation is periodically reviewed and amended where required to ensure that it is relevant and fit for purpose in view of changes in technology and new and emerging threats. Amendments are reported annually in Form E of the UK's Confidence Building Measures (CBM) submission, which is publicly accessible on the official BTWC website.

D. Article IV

471. Information on national implementation by the UK was supplied to States Parties in previous Review Conference compliance reports, in national Working Papers and statements submitted to various intersessional meetings held since 2003. In addition to penal legislation, the UK also has a wide range of other relevant legislation that gives effect to Article IV, in particular on biosecurity and biosafety.

472. In accordance with Article IV, the UK has taken the 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. Such measures apply to the territory of the UK and territory under the jurisdiction or control of the UK. The legislation includes the Biological Weapons Act 1974, which makes the prohibitions under the Convention offences under domestic criminal legislation. The legislation also specifies penalties for the offences. Since 2011 there have been two prosecutions brought under this Act: one in November 2014 and one in April 2015. Both resulted in convictions. These are the first ever prosecutions brought under the Act and help show the value of implementing legislation in combating the threat posed by non-state actors. The Chemical Weapons Act 1996 is also relevant here as it applies to toxins; a conviction under the 1996 Act for the attempted possession of ricin for non permitted purposes was reported to the 2015 Meeting of Experts.

473. In addition, Part 7 of the Anti-Terrorism, Crime and Security Act 2001 (ATCSA) provides for the security and control of specified, dangerous pathogens and toxins, which

could be used in an act of terrorism to endanger life or cause serious harm. Facilities have a legal obligation to notify the Home Office that they are holding pathogens and toxins specified by Schedule 5 of the Act. The Schedule 5 list is divided into three different categories of security depending on the level of risk of the agents. Materials which present the greatest risk (categorised as Hazard Group 4 in the UK) are looked at on a case by case basis rather than simply fitting into the requirements of the ATCSA legislation. The National Counter-Terrorism Security Office (NaCTSO) and Counter Terrorism Security Advisers (CTSAs) have the responsibility to review physical security measures relating to malicious breaches at laboratories holding Schedule 5 materials. CTSAs are specialist police officers trained in advising businesses and organisations that may be at risk from terrorism in safety and security of premises, personnel and assets. There is a classified guidance document available to CTSAs to maintain national consistency.

474. Each notified site must have a list of designated persons who have access to Schedule 5 materials. ATCSA gives powers for a chief officer of police to see a list of persons with access to Schedule 5 substances and access to the premises. However, the legislation is effectively enforced by CTSAs. ATCSA also allows for a person to be denied access to substances or premises if they are of concern. Minimum monitoring equates to an annual visit from the local CTSA. Each institution/laboratory is responsible for training their biosecurity staff to meet the requirements of ATCSA with respect to personnel security.

475. On biosafety aspects, work with pathogens is covered by three sets of regulations. These are:

(a) The Control of Substances Hazardous to Health Regulations 2002 and the associated Approved List of Biological Agents[6].

(b) The Genetically Modified Organisms (Contained Use) Regulations 2014, which consolidate previous legislation relating to genetically modified organisms taking a more risk based and proportionate approach and taking account of relevant advances in technology, including synthetic biology.

(c) The Specified Animal Pathogens Order 2008.

476. The arrangements for regulating animal pathogens were revised in 2015 – the Health and Safety Executive (HSE) became the authority for issuing licences in relation to the contained use of specified animal pathogens, in addition to being responsible for inspection and enforcement. New guidance on these arrangements was also introduced. These changes took effect from 1 April 2015 and mean that a more integrated approach to animal and human pathogens is now in place.

477. There is close scrutiny by the HSE of all facilities working with pathogens, with particular focus on those holding Hazard Group (HG) 4 pathogens. This involves the appointment of a designated site inspector and regular visits (at least two per year) arranged according to an agreed intervention plan. In the case of facilities working with HG3 pathogens, routine visits take place every four or five years. HSE has a programme of proactive inspections and interventions in facilities undertaking work with the most hazardous pathogens. Moreover, all three pieces of biosafety legislation make it a legal

[6] The Control of Substances Hazardous to Health Regulations 2002 (COSHH) make reference to the 'approved classification' of a biological agent. The Approved List is the list of classifications of biological agents approved by HSE for this purpose. http://www.hse.gov.uk/pubns/misc208.pdf

requirement to notify HSE if there has been a breach of containment or a dangerous occurrence.[7] Any breaches of legislation are enforced and addressed by HSE.

478. As noted above, the effectiveness of the necessary measures to prohibit and prevent the proscribed activities under the Convention is regularly reviewed. Legislation and Regulations are amended as appropriate, and amendments are reported annually in Form E of the UK's Confidence Building Measures (CBM) submission, which is publicly accessible on the official BTWC website.

479. The UK also takes non-legislative measures that contribute to ensuring national implementation of the Convention:

480. The UK Ministry of Defence has guidelines to ensure that its biological defence research and development programmes are in compliance with the BTWC. These guidelines codify existing approaches and practices and set out the procedures and responsibilities within the oversight mechanism to ensure that research is consistent with obligations under the Convention and with relevant domestic law.

481. The Academic Technology Approval Scheme (ATAS) was introduced on 1 November 2007 and is an essential part of the UK's commitment to counter proliferation. The ATAS is specifically designed to ensure that those international students applying for postgraduate study in certain sensitive subjects at UK higher education establishments do not acquire knowledge that could potentially be used in WMD programmes.

482. In the 2015 Meeting of Experts, the UK reported that as part of the Global Health Security Agenda (GHSA) it had volunteered to host a pilot external evaluation and assessment of GHSA capabilities. The GHSA is an effort by nations, international organisations, and civil society to accelerate progress toward a world safe and secure from infectious disease threats; to promote global health security as an international priority; and to spur progress toward full implementation of the World Health Organisation (WHO) International Health Regulations 2005 (IHR), the World Organisation for Animal Health (OIE) Performance of Veterinary Services (PVS) pathway, and other relevant global health security frameworks. This pilot evaluation took place in June 2015. The primary objective of the assessment was to assess the utility of the GHSA Assessment Tool, using information from the UK experience of applying the tool to make proposals for improving it. The secondary objective was to use the assessment tool to describe and review structures and functions in the UK, which are essential for preventing, detecting, and responding to infectious disease threats. Many of the aspects covered in its report are relevant for BTWC implementation. The report can be accessed at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456984/IndependentReport_GHS_acc.pdf

483. The UK recognises the importance of activities for awareness-raising, education and oversight of science. In this context, the UK has funded work, in conjunction with Canada, to develop a biosecurity education textbook by the University of Bradford. This book, Preventing Biological Threats: What You Can Do, and its accompanying Biological Security Education Handbook are primarily aimed at undergraduates studying life sciences and their lecturers. However, they are also intended to raise awareness and knowledge of biological security of everyone active in the life sciences, ranging from those engaged in

[7] Under Schedule 2 of the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 2013 a dangerous occurrence involving a biological agent is defined as any accident or incident which results or could have resulted in the release or escape of a biological agent likely to cause severe human infection or illness. http://www.legislation.gov.uk/uksi/2013/1471/schedule/2/made

research to those engaged in management and policy-making, both nationally and internationally.[8]

484. The Biochemical Security 2030 – Towards Improved Science-based Multilevel Governance project at the University of Bath highlighted the relevance of outreach and education and identified universities as a potential starting point for those seeking to foster a culture of responsibility within the life sciences. This project brought together academics and policy makers in order to improve response of the biological and chemical weapon prohibition regimes to advances in science and technology. A key question within the project was how to ensure such regimes were responsive to challenges at the local, national and international level. Further detail is at:

http://www.paccsresearch.org.uk/biochemical-security-2030-towards-improved-science-based-multilevel-governance/

485. In addition, in July 2015 three main funders of academic research in the life sciences in the UK – the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Wellcome Trust released an updated joint statement on managing risks that the outputs of life science research could be misused for harmful purposes.[9] This covers issues such as balancing benefit and risk; dissemination of research; international collaboration and training, promoting good research practice; and ensuring public trust. It also outlines key provisions implemented in their grant application processes and funding requirements to help ensure that risks of misuse associated with research proposals are identified and assessed during the grant funding process. The UK national statement on national implementation provides more detail on these provisions:

http://www.unog.ch/80256EDD006B8954/(httpAssets)/F6D795A232DDBC63C1257EA70058F410/$file/SAI+NATIONAL+IMPLEMENTATION+SPEAKING+NOTE+2015+MXP.pdf

486. In accordance with paragraph 18 of the Final Declaration of the Sixth Review Conference, the UK has designated a national focal point for coordinating national implementation of the Convention; contact details are posted on the secure area of the official BTWC website.

E. Article V

487. The UK supports fully the decisions of States Parties recorded in the Final Declarations of previous Review Conferences on consultation and co-operation mechanisms. The UK has not requested a formal Consultative Meeting of States Parties under the provisions of Article V between 2011 and 2016.

488. In accordance with the relevant decisions of States Parties at the Second, Third, Sixth and Seventh Review Conferences of the Convention the UK has submitted confidence-building measures to States Parties, via the Implementation Support Unit (ISU) within the UN Office for Disarmament Affairs Geneva office each year before the April 15 deadline. The information submitted by the UK in 2012, 2013, 2014, 2015 and 2016 is available online at:

http://www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument

[8] http://www.brad.ac.uk/social-sciences/peace-studies/research/publications-and-projects/guide-to-biological-security-issues/
[9] https://wellcome.ac.uk/funding/managing-grant/managing-risks-research-misuse

F. Article VI

489. The UK has not lodged any complaints with the United Nations Security Council concerning any other State Party acting in breach of its Article I or II obligations.

490. The UK continues to nominate experts and laboratories for the rosters available to the United Nations Secretary General's Mechanism (UNSGM) for the timely and efficient investigation of alleged use under these procedures, and supports further strengthening of the mechanism. Since 2011 the UK has provided training courses for qualified experts nominated to the roster on command and control and investigation, negotiating and interviewing skills as well as supporting the UN Office for Disarmament Affairs efforts to build up the UNSGM's operational capabilities.

G. Article VII

491. No State Party has requested assistance from the UK under Article VII. As reported during the discussion on Article VII issues at the 2015 Meeting of Experts the UK, looking to the lessons of the Ebola outbreak in West Africa, is developing plans to establish a more robust national rapid response workforce for public health emergencies and will establish a new group of six to ten expert staff – mainly epidemiologists, infection control specialists and infection control doctors – who will be on permanent standby, ready to deploy to help countries respond to disease outbreaks. A 'reservist force', including hundreds of doctors, nurses and public health experts, will be ready for call-up if the outbreak is not contained at an early stage. This will require training of a wider cadre of reservist specialists in surveillance, outbreak response, epidemiology, diagnostics, infection prevention and control, relevant social sciences and clinical and applied research, and when required to be deployed as part of a larger scale response.

H. Article VIII

492. The UK ratified the 1925 Geneva Protocol on 9 April 1930. At the Third Review Conference of the BTWC in 1991, the UK informed States Parties of the withdrawal of the part of its reservation to that Protocol covering biological and toxin weapons and formally notified the Government of France, as Depositary, in writing on 8 November 1991. On 20 December 2002 the UK formally notified the Depositary that the UK had lifted its remaining reservations to that Protocol with respect to chemical weapons.

I. Article IX

493. The UK ratified the Chemical Weapons Convention (CWC) on 13 May 1996. The National Authority to implement the CWC in the UK forms part of the Department for Business, Energy and Industrial Strategy (BEIS), and is co-located in both BEIS and in the new Counter Proliferation and Arms Control Centre that was established on 25 July 2016. Further information on the implementation of the CWC in the UK is available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/48294/4669-chemical-weapons-conv-uk-nat-auth.pdf

494. The Annual Report to Parliament on the implementation of the Chemical Weapons Act 1996 in 2015 can be found at this site:

https://www.gov.uk/government/publications/annual-report-for-2015-on-the-operation-of-the-chemical-weapons-act-1996

J. Article X

495. The UK both facilitates and participates in the fullest possible exchange of equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. The UK contributes individually and with other states, international organisations, non-governmental organisations, and other appropriate entities, to further the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease and for other peaceful purposes. Pursuant to paragraph 61 of the Final Declaration of the Seventh Review Conference, which encouraged States Parties to provide information, at least biannually, on how they implement Article X, the UK has provided detailed reports on its implementation of this Article during the intersessional programme 2012–2015. This includes information submitted as part of the European Union in its 2012 and 2013 reports[10], with the Global Partnership[11]; and most recently nationally at the Meeting of States Parties in December 2105. This latter report is at:

http://www.unog.ch/80256EDD006B8954/(httpAssets)/4A5A6A7142EB9857C1257F060039A7B8/$file/2015+UK's+INF+paper+on+Article+X.pdf

496. Specific examples of Article X related activities are summarised in the Annex to this report.

497. The UK implements the Convention in a manner designed to avoid hampering the economic or technological development of States Parties or international cooperation in the field of peaceful bacteriological (biological) activities. This includes the international exchange of bacteriological (biological) and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention. The UK takes this opportunity to inform States Parties that between April 2011 and 31 March 2016, 848 individual export and 30 Open Individual Export Licenses were granted to export pathogens, toxins and equipment relevant under the Convention. Only four licence applications were refused during this period.

K. Article XII

498. The UK has provided a report on compliance at each Review Conference of the Convention along with papers on scientific and technological development; it submitted five Working Papers on S&T topics in the last intersessional programme 2012-2015.

499. The UK fully supports periodic reviews of the operation of the Convention, and has made a specific proposal in BWC/CONF.VIII/PC/WP.4 on how scientific and technological developments might be more effectively addressed in the context of the Convention in a future intersessional programme to be agreed at the Eighth Review Conference.

L. Article XIV

500. The UK acts as one of three Depositaries to the Convention and continues to fulfil its obligations as a Depositary Government in cooperation with the other two Depositaries, including providing advice to non-states parties and successor states on the procedures and

[10] BWC/MSP/2012/MX/INF.7 and BWC/MSP/2013/INF.4.
[11] BWC/MSP/2015/WP.5.

documentation required in order to deposit instruments of ratification, accession and succession.

M. Other Activities which support compliance with the BTWC

501. The UK co-operates with other States Parties to the BTWC and other states, intergovernmental organisations, and non-governmental organisations to fulfil its obligations under the Convention. Examples of the co-operation and activities undertaken include:

(a) Contribution to the Global Partnership in the biological area.

(b) Activity to support the effectiveness of UK export licensing and export control procedures via participation in the Australia Group.

(c) Support for UN Security Council Resolution 1540 (2004), including the submission of reports to the Committee as required.

(d) Activity to deter and prevent the acquisition of materials and equipment related to offensive biological weapons programmes via support for the activities of the Proliferation Security Initiative.

502. The UK considers the two following EU Council Decisions agreed since the last Review Conference as important means for helping it achieve its national objectives on making the Convention effective:

(a) Council Decision 2012/421/CFSP of 23 July 2012 in support of the Biological and Toxin Weapons Convention (BTWC), in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction.

(b) Council Decision (CFSP) 2016/51 of 18 January 2016 in support of the Biological and Toxin Weapons Convention (BTWC) in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction.

Annex

Examples of UK Article X Related Activities

503. The UK is the largest donor to Gavi, the Vaccine Alliance. Between 2011 and 2015, the UK contributed £1.32 billion to Gavi. The UK investment over the five year period between 2011 and 2015 immunised over 60 million children against vaccine preventable diseases, which is estimated to have saved over one million lives. Between 2016 and 2020, the UK is investing £1.44 billion in Gavi. This investment will ensure a commitment to immunise 76 million children against vaccine preventable diseases and save 1.4 million lives is met.

504. The £1 billion Ross Fund was announced by the Chancellor of the Exchequer in November 2015 and is managed by the Department for International Development (DFID) and the Department of Health. The Ross Fund aims to develop, test and deliver a range of new products (including vaccines, drugs and diagnostics) to help combat the world's most serious diseases in developing countries. The government created this fund for research and development in products for infectious diseases and to strengthen delivery of new products, bringing together its investment into:

(a) Anti-microbial resistance (AMR) that is becoming an increasing threat globally, including diseases such as malaria and TB, with emerging drug and insecticide resistance.

(b) Diseases with epidemic potential, such as Ebola, that can rapidly spread if not stopped early.

(c) Neglected tropical diseases (NTDs) that affect over a billion people worldwide, causing disability, disfigurement and death.

505. The Fund will consist of a range of world leading investments in research and development, and will include over £350 million for development of new products, in addition to research into how these can most effectively be delivered. These will include:

(a) Vaccines and diagnostics to prevent and respond to future disease outbreaks, such as Ebola.

(b) Drugs, diagnostics and insecticides to tackle the growing threat of diseases of emerging resistance including malaria and TB.

(c) Drugs and diagnostics for NTDs.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/494584/Ross_Fund_Publication_final.pdf

506. Following the Zika Rapid Response Initiative launched by the Medical Research Council in February 2016, which saw £1m of funding made available through the Government's Global Challenges Research Fund, an additional £1m and up to £2m was contributed by the Wellcome Trust and the Newton Fund respectively, totalling up to £4m worth of funding. Twenty-six high quality projects with a combined value of £3.2m are being funded. Details are at:

http://www.mrc.ac.uk/documents/pdf/zika-award-list-summaries/

507. The UK Medical Research Council and the UK Department for International Development (DFID) announced on 15 June 2016 a further call for proposals for the prestigious African Research Leader awards. This jointly funded scheme aims to strengthen research leadership across sub-Saharan Africa by attracting and retaining exceptionally talented individuals who will lead high quality programmes of research on key global health issues pertinent to the region.

508. Following the major role played by the UK in Sierra Leone during the Ebola outbreak 2014-2015, working with the UN, the WHO and the wider international community, DFID has funded Public Health England (PHE) by over £6 million to strengthen Sierra Leone's laboratory diagnostic capacity and emergency preparedness and response capability, including training and a programme of skills transfer to local staff.

509. PHE has set-up a Collaborating Centre for emergency preparedness and response in Bengaluru, India, under which biosafety training courses are being offered by PHE's Novel and Dangerous Pathogens Training Unit. PHE has also recently delivered biosafety training courses in Israel and Jordan.

510. PHE is working with the Jawaharlal Nehru Centre for Advanced Scientific Research in Bengaluru, India, to combat resistance to existing antibiotics and other related drugs, by seeking new and novel anti-microbial compounds.

511. Newcastle Disease is one of the biggest problems for poor people keeping poultry in rural and peri-urban areas in Africa. Serious outbreaks can kill 80-90% of backyard chickens. DFID funding has helped to develop a form of the Newcastle Disease vaccine that is suitable for small-scale poultry producers - in dissolvable tablet and pellet form

rather than in large batches that require refrigeration and individual administration. In 2015, 10m doses were sold to small-holders, enough to protect 200,000 households. Further detail is at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/298475/Newcastle-Disease-Vaccine.pdf

512. Since the last Review Conference the UK's International Biological Security Programme has helped fund the World Organisation for Animal Health's (OIE) work on the independent assessment of veterinary services, through PVS Pathway missions, in Azerbaijan, Belarus, Jordan, Pakistan and Yemen, and which has helped improve knowledge of veterinary gaps and areas for improvement in those countries, with a view to rapid detection, diagnosis and control of diseases.

United States of America

A. Introduction

513. The United States signed the Biological and Toxin Weapons Convention (BWC) on April 10, 1972, and ratified the Convention on March 26, 1975. The United States is in full compliance with all of its obligations under the BWC.

514. The United States is committed to reducing the risks of acquisition or use of biological agents as weapons by either States or non-state actors and to minimizing the consequences of such events should they occur. The United States' approach, described in the 2009 National Strategy for Countering Biological Threats,[12] encompasses improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to prevent, detect, and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and interdict those who seek to misuse the life sciences.

515. The key elements of U.S. compliance set forth below are intended to underscore multi-faceted domestic measures and are not an exhaustive list of all national-level compliance tools. Further, many measures are mutually reinforcing, fulfill more than one purpose, and touch on more than one BWC article. For example, import and export licensing procedures help guard against misuse of the life sciences and contribute to fulfillment of Article III and IV obligations, but they also promote the fullest possible exchange of equipment, materials, and knowledge for peaceful purposes, in accordance with Article X, by minimizing the risk of diversion for prohibited purposes.

516. As part of being in compliance, effective implementation of the BWC is an ongoing responsibility, rather than a task met by passing a law or issuing a regulation. A State Party must continue to invest adequate resources to implement and enforce laws, regulations, and other measures once adopted. The United States takes a robust and multi-faceted approach to implementing its obligations under the BWC. Implementing legislation and regulations comprise part of the national architecture, but such measures are complemented by an array of mutually reinforcing tools, including policy and other guidance documents, outreach and education, investment, and assistance to achieve the aims of the Convention. Laws and regulations that prohibit and punish violations are necessary, but so are the guidance, policies, and awareness-raising initiatives that prevent violations or other risky behaviors.

[12] http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

517. Moreover, changes in technology, industry, and the nature of the biological weapons threat require States Parties to regularly review laws, regulations, policies, and guidance to ensure they remain relevant and effective. Although the United States considers its approach comprehensive, we continue to look for ways to better address the biological weapons threat and improve national implementation of the BWC. Advisory committees,[13] federal and non-governmental studies, mandated review cycles,[14] and other resources and processes are critical components of this process.

518. This paper presents an article-by-article analysis of the United States' compliance with its obligations under the BWC. Where appropriate, each article below contains one section outlining the fundamental aspects of U.S. compliance, with a principal focus on relevant domestic laws, regulations, and policy documents; and one section addressing how the United States implements each article, highlighting concrete examples of how the United States executes and enforces compliance at the national level. All items in bold text are listed in the appendix at the end of the document.

B. Article I

Compliance

519. The United States fully complies with its Article I obligations requiring BWC States Parties, "never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; and weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."

Implementation

520. Pursuant to Section 403 of the Arms Control and Disarmament Act of 1961, as amended, the Executive Branch of the United States is required to annually assess and report to Congress on, among other things, U.S. adherence to obligations undertaken in arms control, nonproliferation, and disarmament agreements and related commitments.

521. Through its deep-seated legal traditions, commitment to the rule of law, and belief in the importance of arms control agreements to enhance international security, the United States fully complies with its BWC obligations. As a reflection of the seriousness with which the United States views these obligations, it has established legal and institutional procedures to ensure U.S. compliance. Individual agencies within the Executive Branch have established policies and procedures to ensure that plans and programs under those agencies' purview remain consistent with U.S. international obligations. For example, U.S. Department of Defense (DoD) Compliance Review Groups oversee and manage DoD compliance with arms control, nonproliferation and disarmament agreements, and related commitments. Within the Department of Homeland Security's (DHS's) Compliance Assurance Program Office, the Treaty Compliance Team reviews DHS-sponsored activities involving biological agents and related surrogates or simulants for compliance with the BWC. Further, the DHS Deputy Secretary chairs a committee that reviews DHS-sponsored activities in appropriate cases, including when such activities may raise potential treaty

[13] E.g., the National Science Advisory Board for Biosecurity established by the U.S. Government in 2006 to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research to all Federal departments and agencies with an interest in life sciences research.

[14] E.g., the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary by the Department of Agriculture and the Department of Health and Human Services.

compliance or perception concerns, and ensures that all DHS programs comply with treaty requirements. Finally, Congress performs oversight functions through committee hearings and budget allocations.

C. Article II

Compliance

522. The United States fully complies with its Article II obligations. The U.S. offensive biological weapons program was dismantled following President Richard M. Nixon's 1969 statement renouncing the use of biological weapons[15] and the issuance of National Security Decision Memorandum 35.[16] President Nixon's statement included the following:

> *...the United States of America will renounce the use of any form of deadly biological weapons that either kill or incapacitate. Our bacteriological programs in the future will be confined to research in biological defense, on techniques of immunization, and on measures of controlling and preventing the spread of disease.*

523. In 1970, the U.S. ban on biological weapons was extended to cover toxins, regardless of their means of production.[17],[18] The dismantlement process was completed prior to entry into force of the Convention on March 26, 1975.

Implementation

524. The White House in December 1975 directed the heads of all Executive Departments and Agencies to certify that all activities of those departments and agencies which retain any biological agents and toxins were conducted only for justifiable peaceful purposes; that the total quantities of materials held were committed or reserved solely to those activities; and that any weapons, equipment, or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict had been destroyed or diverted to peaceful purposes. In March 1976, the certifications were forwarded to the Department of State (DOS) to be retained as part of the permanent record of U.S. compliance with the BWC.

525. The United States reported on past offensive and defensive biological research and development programs dating back to 1941 on Form F of its 1997 Confidence-Building Measure (CBM) submission. There have been no updates to Form F since 1997.

D. Article III

Compliance

526. The United States fully complies with its Article III obligations through a comprehensive set of legislative, regulatory, and administrative measures to regulate transfers relevant to Article III. These measures include lists of materials and technologies requiring authorization to export, "catch all" controls on unlisted items, and civil and

[15] President Richard Nixon, "Statement on Chemical and Biological Defense policies and Programs, November 25, 1969," *Public Papers of the Presidents*. Washington DC. U.S. Government Printing Office, 2004. 968-969

[16] National Security Decision Memorandum 35, Washington DC, November 25, 1969 in FRUS, document 165. https://history.state.gov/historicaldocuments/frus1969-76ve02/d165.

[17] Office of the White House Press Secretary (Key Biscayne, FL), Statement on Toxins, February 14, 1970, in FRUS, document 189. www.state.gov/r/pa/ho/frus/nixon/e2/83627.htm

[18] National Security Decision Memorandum 44, Washington DC, February 20, 1970 in FRUS, document 190. www.state.gov/r/pa/ho/frus/nixon/e2/83628.htm

criminal penalties for violations. Further, the U.S. export licensing system evaluates the potential dual-use applications of items; relevant information on the recipient; stated end-use and end-use assurances; and risks of unauthorized misuse, diversion, or retransfer. The guidelines provided in the legislation and regulations described below are designed to limit the risks of proliferation of biological weapons by States and non-state actors.

527. The Export Administration Act of 1979 (EAA), as amended, directs the establishment of "a list of goods and technology that would directly and substantially assist a foreign government or group in acquiring the capability to develop, produce, stockpile, or deliver chemical or biological weapons, the licensing of which would be effective in barring acquisition or enhancement of such capability." The Export Administration Regulations (EAR) implement the EAA and contain the Commerce Control List required by the EAA. Violations of the EAA, the EAR, or an order, license, or authorization issued thereunder can incur administrative penalties (including civil monetary penalties, denial of export privileges, and exclusion from practice), criminal fines, and imprisonment.

528. The Arms Export Control Act of 1976 (AECA) authorizes the President to "control the import and the export of defense articles and defense services" and to "designate those items which shall be considered as defense articles and defense services for the purposes of this section and to promulgate regulations for the import and export of such articles and services." The International Traffic in Arms Regulations implement the AECA and contain the United States Munitions List (USML) required by the AECA. Category XIV of the USML covers "Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment." Violations of the AECA can incur civil monetary penalties and criminal penalties of fines and imprisonment.

529. The Biological Weapons Anti-Terrorism Act of 1989 (BWATA), as amended, prohibits transfers of "any biological agent, toxin, or delivery system for use as a weapon, or knowingly [assisting] a foreign state or any organization to do so." The Intelligence Reform and Terrorism Prevention Act of 2004 prohibits the import, export, direct or indirect transfers, and receipt of the variola virus, except under the authority of the Secretary of Health and Human Services. The USA PATRIOT[19] Act of 2001 prohibits "restricted persons"[20] from transporting select agents in interstate or foreign commerce, possessing select agents in or affecting commerce, or receiving any select agent or toxin[21] that has been shipped or transported in interstate or foreign commerce.

Implementation

530. In implementing Article III, the United States rigorously enforces the laws and regulations described above and conducts regular outreach to all stakeholders, including industry and academia. Each year, the Department of Commerce/Bureau of Industry and Security (DOC/BIS) hosts a three-day Update Conference for exporters to learn first-hand from U.S. Government officials about current issues and trends in export control policies, regulations, and practices. It also hosts smaller export control seminars throughout the year and across the country[22] and posts free online trainings in a variety of formats.[23] These resources are aimed at U.S. exporters, but international firms and foreign governments also

[19] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism
[20] See https://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap10-sec175b.pdf for the definition of a restricted person.
[21] A select agent or toxin is one that has the potential to pose a severe threat to public health and safety, to animal health or animal products, or to plant health or plant products. They are listed in 7 CFR §331.3 (plants), 9 CFR §121.3 and §121.4 (animals), and 42 CFR §73.3 and §73.4 (public health).
[22] https://www.bis.doc.gov/index.php/compliance-a-training/current-seminar-schedule
[23] http://www.bis.doc.gov/index.php/compliance-a-training/export-administration-regulations-training/online-training-room

use them, as they can be useful to understand U.S. requirements related to re-exports, in-country transfers, and other issues.

531. A 2009 presidentially directed[24] review of the U.S. export control system determined that the export control system was overly complicated and redundant and diminished the focus on the most critical national security priorities. As a result, the Administration launched the Export Control Reform Initiative to enhance U.S. national security and strengthen the United States' ability to counter threats such as the proliferation of weapons of mass destruction. The Administration is implementing the Initiative in three phases. In Phases I and II, definitions, regulations, and policies for export controls will be reconciled and simplified. Phase III will create a single control list, a single licensing agency, a unified information technology system, and an enforcement coordination center.[25]

532. Either the DOC or DOS reviews each license application, keeping in mind both accuracy and timeliness. For example, between 2010 and 2014, DOC/BIS received an average of nearly 25,000 applications per year for tangible items, software, and technology, and 1 percent or fewer of these applications were denied. DOC/BIS's average processing time per application has fallen to a low of 23 days, 67 days below the required completion time of 90 days per the EAR and Executive Order 12981.[26,27]

533. The DOC and DOS also conduct targeted end-use checks before and after approving licenses and after shipments have been made. These checks serve to increase confidence and cooperation; expedite future requests; facilitate transfer of more advanced technology; prevent diversions; protect end-users from untrustworthy intermediaries; foster communication among the U.S. Government, recipient country, and industry; establish an expectation of due diligence by exporters and importers; and educate industry on laws and regulations.

534. The usefulness and necessity of such checks to maintaining the integrity of the export control program are proven by the high occurrence of unfavorable findings. Of the 3,609 end-use checks completed by the DOS's Blue Lantern End-Use Monitoring Program from 2011-2015, 21 percent were deemed unfavorable, meaning that the findings of fact were not consistent with information in the license application. The most common causes of unfavorable determinations in 2015, accounting for 85 percent of such determinations, were the discovery of derogatory information concerning the end user, refusal to cooperate, unauthorized retransfer or re-export, and the involvement of a foreign party in the transaction that is not listed on the license or application.

E. Article IV

Compliance

535. The United States fully complies with its Article IV obligations through laws, regulations, and other measures designed to prohibit and prevent the development, production, stockpiling, acquisition, or retention of items specified in Article I. Mr. Christopher Park, Director, Biological Policy Staff, DOS, is the U.S. Designated National Authority for implementation of the Convention.

[24] http://www.dtsa.mil/SitePages/about-dtsa/directorates/technology-security-foreign-disclosure/PSD%208%20%20(%2021%20Dec%202009).pdf
[25] http://2016.export.gov/ecr/
[26] http://www.bis.doc.gov/index.php/forms-documents/doc_view/1266-2014-statistical-analysis-of-bis-licensing
[27] https://www.gpo.gov/fdsys/pkg/FR-1995-12-08/pdf/95-30106.pdf

536. In addition to prohibiting transfers of biological agents, toxins, or delivery systems, the BWATA, as amended, prohibits knowingly developing, producing, stockpiling, acquiring, retaining, or possessing any biological agent, toxin, or delivery system for use as a weapon, or knowingly assisting a foreign state or any organization, including terrorist organizations, to do so. Similarly, the Intelligence Reform and Terrorism Prevention Act of 2004 prohibits the use, production, engineering, synthesis, acquisition, or possession of variola virus, except under the authority of the Secretary of Health and Human Services. The USA PATRIOT Act also prohibits possession by any individual of a "biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." The USA PATRIOT Act further prohibits placing a biological agent or toxin for use as a weapon on a mass transportation vehicle and setting fire to a biological agent or toxin near a mass transportation facility.

537. A 1999 statute (Public Law 106-54) prohibits teaching or demonstrating the making or use of a weapon of mass destruction, or distributing information pertaining to the manufacture or use of a weapon of mass destruction, with the intent that the teaching, demonstration, or information would be used for a federal crime of violence. The USA PATRIOT Improvement and Reauthorization Act of 2005 prohibits transportation of biological materials within U.S. jurisdiction with the intent to commit a crime. The Violent Crime Control and Law Enforcement Act of 1994 prohibits the use of weapons of mass destruction, including threatening, attempting, or conspiring to use weapons of mass destruction.

538. The Antiterrorism and Effective Death Penalty Act of 1996 directed the creation of a list of biological agents with the potential to pose a severe threat to public health and safety and the creation of the Select Agent Regulations to ensure proper biosafety and biosecurity measures for those agents. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agriculture Bioterrorism Protection Act of 2002 give the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) the authority to implement the Federal Select Agent Program (FSAP). The USDA, through the Animal and Plant Health Inspection Service, regulates select agents and toxins of concern to plant health or plant products and to animal health or animal products. The HHS, through the Centers for Disease Control and Prevention (CDC), regulates select agents and toxins of concern to public health and safety.

539. The FSAP and associated regulations contribute to U.S. compliance with Article IV by helping to secure especially dangerous pathogens and prevent their unauthorized possession, loss, theft, misuse, diversion, or release. Entities seeking to work with a select agent or toxin must register with the applicable department (HHS or USDA, depending on the agent or toxin). The Select Agent Regulations also cover biocontainment; biosafety; biosafety and security training; and facility, personnel, and shipment security requirements for an entity required to register to possess, use, or transfer select agents and toxins, including specific requirements for Tier 1 select agents and toxins.[28] The USA PATRIOT Act prohibits a "restricted person" from shipping or possessing a select agent or toxin. The Department of Transportation prescribes technical regulations for shipping hazardous materials, including select agents and toxins.

540. Enhancing a national biosafety and biosecurity system that protects scientists, healthcare workers, and the public from exposure to harmful pathogens is a critical part of

[28] Tier 1 select agents and toxins are those "biological agents and toxins [that] present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety" (www.selectagents.gov/faq-general).

the United States' efforts to conduct state-of-the-art life sciences research and to make new lifesaving treatments, vaccines, and diagnostics widely available. Over the past two years, the United States has conducted a comprehensive review of its biosafety and biosecurity enterprise. Experts from within and outside of the Federal Government reviewed the current system, discussed recent incidents, identified best practices for the future, and urged implementation of a set of recommendations published on October 29, 2015.

541. The recommendations highlight several key principles for the national biosafety and biosecurity system, including: transparency, swift incident reporting and accountability to the public, and material stewardship that includes strong inventory management and control measures. These principles emphasize a commitment to protecting Americans and the global community, and ensuring a system designed to prevent dangerous actors from accessing or misusing sensitive biological material. In addition, while the focus of the recommendations is aimed at facilities that possess, use, or transfer the most dangerous agents, these principles should also be applied to work that is conducted with any biological agent that could pose a serious threat to public health or agriculture.

542. In addition, in 2014, thousands of facilities across the United States underwent intensive internal assessments as part of a "Safety Stand-Down." This effort resulted in a review of laboratory biosafety and biosecurity best practices and protocols, as well as plans for more consistent inventory monitoring. By continuing to review inventories, laboratory safety procedures, and security best practices, facilities can help achieve a laboratory culture of responsible conduct. Therefore, the U.S. Government continues to strongly encourage the application, at non-Federal as well as Federal facilities, of core principles, best practices, and the recommendations released on October 29, 2015.[29]

543. The U.S. Government maintains national policy that prescribes processes and procedures for the U.S. Government and U.S. Government-funded research, including classified life sciences research. Agencies that fund, direct, or execute classified life sciences research are required to implement processes to ensure activities comply with applicable law, standards, regulations, policies and international legal obligations.

544. The U.S. Government has issued two policies for oversight of life sciences dual-use research of concern (DURC) to "preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research." The 2012 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern[30] requires U.S. federal departments and agencies that fund life sciences research to identify and manage the risks associated with certain types of DURC, while the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern[31] complements the 2012 policy by establishing institutional review processes and oversight requirements for institutions receiving federal funding for life sciences research. Together, the two policies support U.S. compliance with Article IV by engaging life sciences research institutions and federal funding agencies in shared responsibility to address the risk that knowledge, information, products, or technologies generated by DURC could be used for harm.

545. The U.S. Government advocates and conducts regular reviews of advances in science and technology to ensure its policies are sufficient to address potential risks. In October 2014, the U.S. Government announced a pause in new funding for gain-of-function (GOF) research on influenza, Middle East Respiratory Syndrome (MERS), or Severe Acute Respiratory Syndrome (SARS) viruses until completion of a deliberative process to review

[29] https://www.whitehouse.gov/blog/2015/10/29/national-biosafety-and-biosecurity-system-united-states
[30] http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf
[31] http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

the risks and benefits of such research.[32] As part of the process, the National Science Advisory Board for Biosecurity was charged to advise the U.S. Government on risk and benefit assessments for GOF research. Its recommendations on a conceptual approach to the evaluation of proposed GOF research were provided to the U.S. Government in May 2016.

Implementation

546. Awareness-raising initiatives are designed to maximize compliance with laws, regulations, and national policies. Examples include online FSAP resources for training and compliance assistance and guidance,[33] resources on implementation of the 2014 policy on institutional oversight of dual-use research of concern,[34] and additional guidance such as Biosafety in Microbiological and Biomedical Laboratories (BMBL),[35] NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,[36] and Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA.[37]

547. The U.S. Government also hosts workshops and other public events related to FSAP and the DURC policies. For example, the 2nd and 3rd USDA Agricultural Research Service International Biosafety and Biocontainment Symposia in 2013 and 2015 included sessions on the Select Agent Regulations, personnel reliability programs, building a culture of responsibility, bioterrorism awareness, biorisk management, global health security, and other topics related to biosafety and biosecurity.[38], [39] The U.S. Government also sponsored international participants to attend the Symposia. In 2015 the U.S. Government hosted a public Stakeholder Engagement Workshop, attended by nearly 200 domestic and international stakeholders, to improve communication about the 2014 institutional DURC policy.[40]

(a) 540. Investigation and prosecution of violations of BWC-related criminal statutes demonstrate U.S. implementation of its Article IV obligations. The Federal Bureau of Investigation (FBI) maintains capabilities to investigate allegations of activities prohibited by BWC-related criminal statutes, and the Department of Justice prosecutes violations of BWC-related criminal statutes. Below are examples of recent prosecutions of violations and attempts to violate statutes that demonstrate investigatory capabilities and successful enforcement of the criminal statutes.

(b) Cheng Le was sentenced on March 8, 2016, to 192 months' imprisonment stemming from his efforts to obtain and then sell ricin for use as a weapon. Le attempted to purchase ricin through the dark web and revealed his intent to resell the ricin to at least one secondary buyer.

(c) Jesse Korff was sentenced on February 18, 2015, to 110 months' imprisonment for developing, stockpiling, and transferring ricin and abrin, attempting to export the toxins, and conspiracy to kill or injure persons in a foreign country. Korff made

[32] http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf
[33] http://www.selectagents.gov/resources.html
[34] http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx
[35] http://www.cdc.gov/biosafety/publications/bmbl5/index.htm
[36] http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
[37] http://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx
[38] http://arssymposium.absa.org/past-symposia/2013-program/
[39] http://arssymposium.absa.org/past-symposia/2015-program/
[40] http://www.phe.gov/about/OPP/DURCworkshop/Pages/default.aspx

biological toxins for use as weapons and was selling them over the internet, knowing the buyers intended to use them to kill other people.

(d) Jeff Boyd Levenderis was convicted on June 4, 2014, of possessing ricin for use as a weapon, of possessing ricin of an unauthorized type or quantity without justification, and of two counts of making false statements to agents of the Federal Bureau of Investigation. Levenderis was sentenced to six years' imprisonment.

(e) James Everett Dutschke pleaded guilty on January 23, 2014, to developing and possessing ricin for use as a weapon and mailing ricin-laced letters to the President of the United States, a U.S. Senator, and a Mississippi Justice Court judge. Dutschke was sentenced to 300 months' imprisonment and 5 years of supervised release.

(f) Ray H. Adams and Samuel J. Crump were convicted on January 17, 2014, of possessing and conspiring to possess ricin for use as a weapon and later each sentenced to ten years' imprisonment and five years' supervised release.

(g) Shannon Guess Richardson pleaded guilty on December 10, 2013, to possession of a toxin for use as a weapon and was sentenced to 216 months' imprisonment and ordered to pay $367,222.29 in restitution.

548. The FBI also documented some of its capabilities for the international community in the International Edition of the 2015 Criminal and Epidemiological Investigations Handbook.41

F. Article V

Compliance

549. The United States fully complies with its Article V obligations and believes that maintaining and promoting confidence that States Parties are abiding by their commitments is essential to ensuring the stability and integrity of the Convention. This obligation is a useful tool for fulfilling States Parties' mutual responsibilities of building a shared confidence in compliance with the BWC. Rather than stigmatizing the entities or activities about which questions are raised, regular cooperative bilateral and multilateral consultations can improve communications among States Parties and increase transparency.

550. In the interest of promoting transparency and confidence, the United States submitted working papers to BWC meetings on its Select Agent Regulations,42 its policies on oversight of life sciences dual-use research of concern,[43] and its policies on high-containment laboratories[44] and, at the 2015 Meeting of Experts, provided a representative from the DoD to respond publicly to questions about shipments of incompletely inactivated Bacillus anthracis from a biodefense facility and follow-on corrective actions.

[41] https://www.fbi.gov/about-us/investigate/terrorism/wmd/criminal-and-epidemiological-investigations-handbook-2015-international-edition-2/view
[42] https://documents-dds-ny.un.org/doc/UNDOC/GEN/G13/621/52/PDF/G1362152.pdf?OpenElement
[43] http://www.unog.ch/80256EDD006B8954/(httpAssets)/C336C696FC33D3C4C1257D4900481A1F/$file/BWC_MSP_2014_MX_WP.7.pdf
[44] http://www.unog.ch/80256EDD006B8954/(httpAssets)/ABE75C5BA42376B2C1257E97004332CC/$file/BWC_MSP_2015_MX_WP4.PDF

Implementation

551. The United States supports a broad range of efforts to strengthen implementation and enhance transparency and assurance of compliance with the BWC.

552. First, the United States submits annual confidence-building measures (CBMs) as agreed by the Second Review Conference in 1986 to "prevent or reduce the occurrence of ambiguities, doubts, and suspicions" and makes them publicly available through the ISU website. The United States considers annual CBM participation an effective way for States Parties to demonstrate their implementation of the BWC and to enhance confidence among States Parties that others are fulfilling their obligations. Submission of annual CBM returns is a politically binding commitment and, accordingly, the United States has submitted a CBM every year since 1987.

553. Second, the United States supports efforts to enhance transparency of biological defense programs using CBMs and other tools and takes efforts to be responsive to others' concerns. For example, in 1997 the United States participated in consultations with Cuba regarding questions of U.S. compliance. More recently, in 2016 the United States and the Russian Federation engaged on matters of U.S. compliance and implementation of the BWC. These consultations can provide a constructive framework to address both broad implementation challenges that affect many States Parties and specific questions and concerns in a cooperative manner.

554. Finally, affirming the value the United States places on voluntary initiatives that demonstrate transparency and build confidence in compliance, the United States has partnered with Canada, Chile, Ghana, and Mexico on a BWC Implementation Review project. The purpose of the exercise is to strengthen national implementation and promote transparency among the participating countries. The concept for the project involves exchanging reports on measures to implement the Convention and holding meetings of experts in each capital to discuss the implementation measures in the reports.

G. Article VI

Compliance

555. The United States fully complies with its Article VI obligations. The United States has not lodged a complaint with the United Nations (UN) Security Council (UNSC) but has taken steps to demonstrate its intent to support and cooperate with an investigation by the UN Secretary General's Mechanism (UNSGM) on U.S. territory.

Implementation

556. One example of implementation of Article VI obligations is the strong U.S. commitment to facilitating investigations of alleged use of biological weapons. In particular, at the Third Review Conference, BWC States Parties agreed "to cooperate fully with the United Nations Secretary General in carrying out such [alleged use] investigations." In support of this agreement and in recognition that the only realistic tool for an investigation of alleged biological weapons use is the UNSGM, the United States committed to cooperating with an investigation in a letter to the UN Secretary General dated April 4, 1991. In the letter, the United States pledged "to cooperate fully with you in your investigation of such reports [of possible use of chemical, biological, and toxin weapons in violation of international law], consistent with safety and domestic legal constraints. Such cooperation would include receiving a team of qualified experts on U.S. territory should you have occasion to request such an investigation."

557. The United States also contributed to developing the capabilities of the UNSGM by holding a workshop in 2016 in cooperation with the UN Office for Disarmament Affairs (UNODA). Participants at the workshop exchanged ideas to build a strategy for helping UNODA improve its capability to conduct investigations of alleged biological weapons use.

H. Article VII

Compliance

558. The United States is prepared to comply with Article VII should it be invoked. Specifically, the United States has capabilities to provide and to support international assistance, including technical, public health, and medical assistance, to a requesting State Party deemed to have been exposed to danger as a result of violation of the Convention.

559. Additionally, the United States complies with Article VII by supporting efforts to strengthen the UNSGM to investigate allegations of biological weapons use. The UNSGM has significance for Article VII, in addition to the relevance to Article VI discussed above. For instance, if a State Party believes it has been exposed to danger as a result of a violation of the Convention, but lacks the technical capabilities or capacities to produce the evidence needed to present its case to the UNSC, then the UNSGM could assist this effort.

Implementation

560. U.S. efforts to strengthen implementation of Article VII have focused on ensuring an efficient, effective response to an outbreak at the earliest possible point and on ensuring that transition to formal activation of Article VII provisions is seamless and complementary to any ongoing public health or animal health response.

561. Specifically, the U.S. Government maintains capabilities within multiple Departments and Agencies, including HHS, CDC, and the U.S. Agency for International Development's Office of U.S. Foreign Disaster Assistance, among others, to support international assistance. The U.S. Government also maintains relationships with private sector and non-governmental organizations to request their assistance to supplement and otherwise amplify these capacities, if needed.

562. Recognizing that key capabilities must be in place within both sending and receiving countries in order for international assistance to be effective, the United States supports implementation of the International Health Regulations (2005), which obligate nations to develop capacity to respond to public health emergencies of international concern, and the Global Health Security Agenda, which facilitates building the capacity of nations to respond to human and animal infectious disease events. The United States also recognizes the integral role of international agreements, initiatives, and organizations committed to enhancing preparedness and response efforts for humanitarian disasters and public health emergencies, including the G7 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.

563. Though the UNSGM has investigated and confirmed cases of chemical weapons use, it has never been used to investigate an allegation of biological weapons use. The capability should be developed and maintained so that, like domestic response capabilities, it is ready and able to carry out its mission should the UN Secretary General decide it is needed. The United States is working with UNODA and other concerned States and international organizations to strengthen the capability and capacity of the UNSGM. The United States has participated in workshops to develop the network of laboratories that would be available to test samples and in April 2016 hosted a workshop with policy,

technical, and field experts to develop a collaborative strategy for contributing to a basic operational capacity within two years.

I. Article VIII

564. The United States fully complies with its obligations under the 1925 Geneva Protocol. The United States signed the Protocol on June 17, 1925, and deposited its instrument of ratification on April 10, 1975. At that time, there was no ban on the possession or stockpiling of chemical weapons. The U.S. reservation to the Protocol, which applied only to "the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials, or devices," was intended to deter the use of chemical weapons against the United States or its allies.

565. On May 13, 1991, during the Chemical Weapons Convention negotiations, President George H.W. Bush announced that "[t]o demonstrate the United States commitment to banning chemical weapons, we are formally forswearing the use of chemical weapons for any reason, including retaliation, against any state, effective when the Convention enters into force."[45] This pronouncement and our obligations as a State Party to the Chemical Weapons Convention prohibit all activities that were reserved under the Protocol and such legal obligations apply, despite existence of the reservation.

J. Article IX

566. The United States signed the Chemical Weapons Convention on January 13, 1993, and deposited its instrument of ratification on April 25, 1997.

K. Article X

567. The United States fully complies with its Article X obligations. Through Article X activities, the United States envisions building two international norms. First, participation in the "exchange of equipment, materials and scientific and technological information" should be encouraged to improve biosecurity and work actively against the proliferation of biological weapons. Second, "the further development and application of scientific discoveries…for disease prevention and other peaceful purposes" are essential to working actively toward improved quality of life for all. Specifics on U.S. activities under Article X can be found in the Article X paper submitted by the United States to the Implementation Support Unit in advance of the Eighth Review Conference.

Appendix

Summary of Laws, Regulations, Policies, and Other Documents

Laws (in chronological order)

- Arms Control and Disarmament Act of 1961

[45] http://www.presidency.ucsb.edu/ws/index.php?pid=19575

  - https://www.gpo.gov/fdsys/pkg/USCODE-2014-title22/pdf/USCODE-2014-title22-chap35-subchapIV-sec2593a.pdf
  - Requires the President to submit reports to Congress on the status of U.S. policy and actions with respect to arms control, nonproliferation, and disarmament
- Arms Export Control Act of 1976
  - http://uscode.house.gov/statutes/pl/94/329.pdf
  - Authorizes the President to control the export of defense articles and services
- Export Administration Act of 1979
  - http://legcounsel.house.gov/Comps/eaa79.pdf
  - Authorizes the Department of Commerce to regulate the export or re-export of U.S.-origin dual-use goods, software, and technology
- Biological Weapons Anti-Terrorism Act of 1989
  - http://thomas.loc.gov/cgi-bin/query/z?c101:S.993.ENR:
  - Prohibits knowingly developing, producing, stockpiling, transferring, acquiring, retaining, or possessing any biological agent, toxin, or delivery system for use as a weapon, or knowingly assisting a foreign state or any organization, including terrorist organizations, to do so
- Violent Crime Control and Law Enforcement Act of 1994
  - https://www.gpo.gov/fdsys/pkg/BILLS-103hr3355enr/pdf/BILLS-103hr3355enr.pdf
  - Prohibits the use of weapons of mass destruction, including threatening, attempting, or conspiring to use weapons of mass destruction
- Antiterrorism and Effective Death Penalty Act of 1996
  - https://www.gpo.gov/fdsys/pkg/PLAW-104publ132/html/PLAW-104publ132.htm
  - Directed the creation of a list of biological agents with the potential to pose a severe threat to public health and safety and the regulation of biosafety and biosecurity measures for those agents
- USA PATRIOT Act of 2001
  - https://www.gpo.gov/fdsys/pkg/PLAW-107publ56/html/PLAW-107publ56.htm
  - Establishes penalties for the unauthorized possession or transfer of biological select agents and toxins, and restricts the persons who can have access to listed biological select agents and toxins
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
  - http://www.selectagents.gov/resources/PL107-188.pdf
  - Authorizes the regulation of the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety
- Agriculture Bioterrorism Protection Act of 2002

  - http://www.selectagents.gov/resources/PL107-188.pdf
  - Authorizes the regulation of the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products
- Intelligence Reform and Terrorism Prevention Act of 2004
  - https://www.nctc.gov/docs/pl108_458.pdf
  - Prohibits knowingly producing, engineering, synthesizing, acquiring, transferring directly or indirectly, receiving, possessing, importing, exporting, or using, or possessing and threatening to use, variola virus, except under the authority of the Secretary of Health and Human Services
- USA PATRIOT Improvement and Reauthorization Act of 2005
  - https://www.congress.gov/109/plaws/publ177/PLAW-109publ177.pdf
  - Prohibits transportation of biological materials within U.S. jurisdiction with the intent to commit a crime

Regulations (in alphabetical order)

- Export Administration Regulations
  - https://www.gpo.gov/fdsys/pkg/CFR-2011-title15-vol2/pdf/CFR-2011-title15-vol2-subtitleB-chapVII-subchapC.pdf
  - Implement authorities in the Export Administration Act of 1979, as amended
- International Traffic in Arms Regulations
  - http://www.ecfr.gov/cgi-bin/text-idx?SID=7f87f58daca8205a719c8aa090640178&mc=true&tpl=/ecfrbrowse/Title22/22CIsubchapM.tpl
  - Implement authorities in the Arms Export Control Act of 1976
- Select Agent Regulations
  - http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=7y5.1.1.1.9&r=PART
  - http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=9y1.0.1.5.58&r=PART
  - http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61
  - Implement relevant sections of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002

Policies (in alphabetical order)

- Executive Order 12981
  - https://www.gpo.gov/fdsys/pkg/FR-1995-12-08/pdf/95-30106.pdf

  - Details procedures for export license application submitted under the Export Administration Regulations

- National Security Decision Memorandum 35
  - https://history.state.gov/historicaldocuments/frus1969-76ve02/d165
  - Renounced the use of biological weapons by the United States
- National Strategy for Countering Biological Threats
  - http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
  - Guides U.S. Government efforts to prevent bioterrorism incidents by reducing the risk that misuse of the life sciences will result in the use of biological agents to cause harm and complements existing preparations to advance U.S. abilities to respond to public health crises of natural, accidental, or deliberate origin
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
  - http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
  - Addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented
- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern
  - http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf
  - Establishes regular review of U.S. Government-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be Dual Use Research of Concern (DURC) in order to mitigate risks as appropriate and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC

Guidance (in alphabetical order)

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - http://www.cdc.gov/biosafety/publications/bmbl5/index.htm
  - Details the code of practice for biosafety and biocontainment in the United States
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
  - http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
  - Detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules
- Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA
  - http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf

  - Aims to reduce the risk that synthetic DNA will be deliberately misused to create dangerous organisms

- International Edition of the 2015 Criminal and Epidemiological Investigations Handbook
  - https://www.fbi.gov/about-us/investigate/terrorism/wmd/criminal-and-epidemiological-investigations-handbook-2015-international-edition-2/at_download/file
  - Developed to facilitate the use of resources and maximize communication and interaction among law enforcement and public health in an effort to minimize potential barriers during a response to a biological threat.