

**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**

10 October 2016

English only

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Geneva, 7-25 November 2016

Item 10 of the provisional agenda

**Review of the operation of the Convention  
as provided for in its Article XII**

**Implementation of Article X of 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 the implementation of Article X, to be compiled from information submitted by States Parties, including information submitted pursuant to paragraph 61 of the Final Declaration of the Seventh Review Conference (see BWC/CONF.VIII/PC/9, paragraph 26(h)). 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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## Australia

1. The following report on Australia's implementation of Article X is provided in response to the request from the Secretariat of the BWC Implementation Support Unit of 25 May 2016 for background information for the Eighth Review Conference. This also represents Australia's 2015 update of its annually provided Article X report.

2. 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.

3. Consistent with this agreement by States Parties, Australia continues to encourage other States Parties to share details on national efforts to implement Article X and we welcome the reports already provided by a number of States Parties. This paper provides an update to Australia's 2012<sup>1</sup>, 2013<sup>2</sup> and 2014<sup>3</sup> report on national implementation of Article X.

### A. General perspectives on implementation of Article X

4. As expressed previously, facilitating international exchange of equipment, materials and scientific and technological information for the peaceful use of the life sciences helps to prevent the global spread of infectious diseases. It also builds capacity to respond to disease outbreaks (whether caused naturally or through the hostile use of biological agents or toxins) and can provide incentives for States to accede to the BWC.

5. In fulfilling our obligations under Article X, Australia considers that a broad range of activities fit within the scope of that article. At the various BWC meetings, discussion on the challenges and obstacles to developing international cooperation and assistance highlighted the need for States Parties to work across sectors within their governments to identify and address logistical, legal and regulatory barriers. In Australia's case, such whole-of-government arrangements underpin the facilitation of international exchange, as described in Article X. These legislative, regulatory and policy arrangements allow for legitimate and beneficial activities and innovation in the life sciences, notably by academic and research institutions, and industry.

6. The Australian Government provides a range of non-sector specific programs and initiatives that support research, development and commercialisation in the life sciences industry and other forms of biotechnology such as industrial and agricultural biotechnology. Many Australian Government activities and international programs directly reflect and/or support exchanges in biological sciences and the peaceful use of biotechnologies. These activities and programs complement the commercial, educative and collaborative activities of Australian industry and academic and research institutions internationally. In its annual BWC Confidence Building Measures submission (form C),

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<sup>1</sup> MSP/2012/MX/INF.8

<sup>2</sup> MSP/2014/INF.5

<sup>3</sup> MSP/2015/MX/INF.1

Australia provides information on relevant research and other activities undertaken within Australian Government agencies. This information is made publicly available. As set out in Australia's previous BWC Article X implementation reports, many of these programs and activities focus on Australia's contribution to building capacity to counter biological terrorism and to combat emerging infectious diseases and pandemics.

## **B. Countering biological terrorism and counter-proliferation**

7. In our earlier reports, Australia outlined efforts in countering biological terrorism and counter-proliferation that fall within the scope of Article X and help to strengthen cooperation and protection. In particular, Australia's collaboration with partners has focussed on strengthening regional capacity in counter-terrorism within the Asia-Pacific region.

8. Some recent examples include:

(a) Australia is participating in two of the 11 Global Health Security Agenda (GHS) packages as a contributing country. One of these is the "Linkages and Multi-sectoral Rapid Response Action" package which aims to enable a country to conduct a rapid whole of government response, including the capacity to link public health and law enforcement, and to provide or request effective and timely international assistance in the event of a biological incident that is suspected or confirmed to be deliberate.

(b) Australia continues to participate in international and domestic counter-terrorism and counter-proliferation CBR capability building exercises and training programmes including the ongoing provision of funding for the delivery of a quality assurance program to enhance laboratory capacity and capability to test for biological agents of security concern within Australia and within specified overseas laboratories.

(c) Australia continues to develop a medical countermeasures development capability that benefits from collaboration with like-minded partners in the quadrilateral defence and public health community.

(d) In 2015, Australia revised and exercised its *Health, Chemical, Biological, Radiological and Nuclear Incidences of National Consequences (CBRNINC)* Plan in order to refine response arrangements. Other related plans for the Health sector, such as response plans for incidences of smallpox and biological toxins (abrin and ricin) are currently being revised with a view to finalisation in late 2016.

9. In this collaboration with partners, Australia continues to underline the need to strike an appropriate balance between enabling peaceful biological research consistent with the objectives of the BWC, and minimising the possibility of misuse of this research and associated biological materials, equipment and technology.

## **C. Addressing pandemics and emerging infectious diseases**

10. As emphasised in earlier reports, Australia takes efforts to build capacity for addressing pandemics and emerging infectious diseases in our region seriously.

(a) Australia's *Health for Development Strategy 2015-2020* aims to improve regional health security through promoting strengthened health systems that can address emerging infectious diseases and drug resistance, and assisting regional collaboration. In July 2016 at the Southwest Pacific Dialogue Australia announced investment of AUD100 million in a Health Security Partnerships Initiative to apply Australian expertise and research to regional health and development outcomes, including new technologies and medicines for our region.

(b) These efforts support Australia's implementation of BWC Article X, and recognise that the prevention, detection and control of pandemics and emerging infectious diseases are a global public good which no one country can provide on its own.

11. Australia's efforts in building capacity to combat infectious diseases involves a range of Australian Government agencies and close collaboration with regional partners and multilateral organisations (such as the World Health Organisation, WHO). Some practical examples of Australia's funding for this capacity building include:

(a) In 2015 Australia voluntarily contributed funding of AUD6 million to the WHO Health Emergencies Programme, including AUD1 million to the Emergency Medical Teams initiative; and AUD8 million over 3 years to the World Bank to establish a Multi Donor Trust Fund to support national governments' financing of health systems to address a range of infectious diseases and health threats.

(b) Australia is also contributing to the GHSA package focussing on preventing antimicrobial resistance (AMR) and has a "One Health" approach to coordinate Australia's efforts across animal and human health, agriculture and food sectors to reduce, monitor and respond to AMR. The objectives of Australia's National Antimicrobial Resistance Strategy 2015-2019 focus on: infection prevention and control; surveillance; antimicrobial stewardship; international engagement; communication and education; research and development; and governance.

(c) Australian experts are participating in the Joint External Evaluations (JEE) which assess country capacity to meet International Health Regulations and GHSA competencies.

(d) In recognition of the reduced number of new cases of Ebola in West Africa, Australia downscaled its border screening measures on 13 November 2015.

(e) Australian aid also has a long history in addressing the spread of diseases from animals to humans in South-East Asia. Australia has contributed to the *Stop Trans boundary Animal Disease and Zoonoses* (STANDZ) Initiative through the World Organisation for Animal Health (OIE) (AUD12.79 million 2011-2017); and to working with the Government of Indonesia through the *Australia-Indonesia Partnership for Emerging Infectious Diseases* (AIPEID) to strengthen human and animal health systems (AUD9.9 million 2015-2018).

(f) Through its OIE Reference Laboratory delegations, the Australian Animal Health Laboratory (AAHL) within the Commonwealth Scientific and Industrial Research Organisation (CSIRO) provides assistance to the south-east Asian, south Asian and Pacific regions for diagnosis and characterisation of a range of emergency animal diseases (including zoonoses) in terrestrial and aquatic species. In 2015 this included identification and characterisation of highly pathogenic avian influenza viruses from outbreaks of disease in Myanmar and Laos and avian paramyxovirus from outbreaks in the Philippines. AAHL also contributes to research and diagnostic preparedness for a range of emergency animal diseases (including zoonoses) through various national and international collaborations, including with the Food and Agriculture Organisation (FAO), OIE, Australian Centre for International Agricultural Research (ACIAR), and Australian Department of Agriculture and Water Resources.

#### **D. Offers of Assistance**

12. As Chair of the Australia Group (AG) we have submitted to the BWC Implementation Support Unit an "offer of assistance", on behalf of the AG membership,

enabling States Parties to request assistance from the AG membership about the implementation of export controls for chemical and biological transfers.

13. Australia has been a longstanding advocate of universality of the BWC and has provided support to Myanmar to facilitate its attendance at various BWC meetings, most recently at the 2015 Meeting of Experts. Australia supported the 2016 BWC sponsorship programme which will enable experts from 25 States Parties to attend the August BWC Preparatory Committee meeting and the November BWC Review Conference. Australia also supported participation in the 2015 Global Parliamentary Campaign for Universality and National Implementation of the BWC, organised by the Parliamentarians for Global Action (PGA).

14. This report is a summary of the collaborative work Australia has recently undertaken, and complements our previous reports on Implementation of Article X. Australia's commitment to capacity building remains a practical and mutually beneficial effort within the scope of Article X toward better health, social and economic outcomes and improvements in biosecurity. Australia's continuing commitment to meeting its Article X obligations, as demonstrated by the examples selected for inclusion in this report, further helps demonstrate the way enhanced international cooperation and assistance can reinforce the security objectives of the BWC.

## **Belgium**

### **A. The Institute for Tropical Medicine in Antwerp, Belgium – a partner for health professionals from the South (<http://www.itg.be/itg>).**

15. For many years the Institute for Tropical Medicine in Antwerp (ITM) has been providing scholarship programmes for health professionals from the South, for training at advanced master level and for experts in specific fields of science through short courses. The majority of participating students benefit from scholarships financed by Belgian Development Cooperation. For this purpose EUR 12.9 million were available for the period 2008-2013. The ITM also receives core funding from several governmental entities. The ITM currently offers three Master tracks and nine specialised short courses covering the fields of tropical clinical sciences, public health (health systems policy & management and disease control) and tropical animal health. All Masters and short courses included in the scholarship programme are accredited through international bodies.

16. Furthermore Belgian Development Cooperation helps the ITM to cooperate with and support similar institutions in the South in order to mutually reinforce capacities and accomplish their respective scientific and societal missions in the fields of tropical medicine for humans and animals, disease control and health services management. The ITM has been cooperating with and supporting numerous institutions in Latin-America, Africa and Asia.

### **B. B-LiFE - Biological Light Fieldable Laboratory for Emergencies**

17. The B-LiFE laboratory was deployed in Guinea (N'Zerekore) between 20 December 2014 and 22 March 2015 as part of the humanitarian assistance protocol B-FAST (Belgian First Aid and Support Team). The main goal of the laboratory was to conduct a rapid DNA-based identification (~3 hours) of Ebola virus in samples from suspected patients originating from Forest Guinea. Several scientific projects were carried out concomitantly, such as the testing of an antiviral drug. An epidemiological mapping of Ebola disease in the N'zerekore region was developed and the generated results were stored into a central

database that could be consulted by World Health Organization (WHO) and European Centre for Disease Control (ECDC) experts.

## **Bulgaria**

18. The National Center for Infectious and Parasitic Diseases (NCIPD) was designated as WHO Collaborating Center for research and training in surveillance of communicable diseases and antimicrobial resistance, among its tasks being the coordination and collaboration in this field with partners in countries in Southeast Europe, North Africa and Central Asia. The Center collaborated, inter alia, with NAMRO (Cairo) on haemorrhagic fevers, partners in the FYROM on polio and swine flu diagnosis, in Turkmenistan, Uzbekistan, Kyrgyzstan, as well as in Armenia on malaria diagnosis.

19. Through twinning projects with The Netherlands and Italy (PHARE projects) aimed at strengthening the combat capacity against infectious diseases, NCIPD received equipment for identification of highly pathogenic bacterial and viral agents. As a part of these twinning projects, an intensive post-graduate educational programme was implemented, involving epidemiologists, microbiologists and virologists working in the field of surveillance of infectious diseases with a focus on early warning.

20. The Republic of Bulgaria has collaborated with EU partners and participated in activities carried out through the Executive Agency for Health and Consumers, the European Center for Disease Prevention and Control (ECDC), the EU Early Warning and Response System, etc.

## **Cyprus**

21. 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**

22. The Czech Republic is firmly committed to the implementation and strengthening of the Biological and Toxin Weapons Convention. In line with the decision taken during the first Preparatory Committee meeting in April 2016 the Czech Republic provides information on the national endeavours with regards to the article X of the Convention.

23. Complementary to the EU initiatives described in the Working Paper "Implementation of Article X of the BWC by the European Union Institutions and the European Union Member States" (BWC/CONF.VIII/PC/WP.20) the Czech Republic engages with the other State Parties to the BTWC or international organisations in several others bilateral and multilateral international projects enabling facilitation of the exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.

24. The Czech Republic is continuously involved in the work of relevant organizations in the UN system (Food and Agriculture Organization and the World Health Organization) and EU institutions where it is actively taking part in their projects related to infection prevention and control in health care.

25. These activities are also supported in the framework of the Czech Official Development Assistance, both in the bilateral and multilateral development cooperation and in the humanitarian response to biological threats.
26. In the framework of bilateral development cooperation, the Czech Republic concentrates i. a. on the elimination of environmental and health related hazards and on promotion of biosafety and biosecurity related veterinary capacities (e.g. a joint project of Czech Development Agency *CzDA*, Swedish Development Agency *Sida* and the American Development Agency *USAID* in Bosnia and Herzegovina aimed at strengthening the capacity of national veterinary laboratories and veterinary inspection services involved in the implementation of the NRMP in accordance with EU standards).
27. Another particular example has been the comprehensive response to the Ebola epidemics which included both in-kind, expert and financial assistance to the affected countries, support to the UN mission (UNMEER) and to the related multi-donor trust fund as well as an active participation in the comprehensive EU response.
28. The Czech Republic participates within the European Medical Corps which is part of the European Emergency Response Capacity established as follow-up to the Ebola response under the EU Civil Protection Mechanism. The aim of the European Medical Corps is to provide a rapid European response to emergencies with health consequences both inside and outside Europe. By March 2016, nine Member States (Belgium, Luxembourg, Spain, Germany, the Czech Republic, France, the Netherlands, Finland, and Sweden) have contributed with specialised medical teams, field hospitals, mobile laboratories, medical evacuation capacities and logistical support teams.
29. Czech universities and research institutes are actively engaged in international exchange of knowledge through participation in international research projects and hosting international symposiums dealing with health, bacteriology and biotechnology issues. The Czech Republic regularly provides scholarships (jointly managed by the Ministry of Foreign Affairs and the Ministry of Education, Youth and Sports) to students from developing countries to enable them to study at Czech public universities.
30. The Czech Republic has also submitted an offer for assistance into The Assistance and Cooperation Database on the BTWC web portal.

## Denmark

31. Statens Serum Institut (SSI) prevents and controls infectious diseases, biological threats and congenital disorders. Since 1978 SSI researchers have been in charge of a major health research project in Guinea-Bissau, West Africa. The project, called Bandim, is financed primarily by external funds via Danida, the EU, the Danish National Research Foundation and private funds such as the Novo Nordisk Foundation. The main focus of the project is demography surveillance of more than 100.000 people in 6 suburbs of the capital Bissau and additional 180 clusters of woman and their children in the rural areas. The thorough registration process provides the Bandim Health Project with a unique opportunity to study the population effects of new health interventions such as the introduction of new vaccines, vitamin A supplementation or the distribution of bednets to prevent malaria.
32. The registering of the population in the area has meant that the project returns valuable research results and health statistics to the population. One of the most important findings was that a new measles vaccine used in low-income countries was associated with a twofold increase in mortality among girls. The discovery led to the withdrawal of the vaccine. In addition, the participants are offered free health consultations and essential medicine. So far, the project has educated 12 local graduates (MAs) and six local PhDs.



Another and major part of SSI's research focus has been on "forgotten and overlooked" diseases such as tuberculosis, malaria and HIV, which threaten mainly developing countries. The vaccine research program at SSI has special expertise in the production of synthetic vaccines that in contrast to live, but inactivated vaccines cannot trigger a disease outbreak. The vaccines are of special interest because they are safe, cheap to produce and potentially flexible. E.g. SSI's inactivated polio vaccine has been prequalified by the WHO, which means that the vaccine will be considered when UN organizations purchase vaccines. Since 1988, WHO's goal has been to eradicate the disease.

## **Estonia**

33. Estonia fulfils Convention article X obligations partly through Ministry of Social Affairs (MoSA) and its competent authority Health Board, Estonia (HB).

34. HB is performing communicable disease surveillance, including the surveillance of diseases with epidemic potential, epidemiologic intelligence, early warning and response activities and microbiology laboratory biorisk management under WHO and ECDC recommendations. HB has established the early warning and response system, including rapid response teams of epidemiologists, for the purposes of alerting, assessing public health risks, recognition of biological emergency situations, including public health emergency of international concern in accordance with the International Health Regulations (IHR), and a serious cross-border threat to health. HB shall notify an alert in the EU Early Warning and Response System (EWRS) if the emergence or development of a serious cross-border threat to health fulfils the established criteria.

35. Estonia has close collaboration with WHO and EU partners carried out by ECDC. HB is using diagnostic capacity of WHO Collaborating laboratory centres for poliomyelitis, influenza, measles, and rubella. Estonia provided additional financial support in fighting Ebola and poliomyelitis to international partner organizations (WHO, UNICEF, OCHA) contributing in total EUR 580 000.

36. According to national legislation HB has responsibility to check and issue a license for the management of biorisk materials to laboratories with the objective a) ensuring safety and security of microbial, viral and other biological agents in laboratories, including during transportation in order to prevent contamination of staff and unauthorized access to and removal of agents, b) promoting biosafety, biosecurity and preparedness against intentional misuse of biological agents, c) recovery, investigation and containment of outbreaks and epidemics of communicable diseases.

37. Estonia has well-developed national immunization programme which has warranted high vaccination coverage of 11 vaccine-preventable diseases among children and adolescence in accordance with WHO recommendations.

38. MoSA and HB are responsible for the implementation of the Decision No 1082/2013/EU of the European Parliament and Council of 22.10.2013 on serious cross-border threats to health.

## **Finland**

### **A. General Remarks**

39. Finland provides the following information with regard request for background information on the implementation of Article X.

## **B. Specific Endeavours Relevant to Article X**

### **1. Global Health Security Agenda**

40. Finland was the Chair of the Global Health Security Agenda (GHSA) Steering Group in 2015.

41. The GHSA was launched by the United States in February 2014 to advance a world safe and secure from infectious disease threats, to bring together nations from all over the world to make new, concrete commitments, and to elevate global health security as a national leaders-level priority. Through a partnership of approximately 50 nations, international organizations, and non-governmental stakeholders, GHSA is to prevent, detect and respond to infectious diseases by facilitating collaborative, capacity-building efforts to achieve specific and measurable targets around biological threats, while accelerating achievement of the core capacities required by the relevant global health security frameworks.

42. During its year as a chair Finland initiated the GHSA country evaluation processes, which seeks to measure a state's capacity to respond to a potential health security threat. Prior to this, the WHO did not have a mechanism for external evaluations but it relied on self-reporting of the Member Countries. The GHSA tool has now been adopted as the base of WHO's Joint External Evaluation-tool. After completing the year as a Chair, Finland remains an active member of the Steering Group and has continued its active engagement in the country evaluations. Finland is leading an Alliance of interested countries and organizations in support of the external evaluations in order to better link assessments with national planning and development financing.

### **2. Participation in Global Partnership**

43. Finland is actively involved in the international cooperation initiative Global Partnership, which functions as part of G7-cooperation. The Global Partnership addresses non-proliferation, disarmament, counterterrorism, and nuclear safety issues through cooperative projects. Finland funds two projects as part of its Global Partnership activities. In January 2016 Finland also announced its participation to the Ukraine Biocoordination Assistance Team.

### **3. Strengthening Biosafety and Biosecurity in Tanzania**

44. The Ministry for Foreign Affairs of Finland funds a project on biosafety and biosecurity in Tanzania. This project aims at preventing unintentional and intentional spread of infectious diseases by strengthening the know-how of diagnosing. The existence and outbreaks of diseases that are dangerous to life place great strain to the national healthcare systems. Efforts to identify microbes that cause infectious diseases are vital to any nation's public health system. The Finnish Centre for Biothreat Preparedness (BUOS)/Center for Military Medicine (SOTLK) administers and implements the biosafety and biosecurity project, together with the Tanzanian counterpart (Ministry of Livestock and Fisheries Development). Local expertise, detection abilities and developing of biosecurity know-how reduces potential biothreat, thus contributing towards building global security.

## **France**

45. France fulfils its obligations under Article X through many projects, among which two organizations' activities might be highlighted:

## **A. The Institut de Recherche pour le Développement (IRD)**

46. The IRD is a French research institute which, working with Southern partners, addresses international development issues. The aims underpinning all its work are to improve health and public health with a view to achieving the global Millennium Development Goals. Through partnership-based research, training and innovation, it is present in more than 50 countries in Africa, the Mediterranean basin and Latin America. Its projects are jointly run with partners and are based on an interdisciplinary approach. They address questions vital for Southern countries, such as tropical diseases, the links between health and environment, water resources or food security.

47. One emblematic project conducted by IRD, in the field of biological research, is RISA (Résistance Insecticide Santé Agriculture), a team working on insecticide resistance, health and agriculture, formed in 2009 and following a thesis funded by the IRD. It unites regional efforts to assess the impact of pesticide use in Africa on insecticide resistance in the malaria vector *Anopheles gambiae* and the plant pests *Bemisia tabaci* and *Plutella xylostella*. Research is conducted in Benin, Burkina Faso and Togo. The aim, at a time when food resources are strained, is to introduce crop protection programme management strategies that will limit the ecotoxicological risks connected with large-scale pesticide use.

## **B. The Institut Pasteur International Network (RIIP)**

48. The RIIP is a partnership of 33 research and public health institutes on five continents. With its global presence and the top-level expertise of its scientists, the RIIP is well positioned to perform infectious disease surveillance and participate in the global response to major epidemics. The Network hosts several Reference Centres and WHO Collaborating Centres, which carry out constant surveillance for diseases with epidemic potential such as influenza, cholera, dengue, yellow fever and emerging infectious diseases. As such, RIIP member institutes provide technical advice at the national and international level. The RIIP interacts with local and international public health authorities and works closely with health ministries, the WHO's Global Outbreak Alert and Response Network (GOARN) and the Institut Pasteur's Laboratory for Urgent Response to Biological Threats (CIBU).

49. Research is conducted on several infectious diseases, among which: HIV/AIDS, tuberculosis, malaria, influenza, dengue, rabies, viral hepatitis, bacterial meningitis, antibiotic resistance, leishmaniasis, diarrheal diseases. The RIIP also strives to improve scientific capabilities and human resources around the world. To achieve this, the RIIP develops training programs in partnership with universities and local stakeholders. Over 100 RIIP trainees come every year to complete their training by taking courses or serving traineeships in Paris.

50. The Institut Pasteur and the Institut Pasteur International Network provide international grants for traineeships and courses taken in Paris.

## **Germany**

### **A. General remarks**

51. The Preparatory Committee decided to request that the Implementation Support Unit prepare eight background information documents, including background information on the implementation of Article X, to be compiled from information submitted by States Parties. With regard to this request, Germany wishes to provide the following information on

activities related to Article X issues, including information submitted pursuant to paragraph 61 of the Final Declaration of the Seventh Review Conference, which encouraged States Parties "to provide at least biannually appropriate information" on their implementation of Article X.

52. Germany submitted an updated report on its implementation of Article X in 2014 with a special focus on the German Partnership Program for Excellence in Biological and Health Security (BTWC/MSP/2014/WP.10). In 2015, Germany contributed to a group report on the implementation of Article X describing concrete projects around the world to combat Weapons of Mass Destruction-related terrorism and proliferation (BTWC/MSP/2015/WP.5).

53. To underscore its full support for Article X and to meet its obligation under the BTWC, Germany wishes to provide the following information on activities related to Article X. In so doing, special focus is given to the German Partnership Program for Excellence in Biological and Health Security. This programme was launched in 2013 within the framework of the G7 Global Partnership against the Spread of Weapons and Materials of Mass Destruction. Until the end of 2016, Germany will have supported projects in more than 20 countries worth nearly 27 million euros. Article X of the BTWC requires States Parties to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes, as well as to cooperate in contributing 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. Germany understands the requirements set out in Article X not in the narrow sense, but sees cooperation and assistance within the wider perspective of Official Development Assistance (ODA) as defined by the Development Assistance Committee of the Organization for Economic Co-operation and Development (OECD). Germany conforms to the OECD<sup>4</sup> definition of ODA that includes activities financed abroad as well as activities in donor countries such as education and vocational training (including grants and travel costs) provided to partner country nationals in donor countries. More detailed information is listed in section D under "General endeavours relevant to Article X" below.

54. This report deliberately concentrates on Government-funded cooperation and assistance activities as well as activities funded indirectly by Germany such as EU projects led by German agencies. The German Government has no direct influence over private equity activities in the field of life sciences abroad by industry or other non-governmental stakeholders or over grants provided by non-governmental organisations from their own financial resources.

## **B. Specific endeavours relevant to Article X**

### **1. German Partnership Program for Excellence in Biological and Health Security**

55. This programme was launched by the German Federal Foreign Office in 2013 within the framework of its engagement in the Global Partnership against the Spread of Weapons and Materials of Mass Destruction. The overall objective is to implement long-term projects in the field of biosafety and biosecurity embedded in activities aimed at improving detection and diagnostic capabilities of hazardous biological agents of concern in the BTWC context. The programme aims to prevent any misuse of infectious agents that could pose a threat, and also to enhance national public health capacities of partner countries.

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<sup>4</sup> <http://www.oecd.org/dac/stats/officialdevelopmentassistancedefinitionandcoverage.html>

Furthermore, it fosters responsible conduct in life sciences, strengthens health security and addresses bio risk management by using a comprehensive methodological approach. It is comprised of various modules regarding awareness-raising, networking, capacity development, detection and diagnostics, surveillance as well as biosafety and biosecurity. The programme was built around the Global Partnership's Biological Security Deliverables and is being implemented by leading German research institutions in cooperation with leading institutions in the partner countries. In 2016, activities conducted thus far were evaluated by CEVAL, an independent centre of evaluation. Overall, the program, its organisational structure and its contribution to the global objectives of the Global Partnership against the Spread of Weapons and Materials of Mass Destruction as well as to the aims of the BTWC were assessed positively.

56. Under the leadership of the German Federal Foreign Office, the programme is being coordinated by a programme office based at the German Federal Foreign Office that is jointly managed by the Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH (GIZ) and the Robert Koch Institute — Federal Institute for Infectious and Non-communicable Diseases (RKI). While GIZ and RKI jointly implement the comprehensive programme approach in the partner countries the Sudan, Morocco and Tunisia, specialised German institutions including the Bernhard Nocht Institute for Tropical Medicine (BNI-TM), the Friedrich Loeffler Institute, the Federal Research Institute for Animal Health (FLI) and the Bundeswehr Institute of Microbiology (IMB) are commissioned to run specific projects in their respective areas of work around the world.

57. Within the scope of programme activities in West Africa, special focus was given to the fight against the Ebola outbreak in 2014 and 2015. With regard to paragraph 33 of the Final Declaration of the Seventh Review Conference, the programme was adjusted to take into account the emerging need for urgent steps against the spread of Ebola in Guinea, Liberia, Nigeria, Mali and Sierra Leone. Support also included the establishment of a "cordon sanitaire" in neighbouring countries which were not affected directly. This engagement is in line with the aims of the programme.

## 2. German Partnership Program for Excellence in Biological and Health Security

Table 1

| <i>Title of measures</i>  | <i>Partner country</i> | <i>Implementing agency</i>  | <i>Time frame</i> |
|---|------------------------|---|-------------------|
| Partnership project with Morocco with activities in the areas of surveillance, biosafety and biosecurity, detection and diagnostics, awareness-raising, networking and capacity development | Morocco                | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) & Robert Koch Institute | 2013-2016         |
| Partnership project with Tunisia with activities in the areas of surveillance, biosafety and biosecurity, detection and diagnostics, awareness-raising, networking and capacity development | Tunisia                | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) & Robert Koch Institute | 2013-2016         |
| Partnership project with the  | The Sudan              | Deutsche Gesellschaft   | 2013-2016         |

| <i>Title of measures</i>  | <i>Partner country</i> | <i>Implementing agency</i>   | <i>Time frame</i> |
|---|------------------------|--|-------------------|
| Sudan with activities in the areas of surveillance, biosafety and biosecurity, detection and diagnostics, awareness-raising, networking and capacity development                    |                        | für Internationale Zusammenarbeit (GIZ) & Robert Koch Institute  |                   |
| Financial support for the WHO Ebola Response Roadmap  | West Africa            | WHO  | 2014              |
| Expert deployment in the European Mobile Lab (EMLab) to strengthen diagnostic capacities for the fight against Ebola  | West Africa            | Bernhard Nocht Institute for Tropical Medicine, Robert Koch Institute, Bundeswehr Institute of Microbiology              | 2014              |
| (1) Training and networking of decision-makers and experts in biosecurity and biosafety and (2) strengthening of biosecurity rules and regulations in the framework of the IHR      | Uzbekistan             | WHO & Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)  | 2013-2014         |
| Awareness-raising and networking for approximately 100 experts in biosecurity and biosafety at a regional conference in Central Asia on "The Future of Biosafety and Biosecurity"   | Kyrgyzstan             | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)  | 2014              |
| Training and networking for laboratory staff  | Tajikistan             | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)  | 2013-2014         |
| Contamination prevention by training, material support and networking with partner institutions   | Mali                   | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) & Fondation Mérieux  | 2014-2015         |
| Mobile Lab Project: establishment of a mobile laboratory capacity for diagnostics of Ebola and other dangerous pathogens and training on diagnostics and maintenance for laboratory | Mali                   | Bundeswehr Institute of Microbiology & Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) & Fondation Mérieux | 2014-2016         |
| Establishment of a German-Georgian network for biosecurity and diagnosis of dangerous   | Georgia                | Bundeswehr Institute of Microbiology   | 2013-2016         |

| <i>Title of measures</i>   | <i>Partner country</i>                       | <i>Implementing agency</i>                     | <i>Time frame</i> |
|--|--|--|-------------------|
| infectious diseases  |  |  |                   |
| Establishment of a German-Kazakh network for biosecurity and diagnosis of dangerous infectious diseases  | Kazakhstan                                   | Bundeswehr Institute of Microbiology           | 2013-2016         |
| Establishment of a German-Tanzanian network for biosecurity and diagnosis of dangerous infectious diseases   | Tanzania                                     | Bundeswehr Institute of Microbiology           | 2013-2016         |
| Project on brucellosis   | Pakistan                                     | Friedrich Loeffler Institute                   | 2013-2016         |
| Prevalence and diagnostics of Brucella, Q fever and viral haemorrhagic fever infections in Egypt   | Egypt  | Friedrich Loeffler Institute                   | 2013-2016         |
| Regional project on prevalence and diagnosis of Crimean-Congo-haemorrhagic fever, valley fever and zoonotic paramyxovirus-infections   | Mauritania, Sierra Leone, Cameroon, DR Congo | Friedrich Loeffler Institute                   | 2013-2016         |
| Establishment of modern and mobile diagnostics for the Ebola virus disease   | Guinea                                       | Bernhard Nocht Institute for Tropical Medicine | 2014-2015         |
| Global Partnership-Initiated Biosecurity Academia for Controlling Health Threats (GIBACHT): training of scientists from Africa and Asia to prevent highly dangerous diseases | Africa & Asia                                | Bernhard Nocht Institute for Tropical Medicine | 2013-2016         |
| Diagnostics and surveillance of viral haemorrhagic fevers, in particular Ebola   | Nigeria                                      | Bernhard Nocht Institute for Tropical Medicine | 2013-2016         |
| Improvement of infectious disease surveillance and the fight against the arbovirus in mosquitoes in Rio de Janeiro in preparation for the Olympic Games in 2016              | Brazil                                       | Bernhard Nocht Institute for Tropical Medicine | 2013-2016         |
| Diagnostics and surveillance of Crim-Congo-viral haemorrhagic  | Kosovo                                       | Bernhard Nocht Institute for Tropical Medicine | 2013-2016         |
| Exchange of scientific   | Turkmenist                                   | Robert Koch Institute                          | 2014              |

| <i>Title of measures</i>   | <i>Partner country</i> | <i>Implementing agency</i>   | <i>Time frame</i> |
|--|------------------------|--|-------------------|
| knowledge on biosecurity and biosafety including exchange of experts | an                     |  |                   |
| Support for Ebola diagnostics  | Côte d'Ivoire          | Robert Koch Institute  | 2014-2016         |
| Strengthening diagnostics, surveillance and training of scientists   | Ukraine                | Bernhard Nocht Institute for Tropical Medicine & Friedrich Loeffler Institute & Bundeswehr Institute of Microbiology & Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) | 2016-2017         |

### 3. Other Ebola-related activities

58. The Ebola crisis in West Africa has shown the devastating impact that weak health systems can have, not only for the countries concerned, but for entire regions, and even on a global scale. Germany has committed funding to strengthen health systems in countries and regions in Africa. The overall objective is to strengthen the health sector and regional organisations (EAC, ECOWAS, CEMAC) to take appropriate actions against the international spread of diseases through adequate early warning and diagnosis capacities, public education campaigns, disease surveillance, diagnostics and well-equipped laboratories. The focus is on further training for health personnel and the development of laboratories contributing to improved preparedness and crisis response.

### 4. Other activities

59. During the BTWC Meeting of States Parties (Geneva, 14 to 18 December 2015), Germany and partner countries of the programme delivered joint statements with a particular focus on strengthening cooperation and assistance under Article X. In addition to these statements, the link between the significance of the BTWC and the excellent cooperation between the partner countries and Germany in the framework of the programme was underlined.

In its capacity as Chair of the G7 Global Partnership Group in 2015, Germany delivered a statement on behalf of 29 members reaffirming its commitment to the preparatory process to help generate positive momentum towards making the BTWC a more efficient and operational instrument.

### 5. Medical Biodefense Conference

60. In April 2016, the international 15<sup>th</sup> Medical Biodefense Conference was held in Munich. The Bundeswehr Institute of Microbiology hosted more than 500 military and civilian experts in the fields of biodefence, biosecurity, public health and emerging infectious diseases from 51 nations, reflecting its inclusive approach to exchange of expertise. The high-profile meeting was organised in cooperation with the German Society for Military Medicine and Pharmacy. Presentations and poster sessions were compiled from almost 300 scientific submissions. The conference's scientific programme addressed the whole range of medical biodefence topics, from political to scientific issues, theoretical to



practical matters, and mass casualties to casuistics. With regard to the Ebola outbreak in West Africa, the lessons learned were assessed. Moreover, numerous speakers addressed the recent developments related to the Zika virus epidemic in the Americas and gave updates on MERS, plague, anthrax, tick-borne encephalitis and other diseases caused by agents of concern. A session was dedicated to the activities of the German Partnership Program for Excellence in Biological and Health Security.

**6. Previous EU Joint Action Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP)**

61. From 2011 to 2015, the German Robert Koch Institute coordinated the European Joint Action QUANDHIP – Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens. Information on this project is available on <http://www.quandhip.info> and on <http://www.rki.de>. The project linked 37 highly specialised laboratories from 22 European countries. The aim of QUANDHIP was to establish a universal exchange of best diagnostic strategies able to support a common response strategy to outbreaks and intentional release of highly pathogenic infectious agents. This initiative provided assistance in improving the diagnostic quality of highly pathogenic bacteria and viruses and set up an operational network of laboratories able to respond to cross-border biological events. To make the results applicable and profitable at the international level, best practices and lessons learned have been published and are also accessible on the QUANDHIP website. Several external quality assurance exercises were conducted for quality-assured diagnostics of risk group 3 bacteria and risk group 4 viruses. The results showed a very high level of preparedness by the participating diagnostic laboratories, although further improvement should be achieved.

**7. EU Joint Action Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)**

62. Based on considerable parts of QUANDHIP, the Robert Koch Institute is coordinating the EU Joint Action Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE) from 2015 to 2018. It operates as a European network of some 40 highly specialised diagnostic laboratories focused on risk group 3 and 4 bacteria and viruses in 25 European countries. The EMERGE Joint Action is in compliance with European policy (Decision No 1082/2013/EU), where the need for an efficient, rapid and coordinated response to high threat pathogens is defined. EMERGE provides a platform for the establishment and consolidation of a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad. State-of-the-art and new diagnostic methods for high-threat pathogens, including in-house and commercial kits, will be evaluated for their applicability and recommended in outbreak situations when suitable. External quality assurance exercises will ensure best approaches for laboratory responsiveness in outbreak situations. These activities will be supported by appropriate training to share best practices of diagnostics and bio risk management. In conclusion, the general objective will be to ensure efficient responses to serious emerging and re-emerging cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens. Information is available on <http://www.emerge.rki.eu>.

**C. Pandemic Preparedness Initiative**

63. Growing mobility, international networking and the expansion of global trade and traffic increase the risk of infectious diseases spreading rapidly across national borders. The international community is well aware of the threats and challenges posed by new pandemics. In 2007, a revised version of the International Health Regulations entered into

force. These global rules enhance national, regional and global public health security, require countries to report certain disease outbreaks and public health events to the WHO and help partner countries to improve their pandemic preparedness.

64. From 2009 until 2013, the Pandemic Preparedness Initiative (PPI) supported global, regional and national projects to limit the spread of pandemics and mitigate potential damage. This initiative was commissioned by the German Federal Ministry for Economic Cooperation and Development in close collaboration with local Gesellschaft für Internationale Zusammenarbeit GmbH (GIZ) offices. In this period, the PPI issued more than 9.8 million euros in grants to partners in 20 countries in sub-Saharan Africa, Eastern Europe, Central Asia and Asia in response to specific requests for assistance to improve national pandemic preparedness planning, risk communication strategies and health promotion activities, disease surveillance and diagnostic capacity, and vaccine manufacturing capacity.

**1. Efficiency by Edification (Effizienz durch Fortbildung, EFFO)**

65. During the peak of the Ebola outbreak, the Robert Koch Institute initiated, in cooperation with the German Working Group of Competence and Treatment Centres for highly contagious and life-threatening diseases (STAKOB), a project financed by the Federal Ministry of Health. The project — with an overall budget of about 2.2 million euros — was originally planned to run from 2014 to 2016, but has been extended for two years until 2018. The project includes training programs for healthcare facilities in West Africa which are involved in the identification of and care for suspected Ebola cases. The activities complement the existing measures in the partner countries and are therefore part of the national preparation for an Ebola outbreak. The training programme is developed through a participatory process and is evaluated scientifically. EFFO is part of the German long-term commitment to the fight against the outbreak of the Ebola virus disease. Participating countries are Côte d'Ivoire, Senegal, Burkina Faso and the Sudan.

**2. Global Health G7 Concept: contribution to the improvement of international health**

66. In the context of the G7 Summit in Elmau 2015, Germany, the G7 partners committed to assisting countries with the implementation of the World Health Organization's International Health Regulations (IHR) through bilateral programmes as well as multilateral initiatives. In order to achieve this, they offered to support at least 60 countries over the next five years, building on countries' expertise and existing partnerships.

67. Following the G7 Commitment, the German Federal Ministry for Economic Cooperation and Development initiated a programme to help countries in Africa to strengthen their health systems in the long term in order to make them more resilient to health crises and to improve response strategies. The programme started in 2015 with a budget of 55 million euros. 150 million euros will be allocated each year until 2019. The programme has a special focus on strengthening pandemic response mechanisms, improving human resources for health and providing access to affordable medicines and vaccines.

68. In addition, joining forces, the Federal Ministry for Economic Cooperation and Development and the Federal Ministry of Health have allocated 20 million euros for a period of five years for the implementation of the programme.

69. Functioning and resilient health systems, including the capacity to prevent, detect and respond to an epidemic outbreak, are essential for preventing health crises. Based on these criteria, the German Federal Chancellor and the WHO Director-General launched the roadmap initiative "Healthy Systems – Healthy Lives" in September 2015. The main aim of

the roadmap process is to develop a joint understanding and a concise set of recommendations to improve the way in which health systems will be strengthened.

## D. General endeavours relevant to Article X

### 1. ISU Sponsorship Program

70. Germany has continuously supported the ISU Sponsorship Program with voluntary contributions to enable experts and diplomats from States Parties to attend Meetings of States Parties and Meetings of Experts in Geneva. The Sponsorship Program intends to support those countries which are not able to send experts from their capitals and to promote universalisation.

### 2. Education

71. Academic education provides the basis for future scientific and technological information and material exchange. Without a broad basis of well-educated personnel, sustainable development and cooperation in the fields of life sciences will not be possible. German universities, which are operated by the federal states (Länder), provide open access free of tuition fees for undergraduate and postgraduate students from all countries. As a result, more than 11 per cent of all students at German universities came from abroad in the academic year 2014/2015, i.e. more than 320,000 students, including more than 24,000 students enrolled in subject areas related to bio and health sciences.

72. Places for foreign students at German universities are financed by the Federal Government. Since 2007, partnerships between German universities and clinics as well as between medical schools and clinics in partner countries have been supported as part of Germany's development cooperation policy.

### 3. ODA 2010-2014

73. In 2015, Germany provided 17.78 billion US dollars net in official development assistance (ODA). ODA is primarily provided by the Federal Ministry for Economic Cooperation and Development. Comprehensive and detailed data on German ODA is published on the OECD website. The following table shows the total bilateral ODA commitments in the categories *General Health* and *Basic Health*. *General Health* covers sub-categories such as health policy and administrative management, medical education/training, medical research and medical services. *Basic Health* includes basic healthcare, basic health infrastructure, health education, infectious disease control, malaria control, tuberculosis control and health personnel development.

Table 2

|                | 2010   | 2011   | 2012   | 2013   | 2014   |
|----------------|--------|--------|--------|--------|--------|
| Health (total) | 425.27 | 405.97 | 425.26 | 501.13 | 518.23 |

(in millions of US dollars)

74. Regarding future ODA support for the health sector, Germany would like to highlight its contribution of 66,345,260 US dollars to the WHO budget for the biennium 2016-2017.

## Greece

75. Mediterranean Zoonoses Control Programme of the World Health Organization and its Coordinating Centre in Athens, Greece The Mediterranean Zoonoses Control Centre (MZCC) started its operation in February 1979 following a special agreement between WHO and the Greek Government. During the last years, the activities of the MZCP co-ordinated by the MZCC and with the support and contribution of the Greek Government, have been as follows: besides the regular MZCP activities development, the Greek Government provided an extraordinary financial contribution to implement 2 projects in Syria and Jordan on the inter-sectoral epidemiological surveillance of Brucellosis in humans and animals. Both were successfully concluded. The Government of Greece is available to further support the MZCP and its Coordinating Centre in Athens, financially and technically. This will permit further expansion and enrichment of the capacity building activities of this regional programme. To this end, negotiations are on the way with WHO and other International Organizations.

National Reference Laboratory for Arboviruses and Haemorrhagic Fever Viruses, Aristotle University of Thessaloniki, School of Medicine, Dept. of Microbiology

76. Training of scientists from the Central African Republic, Nigeria, Iran, China, Albania and Bulgaria on the rapid diagnosis and molecular epidemiology of viral haemorrhagic fevers. Their expenses were jointly covered by EU Research Programmes (INCO), WHO and the Greek Government.

77. Ministry of Rural Development and Food (MRDF) - General Veterinary Directorate

(a) Programme TAIEX. Study visit on Protection and Control Strategies, monitoring and reporting system of Echinococcosis and Hydatidosis (May 2011 with the participation of Greece and Turkey).

(b) Control and eradication programmes of Bovine Brucellosis, Sheep and Goat Brucellosis and Bovine Tuberculosis (July 2009 with the participation of Greece and Armenia).

(c) Control of Foot and Mouth Disease (FMD) Includes activities such as serosurveillance, vaccination campaigns and training workshops.

(d) Monitoring of Zoonoses and Zoonotic agents, antimicrobial resistance of zoonotic agents and food borne outbreaks. Zoonoses Monitoring - Implementation of National control and eradication programmes based on European Veterinary Legislation (Directive 2003/99/EC). Covers mandatory monitoring for the major zoonoses: Brucellosis, Tuberculosis, Echinococcosis, Salmonellosis, Campylobacteriosis, Listeriosis, Trichinellosis, Verotoxigenic Escherichia coli. Participation of the the Balkan Tripartite (EuFMD/EC/O.I.E) Group of Bulgaria, Greece and Turkey.

Ministry of Foreign Affairs

78. Greece contributes to the Global Fund to Fight AIDS, Tuberculosis and Malaria and supports EU activities in the area of HIV/AIDS, whilst it also contributes to UNAIDS.

Ministry of Health and Social Solidarity

79. The Hellenic Center for Disease Control and Prevention, Athens, Greece (Zoonoses and Foodborne diseases Bureau), coordinated the WP8 Zoonoses of the EpiSouth from 2006 to 2010, for the 27 Mediterranean and Balkan countries participating to the network. The aim was the construction of a firm network of public health institutes, epidemiologists

and laboratory experts, for the exchange of epidemiological data and the diffusion of public health alerts concerning infectious and non-infectious agents.

80. From 2010 to 2013 the Hellenic Center for Disease Control and Prevention, Athens, Greece is participating in the EpiSouthPlus, as member of the steering committee of the WP5, co-led by the Instituto de Salud Carlos III (Spain) and the Institut National de Santé Publique (Algeria) Public Health Preparedness and Response, and the WP7 co-led by the World Health Organization - Lyon office (WHO-LYO) and the Italian National Institute of Health (ISS), aimed to facilitate IHR implementation in the EpiSouth Region.

## Hungary

81. Hungary facilitates the exchange of equipment, materials, scientific and technological information concerning the use of bacteriological (biological) agents and toxins for peaceful purposes. Hungary also supports the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease and for other peaceful purposes.

82. Hungarian medical system often provides medical help in different parts of the world in cases of natural disasters, including the prevention of epidemics. For example: At the end of last year a Hungarian group of doctors with appropriate equipment and the necessary drugs provided support for the treatment and for the prevention of the outbreak of dangerous epidemics in flood stricken Thailand. In such cases Hungarian specialists use "the available best technology", and in conjunction with that they also provide assistance to the local experts on how to apply that technology. In addition to providing assistance for the diseased people, the National Centre of Epidemiology has further developed its international relations in the area of the prevention of different epidemic diseases.

83. Several thousand of foreign students study at Hungarian universities and follow courses in foreign language (English and German), thus foreign students can study without knowing Hungarian. Accordingly universities and the academia provide ample opportunities for them to familiarise themselves and learn about the latest developments in the scientific technical field.

84. A number of young foreign PhD students and high academics are involved in scientific research and studies at the Hungarian universities and scientific research institutes of the Hungarian Scientific Academy. The themes of these studies and research programmes in the field of biology (bacteriology, viruses), biochemistry, chemistry (toxins), and related engineering disciplines (equipment), or medical sciences (epidemics) may be relevant in the context of the BWC.

## India

85. In its interim report dated 18 May 2016 (BWC/CONF.VIII/PC/2), the Preparatory Committee to the 8<sup>th</sup> BTWC Review Conference had requested the Implementation Support Unit to prepare a background information document on Implementation of Article X of the Convention, to be compiled from information submitted by States Parties.

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

(a) India is firmly committed to fulfilling all of its obligations under the BWC and in particular, attaches high importance to the full and effective implementation of Article X of the Convention. The promotional aspects related to cooperation and assistance are crucial elements in strengthening of the Convention and in achieving universal adherence. India has regularly shared its experiences in implementation of Article X in

BWC meetings including during the Seventh Review Conference and the intersessional Meetings of States Parties.

(b) India has developed significant capabilities in biological sciences and technology for peaceful purposes and places considerable emphasis on broadest possible international cooperation in this field, in particular with developing countries. This is consistent with Article X which embodies an international commitment to partnership, assistance, sharing of information, exchanges and the development of mutually beneficial outcomes. The following provides an overview of India's engagement—both bilateral and multilateral, of relevance to the implementation of Article X.

(c) India has extensive cooperation in the health sector and medicine with a large number of countries, as detailed in its Working Paper (WP.12) submitted to the 2014 Meeting of States Parties to the BTWC.

(d) India has supported the role of the World Health Organization, the Food and Agricultural Organization and the World Organization for Animal Health and implements various regulations including the WHO's 2005 International Health Regulations. India supports enhancing effective cooperation and coordination between relevant international and regional organizations for use of biological agents and toxins for peaceful purposes. India has been regularly reporting on outbreaks of infectious diseases, not only those that are mandatory to notify but also all the other re-emerging and newly emerging diseases. As and when required, India has sought cooperation from foreign partners for advanced technologies for surveillance, detection, and diagnosis of highly infectious and pathogenic agents which can cause diseases in humans and animals.

(e) India has produced and supplied diagnostic kits for some emerging and reemerging infectious diseases such as Japanese Encephalitis, Dengue and Chikungunya to other developing countries through the WHO SEARO. The diagnostic kits developed by India are cost-effective as compared to other available products and therefore better suited for needs of developing countries. India has also provided through the WHO and bilaterally (Timor-Leste Myanmar, Nepal) reagents helpful for diagnosis of a number of diseases including H1N1, H5N, MERS CoV etc. India has provided technical expertise in recent years to countries such as Nepal, Timor-Leste, Myanmar, Indonesia and Thailand. In training courses organized in India, participants from the following countries participated: Bangladesh, Bhutan, Myanmar, Thailand, Indonesia, Nepal, Sri Lanka and Timor-Leste. India has also conducted a workshop on biosafety and biosecurity for participants from Nepal and Bangladesh.

(f) In the field of plant health and protection, a number of training programmes were organized in India, both bilaterally or through regional bodies such as SAARC, which had participants from a number of countries including: Afghanistan, Bhutan, Bangladesh, Brunei, Cambodia, Egypt, Indonesia, the Islamic Republic of Iran, Lao People's Democratic Republic, Malaysia, Maldives, Myanmar, Namibia, Nepal, Pakistan, Peru, Philippines, Sri Lanka, Tajikistan, Thailand, Uzbekistan and Vietnam. Similarly, in the field of animal Health, India has cooperated with a number of countries including Afghanistan, Bangladesh, Bhutan, Myanmar, Nepal and Sri Lanka.

(g) In September 2013, India hosted the 31<sup>st</sup> WHO SEARO Health Ministers meeting which focussed on a number of issues including a Regional Action Plan for prevention and control of non-communicable diseases, Pandemic Influenza Preparedness etc. In January 2013, the 2<sup>nd</sup> BRICS Health Ministers meeting adopted the Delhi Communiqué for increased cooperation amongst BRICS countries in the field of health. At the SAARC Summit in Kathmandu on 26 November 2014, India's Prime Minister announced India's support for SAARC in meeting the short fall in funds for establishing the SAARC Regional Reference Laboratory for TB and HIV, vaccines for children, monitoring

and surveillance of polio free countries and provide vaccines where Polio might reappear and immediate visas for those seeking medical treatment in India. India is also organizing a Regional Workshop, along with EU and UNODA, in New Delhi on 29-30 August 2016 as part of the preparation for the 8<sup>th</sup> Review Conference.

(h) India announced a contribution of more than US \$ 12 million to the Ebola Response Multi Partner Trust Fund, the WHO and the purchase of protective gear for addressing the recent Ebola Disease outbreak. In August 2014, India had provided immediate bilateral financial assistance for purchase of medical supplies to three of the affected countries — Sierra Leone, Liberia and Republic of Guinea. Diagnostic support was provided to Sri Lanka through WHO-SEARO for diagnosis of suspected Ebola.

(i) India has a well-established pharmaceutical industry and is a major exporter of high quality and affordable pharmaceutical drugs and vaccines. A case in point are generic drugs which have resulted in dramatic reduction in cost of treatment, for instance of HIV/AIDS. India has emphasized the importance of access to affordable, quality, safe medicines, vaccines and medical equipment to all, in particular those in developing countries through appropriate policies and regulations.

(j) While international exchanges are an important pillar for implementation of Article X, and considerable progress has taken place in recent years, there exist gaps in access to and availability of advanced technologies for application in peaceful uses, for example, in obtaining equipment or materials, training opportunities, obtaining clinical samples or access to affordable medicines and vaccines and complex visa procedures for scientists which hinders timely and regular collaboration in areas of common interest to the scientific community.

(k) The implementation of Article X should facilitate the fullest possible exchange of equipment, materials and technology related to the use of biological agents and toxins for peaceful purposes. The measures taken to mitigate biological risks should be proportional to assessed risks and not hamper peaceful activities including through international cooperation. Strengthened implementation of Article III would ensure that the cooperation envisaged under Article X is not abused. Thus 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. India is committed to maintaining effective export controls on par with the highest international standards with respect to transfers of biological agents and toxins for peaceful purposes and we had made specific proposals during the BWC meetings.

(l) India has actively contributed to discussions on the agenda on Article X during the last intersessional period, and supports continued consideration of Article X during the next intersessional period.

## **Iraq**

### **A. Background**

87. The BTWC Seventh Review Conference in December 2012 in Geneva confirmed the importance of implementation of Article X and recalls that States Parties have a legal obligation 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 and not to hamper the economic and technological development of States Parties. The Conference reaffirms the

commitment to the full and comprehensive implementation of this Article by all States Parties.

88. The Conference encourages States Parties to provide at least biannually appropriate information on how they implement this Article to the Implementation Support Unit within the United Nations Office for Disarmament Affairs, and requests the Implementation Support Unit to collate such information for the information of States Parties. The Conference welcomes the information provided by a number of States Parties on the cooperative measures they have undertaken towards fulfilling their Article X obligations.

89. This background document provides information summaries about the cooperation with States parties to the BW Convention regarding Cooperation programs and assistance in building and development national capacity in the field of bio risk management, border control and import and export mechanism of biological dual-use items.

## **B. Promoting Cooperation and Assistance**

90. Iraq through the Iraqi National Monitoring Authority started to set up several bilateral cooperation Programs with the other State Parties to the BTWC and international organizations such as, United States, Switzerland, United Kingdom, Netherlands , Norway, Canada, 1540(2004) Committee ,in addition to the European Union through the CBRN centers of excellence to assist in the implementation of the BWC Convention , facilitate the exchange of experiences, sharing lessons learned concerning the technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and assist in building national capacity in the biological field and public health. A significant part of this corporation is focused on laboratory bio risk management, disease detection and control, Specific activities included:

(a) Bio risk assessments followed by biosecurity upgrades in public and animal health laboratories.

(b) Sustainable bio risk management capacity building through biosafety and biosecurity technical trainings as well as facilitating a broader awareness of biological nonproliferation issue.

(c) Enhancing public and animal disease detection and control capabilities through international scientific and technical exchanges.

(d) Laboratory bio risk management awareness training on facilitating the use of the new standards for bio safety and bio security, with a view of enhancing national disease control and preparedness, supporting the implementation of the Biological Weapons Convention.

91. Since 2009, a part of Iraq's assistance request has been met, through those joint cooperation efforts. Iraq received assistance in some areas that cover a number of aspects relating to BW convention and control biological materials, including development and implement appropriate, sustainable, and effective laboratory biosafety and biosecurity measures, guidelines, training courses, building national capacity in the field of bio risk management according to the international standards to reduce biological threats, prepare for, and respond to, a biological incident, disease surveillance, detection, response, border control and the development of mechanisms to monitor the import and export of dual-use items including biological materials. Iraq now participates in more than 10 joint programmers with EU CBRN centers of excellence. Some of those projects address issues such as, knowledge development and transfer of best practices on biosafety, biosecurity and bio risk management; strengthening laboratory biosafety and biosecurity; creation of an



international network of universities and institutes for raising awareness on dual-use concerns in biotechnology.

92. The outcomes of this cooperation led to hold and organize several outreach workshops, consultations and training for competent authorities in the relevant sectors and for laboratory managers/staff at the national levels, aiming at a deeper understanding of bio-risk reduction practices and their effective implementation in laboratories and other facilities, including during transportation as appropriate.

### **1. Defense Threat Reduction Agency's (DTRA) Cooperative Biological Engagement Program (CBEP)**

93. The Defense Threat Reduction Agency's (DTRA) Cooperative Biological Engagement Program (CBEP) was developed to assist partner nation governments in addressing obligations assumed by the BW Convention and the UN-SCR 1540 (2004), which binds states to adopt legislation to prevent the proliferation of nuclear, chemical and biological weapons and their means of delivery and establish a domestic control over related materials to prevent their illegal trafficking and also enhance any international cooperation on such efforts.

### **2. Objectives of CBEP in Iraq**

(a) Enhance Biosecurity and Biosafety standards and procedures of the health and biological labs in Iraq.

(b) Strengthen the technical capabilities of the Iraqi health personnel of the human and animal labs to detect, diagnose, and report outbreaks of infectious disease, especially those associated with Select Agents, in accordance with World Health Organization (WHO) and World Organization for Animal Health (OIE) guidelines.

(c) Provide education and training to enhance clinical, laboratory and epidemiological safety and security with regard to EDPs management and bio risk operations, specially related to the dangerous pathogens.

### **3. Achievements**

94. Over the past five years following achievements have been achieved within the Cooperative Biological Engagement Program (CBEP), which is part of a cooperation project with the US Defense Agency to reduce the risks DTRA and building national capacities in the field of biological risk management:

(a) During the period between the year 2011 and until the beginning of 2013, the Defense Threat Reduction Agency's (DTRA) in collaboration with Sandia Labs holding several workshops and training courses on biosecurity and biosafety procedures to the specialists in the Iraqi relevant ministries within biosecurity program in Iraq.

(b) Implement a program to develop some important laboratories in the central public health laboratories adoption biosecurity procedures and techniques.

(c) Rapid Upgrade and laboratory equipment's in of Health, Agriculture and Science and technology ministries.

(d) Steps for Improving Bio surveillance capacities of the Iraqi ministries and labs.

(e) Formulate the National Standard Operating Procedures SOPs of the Bio risk operations and procedures applied in the public and animal health labs:

(i) Sample Handling, Storage and Transportation and Shipping

- (ii) Personnel Protection Equipment's
- (iii) Laboratory Spill Response.
- (iv) Biological Inventory management.
- (v) Biological Safety Cabinet.
- (vi) Waste Handling and Disposal
- (vii) Operational and maintenance

**4. Support of the National Biorisk management Committee**

95 Since the founding of the National Biorisk management Committee in Iraq in 2012, the Defense Threat Reduction Agency's (DTRA) in collaboration with Sandia Labs support the Committee by conducting six workshops and training courses on biosecurity and biosafety procedures and training on the basics of managing biological risks in accordance with international standards.

**5. Collaboration between the Norwegian Defense Research Establishment (FFI) and the Iraqi National Monitoring Authority (INMA)**

96. Collaboration between the Norwegian Defense Research Establishment (FFI) and the Iraqi National Monitoring Authority (INMA) to strengthen Iraq's national framework for non-proliferation of biological weapons, biological agents and their means of delivery. (The project is currently stalled) .

**6. Canada's Global Partnership Program (GPP)**

97. Collaboration between the Canada's Global Partnership Program (GPP) and the Government of Iraq concerning cooperation to address threats posed by biological and chemical weapons and related materials. Significant progress has been made to address chemical and biological threats through this cooperation program.

**7. Collaboration with Interpol to address threats Program**

98. Cooperation between the Interpol and the Government of Iraq to address biological and chemical threats and strengthen national capacities.

**C. Conclusion**

99. This cooperation can complement and reinforce national implementation measures of the BW Convention and assist on capacity-building, in biosafety and biosecurity, and for detecting, reporting, and responding to outbreaks of infectious disease or biological weapons attacks, including in the areas of preparedness, response, and crisis management and mitigation; In addition to increase awareness of the employees concerning the importance of biosafety and biosecurity measures and procedures in order to ensure the safety of workers and the security of pathogens and toxins in laboratories and facilities and during transportation, to prevent the access of non-state actors to the biological sensitive materials , loss , theft or diversion and then use them for purposes prohibited by the BW Convention and Security Council Resolution 1540(2004).

## Ireland

### A. Ireland Vietnam Blood Borne Initiative (IVVI)

100. UCD & NIHE: Irish Aid contribution € 2.5 million

101. Bringing Vietnamese research capacity to a new level: Laboratory Facility and Skills Development.

102. The Ireland-Vietnam Blood-Borne Virus Initiative (IVVI) began in 2007 with funding from Irish Aid and Atlantic Philanthropies. The goal was to develop the infrastructure and capacity needed to better diagnose viral diseases such as HIV, Hepatitis B and C, and the Human T Lymphotropic Virus (HTLV). The project also aimed to improve Vietnam's health policies, which will in turn reduce the burden of infectious diseases.

103. Ireland's National Virus Reference Laboratory in University College Dublin and the Vietnam's National Institute of Hygiene and Epidemiology (NIHE), are the two driving forces behind IVVI.

104. Through IVVI, 33,000 individuals representing a large cross-section of the population, including blood donors, renal dialysis patients, blood transfusion patients, pregnant women and the general population have been tested. Along with large scale testing, IVVI has also provided virus testing for outbreaks, such as measles in northern Vietnam and swine influenza (H1N1). To help IVVI achieve its targets in training and testing, financial support went towards building a modern diagnostic laboratory at NIHE in Hanoi. New approaches have cut the cost of tests. In addition to construction of a high tech facility, nine NIHE staff members have completed a Master's degree in clinical and diagnostic virology in University College Dublin and now have the capacity to manage the NIHE/IVVI laboratory and implement studies that will help improve healthcare in Vietnam. Joint research work between the University College Dublin and NIHE will continue with these trained researchers.

105. The NIHE/IVVI laboratory has been recognised as a reference laboratory by the Ministry of Health. It has received international ISO accreditation and was formally accredited by WHO as a National Laboratory for HIV Anti-Retroviral Drug Resistance testing in August 2012. The Laboratory will shortly begin studies with WHO and the Vietnam Administration for AIDS Control (VAAC) of the Ministry of Health in Vietnam to evaluate HIV Drug Resistance in Northern Vietnam

106. The IVVI was enrolled in the Treat Asia Quality Assurance Scheme (TAQAS) for HIV-1 genotypic Antiretroviral Drug Resistance Testing and accreditation by the NRL was achieved in March 2012.

### B. Chemical, biological, radiological and nuclear (CBRN) training course for humanitarian workers.

107. In September 2015, the Irish Defence Forces conducted a week long Survive to Function course for humanitarian workers to enable them to recognise and survive the effects of chemical, biological, radiological or nuclear (CBRN) agents. The course was run by the Defence Forces School of Military Engineering for 14 International Committee of the Red Cross (ICRC) personnel, largely medical, from Ireland, Norway, Denmark, Italy, Canada, the UK, Croatia, Israel and France. Survivability and decontamination were central to the training and the ICRC students were taught to use their own equipment and in order

to survive in a hazardous environment, while continuing to perform their primary function of providing humanitarian assistance.

### **C. Ireland- Response to the Ebola crisis**

108. In 2014 Ireland provided over €18.5 million to the affected countries in West Africa, through NGO and UN partners. Some €10 million was provided for our annual development programmes in our partner countries, Sierra Leone and Liberia. A primary focus of these programmes was on strengthening health systems in the two countries, which had been significantly impacted by the Ebola outbreak.

109. Funding of over €6 million was provided for Ebola treatment facilities in both Sierra Leone and Liberia, as well as for contact-tracing, community sensitisation, Ebola-response fleet management and child nutrition programmes, among other activities. This included a contribution of €1 million to the UN Ebola Response Multi-Partner Trust Fund established by the UN Secretary General to ensure coherent involvement by the UN system in the overall response to the Ebola outbreak. The contribution to the Trust Fund was earmarked for Sierra Leone and Liberia.

110. In 2015, the Irish Aid programme in Sierra Leone and Liberia continued to focus on the effects of the Ebola outbreak. Programme funding of €5.4 million for Sierra Leone and €5.4 million for Liberia was disbursed. A key focus of this funding programme was to strengthen the country's health systems and basic primary health care services. The largest proportion of funding is channelled through the Liberian Ministry of Health & Social Welfare's Health Sector Pool Fund.

### **D. Gain of Function - Experimental Applications Relating to Potentially Pandemic Pathogens report by the EASAC with input from the Royal Irish Academy.**

111. The Royal Irish Academy is one of Ireland's leading bodies of experts in the humanities and sciences.

112. In October 2015, The Royal Irish Academy, as a member of the European Academies Science Advisory Council (EASAC), hosted a briefing seminar on the latest EASAC Report on "Gain of Function: Experimental Applications Relating to Potentially Pandemic Pathogens".

113. This report was produced by a working group of 17 expert scientists nominated by EASAC member academies across 10 European countries, which also included input from RIA experts. In the specific context considered by this report, "gain of function (GoF)" refers to the experimental modification of the influenza virus, particularly the H5N1 variant, to alter its transmission potential with the aim of better understanding the factors that determine its pandemic potential to spread from animals to human, and between humans through an aerosol route.

114. This report is particularly timely, as it considers current controversies about the possible impact of GoF research with regard to biosafety (i.e. the safety of researchers conducting this research and the general public) and biosecurity (i.e. the potential for use as a biological weapon). This report emphasises a layered approach to biosafety with integration of responsibilities and action at researcher, research institution, research funder, national EU, and global levels.

115. A link to the report can be found at the following link:  
[https://www.ria.ie/sites/default/files/easac\\_gof\\_web\\_complete\\_centred\\_2.pdf](https://www.ria.ie/sites/default/files/easac_gof_web_complete_centred_2.pdf)

116. In addition, a link to the RIA briefing seminar can be found at the following link: <https://www.ria.ie/news/policy-and-international-relations/breakfast-briefing-gain-function-experimental-applications-0>

## Italy

117. Over the last years (2011-2016), the Italian Development Cooperation and its national partners have designed interventions in the health sector, following the strategic guidelines included in the policy document "Global health: leading principles of the Italian Cooperation", which was first approved in 2009 and reviewed in 2014.

118. The document defines the fight against infectious and tropical diseases - HIV/AIDS, tuberculosis, malaria, polio, viral hepatitis and bacterial meningitis - as a policy priority, aiming at providing prevention and immunization measures, medical treatment and social assistance to affected communities. The document sets the framework of reference for those initiatives primarily intended to offer assistance to developing countries in order to improve their policies and practices in fields such as: organization and management of basic social and health services, control of infectious diseases, environmental health, medical and surgical emergencies and fight against mother and infant mortality.

119. In 2015 Italy has assigned about 11% of its Official Development Assistance (ODA) to interventions in the health sector for an overall amount of EUR 70 million. Out of this amount, EUR 3,280,000 have been allocated for specific projects in the field of control of infectious and tropical diseases. Additional financing has been mobilized for emergency interventions. On average, over the last years, the Italian Cooperation has annually earmarked EUR 100 million for projects in the field of health and sanitation.

120. Italy has a long-standing tradition of commitment in the fight against large scale pandemics, as demonstrated by its regular contribution to the Global Fund to Fight Against AIDS, Tuberculosis and Malaria, which amounts to EUR 100 million for the period 2014-2016. Thanks to programs financed by the Fund in 140 countries, over 8.7 million lives have been saved from diseases.

121. Italy is part of the Global Health Security Agenda (GHSA), a growing partnership of nearly 50 nations, international organizations and non-governmental stakeholders to help build countries' capacity to respond to infectious disease threats. Under the GHSA framework, Italy has been a frontrunner in the immunization sector, acting predominantly in the Mediterranean basin and developing common epidemic identification mechanisms for the benefit of the health system of partner countries.

122. In the field of infectious diseases, activities of major interest have been implemented by the Italian National Institute of Infectious Diseases "Lazzaro Spallanzani", which is internationally recognized as a leading biosafety provider, able to apply the most advanced standards in the treatment of patients and to conduct research with innovative equipment, including a Bio Safe Level 4 (BSL 4) laboratory. In Tanzania, the Institute set up a BSL 3 laboratory in Bagamoyo, which has later become one of the most advanced laboratories in East Africa for control of highly infectious diseases such as viral haemorrhagic fevers (Ebola, Marburg, Dengue Fever, etc.). Furthermore, in the framework of a series of emergency projects launched by the Italian Cooperation to help Sierra Leone, Liberia and Guinea in the response against Ebola during 2015, the medical team from the Institute supported evacuation operations and addressed the needs of the population with prophylactic treatments and training for local health operators. The intervention has been carried out in coordination with Italian NGOs already operating on the ground and engaged in the provision of medical supplies to local communities. Already some time before, the World Health Organization (WHO) gave Italy the task to elaborate an evacuation plan for

UN staff in African countries with a high risk factor for infectious diseases. The plan was to be implemented in conjunction with the Spallanzani Institute, relying on its wide-ranging experience in medical treatment and research.

123. To support the international response against the 2015 Ebola outbreak, Italy has also financed the World Food Programme to ensure access to basic nutrition for the affected communities; the WHO to implement the comprehensive Ebola response roadmap and UNICEF to undertake information campaigns about contagion risks and protection measures. The Italian Cooperation has also mobilized the International Federation of the Red Cross to support the Sierra Leone Red Cross Society for awareness messaging, contact tracing and case treatment.

124. Further in Africa, the Italian Cooperation funded three relevant projects in fields related to Article X interventions: (i) the program to support the Ministry of Health of South Africa in the implementation of a global response to HIV & AIDS, in particular the experiment of a therapeutic HIV vaccine in conjunction with the Italian National Institute of Health; (ii) the support for the National Plan of Burkina Faso for Health Development through a capacity building initiative, implemented by the Department of Public Health of the University of Rome "La Sapienza" and focused on the response against malaria; (iii) a capacity building initiative in Ethiopia to reverse the spread of communicable diseases, notably the HIV/AIDS, by improving the retention in care of the affected patients.

125. In Iraq, notably in the Autonomous Region of Kurdistan, an epidemiological monitoring and surveillance system is currently being set up in order to update data on diseases' trend with standardized procedures. The project, implemented by the Biomedicine Department of the University of Rome "Tor Vergata", includes training activities for 150 specialized operators in the field of biomedical treatment and management of epidemiological surveillance programmes.

126. In Vietnam, notably in the city of Hue, in collaboration with the University of Sassari, the Italian Cooperation has set up a centre for control of viral diseases, including the construction of a BSL 3 laboratory for diagnosis and an intensive care unit for treatment of patients. In the framework of the project, the Italian Cooperation has also funded the launch of a two years master course on microbiology and virology in public health, to which students from the region (Vietnam, Laos, and Myanmar) can apply.

## **Japan**

127. The Biological and Toxin Weapons Convention (BWC) plays an increasingly important role in the field of non-proliferation and disarmament, particularly due to the current biological threats, such as terrorism by non-state actors which cause a great deal of concern. In order to diminish the threat of biological weapons, it is indispensable to promote the universalization of the Convention. In addition, it is also critical for States Parties to collaborate to counter biological threats. In this regard, Japan attaches great value on international cooperation and assistance to enhance national capacity for implementation of the BWC.

128. To this end, Japan provides information on its international cooperation and assistance in the period between August 2011 and July 2016 on the implementation of Article X of the BWC.

**A. Bilateral cooperation in the field of public health**

129. Japan has contributed to capacity building in developing countries in the field of public health through several aid and loan schemes, such as technical cooperation projects and technical assistance through training courses. While taking preventive measures against the development of biological weapons, it is necessary to take effective measures in order to rapidly and properly respond to public health emergencies and to minimize their impacts. In this regard, it is important to improve capacities for surveillance, detection, and diagnosis of infectious diseases. Japan's contribution has enhanced such capacities in recipient countries.

**B. Assistance for South-South Cooperation in the field of infectious diseases**

130. Japan assists South-South cooperation because we find it highly significant that developing countries are mutually deepening their ties by helping each other achieve independent development.

**C. Contributions for measures against public health emergency through multilateral frameworks**

131. Assistance in accordance with Article X should be implemented in a manner which avoids the duplication of work and uses resources efficiently. Therefore, Japan is unifying various initiatives towards the purpose of the BWC. Japan has actively contributed to the activities of international organizations, such as the World Health Organization (WHO), the World Organisation for Animal Health (OIE), and the Food and Agriculture Organization of the United Nations (FAO). Their independent activities and engagement could assist in BWC. Japan is also participating in the Global Health Security Agenda (GHS), a multilateral initiative to spur progress towards full implementation of the World Health Organization's International Health Regulations (IHR) so that the countries can prevent, detect, and rapidly respond to biological threats.

**D. Regional cooperation for countering biological threats**

132. Considering the fact that biological threats could expand beyond national borders, regional cooperation activities is key to increase preparedness against biological threats. Japan has participated in regional cooperation against biological threats including terrorism by non-state actors.

**E. Other initiatives**

133. Rapid progress of science and technology could have an influence on both increase and decrease of biological threats. In order to assess possible impacts from scientific and technical viewpoints, intellectual exchange among experts is useful. Therefore, Japan has contributed to promoting intellectual exchange by sending experts to relevant meetings.

**F. International cooperation and assistance of Japan related to the Biological and Toxin Weapons Convention (August 2011 – July 2016)**

Table 3

**Contributions for measures against public health emergency through multilateral framework**

|    | <i>Project</i>  | <i>Year</i> | <i>Budget</i>                         |
|----|---|-------------|---------------------------------------|
| 1  | OIE, FAO<br>(The Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs))   | 2011        | 568,859<br>USD                        |
| 2  | OIE<br>(OIE/Japan Trust Fund Programme for Strengthening Highly Pathogenic Avian Influenza Control in Asia)   | 2011        | 674,370<br>USD                        |
| 3  | OIE<br>(Strengthening of diagnostic capacity of national laboratories on priority animal disease in collaboration with OIE Reference Laboratories.) | 2011        | 203,239<br>USD                        |
| 4  | OIE<br>(Improvement of animal health in the Asian and Pacific region/Support for Development of international standards )                           | 2011        | 145,375<br>USD and<br>149,800<br>EURO |
| 5  | OIE, FAO<br>(The Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs))   | 2012        | 633,901<br>USD                        |
| 6  | OIE<br>(OIE/Japan Trust Fund Programme for Strengthening Highly Pathogenic Avian Influenza Control in Asia)   | 2012        | 667,964<br>USD                        |
| 7  | OIE<br>(Strengthening of diagnostic capacity of national laboratories on priority animal disease in collaboration with OIE Reference Laboratories.) | 2012        | 168,631<br>USD                        |
| 8  | OIE<br>(Improvement animal health in the Asian and Pacific region/Support for Development of international standards )                              | 2012        | 124,588<br>USD and<br>152,223<br>EURO |
| 9  | OIE, FAO<br>(The Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs))   | 2013        | 562,291<br>USD                        |
| 10 | OIE<br>(Prevention and Control of Zoonoses under One Health approach and strengthening capacity of Veterinary Services)                             | 2013        | 739,324<br>USD                        |
| 11 | OIE<br>(Improvement animal health in the Asian and Pacific region/Support for Development of international standards )                              | 2013        | 103,972<br>USD and<br>152,223<br>EURO |
| 12 | OIE, FAO<br>(The Global Framework for the Progressive Control of  | 2014        | 432,020<br>USD                        |



| <i>Project</i>   | <i>Year</i> | <i>Budget</i>                        |
|--|-------------|--------------------------------------|
| Transboundary Animal Diseases (GF-TADs))   |             |                                      |
| 13 OIE<br>(Prevention and Control of Zoonoses under One Health approach and strengthening capacity of Veterinary Services)   | 2014        | 637927<br>USD                        |
| 14 OIE<br>(Improvement animal health in the Asian and Pacific region/Support for Development of international standards )  | 2014        | 59,510<br>USD and<br>152,223<br>EURO |
| 15 OIE<br>(Improvement animal health in the Asian and Pacific region/Prevention and control of major transboundary animal diseases (TADs) and support to improve animal health situation in the Asia-Pacific region) | 2015        | 344,864<br>EURO                      |
| 16 OIE<br>(Improvement animal health in the Asian and Pacific region/Prevention and Control of Zoonoses under One Health approach and strengthening the capacity of Veterinary Services)                             | 2015        | 451,114<br>EURO                      |
| 17 OIE<br>(Support for Development of international standards)   | 2015        | 152,223<br>EURO                      |
| 18 FAO (Strengthening International Responses to Transboundary Animal Diseases)  | 2015        | 498,392<br>USD                       |

Table 4

**Regional cooperation for countering biological threats  
Participation in seminars and conferences against biological terrorism**

| <i>Project</i>   | <i>Year</i> | <i>Host</i>           |
|--|-------------|-----------------------|
| 1 ARF workshop on disease and surveillance and detection   | Sep<br>2011 | Philippines           |
| 2 The 13th Defence Services Asia in 2012 (CBRNe Forum)   | Apr<br>2012 | Malaysia              |
| 3 ARF workshop on preparedness and response to a biological event  | Sep<br>2012 | Philippines           |
| 4 Global Health Security Action Group Laboratory Network (GHSAG-LN)  | Nov<br>2012 | Italy<br>(Rome)       |
| 5 Global Health Security Action Group Laboratory Network (GHSAG-LN)  | Jun<br>2013 | Canada (To-<br>ronto) |
| 6 The 4th wet lab workshop of the Global Health Security Action Group Laboratory Network (GHSAG-LN) on diagnostic electron microscopy of pathogens | Oct<br>2013 | Germany<br>(Berlin)   |

|    | <i>Project</i>  | <i>Year</i>  | <i>Host</i> |
|----|---|--------------|-------------|
| 7  | Chemical and Biological Defense Science and Technology Conference                       | May 2015     | USA         |
| 8  | Global Conference on Biological Threat Reduction  | Jun-Jul 2015 | OIE         |
| 9  | ARF Cross-Sectoral Security Cooperation on Bio-Preparedness Table-Top Exercise Workshop | Aug 2015     | Philippines |
| 10 | S&T Trends Symposium to support the Biological and Toxin Weapons Convention             | Sep 2015     | Poland      |

Table 5

**Other initiatives**

|   | <i>Project/Workshop</i>   | <i>Year</i>                    | <i>Host</i>                                       |
|---|---|--------------------------------|---|
| 1 | The Japan Initiative for Global Research Network on Infectious Disease (J-GRID) | The Second Phase (2010 - 2014) | 13 collaborative research centres in Asia, Africa |
| 2 | Dual Use Research of Concern (DURC)   | Dec 2011                       | Bethesda, MD (USA)                                |
| 3 | CBRNe Convergence, 5th Annual CBRNe World Conference and Exhibition             | Nov 2012                       | USA   |

**Moldova**

134. Under the Article X of the Biological Weapons Convention:

"(1) 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 cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.

(2) 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 cooperation in the field of peaceful bacteriological (biological) activities, including 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."

135. In the light of Article X of the Biological Weapons Convention, the Republic of Moldova is strongly committed to the promotion of the international cooperation bilaterally and multilaterally.

136. The Republic of Moldova continues to strengthen the existing international organizations and networks working on infectious diseases, in particular with EU, WHO, FAO, OIE.

137. A project on cooperation with the European Neighbourhood Policy (ENP) partner countries entitled as "Preparatory measures for the participation of the Neighbourhood countries in European Food Safety Authority (EFSA)" has been implemented during the period from 1 February 2014 to 31 January 2016 with participation of the Republic of Moldova.

138. The overall objective was to promote the understanding of EFSA's work in the ENP countries, share expertise and create information exchange mechanisms.

139. Through this EFSA project, the Republic of Moldova cooperated with network contact points of 14 countries: Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Morocco, the State of Palestine<sup>1</sup>, Tunisia and Ukraine.

140. More detailed information could be found at web-page: [https://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/1037e.pdf](https://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1037e.pdf).

141. In order to improve surveillance and monitoring of emerging arbovirolosis in the Mediterranean basin and Black Sea regions based on the One Health approach, in the framework of the EU-funded MediLabSecure Project, since 2014 year, the Republic of Moldova collaborates with 19 non-EU states from:

(a) Balkans Region (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, The Former Yugoslav Republic of Macedonia, Serbia, and Turkey);

(b) Black Sea Region (Armenia, Georgia, Moldova, and Ukraine); and

(c) North Africa and Middle East Region (Algeria Egypt Jordan Lebanon Libya Morocco Palestine) in order to improve surveillance and monitoring of emerging arbovirolosis in the Mediterranean basin and Black Sea regions, in the framework of the One Health approach.

142. More detailed information could be found at web-page: [http://www.medilabsecure.com/countries\\_moldova.html](http://www.medilabsecure.com/countries_moldova.html)

143. The Republic of Moldova established an international collaboration within surveillance and research networks, as follows:

(a) **With CDC for:**

(i) Rotavirus vaccine effectiveness;

(ii) Norovirus, and hepatitis viruses.

(b) **With WHO for:**

(i) Influenza — WHO reference laboratory for influenza, exchange of information, sentinel site, sending of isolates to the WHO collaborating center in London

(ii) Polio — WHO reference laboratory for polio

(iii) Rubella and measles (WHO reference laboratory, Moscow)

(c) **With EU Networks through:**

(i) Danish veterinarian institute (SalmSurv);

- (ii) Romanian institute.
- (d) Under Twining projects with:**
  - (i) Laboratories in Moscow and in the Saratov university (e.g. arboviruses)
- (e) With Black Sea Network:**
  - (i) Pact for stability for public health problems (AMR, TB, HIV working groups).

144. The Republic of Moldova continues to develop effective national infrastructure and to improve national capability to survey, detect, diagnose and combat human, animal, plant diseases, as well as other possible biological threats through international cooperation and integrate these efforts into national and/or regional emergency and disaster management plans.

**A. NATO Science for Peace and Security Project 984898 "Developing capability to mitigate the risk of biological agents in the Republic of Moldova"**

145. So, in the framework of the multi-year flagship NATO Science for Peace and Security Project 984898 with title "Developing capability to mitigate the risk of biological agents in the Republic of Moldova", NATO is helping the Republic of Moldova to address the threats from biological agents, such as Anthrax, through:

**(a) Building domestic capability to mitigate the biological risks in the Republic of Moldova:**

- (i) To develop the guidelines and training materials on anthrax agent sampling, microbiological diagnostics, risk assessment and remediation;
- (ii) To develop tools and methodologies to monitor the biological activities of anthrax agent;
- (iii) To support young researchers in the project through trainings, develop the relevant competences;
- (iv) To provide trainings to the project participants regarding enhancing the surveillance capacities, risk assessment, statistical sampling, analysis, risk identification, laboratory equipment, health and safety and remediation of anthrax agent in the contaminated soil;
- (v) To develop mobile intervention capacity on bio-security of the Anthrax agent;
- (vi) To provide trainings and develop competence for the young researchers.

**(b) Development and application of various remediation techniques;**

**(c) Mapping of the anthrax agent** throughout Moldova by historical data collection and analysis, statistical sampling by mobile laboratory and record them through a specialized software.

**(d) Raise awareness** of the risks of Anthrax and the subject project nationwide and locally as well as in the region.

146. In the framework of the EU CBRN Center of Excellences Initiative, the Republic of Moldova cooperates with EU and non-EU states to mitigate CBRN risks of criminal, accidental or natural origin.

**B. EU CBRN CoE Project 43 "EU Outreach Programme 2015-17 on export control of dual-use goods"**

147. The Republic of Moldova cooperates with partner countries (Albania, Azerbaijan, Belarus, Bosnia and Herzegovina, China, former Yugoslav Republic of Macedonia, Georgia, India, Kosovo<sup>5</sup>, Lebanon, Montenegro, Morocco, Pakistan, Serbia, South Africa, Tunisia, Ukraine, United Arab Emirates) to improve the effectiveness of export control systems for dual-use items, as well as to combat the proliferation of weapons of mass destruction and related materials, equipment and technologies.

148. More detailed information could be found on web-page: <http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/79/Project-43-EU-Outreach-Programme-2015-17-on-export-control-of-dual-use-goods.aspx>.

**C. EU CBRN CoE Project 40 "Strengthening health laboratories to minimise potential biological risks"**

149. The Republic of Moldova cooperates with partner countries (Armenia, Azerbaijan, Egypt, Iran, Jordan, Kyrgyzstan, Morocco, Oman, Pakistan, Somalia, Sudan, Tajikistan, Tunisia, Turkmenistan, United Arab Emirates, Uzbekistan, Yemen) in order to minimise potential biological risks through the enhancement of laboratory biosafety, biosecurity, quality management and diagnostic capacity, as well as to safely and rapidly detect and respond to natural or deliberate biological events of national and international concern.

150. More detailed info could be found at: <http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/76/Project-40-Strengthening-health-laboratories-to-minimise-potential-biological-risks.aspx>

**D. EU CBRN CoE Project 36 "Further development and consolidation of the Mediterranean Programme for Intervention Epidemiology Training (MediPIET)"**

151. In the framework of the EU CBRN CoE Project 36 "Further development and consolidation of the Mediterranean Programme for Intervention Epidemiology Training (MediPIET)", the Republic of Moldova cooperates with Albania, Algeria, Armenia, former Yugoslav Republic of Macedonia, Georgia, Lebanon, Tunisia, and Ukraine in order to consolidate a competent public health workforce in field epidemiology capable of facing national and cross-border emergencies posed by communicable diseases. Besides, the Republic of Moldova through National Center for Public Health was selected as training site in the regional networks of training infrastructures and of field epidemiologists easily mobilised in case of cross-border outbreaks and other health threats.

152. More detailed info on: <http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/72/Project-36-Further-development-and-consolidation-of-the-Mediterranean-Programme-for-Intervention-Epidemiology-Training-MediPIET.aspx>

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<sup>5</sup> This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

**E. EU CBRN CoE Project 23 "Building capacity to identify and respond to threats from chemical, biological, radiological and nuclear substances"**

153. In the framework of the EU CBRN CoE Project 23 "Building capacity to identify and respond to threats from chemical, biological, radiological and nuclear substances", the Republic of Moldova cooperates with Albania, Cambodia, Iraq, Senegal and Tunisia on building capacities for identifying and responding to threats from chemical, biological, radiological and nuclear substances.

**F. EU CBRN CoE Project 18 "International Network of universities and institutes for raising awareness on dual-use concerns in bio-technology"**

154. The Republic of Moldova is a member of the International Network of universities and institutes for raising awareness on dual-use concerns in bio-technology, established in the framework of the EU CBRN CoE Project 18. In this network, Moldova cooperates with Albania, Algeria, Burkina Faso, Croatia, Egypt, Gabon, Georgia, Jordan, Lebanon, Libya, Mali, Mauritania, Morocco, Pakistan, Philippines, Senegal, Serbia, Tunisia, Ukraine, Vietnam, Yemen. The main object of the network is to raise awareness of dual-use (peaceful use and misuse) concerns in bio-technology for academics, scientists, researchers, technicians and students, as well as to foster the sharing and transfer of best practices in bio-safety and bio-security.

**G. EU CBRN CoE Project 11: Promoting good practice and inter-agency procedures for assessing the risks of chemical, biological, radiological and nuclear misuse**

155. During 2013-2014 years, under EU CBRN CoE Project 11 on Promoting good practice and inter-agency procedures for assessing the risks of chemical, biological, radiological and nuclear misuse, the Republic of Moldova cooperated with Algeria, Bosnia and Herzegovina, Brunei Darussalam, Cambodia, former Yugoslav Republic of Macedonia, Jordan, Lao PDR, Morocco, Serbia, Vietnam in order to strengthen public security by upgrading capabilities and methodologies to comprehensively assess the risks of terrorism and misuse involving chemical, biological, radiological and nuclear materials and technologies.

**H. EU CBRN CoE Project 7: Guidelines, procedures and standardisation on biosafety/biosecurity**

156. During 2013-2015 years, under EU CBRN CoE Project 7 "Guidelines, procedures and standardization on biosafety/biosecurity", the Republic of Moldova cooperated with former Yugoslav Republic of Macedonia and Serbia in order to establish domestic procedures to regulate the manufacture, use, import, export, transport and storage of hazardous micro-organisms in line with international standards and guidance.

**I. EU CBRN CoE Project 4: Inter-agency CBRN Response Programme (ICP)**

157. In the period of 2013-2015 years, the Republic of Moldova cooperated with Albania, Armenia, Bosnia and Herzegovina, Croatia, former Yugoslav Republic of Macedonia,

Georgia, Montenegro, Serbia, and Ukraine, in the framework of EU CBRN CoE Project 4 "Inter-agency CBRN Response Programme (ICP)" in order to share best practices and to improve the inter-agency response.

158. The Republic of Moldova adds a value to area of epidemiological surveillance and control of communicable diseases throughout information exchange with Domestic Surveillance System 24/7 connection with:

- (i) WHO via National Center for Public Health of the Ministry of Health of the Republic of Moldova
- (ii) FAO via National Agency for Food Safety;
- (iii) OIE.

159. The Republic of Moldova contributes to the International reporting and potential for case reporting to EU level. Communicable disease statistics are supplied annually, on an aggregate basis, to WHO (CISID and EUROFLU).

(a) Detailed anonymous TB case reports are made to WHO on an agreed basis with ECDC.

(b) Reporting to WHO under the International Health Regulation - 2005 are made as required and self-assessment system reports have been submitted annually according to WHO requirements.

## Netherlands

160. The Netherlands attaches great importance to cooperation and assistance under Article X of the Biological and Toxin Weapons Convention (BWC) 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 organization and other relevant partners.

### A. Dutch contributions to relevant organizations and initiatives

161. The Netherlands has a strong tradition in international cooperation on biosafety and biosecurity and belongs to the world's largest donors to the specialized UN agencies that are relevant for implementing Article X of the BWC. In this regard, the longstanding Dutch support to the World Health Organization (WHO) is particularly worth noting. The Netherlands seeks to support the WHO's work with a sizeable contribution, of which a large part is un-earmarked. The WHO undertakes various initiatives, including guiding public health responses to biological (and chemical) weapons, as well as ensuring access to quality and use of medical products and technologies.

162. Moreover, the Netherlands plays an active role in the Global Health Security Agenda (GHSA). This initiative, which is joined by over 50 countries, should be seen as an accelerator to implement the International Health Regulations of the WHO. The Netherlands, together with the UK, Germany, Sweden, Canada and Japan, is coordinating the work package on antimicrobial resistance. Moreover, the Netherlands is participating in the work package on zoonotic diseases. The GHSA also addresses issues regarding biosafety, workforce / capacity-strengthening and monitoring. It aims to better align both multilateral and bilateral support activities, based on voluntary Joint External Evaluations.

The Netherlands will be hosting the next High Level meeting of the GHSA in October 2016.

163. In addition, the Netherlands has, since the Global Alliance for Vaccines and Immunisation (GAVI) was launched in 2000, contributed EUR 200 mln between 2011-2015 and EUR 250 mln between 2016-2020 to this global public-private partnership for immunization. GAVI aims at enlarging the "standard package" of vaccination with relatively expensive vaccines, such as vaccines against yellow fever, hepatitis B and pneumonia. Research is planned on new vaccines against AIDS, tuberculosis and malaria. In this context, the Netherlands donates bilaterally to the Global Fund to Fight AIDS, Tuberculosis and Malaria and to the WHO. With contributions totalling over EUR 900 mln the Netherlands is the tenth-largest public donor to the Global Fund. NL also contributed EUR 252 mln to the WHO in the period 2000-2010, of which EUR 126 mln for the termination of polio, and around EUR 140 mln between 2011-2016. In addition, the Netherlands has, since 2011, committed more than EUR 170 mln to the development of new drugs, vaccines and diagnostics through international product development partnerships and the European Developing Countries Clinical Trials partnership.

## **B. Dutch contribution to the fight against Ebola**

164. Since the Ebola outbreak in West Africa, the Netherlands has been an active partner in the fight against Ebola. The Netherlands offered the services of the Joint Support Ship "Karel Doorman" twice to ship in-kind assistance to the affected countries. The Netherlands donated EUR 5 mln of humanitarian goods which consisted of for instance ambulances, beds and gloves. The vessel also transported in-kind aid donated by EU member states and UN agencies.

165. The Netherlands provided additional financial support in fighting Ebola to important partners such as the WHO, UNICEF, the Dutch Red Cross and Medicins sans Frontieres. Also a consortium of Dutch NGOs was funded in order to alleviate suffering of the people in the three affected countries. Because of the shortage of medical capacity, the Netherlands deployed 60 laboratory workers to analyse blood samples in the donated mobile laboratories. In total, the Netherlands contributed around EUR 62 mln of humanitarian aid to support the fight against Ebola.

166. The Netherlands long term contribution to recovery after the Ebola crisis consisted of two important pillars: economic recovery for the affected countries and strengthening health systems, both in the affected countries and through the strengthening of international emergency medical response. To strengthen health systems, a flexible and effective medical emergency response is crucial in crises like Ebola. Therefore, the Netherlands facilitates, through a contribution of EUR 2,2 mln, a trilateral collaboration between Ghana and Sierra Leone on one side, and Rwanda and Guinea on the other, in order to contribute to the establishment of a robust preparedness system. Furthermore, the Netherlands has been a strong advocate for reforms of the WHO to develop capacity on emergency preparedness and response. The WHO's Contingency Fund for Emergencies is an important mechanism that can quickly provide funds to outbreaks to prevent an epidemic. The Netherlands has contributed EUR 1 mln to this WHO fund. During the Ebola crisis, there was a lack of medical capacity. The WHO has founded the Global Health Emergency Workforce to create a worldwide network of medical capacities. The Netherlands has offered its medical evacuation capacity and hospital beds to this pool. Awaiting further development of the Workforce, the Netherlands is exploring options to contribute through medical and emergency experts. The Dutch contribution is channelled through the EU-led European Medical Corps. As member of the WHO Executive Board, the Netherlands will maintain her active role in the discussions around reforms in the WHO.



### C. International cooperation projects on biosafety and biosecurity

167. The Netherlands is also active in several international cooperation projects to enhance biosecurity and biosafety, strengthen information sharing on national biosecurity measures, enhance awareness raising and promote responsible bioscience.

160. In April 2016, the Netherlands Biosecurity Office organized the third meeting of the European Biosecurity Regulators Forum (EBRF). This Forum has its origin in work conducted by a group of six European countries in the context of the EU CBRN Action Plan (Action B2), which aimed to share best practices and examples of national implementation of biosecurity measures in a guideline document and thereby to strengthen European biosecurity. The group is reconvened in the EBRF with an expanded focus, including the securing of biological substances, awareness raising and responsible science in relation to dual-use technologies. During the meeting, the outcomes of the CBRN Action Plan were presented by a representative of European Commission, DG Migration and Home Affairs, and risks and economics of intentional releases of plant pathogens were presented and discussed. Moreover, the group discussed the issue concerning technologies with misuse potential. The EBRF is planning to present a working paper on this topic at a side event at the BWC Review Conference in November 2016.

168. The Centre for Infectious Disease Control at the Netherlands Institute for Public Health and the Environment (RIVM) is involved in several international initiatives to enhance biosafety and biosecurity, and CBRN first response. Within the framework of the Global Partnership against the Spread of Weapons and Materials of Mass Destruction, the Netherlands funded several projects under the Biosecurity Engagement Programme of the US Department of State in Uganda. The Centre for Infectious Disease Control at the RIVM is implementing a biosecurity project in Uganda, funded by the Dutch Ministry of Foreign Affairs as part of the Global Partnership. The project has been initiated in 2014 with the aim to contribute to the biosafety and biosecurity situation in Uganda, and to develop a suitable training program for local partners with specific needs in this direction. In addition, the project focuses on initiatives including biosafety and biosecurity curriculum development at Ugandan Universities and the implementation of a plague laboratory in the Arua border district. Furthermore, the RIVM participates in the EU CBRN Centres of Excellence project "Strengthening CBRN first response capabilities and regional cooperation in South East Europe, Southern Caucasus, Moldova and Ukraine", including the preparedness and first response in case of intentional and non-intentional release of biological agents. Lastly, the European Framework 7 project (GIFT), coordinated by the Netherlands Forensic Institute (NFI), aims to develop and provide a forensic toolbox focusing on procedures, practices and guidelines for common CBRN forensic measurements and handling instructions on a European level. In relation to biological agents, the RIVM participates in the development of biologically safe procedures for forensic investigation of CBRN contaminated exhibits.

169. The Netherlands has several MoUs with countries to collaborate in the field of prevention and control of infectious diseases, including the implementation of the International Health Regulations. Activities are ongoing in India, Russia and China.

170. Lastly, the Royal Netherlands Academy of Arts and Sciences (KNAW) has been involved, in cooperation with various ASEAN Academies of Science and the U.S. National Academy of Sciences (US-NAS), in a number of biosecurity meetings in the ASEAN region during the past years. In Bogor Indonesia (August 2014), the KNAW organized a successful workshop together with the Indonesian Academy of Science (APII) on relevant scientific and technical developments from a biosecurity perspective, such as gain of function research and the need of education and awareness raising. The aim was to bring together stakeholders from relevant institutions, academies of science, industry and

government (from Indonesia, Singapore, Malaysia, Thailand, Vietnam and the Philippines) to share methods and experiences regarding education and awareness raising. A follow-up workshop in Jakarta in May 2015 mainly focused on the relevance of gain of function research for the ASEAN region. Furthermore, the Indonesian Code of Conduct on Biosecurity was presented which is inspired by and partly based on the Dutch Code of Conduct. More workshops on responsible science related to biosecurity were held in 2015 in Yogyakarta and in Kuala Lumpur.

171. To showcase these biosecurity-related developments in science and technology in the ASEAN countries to a wider audience, the US-NAS and the KNAW organized two meetings during the Meeting of States Parties (MSP) of the BWC in December 2015. Relevant issues in the field of S&T, which should be dealt with during the 8<sup>th</sup> Review Conference, were identified and highlighted by participants from Malaysia, Indonesia, the Philippines, Thailand and Vietnam. Moreover, the meetings provided an opportunity for these scientific experts to become acquainted with the BWC and interact with governmental experts on biosecurity activities in the ASEAN region.

## Norway

172. 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.

173. 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](http://www.fhi.no).

174. 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>)

175. A full discussion and listing of relevant research activities would be beyond the scope of this report. However, a few links are given below.

(a) The Bergen Centre's 2015 activities are listed here: [http://www.uib.no/sites/w3.uib.no/files/attachments/cih\\_report\\_2015\\_web\\_0.pdf](http://www.uib.no/sites/w3.uib.no/files/attachments/cih_report_2015_web_0.pdf)

(b) The websites of three of the relevant research groups at the University of Oslo are as follows:

(i) Global Governance for Health, The Lancet-UiO Commission  
<http://www.med.uio.no/helsam/english/research/global-governance-health/index.html>

(ii) International Community Health, Institute of Health and Society  
<http://www.med.uio.no/helsam/english/research/groups/international-health/index.html>

(iii) Preventive Medicine and Epidemiology, Institute of Health and Society  
<http://www.med.uio.no/helsam/english/research/groups/epidemiology/index.html>

176. 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](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)

177. 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.

178. 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)

179. 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.

180. 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.

181. 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.

182. 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.

183. 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.

184. An overview of Norwegian projects over the past five years is given below.

## Projects

### Ebola response

Table 6

| <i>Project Title</i>                       | <i>Ebola response</i>  |
|--|--|
| Partner Country/Region                     | Africa   |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | WHO, UN multi-partner trust funds, the African Union, the Norwegian Directorate of Health, the Norwegian Research Council, Médecins Sans Frontières, the International Committee of the Red Cross and others   |
| Project Value                              | > NOK 500 million (> USD 60 million, approximately)  |
| Duration                                   | 2014-15  |
| Description                                | Ebola response. Concrete measures include:<br><br>Norway staffed the Ebola Treatment Center (ETC) run by Medicos del Mundo (MdM) in Sierra Leone.<br><br>Norway set up and ran a basecamp providing accommodation for international aid workers in Moyamba, Sierra Leone.<br><br>Norway made a Hercules aircraft from the armed forces |

| <i>Project Title</i> | <i>Ebola response</i>   |
|----------------------|---|
|                      | <p>available for the transport of personnel and equipment to Sierra Leone. The aircraft has made a total of 24 flights.</p> <p>Norway provided NOK 32.7 million to the Research Council of Norway and WHO to support their work to develop an Ebola vaccine.</p> <p>More than 300 Norwegian health workers volunteered to join the efforts in Sierra Leone, and 110 of them were recruited. The Bergen regional health authority was responsible for the recruitment process.</p> <p>Three Norwegian teams, each made up of 15 health workers (doctors, nurses and ambulance personnel), worked in Moyamba.</p> |

#### **Development project — closely related to global health security agenda**

Table 7

| <i>Project Title</i>                       | <i>Establishing the Palestinian National Institute of Public Health &amp; Strengthening IHR-implementation</i>   |
|--|--|
| Partner Country/Region                     | Palestine  |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | World Health Organization<br>Palestinian National Institute of Public Health<br>Norwegian Institute of Public Health   |
| Project Value                              | NOK 36 million (ca. USD 5 million)   |
| Duration                                   | 2011-2016  |
| Description                                | The World Health Organization, in close cooperation with the Norwegian Institute of Public Health, has played a supportive role in building up the Palestinian National Institute of Public Health. The support has consisted of providing professional advice as well as materials and equipment. The project was funded by Norway. |

#### **Disarmament and development projects (BIO)**

Table 8

| <i>Project Title</i>            | <i>Strengthening IHR implementation</i>   |
|---------------------------------|---|
| Partner Country/Region          | Ghana, Malawi, Moldova  |
| Implementing Country            | Norway  |
| Collaborating Institution(s) or | Norwegian Institute of Public Health<br>Ghana Health Service, Public Health Division<br>Public Health Institute of Malawi |

| <i>Project Title</i> | <i>Strengthening IHR implementation</i>   |
|----------------------|---|
| Partner(s)           | National Centre of Public Health, Moldova<br>Palestinian National Institute of Public Health  |
| Project Value        | NOK 18 766 741 (2015 - 2016) – (ca. USD 2,3 mill)   |
| Duration             | 2015-2019   |
| Description          | The International Health Regulations 2005 (IHR) were developed to detect, assess and respond to urgent health threats. Implementation of these regulations has been slow, with only 42 out of 194 countries fulfilling WHO requirements. The Norwegian Institute of Public Health has established a programme aimed at strengthening IHR implementation. The programme is being carried out in collaboration with partner institutions in other countries. 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.<br><br>Global Health Security Agenda project |

Table 9

| <i>Project Title</i>                       | <i>Regional Workshop in preparation for the Eighth BTWC Review Conference</i> |
|--|---|
| Partner Country/Region                     | African Union   |
| Implementing Country                       | Norway  |
| Collaborating Institution(s) or Partner(s) | BTWC Implementation Support Unit  |
| Project Value                              | USD 12 660  |
| Duration                                   | 2016  |
| Description                                | Regional workshop in preparation for the Eighth BTWC Review Conference        |

Table 10

| <i>Project Title</i>                       | <i>Peaceful Uses Initiative</i>              |
|--|--|
| Partner Country/Region                     | Africa                                       |
| Implementing Country                       | Norway                                       |
| Collaborating Institution(s) or Partner(s) | IAEA   |
| Project Value                              | NOK 2 million – (USD 280 000, approximately) |
| Duration                                   | 2015   |

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|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>Peaceful Uses Initiative</i>   |
| Description          | Strengthening Africa's regional capacity for diagnosis of emerging or re-emerging zoonotic diseases, including Ebola Virus Disease (EVD), and establishing early warning systems. |

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Table 11

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|  |  |
|--|--|
| <i>Project Title</i>                       | <i>UNIDIR Framework Agreement for Multi-year Cooperation</i>   |
| Partner Country/Region                     | Global   |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | United Nations Institute for Disarmament Research (UNIDIR)   |
| Project Value                              | NOK 12.5 million - (USD 1.5 million, approximately)  |
| Duration                                   | 2014-2016  |
| Description                                | Support for strategic and structured disarmament and security-building activities that strengthen the ability of developing countries to implement disarmament commitments, as well as UNIDIR's capacity to advance disarmament and sustainable development. |

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Table 12

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|  |   |
|--|---|
| <i>Project Title</i>                       | <i>ILPI WMD Project - Development and Disarmament</i>   |
| Partner Country/Region                     | Global  |
| Implementing Country                       | Norway  |
| Collaborating Institution(s) or Partner(s) | International Law and Policy Institute (ILPI)   |
| Project Value                              | NOK 18 812 000 – (USD 2.2 million, approximately)   |
| Duration                                   | 2014-2016   |
| Description                                | To strengthen the capacity of developing countries, intergovernmental organisations and civil society to implement international obligations and participate in multilateral processes aimed at controlling and eliminating weapons of mass destruction |

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Table 13

| <i>Project Title</i>                       | <i>BTWC Compliance</i>  |
|--|---|
| Partner Country/Region                     | Global  |
| Implementing Country                       | Norway  |
| Collaborating Institution(s) or Partner(s) | Wilton Park Executive Agency  |
| Project Value                              | NOK 201 000 – (USD 24 000, approximately)   |
| Duration                                   | 2014  |
| Description                                | Part-funding to support participation at Wilton Park's conferences, with a particular focus on the next BTWC review conference. |

Table 14

| <i>Project Title</i>                       | <i>Civil Society Engagement</i>  |
|--|--|
| Partner Country/Region                     | Global   |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | BioWeapons Prevention Project  |
| Project Value                              | NOK 1 050 000 – (USD 125 000, approximately)   |
| Duration                                   | 2011-2014  |
| Description                                | Publication of BioWeapons Monitor – a collection of reports from all regions of the world on bioweapons-related activities   |
| Project Title                              | Strengthening expertise and training on disarmament in Central Asia  |
| Partner Country/Region                     | Central Asia   |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | PIR Center Moscow  |
| Project Value                              | NOK 380 000 – (USD 45 000, approximately)  |
| Duration                                   | 2012-2013  |
| Description                                | The project is intended to strengthen expertise and training capacity in the field of disarmament in Central Asian countries through supporting the work of local experts and development of a regional sustainable network of disarmament professionals |



Table 15

| <i>Project Title</i>                       | <i>Project Greenfields</i>   |
|--|--|
| Partner Country/Region                     | Global   |
| Implementing Country                       | Norway   |
| Collaborating Institution(s) or Partner(s) | BWTC Implementation Support Unit   |
| Project Value                              | NOK 370 000 – (USD 55 400)   |
| Duration                                   | 2012   |
| Description                                | An international workshop to start a fresh dialogue, from first principles, among stakeholders who may be able to play a role in coordinated action to manage biological risks more effectively, especially in developing countries. |

Table 16

| <i>Project Title</i>                       | <i>Contribution to UNIDIR's activities</i>  |
|--|---|
| Partner Country/Region                     | Global  |
| Implementing Country                       | Norway  |
| Collaborating Institution(s) or Partner(s) | United Nations Institute for Disarmament Research (UNIDIR)  |
| Project Value                              | NOK 4 650 000 – (USD 550.000, approximately)  |
| Duration                                   | 2011-2013   |
| Description                                | The Grant was given as a general contribution to support UNIDIR's activities for disarmament and development in 2011-2013.<br><br>Particular attention will be given to efforts to reinforce the participation and contributions of developing nations in the multilateral work in the field. |

Table 17

| <i>Project Title</i>                       | <i>Assistance in the practical implementation of UNSCR 1540 on non-proliferation of WMD and their means of delivery</i> |
|--|---|
| Partner Country/Region                     | Global  |
| Implementing Country                       | Norway  |
| Collaborating Institution(s) or Partner(s) | UN Office of Disarmament Affairs (UNODA)  |

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|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>Assistance in the practical implementation of UNSCR 1540 on non-proliferation of WMD and their means of delivery</i>   |
| Partner(s)           |   |
| Project Value        | NOK 3 million - (USD 350 000, approximately)  |
| Duration             | 2010-2013   |
| Description          | Capacity-building at the national level to support the implementation of UNSCR 1540, strengthening the regional implementation process in developing countries, support for country visits, and support for the practical implementation of the programmes of work of the 1540 Committee. |

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## Poland

185. Poland facilitates the exchange of equipment, materials and scientific and technological information concerning the use of bacteriological (biological) agents and toxins for peaceful purposes. Poland also supports the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease and for other peaceful purposes.

186. National Institute for Public Health-National Hygiene Unit (Narodowy Instytut Zdrowia Publicznego-Państwowy Zakład Higieny) is actively contributing to the international cooperation related to maintenance of diagnosis research's readiness as well as of their high quality conduct. These efforts are part of the EMERGE project "Efficient response to highly dangerous and emerging pathogens at EU level" – under the EU Joint Action, Consumer, Health, Agriculture and Food Executive Agency (CHAFEA). These activities, within the scope of BTWC Article X, concern improvement of identification's methods of selected biological agents that are embraced by the BTWC, with the aim to improve protection of public health. The General Karol Kaczkowski Military Institute of Hygiene and Epidemiology is engaged in similar efforts related to strengthening overall capacities in CBRN event response, including biological.

187. Polish universities and research institutes are actively engaged in the international exchange of knowledge in the field of health and bacteriology, including through participation in international research projects and hosting international seminars and symposiums. In this context, it is worth noting the Polish Academy of Science (PAN) which has been actively contributing to the work of the InterAcademy Panel Biological Working group, organizing numerous seminars and workshops.

188. The Government of Poland has been providing scholarships programmes for students and trainees from the developing countries pursuant to bilateral agreements. For example, more than 1200 foreigners from developing countries participated in study programmes and fellowships at undergraduate, graduate and post-graduate levels funded by the Polish government in the period from 2011 to 2016. These programmes covered the fields of medicine, health, physical education and biology. It is estimated that the related costs as well as the value of grants paid by the Ministry of Science and Higher Education and the Ministry of Health amounted to more than EUR 3.3 million.

189. The following study programmes are available for the holders of the scholarships of the Republic of Poland:

(a) Bachelor studies (1st cycle studies) – duration of 3 to 4 years; a student receives Bachelor title;

- (b) Master's studies (2nd cycle studies) – duration of 2 years; designed for students with Bachelor degree; a student receives Master's degree;
- (c) Master's long-cycle studies – duration of 5 to 6 years; a student receives Master's degree or a medical doctor title in case of medical studies;
- (d) PhD studies (3rd cycle studies) – duration of 2, 3 or 4 years depending on a subject; available to students with Master's degree; a student receives PhD degree;
- (e) Medical specialization, the period of training is 4 to 6 years, depending on the requirements of the specialization.

190. Foreign students can also take part in the post-doctoral internships, science internships, specialization courses and medical internships.

## Portugal

191. Portugal fulfils its obligations under article X, partly through the Ministry of Health and two of its institutions: the Directorate-General of Health, and the National Institute of Health "Dr. Ricardo Jorge" (INSA), which is the Portuguese National Laboratory of Reference for disease surveillance and detection.

192. The Directorate-General of Health fosters the development and transfer of best practices on biosafety, biosecurity and biorisk management, and has, since 2012:

- (a) Supported the Ministry of Health of Cape Verde on capacity-building activities regarding virology, bacteriology, and development of national public health laboratory network;

- (b) Shared information with African Portuguese Speaking Countries within vector borne diseases – surveillance, control and response — a goal also promoted by the Ministry's National laboratory of Reference (please, see below);

- (c) Shared documentations with African Portuguese Speaking Countries within the implementation of IHR with regards to airports and ports monitoring systems. Other projects are implemented through INSA. For INSA, the responsible dissemination of technical and scientific information is a priority. Indeed, acknowledging that only through scientific exchange and collaboration with other Partners is it possible to strengthen laboratory response and enhance national capacities as well as those of Partners, INSA has been developing a sustained collaboration with its counterparts in many countries, namely in Europe and in Africa. For this reason, INSA continues to work within the framework of relevant international networks and international organizations, such as:

- (i) the World Health Organization, with whom INSA collaborates for more than 20 years - The Portuguese Reference Centre for tuberculosis is a reference centre of the WHO;

- (ii) those inscribed in European projects connected to biosafety and biosecurity in microbiological laboratories and emergency response and biopreparedness as Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk (EQADeBa); Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP, both virus and bacteria) [http://www.quandhip.info/Quandhip/EN/Home/Homepage\\_node.html](http://www.quandhip.info/Quandhip/EN/Home/Homepage_node.html); Establishment of Quality Assurance for the Detection of Biological Toxins of Potential Bioterrorism Risk (EQUATOX) <http://equatox.net>; European Research Infrastructure on Highly Pathogenic Agents (ERINHA) <http://www.erinha.eu>; and

Iberian network of laboratories of biological alert (IB-Bioalernet). — These projects envisage Quality control schemes involving detection of highly pathogenic microorganisms, early detection of biological threats, development of methods for rapid laboratory diagnosis of biologic agents and simulation of emergency situations in case of a bioterrorism event;

(iii) the Global Outbreak Alert & Response Network (GOARN), of whom INSA is a founding member;

(iv) the CBRN Centres of Excellence (CoEs) Initiative, since 2011.

(v) INSA has also invested in the training of human resources, the improvement of infrastructures and the development of standard operating procedures applied to investigation and research. The following are examples of those activities:

a. Every year, INSA organizes a course on Biosafety and Biosecurity in BSL-3 laboratories, open to other institutions, raising awareness on biological risks and biocontainment measures, where the principles of the BWC are extensively explained to the attendees.

b. INSA also organizes annually one course on Transport of Infectious substances, which follows the instructions of the World Health Organization.

c. INSA is the coordinator of the national surveillance program of vector and vector borne diseases, improving of disease surveillance and outbreak investigation, namely through close cooperation with animal health departments and other human health authorities. All these actions were optimized through the participation in international exercises and trainings.

193. Article X goals are also pursued by other Research and Development (R&D) institutions, such as the Institute of Hygiene and Tropical Medicine (IHMT) of the New University of Lisbon (<http://www.ihmt.unl.pt/> and <http://cmdt.ihmt.unl.pt>)

194. The IHMT is highly recognized both nationally and internationally for its research, postgraduate training, and support to the community, namely in various specialized diagnosis, environmental impact studies, partnerships and joint ventures with industry, IHMT has also an important role in the dissemination and translation of knowledge on tropical diseases and its determinants to students and general society. IHMT is a national reference institution for cooperation and development in health promotion areas and a privileged interlocutor of the Portuguese speaking countries. IHMT courses are certified and evaluated by National Accreditation Agency and cover the fields of Tropical Clinical Sciences, Tropical Animal Health and Public Health, Medical Parasitology and Medical Microbiology, Biomedical Sciences, Infection and Genetics:

- Master programs:
  - Medical Parasitology
  - Medical Microbiology
  - Biomedical Sciences
  - Tropical Health
  - Health and Development
  - Epidemiology
- PhD programs:
  - Biomedical Science

- Tropical Medicine
- International Health
- Human Genetics and Infection

195. IHMT also offers e-learning courses, and in loco, courses in African Portuguese speaking countries. These courses vary from basic laboratory techniques, to Health workforce empowerment. IHMT is a Collaborating Centre for Human Resources of the World Health Organization. IHMT is collaborating with WHO AFRO to develop the following areas:

- (a) Enhancement of epidemiological surveillance and response with focus on training of rapid response team of experts;
- (b) Preparedness and response to vector borne disease outbreaks through capacity building in medical entomology;
- (c) Strengthening of local laboratory capacity;
- (d) Human Resources for Health.

196. IHMT has institutional cooperation protocols, among others, with the National Institute of Health, in Mozambique, Ministry of Health and University "Agostinho Neto" in Angola, and Fundação Oswaldo Cruz, in Brazil. IHMT integrates a network of European and African TB laboratories, currently being extended to North America, South America, and India laboratories. These networks focus the training of human resources, and control of multi-drug resistant (MDR) and extensive drug resistant (XDR) strains of *Mycobacterium tuberculosis*.

197. IHMT is a collaborating partner in Research/ Development projects on Control of Malaria in Angola, Cape Verde, Kenya, Mozambique and São Tomé e Príncipe. IHMT integrates Research projects in African Trypanosomiasis in Kenya, Mozambique, South Africa, Uganda and Republic of Congo. Surveillance of tick and mosquito-borne arboviruses in high-risk at Portuguese and Lusophone countries areas, in particular dengue in Cape Verde, South Africa and Portugal;

198. The Faculty of Sciences of University of Lisbon (FCUL) is another public higher education and research centre in the field of life sciences, with a long history of international cooperation. FCUL has ongoing collaboration with Portuguese speaking countries such as Mozambique, Angola, Cape Verde and Brazil. Students of those countries have been taking FCUL courses throughout the years and this number is rising due to recent cooperation agreements, in particular, we are in the process of receiving about sixty students from Brazil.

199. In addition, Master degree courses in the field of chemistry are developed at the University "Agostinho Neto", in Angola, and at the University "Eduardo Mondlane", in Mozambique, in partnership with the FCUL. Both degrees include Safety as one of the subjects. Furthermore, FCUL is very keen in the exchange of scientific and technological information concerning several aspects of biological agents and toxins for peaceful purposes. FCUL, in close collaboration with its R&D units, provides its researchers with a wide range of multi-user facilities (e.g. computing, microscopy, mass spectrometry, cell cultures, greenhouses, etc.), fostering interdisciplinary experimentation.

## **Serbia**

200. The Republic of Serbia attaches importance to the issue of international cooperation, i.e. to the effective and full implementation of Article X of the Convention in order to generate the benefits for the all State parties.

201. The enhancement of international cooperation is the vital interest of Serbian agencies/laboratories/institutions dealing with health, biosafety and biosecurity issues (Military Medical Academy — Institute of Epidemiology, BATUT Institute of Public Health, Torlak Institute of Immunology and Virology, Central Veterinary Laboratories of Serbia, Chamber of Biochemists, etc.)

202. Especially bearing in mind that the Republic of Serbia is seeking to create facilities with biological containment at biosafety level 3, by upgrading laboratories to meet BSL 3 and 4 standards and by training staff to operate at biosafety level 3. Our national experts are dedicated, skilled and responsible with the genuine desire to meet all biosafety and biosecurity requirements, but additional international expertise, as well as financial and technical assistance is needed and more than welcome. In the Republic of Serbia the maximum laboratory safety capacity is currently at level 2.

203. The standards of systems, processes and laboratories is important to Serbia because of our critical location at the gateway between east and west that is crucial to disease control in Europe, especially in the agriculture sector. Our objective is not only to upgrade the laboratories to meet higher BSL, but also to develop the laboratories' standards to evaluate new facilities. The new challenges are emerging out of the fact that the Republic of Serbia is one of the countries on the Western Balkans migration route. Only in Year 2015 alone, between 800 000 and 1 000 000 migrants transited through the Republic of Serbia on their way to the EU. Lacking the laboratories with BSL higher than 2 presents a factual problem also in the context of this emergent aspect.

204. So, our long-standing objective is to technically improve the general conditions in our facilities, which will help us to meet the higher standards for diagnostics, production, research and development.

## **Seychelles**

205. Seychelles undertakes to facilitate and 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, should the need and opportunity arise.

206. Seychelles shall also co-operate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriological (biological) for the prevention of disease or for other peaceful purposes, should the need and opportunity arise.

## **Slovakia**

207. 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.

208. 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.

## Spain

### A. Through the Instituto de Salud Carlos III

209. The Instituto de Salud Carlos III is the main Public Research Entity funding, managing and carrying out biomedical research in Spain. Its key mission is to support the development of scientific knowledge in the health sciences and to contribute to innovation in healthcare and the prevention of disease.

The Instituto de Salud Carlos III collaborates and provides technical advice on the design of internationalisation policies and strategies for Spanish research in health sciences and on establishing partnerships, in coordination with the Ministry of Economy and Competitiveness. In this regard, it is a leader in Spain and in European and international policies, initiatives and programmes in the area of biomedical and health science research.

It is responsible for national and international representation, coordination and cooperation in many international fora related to biological research and health sciences. For more than twenty years, the Institute has been involved in cooperation projects and international programs aimed at supporting the sustainable development of biological sciences.

210. Among the projects that can be named, Spain would like to underline:

(a) The long-term collaboration activities with the Pan American Health Organization (PAHO) supported by the Spanish Agency for International Development Cooperation (AECID) of the Ministry of Foreign Affairs and Cooperation. This programme is implemented by workshops, seminars, training, funding and direct support to education and training projects, as well as the support to a system of early alarm on the spread of infectious diseases.

(b) The collaboration with the World Health Organization since more than 20 years. Two laboratories of the National Centre for Microbiology have been designated as WHO Collaborating Centers. They act as National Reference Laboratory for HIV infection and Leishmaniasis and carry out quality control programs and field activities in developing countries (Ethiopia, Sudan, etc.).

(c) InfoSaludLaboral: Activity of international cooperation between the National School of Occupational Medicine of the Instituto de Salud Carlos III and PAHO within the framework of the cooperation Agreement between the Kingdom of Spain, through the AECID, and PAHO / WHO.

It is a website (<http://new.paho.org/isl/>) aimed to the scientific community and practitioners of health promotion and prevention of occupational hazards of Spain and the Latin American countries. It is integrated within the framework of action of the PAHO / WHO, facilitating access to and dissemination of information on quality of life and working conditions, prevention and health promotion in the workplace.

(d) The Red Iberoamericana Ministerial de Aprendizaje e Investigación en Salud (Latin American Ministerial Network for Learning and Research on Human Health, RIMAIS) is the result of a commitment by the Costa Rican Ministry of Health at the Fifteenth Ibero-American Summit of Heads of State and Government.

RIMAIS basic goal is to strengthen the ability of Latin American Ministries of Health to perform a guiding function in learning and research in public health based on the socialisation of information and the know-how generated and disseminated via various regional initiatives.

Cooperation with and support for the RIMAIS network forms part of the strategic plans of the Instituto de Salud Carlos III to internationalize Spanish research in health and encourage scientific and technical cooperation with Latin America. It also aims to increase the amount of research and improve its quality and foster policies based on scientific evidence in the countries covered by the network in the light of the challenges currently faced by public health in the Region.

One of the activities envisaged in this connection is cooperation between the RIMAIS and the European Union.

(e) The Instituto de Salud Carlos III is a member of the International Association of National Public Health Institutes (IANPHI), a worldwide initiative of the Bill and Melinda Gates Foundation to strengthen public health systems and to improve their coordination. Set up formally in 2006, the Association seeks joint coordinated responses to the challenges and possible risks of public health in the world today. IANPHI also acts as a platform for collective action by the directors of more than sixty public health institutes all over the world, encouraging and facilitating communication and cooperation between them.

211. Spain is also part of many multilateral programs. Among those, Spain would like to mention:

(a) The TDR (WHO), a worldwide programme of scientific cooperation for research and training in tropical diseases. It has a double mission: To carry out research into the diseases of poverty and develop new, improved approaches to them and to strengthen and develop research skills in the countries where these diseases are prevalent. The Health Institute Carlos III represents Spain in this programme, which is financed by the AECID.

(b) ISCIII and other Spanish institutions are committed to implementing projects to strengthen international cooperation and collaboration in fields related to health and life sciences. Among those, Spain would like to mention:

(i) MediPIET: Further Development and Consolidation of the Mediterranean Programme for Intervention Epidemiology Training (2014-2017).

MediPIET is a EuropeAid-DEVCO funded project under the Instrument contributing to Stability and Peace, linked to the Chemical, Biological, Radiological and Nuclear Centres of Excellence initiative — CBRN CoE. The project is led by the Consortium FIIAPP (International and Ibero-American Foundation for Administration and Public policies) — ISCIII (Instituto de Salud Carlos III), with the scientific leadership of ECDC.

This project has been established under a regional perspective to contribute to the overall objective of enhancing health security in the Mediterranean basin by supporting capacity building for prevention and control of natural or man-made health threats posed by communicable diseases and other threats through a sustainable training programme in intervention epidemiology.

The MediPIET project is aimed at consolidating a competent workforce in intervention epidemiology to carry out essential public health functions for prevention and control of national and cross-border challenges posed by communicable diseases and other health threats enhancing the biological aspect of CBRN CoE.



The main objectives are:

- a. Establishing a network of epidemiologists and trainers in field epidemiology among Public Health institutions of the participating countries in order to contribute to the reinforcement of the prevention and response to health threats
- b. Training field epidemiologists in charge of the essential activities of public health for the prevention and control of communicable diseases and other risks, with a common language in the region
- c. Promoting the collaboration, the exchange of experiences and knowledge between the countries of the Mediterranean and the commitment at the sustainability at national and regional levels
- d. Reinforce institutional capacity at national and regional levels

(ii) ViroRed project (2010-2016): ViroRed is a laboratory network involving many countries from Latin America, Spain and Portugal financed by CYTED. The activities of ViroRed are mainly focused in implementing and improving diagnostic capacities of emerging viral pathogens. This project is being implemented with regional workshops, and direct communication among laboratories, researchers and scientists.

(iii) DengueTools (2012-2016): Innovative tools and strategies for surveillance and control of dengue. This project, funded by EC under the Health theme of the FP7, endeavours to achieve better diagnosis, surveillance, prevention, prediction and/or prevention of the spread of Dengue fever to previously uninfected regions (including Europe) in the context of climate change. The project address three main research areas: i) Novel diagnostic and monitoring tools and strategies for dengue surveillance and early warning systems; ii) Novel strategies for the prevention of dengue in children; and iii) Risk of global spread of dengue and introduction into Europe.

(iv) MediLabSecure (2014-2017): Preventing vector-borne diseases around the Mediterranean and Black Sea regions by creating new networks.

The MediLabSecure project, funded by the European Union DEVCO/EuropeAid, aims at consolidating a Laboratory Network on the emerging viruses that are pathogens for humans and/or animals. It will represent a cluster for awareness, risk assessment, monitoring and control of these vector borne diseases. This cluster will require the interaction of four laboratory sub-networks, one for human health, one for animal health, one for entomology and one for public health reinforcement.

The MediLabSecure network will encompass partner countries around the Mediterranean and Black Sea Regions (19 non-EU countries) by means of a collaborative execution of the stated work packages to address public health-related national needs.

(v) IB-BIOALERTNET (2013-2015): Iberian network of laboratories of biological alert. Accreditation of methods for detection of highly pathogenic agents.

IB-BIOALERTNET is a project supported through the Prevention of and Fight against Crime (ISEC) Programme of EC (DG-HOME). The overall aim of the project was to establish an Iberian Network of laboratories of biological alert enabling the exchange of information, training, technology transfer, standardization

and accreditation of procedures to become an effective tool to respond rapidly and efficiently to biological threats.

(vi) International Cooperation with the Ministry of Health from Equatorial Guinea: Technical Assistance to National Programmes for Endemic Diseases Control of Ministry of Health, Equatorial Guinea funded by AECID (2015-2016):

This project supports Strategic Programmes of Malaria, Neglected Tropical Diseases, HIV/AIDS and TB.

(vii) World Organisation for Animal Health (OIE) Laboratory Twinning Contract between the Universidad Complutense de Madrid (OIE Reference Laboratory for African Swine Fever) and the Central Veterinary Laboratory-Kabete (Kenya) (2013-2015).

The objectives of the project were to study new challenges and measures to prevent African swine fever spread and the development of new diagnostic methods.

(viii) Translational Research to Combat Antimicrobial Resistance in India (2012-2015). The Spanish Ministry of Science and Innovation funded this project implemented by the Universidad Complutense de Madrid. The main objective was to link antimicrobial resistance seen in animals, food and man, including samples of the environment and wildlife.

(ix) Universidad Complutense de Madrid service related to African swine fever epidemiology and risk assessment capacity building in People's Republic of China (2014-2015).

Development of new diagnostic molecular methods. Development of epidemiological models on the risks of entry different infectious diseases in China, by identifying the critical points of each disease and modelling their potential spread. The diseases studied are classified in the list of notifiable to the World Organization for Animal Health (OIE).

(x) Universidad Complutense de Madrid collaboration to develop a food safety laboratory in the North region of Ghana (2012-2014) in order to improve control programs of food-borne zoonoses.

(xi) University collaboration in infectious diseases diagnosis between Universidad Complutense de Madrid and University for Development Studies (UDS) in the North region of Ghana (2011-2014). The goal is to strengthen relationships between both universities by training courses in infectious diseases, personal training and technical advice.

212. Concerning training activities, Spain would like to mention:

(a) The Escuela Nacional de Sanidad (National School of Public Health, ENS - ISCIII) provides basic and advanced training to healthcare professionals. The ENS and the National Centre of Tropical Medicine (ISCIII) offers Master's degree, Higher and Specialist Diplomas, short courses and specialized training seminars aimed at national and international staff involved in comprehensive health care, diagnosis, and treatment of tropical diseases, and/or health cooperation. Among them the following:

(i) Master in Public Health: Training programme designed to further students' careers in the field of Public Health.

(ii) Higher Diplomas: Programmes designed to complete students' professional training in a specific area of Public Health, Health Administration or related disciplines.

- Diploma in International Public Health
  - Diploma in Public Health
  - Diploma in Health Promotion
- (iii) Continuous training courses: Training programmes, with a workload of less than 120 hours, geared to the continuous training of public health professionals:
- Malaria: Clinical, Research, and Control
  - Parasitological Diagnosis of Tropical Diseases
  - Molecular Diagnosis of Tropical Diseases
  - Tropical Medicine and Communicable Disease Control for Health Personnel of International Cooperation
  - Update on Tropical Infections
  - Qualitative Research Applied to Health Research

**B. Through the Fundación Internacional y para Iberoamérica de Administración y Políticas Públicas (FIIAPP) and the EU CBRN Centres of Excellence (CBRN CoE)**

Table 18

|                        |   |
|------------------------|---|
| <i>Project Title</i>   | <i>CBRN 22: Provision of specialized technical training to enhance the first responder's capabilities in case of CBRN incidents</i>   |
| Partner Country/Region | Indonesia; Morocco; Mauritania; Thailand  |
| Implementing Country   | Leader of the Project: France Expertise (France); Partners: FIIAPP (Spain) and National Crime Agency (UK).  |
| Project Value          | 700.000 €   |
| Duration               | 07-Jan-13 / 06-Jan-15   |
| Description            | The European Commission is seeking external support to implement technical aspects related to the EU CBRN Risk Mitigation CoE. The overall objective of this project is to reinforce interagency coordination to respond to CBRN incidents. This includes defining standard operational procedures in response to such incidents, e.g. post-incident management and site restoration. |

Table 19

|                        |  |
|------------------------|--|
| <i>Project Title</i>   | <i>CBRN 23: Building capacity to identify and respond to threats from chemical, biological, radiological and nuclear substances.</i> |
| Partner Country/Region | Albania; Cambodia; Iraq; Moldova; Senegal; Tunisia   |
| Implementing Country   | Leader of the Project: FIIAPP (Spain); Partners: National Crime Agency (UK).   |
| Project Value          | 499.100 €  |

|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>CBRN 23: Building capacity to identify and respond to threats from chemical, biological, radiological and nuclear substances.</i>  |
| Duration             | 07-Jan-13 / 06-Jan-15   |
| Description          | <p>The European Commission is seeking external support to implement technical aspects related to the EU CBRN Risk Mitigation CoE. The overall objective of the project of which this contract will be a part is as follows:</p> <p>-Counter the threat arising from chemical, biological and radioactive or nuclear agents in particular when used in a criminal or terrorist context.</p> <p>-Improve the preparedness and response capabilities of states to unlawful or criminal acts involving CBRN agents.</p> |

Table 20

|                        |  |
|------------------------|--|
| <i>Project Title</i>   | <i>CBRN 33. Strengthening the National CBRN Legal Framework &amp; Provision of specialized and technical training to enhance CBRN preparedness and response capabilities</i>   |
| Partner Country/Region | Burundi; Gabon; Kenya; Morocco; Mauritania; DRC; Rwanda; Senegal; Uganda   |
| Implementing Country   | Leader of the Project: France Expertise (France); Partners: FIIAPP (Spain), DGSCGC (France), Home Office (UK), ENCO, SCK-CEN (Belgium)   |
| Project Value          | 2.700.000 €  |
| Duration               | 15-Sep-13 / 15-Sep-16  |
| Description            | The present procedure aims at awarding a Contract that will technically implement two projects funded by the EU Instrument for Stability (Priority 1) in the framework of the Chemical, Biological, Radiological, and Nuclear - Centres of Excellence (CBRNCoE). |

Table 21

|                        |  |
|------------------------|--|
| <i>Project Title</i>   | <i>CBRN 34. Strengthening Capacities in CBRN event response and related Medical Emergency response under strengthened CBRN event preparedness</i>  |
| Partner Country/Region | Iraq, Jordan, Lebanon  |
| Implementing Country   | Leader of the Project: Military Institute of Hygiene and Epidemiology (Poland); Partners: FIIAPP (Spain), ICIS (Italy), Military Institute of Chemistry & Radiometry, University of Rome Tor Vergata (Italy) |
| Project Value          | 3.914.034 €  |
| Duration               | 10-Apr-14 / 09-Apr-17  |

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|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>CBRN 34. Strengthening Capacities in CBRN event response and related Medical Emergency response under strengthened CBRN event preparedness</i> |
|----------------------|---|

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|             |  |
|-------------|--|
| Description | The main aim of the CBRN CoE initiative is to enhance national CBRN policies and capacities in third partner countries and to promote national, regional and international cooperation in CBRN risk mitigation. The origin of the risk can be criminal (proliferation, theft, sabotage and illicit trafficking), accidental (industrial catastrophes, in particular chemical or nuclear, waste treatment and transport) or natural (mainly pandemics). The CBRN CoE initiative supports the reinforcement of the institutional capacity needed to fight against this risk. |
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Table 22

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|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>CBRN 35. Management of hazardous chemical and biological waste in the African Atlantic Façade region</i> |
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|------------------------|--|
| Partner Country/Region | Albania; Algeria; Armenia; Bosnia and Herzegovina; Egypt; FYROM; Georgia; Jordan; Lebanon; Libya; Morocco; Moldova; Montenegro; Palestinian Territories; Serbia; Tunisia; Ukraine  |
| Implementing Country   | Leader of the Project: FIIAPP (Spain); Partners: ICIS (Italy), AENOR (Spain), GRS (Germany).   |
| Project Value          | 3.871.800 €  |
| Duration               | 01-Jan-14 / 01-Jul-17  |
| Description            | The objective of this project is to enhance (or initiate) best practices in hazardous chemicals and biological waste management in the AAF region and in Tunisia. In terms of content, aspects related to sampling, detection, measurement, protection, decontamination, mitigation, transport, containment, site remediation and disposal should be considered in each country (tailored approach), while keeping a regionally consistent approach as much as possible. This will include the elaboration of comprehensive standard procedures and technology solutions for CB. |

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Table 23

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|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>CBRN 36. Further development and consolidation of the Mediterranean Programme for Intervention Epidemiology Training (MedPIET)</i> |
|----------------------|---|

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|                        |  |
|------------------------|--|
| Partner Country/Region | Albania, Algeria, Armenia, Bosnia and Herzegovina, Egypt, Georgia, Jordan, Kosovo*, Lebanon, Libya, Moldova, Montenegro, Morocco, Palestine, Serbia, The former Yugoslav Republic of Macedonia, Tunisia, Ukraine. These countries belong to three CBRN Centres of Excellence regions: North Africa Secretariat, Middle East Secretariat and South East Europe, Southern Caucasus, Moldova and Ukraine. |
| Implementing Country   | Leader of the Project: FIIAPP (Spain); Partners: Health Institute "Carlos III" (Spain)   |

|                      |   |
|----------------------|---|
| <i>Project Title</i> | <i>CBRN 36. Further development and consolidation of the Mediterranean Programme for Intervention Epidemiology Training (MediPIET)</i>  |
| Project Value        | 6.400.000 €   |
| Duration             | 15-Feb-14 / 20-Dec-17   |
| Description          | This project is contributing to the overall objective of enhancing health security in the Mediterranean region by supporting capacity building for prevention and control of natural or man-made health threats posed by communicable diseases through the further roll-out of the Mediterranean Programme for Intervention Epidemiology Training (MediPIET). |

\* This designation is without prejudice to positions on status, and is in line with UN SCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Table 24

|                        |   |
|------------------------|---|
| <i>Project Title</i>   | <i>CBRN 46: Enhancement of CBRN capacities of South East Asia in addressing CBRN risk mitigation concerning CBRN first response, biosafety and biosecurity, awareness raising and legal framework.</i>                    |
| Partner Country/Region | Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam  |
| Implementing Country   | Leader of the Project: FIIAPP (Spain); Partners: FORMIT (Italy), RIVM (Netherlands)   |
| Project Value          | 3.000.000€  |
| Duration               | 10-jul.-15 / 10-jul.-18   |
| Description            | The overall objective of this project is to enhance CBRN capacities of South East Asia in addressing CBRN risk mitigation in three technical areas (i.e. first response, biosafety and biosecurity, and legal framework). |

## Sweden

### SIDA (Swedish International Development Co-operation Agency) and the Ministry for Foreign Affairs.

213. Sweden's total health aid (SIDA and MFA) amounted to 4 053 million SEK in 2012, an increase with 30 % compared to 2010 (not including health research or humanitarian support). The increase is partially a result of an extra disbursement during 2012 for MDG 4 and 5 (350 million SEK). Major areas of support are, apart from maternal and child mortality, MDG 6 and SRHR.

214. SIDA primarily works with bilateral aid (43% of the total health aid in 2012) but also regionally, and has a budget line for global programs. The Ministry for Foreign Affairs works with multilateral aid (57% of the total health aid in 2012), the GFATM and UNFPA being the two largest recipients.

215. The major areas of support regarding the bilateral health aid according to DAC classification are (2012): reproductive health care (36%), basic health care (23%) and STD

control incl. HIV/AIDS (21%). These three areas together make up 80 % of the total bilateral health aid.

216. The number of countries where SIDA has bilateral programs in place for support of the health sector declined between 2006-2011 due to increased support to conflict affected countries and post-conflict countries. An increase could be seen in 2012 where Sweden had 11 on-going country programs for health aid in Bangladesh, DRC, Somalia, Sudan/South Sudan, Uganda, Zambia, Zimbabwe, Tanzania (hiv/aids), South Africa (hiv/aids), India and Guatemala.

217. SIDA has continued the work on new financial instruments to enable support for product development and innovation in the health sector. The main objective of the process is to create the conditions for mobilizing capital from the private sector, foundations, etc., for research in poverty areas. In the first pilot project, SIDA investigated the possibility of establishing a funding model, to promote the flow of capital into the research and development of pharmaceuticals and diagnostics for poverty related diseases. The model has been tested in the development of new antibiotics and/or the development of a diagnostic tool for detection of antibiotic resistance. Four guarantees are now up and running.

## Switzerland

218. 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 the implementation of Article X as contained in document BWC/CONF.VIII/PC/2, Switzerland submits the following report to States Parties.

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

220. 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.

221. 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.

222. 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').

223. 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).

224. 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.

## **United Kingdom of Great Britain and Northern Ireland**

225. This section outlines an *illustrative* range of UK activities and programmes undertaken (or funded by) by government departments, industry, research councils and academia that give effect to our commitments under Article X; this section is not comprehensive, but is designed to give a flavour of the range and diversity of relevant activities underway. The UK programmes include many with an emphasis on addressing concerns of priority to the developing world, such as low cost vaccines/malaria prevention and treatment. Many projects are multi-sectoral and collaborative and involve partnerships between government, academia, industry, international organisations and counterparts in those countries receiving assistance.

226. It bears repeating that these programmes and activities are being conducted for their intrinsic scientific, humanitarian and developmental value; they are not separately identified as BTWC Article X projects, or conceived exclusively to satisfy an Article X requirement. And that is how it should be. However, they undoubtedly give effect to the objectives of Article X that implementation of the Convention should avoid hampering the economic or technological development of States Parties or international cooperation in the field of peaceful biological activities.

### **A. Government departments, agencies and funded programmes**

#### **1. Antimicrobial resistance**

227. In March 2015 the UK committed £195 million over five years to launch the Fleming Fund to work to counter antimicrobial resistance (AMR) and strengthen infectious disease surveillance world-wide. This fund will focus on enhancing laboratory capacity and surveillance networks in developing countries, particularly where there is no such existing or planned capacity. The UK government will work with the Wellcome Trust, the Bill and Melinda Gates Foundation, the Institute Pasteur International Network and other partners to this end. We are looking at how to use the Fleming Fund to work with countries in implementing the AMR global action plan and building sustainable surveillance capability in line with the International Health Regulations. In this context, the Commonwealth and Public Health England have joined forces to strengthen public health laboratories in low and middle-income Commonwealth countries through a twinning and partnership initiative to share expertise and knowledge. The initiative is focusing initially on the twinning of PHE with a small number of Commonwealth countries including Seychelles, Sierra Leone and Trinidad and Tobago (through the Caribbean Public Health Association, CARPHA, and linking to other countries in that region).

228. On 23 October 2015 the UK and China announced that they will establish the Global Antimicrobial Resistance (AMR) Research Innovation Fund and encourage further investment from other governments and the private sector, helping to address one of the greatest problems facing the world of medicine today. This new fund will invite bids from industry, academia and other bodies. It will aim to create international partnerships to build a global response and support new research to reduce the spread of antibiotic resistance.



The Medical Research Council (MRC), the Biotechnology and Biological Sciences Research Council (BBSRC) and the Economic and Social Research Council (ESRC) are joining forces with the National Natural Science Foundation of China (NSFC) to establish a joint fund of £9M to support research on antimicrobial resistance (the UK contribution will be channelled through the Newton Fund — see paragraph 6 below). A workshop was planned for 24-26 November 2015 in Shanghai, China, to further explore the antibacterial resistance research landscape within the two countries and to establish core themes that will direct the funding.

229. Another example of UK support in this area is a Newton Fund initiative in India which focuses on research into antimicrobial resistant Tuberculosis and minimising the indiscriminate use of antibiotics. Through this initiative, Innovate UK has launched a programme of industrial R&D support with their Indian counterpart which will support collaborative R&D projects on antimicrobial resistance. In addition, major research centres on Antimicrobial Resistant Tuberculosis, and Advanced Technology for Minimising the Indiscriminate use of Antibiotics are being established with the support of the UK Medical Research Council (MRC) and the Government of India Department of Biotechnology (DBT). Significant partnerships have been developed with Indian departments on PhD exchanges, Postdoctoral training schemes and professional development.

## **2. Biosafety, Biosecurity and Infectious Disease Surveillance, Detection and Diagnosis**

230. During 2013/14 and 2014/15, the UK's International Biological Security Programme, managed by the Ministry of Defence, has funded projects which have:

(a) Achieved improvements in physical security and techniques at laboratories / institutes, particularly in FSU countries including Tajikistan, Georgia and Azerbaijan; improved the safety and security of work with dangerous pathogens, for example through the installation of critical safety equipment and the introduction of laboratory techniques that reduce the need to work with live biological agent, as well as the provision of support to the development of biosafety associations e.g. the Biosafety Association of Central Asia and the Caucasus, and the Afghan Biorisk Association;

(b) Strengthened countries' ability to detect and identify disease outbreaks: this has included the introduction of, and training in, modern diagnostic techniques, as well as funding projects conducted by intergovernmental organisations as part of their established biosecurity and biosafety efforts;

(c) Re-established and strengthened, through a four year collaborative research project, basic surveillance capabilities to study key viral pathogens responsible for serious endemic diseases in the Republic of Tajikistan. This included a number of highly dangerous pathogens which appear on one or more 'select agent' lists, such as Crimean-Congo Haemorrhagic Fever (CCHF), often referred to as 'Asian Ebola'. This work underpins Tajik capacity to deal with its regular outbreaks of CCHF, and contributes to international understanding of CCHF virus aetiology and control. Through collaboration with Public Health England, modern molecular diagnostic techniques have been established in-country, reducing the requirement for handling highly infectious live virus in the diagnostic laboratory, thereby directly contributing to improved biosecurity and laboratory safety for this important research.

(d) Jointly funded with the US Biological Engagement and Canadian Global Partnership Programs the development of a regional biorisk management and molecular diagnostics training centre at the Jordan University of Science and Technology. The facility consists of a mock containment laboratory for training scientists, laboratory technicians and laboratory managers, and includes a functional heating, ventilation and air conditioning system, funded by the UK, for training these staff in the management and maintenance of

such systems in containment facilities. This type of knowledge will contribute to laboratory safety by ensuring that these critical systems are properly maintained in trainees' parent laboratories.

(e) Overall, the training centre is intended to serve as a model institution, capable of providing training to scientists in the Middle East/North Africa and South Asia regions on a variety of topics related to biorisk management. There are no other dedicated training facilities in the Middle East/North Africa region capable of providing biosafety training courses which include both practical and classroom based activities. The safe and secure practices promoted will enhance regional laboratory safety and security on a sustainable basis. Jordan is able to provide a suitable environment for conducting such training activities, including for scientists from other countries in the region, such as Libya and Yemen, where access is more difficult for security reasons. This project therefore complements training courses that the UK has previously funded at the Jordan University of Science and Technology, which were focused on modern diagnostic techniques and were delivered to scientists from across the region.

(f) Provided funding for the joint OIE/FAO post-eradication programme to help reduce stocks and improve global security of the rinderpest virus, which is highly pathogenic, highly communicable and potentially devastating to livestock. Primarily affecting cattle, this disease poses a significant threat to food security. The sequestration and security of remaining stocks of this virus in a small number of designated holding facilities is therefore of high priority in order to minimise the risks of any further outbreaks, whether caused deliberately or otherwise. In May 2013, the OIE launched a UK funded international, multilingual media campaign highlighting the importance of the rinderpest sequestration and security programme. The OIE campaign has been successful in identifying 28 facilities which currently hold rinderpest virus; it is proposed that only five facilities should hold stocks in future, significantly reducing the associated risks. In addition, a UK funded efficacy trial is under way at the UK's Pirbright Institute involving a vaccine for Peste des petits ruminants; if the trial is successful, the use of this vaccine could further reduce the need to hold stocks of rinderpest virus, and possibly allow their eventual elimination. The UK has encouraged a joint approach by the OIE and FAO to this programme, and has helped secure funding from other donors.

### **3. The Newton Fund: Bioinformatics, Neglected Tropical Diseases**

231. The Department for Business, Innovation and Skills administers the Newton Fund whose objective is building science and innovation capacity in developing countries. It was launched in April 2014 and will provide £375 million of funding over the course of five years. As part of the Newton Fund, the Genome Analysis Centre (TGAC) was awarded over £50,000 in August 2015 by the British Council to develop advanced bioinformatics capabilities for next-generation rice genomics in Vietnam to aid precision breeding for improvement of this staple crop by exploring 48 local rice varieties. Developing the bioinformatics capacity in Vietnam will allow research Institutes to benefit from advancements in next generation genomics, applying their computational skills to rice breeding to help maintain productivity in the face of changing climates, and potentially develop new higher value rice varieties for the global market.

232. In collaboration with the Agriculture Genetics Institute (AGI) in Hanoi (Vietnam), TGAC is working to characterise the genetic diversity of traditional rice varieties from Vietnam, aiming to develop genomic markers associated with traits of interest such as disease resistance and salt tolerance. In order to make the data accessible, TGAC will set up a public database to host the variant data within the context of the latest genome assemblies and annotation. The programme involves the exchange of scientists from Vietnam to gain expertise in bioinformatics analysis, and from UK to learn about the field phenotyping

activities in Vietnam. Scientists from TGAC, AGI and other participating Institutes will host "Train the Trainer" workshops in the UK to train Vietnamese researchers in bioinformatics and genomic analysis to equip them with the skills to sustain training for researchers in Vietnam for the future.

233. The Newton partnerships between UK and Brazil are continuing to tackle global challenges including infectious and neglected diseases, ensuring a lasting legacy of closer collaboration in science and innovation. In May 2015 the Medical Research Council (MRC), the Economic and Social Research Council (ESRC), a wide range of Brazilian State Funding Agencies and the Brazilian National Council for Scientific and Technological Development invited applications to the UK-Brazil Neglected Infectious Diseases Partnership Call as part of the Newton Fund. The launch of this call followed the success of the UK-Brazil Infectious Disease Workshop, which took place in October 2014. The workshop was convened by the funding agencies participating in this partnership and attended by eminent Brazilian and British researchers in the field of infectious diseases in order to scope the development of the call. This initiative will provide funding for collaborative research projects, focussed on neglected infectious diseases in Brazil. This includes but is not limited to Dengue fever and other vector-borne diseases (e.g. Chikungunya); Leishmaniasis; Chagas disease; Leprosy; Schistosomiasis; intestinal helminth infections; rotaviruses and emerging viruses. In total, up to £4.4m will be made available for this initiative: up to £2.2m on the UK side with equivalent effort matched by the Brazilian funders.

## **B. Academic and research councils**

### **Combating Zoonotic Diseases, Neglected Tropical Diseases and Malaria**

234. The Zoonoses and Emerging Livestock Systems (ZELS) initiative was launched in 2014 as a joint venture by the Biotechnology and Biological Sciences Research Council (BBSRC), the Defence Science and Technology Laboratory (Dstl), the Department for International Development (DFID), the Economic and Social Sciences Research Council (ESRC), the Medical Research Council (MRC) and the Natural Environment Research Council (NERC). It provides £20.5M over a 5-year period for new research and training to reduce the impact of zoonoses on poor people in developing countries and their livestock, and to enhance the scientific capabilities of developing countries for the longer term.

235. The initiative consists of 11 projects that will investigate emerging and endemic zoonotic diseases in developing countries. UK researchers will work in partnership with more than 30 overseas institutes and organisations in ten countries in Africa, south Asia and south-east Asia. The projects will generate scientific evidence to inform the selection of risk-based and cost effective prevention and control options that may contribute to decreasing the likelihood of occurrence, prevent the transmission, and reduce the impact of major zoonotic diseases such as brucellosis, Q fever and Rift Valley fever.

236. The Liberian Neglected Tropical Diseases Department (NTD) is working with the support of various partners including the African Programme for Onchocerciasis Control, the London School of Hygiene & Tropical Medicine (LSHTM), the Schistosomiasis Control Initiative (SCI), and DFID, to implement a number of training, mapping, and treatment programs in the country. DFID, the largest bilateral donor active in Liberia, is supporting an NTD control programme implemented by Liverpool's Centre for Neglected Tropical Diseases and SCI that targets Lassa Fever and schistosomiasis, and includes the delivery of drugs that treat intestinal worms.

237. African scientists working in collaboration with researchers from the London School of Hygiene & Tropical Medicine are recipients of major funding from the Wellcome Trust

and DFID, to establish cutting-edge research and training programmes across the continent. The DELTAS Africa programmes establish world-class research environments at African universities with a strong focus on creating training opportunities for the next generation of researchers. In total, the scheme will award over £46 million (approximately \$70 million US dollars) over an initial period of five years. Many of the awards allow research to be carried out where the health challenges are greatest, for example genetic analysis of drug-resistant malaria across East and West Africa and locally relevant research into zoonotic infectious diseases.

238. A new compound that can kill the parasite that causes malaria is being developed by researchers as a potential treatment for the disease. If successful, it could lead to an affordable anti-malarial drug that requires only a single dose and that also reduces transmission of the disease. The discovery, published on 17 June 2015 in the journal "*Natur*", came about through collaboration between the University of Dundee's Drug Discovery Unit and the Medicines for Malaria Venture (MMV), which was supported by the Wellcome Trust. The malaria parasite *Plasmodium falciparum* has developed resistance to many current drugs, meaning that new therapies are needed to overcome this problem. The compound identified (called DDD107498) works by blocking protein synthesis within the parasite and is effective against multiple life cycles. DDD107498 has been shown to be successful in mouse models of malaria and is now beginning preclinical development. The researchers estimate that a drug developed using the compound would cost around US\$1 per treatment, which would make it affordable for patients living in low-income countries that are most severely affected by malaria.

239. In 2013 the MRC Laboratory of Molecular Biology began collaborating with the Walter and Eliza Hall Institute of Medical Research (WEHI) in Australia to determine a preliminary structure of the *Plasmodium falciparum* cytosolic ribosome by single-particle cryo-electron microscopy. The purified ribosome samples were provided by WEHI. The ribosome is essential for protein synthesis and details of the parasite's specific ribosome structure may lead to the rational design of new treatments for malaria.

240. The Liverpool School of Tropical Medicine (LSTM, Liverpool University)) has major field projects which evaluate, implement and monitor vector control activities in Africa and Asia. LSTM works closely with a range of partners to ensure that its research and educational programmes are responsive to the needs of disease endemic countries. The Liverpool-Guangdong Drug Discovery Consortium, in collaboration with University of Liverpool and Guangdong University of Technology (GDUT) in China, is focussed on the development of new drug therapies for the treatment of tuberculosis (TB), malaria, Neglected Tropical Diseases (NTDs) and other infectious diseases. The Consortium has established the Liverpool-Guangzhou drug discovery joint laboratory, located at GDUT and accommodating a drug discovery team made up of staff and students from GDUT and other parts of China.

## **C. Commercial, research and cross-sectoral**

### **Vaccines and vectors of infectious disease**

241. The UK's leading pharmaceutical companies, research centres, universities and disease experts will come together to focus on the most serious global health threats. The UK Vaccines Research and Development Network, an initiative led by the Department of Health, will bring together the best expertise across the country, with £20 million invested from the outset to focus on the most threatening diseases including Ebola, Lassa, Marburg and Crimean-Congo haemorrhagic fever, with additional investment from the private and research sector.

242. GAVI, the Vaccine Alliance, has a programme to trace children who missed out on immunisation in Sierra Leone as a result of the Ebola Virus Disease Outbreak. The objective is to ensure that they are reached through catch-up programmes. A measles vaccination campaign targeting more than 1.3 million children was undertaken in June 2015 with support from Gavi and the UK's Department for International Development (DFID).

243. The EbolaVac project is part of an international consortium comprising the Wellcome Trust, the UK government and the UK Medical Research Council which aims to accelerate collaborative multi-site trials of candidate Ebola vaccines. EbolaVac seeks to accelerate the clinical development of the GlaxoSmith Kline (GSK) Chimpanzee Adenovirus Type 3 Ebola virus Zaire (ChAd3-EBO Z) vaccine candidate to make the vaccine available to frontline health care workers at risk and to be used in the containment of EBOV outbreaks. This will be achieved by completing Phase I development of vaccine candidate conducted in Lausanne, Switzerland, and evaluating it in (placebo)-controlled, observer-blind Phase II testing at established clinical study centres in West Africa outside of Guinea, Sierra Leone, and Liberia. The EbolaVac consortium is composed of four European partners including The University of Oxford, United Kingdom, The Bernhard Nocht Institute for Tropical Medicine, Germany, The Hospices Cantonaux / University Hospital of Lausanne, Switzerland and the multinational company, GSK, who will ensure the full exploitation of the generated output and knowledge. The project will run until October 2017.

244. GlaxoSmith Kline (GSK) announced on 24 July 2015 that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had adopted a positive scientific opinion for its malaria candidate vaccine Mosquirix<sup>TM</sup>, also known as RTS,S, in children aged 6 weeks to 17 months. Following this decision, the World Health Organization (WHO) will now formulate a policy recommendation on use of the vaccine in national immunisation programmes once approved by national regulatory authorities. RTS,S, which was developed in partnership with the PATH Malaria Vaccine Initiative (MVI), is the first candidate vaccine for the prevention of malaria to reach this milestone. Once a WHO pre-qualification is granted, GSK intends to apply for marketing authorisation in countries in sub-Saharan Africa on a country-by-country basis.

245. GSK has committed itself to a not-for-profit price for RTS,S so that, if approved, the price of RTS,S would cover the cost of manufacturing the vaccine together with a small return of around five per cent that will be reinvested in research and development for second-generation malaria vaccines, or vaccines against other neglected tropical diseases.

246. Oxitec is a British biotechnology company pioneering an environmentally friendly way to control insect pests that spread disease and damage crops. It is currently pioneering a new solution to control harmful insect populations, including the mosquito species *Aedes aegypti* which spreads Dengue Fever and Chikungunya. Oxitec has used genetic modification to create 'sterile' male insects which seek out and mate with females. After an Oxitec mosquito has successfully mated with a wild female, any offspring that result will not survive to adulthood, so the mosquito population declines. This solution introduces a gene into the mosquitoes which stops their cells from functioning normally; this only affects the mosquito, unlike conventional insecticides or pesticides which kill insects indiscriminately. Oxitec and its collaborators have performed open field release tests of Oxitec's *Aedes aegypti* (under permit from the regulators) in several countries (including the Cayman Islands, Malaysia and Brazil) from 2009. In each trial aimed at suppressing the native *Aedes aegypti* population, Oxitec mosquitoes reduced the local population by over 90%, with no noted adverse events or effects.

## D. Examples of UK Article X related activities

247. 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.

248. 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.

249. 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](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/494584/Ross_Fund_Publication_final.pdf)

250. 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/>

251. 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.

252. 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.

253. 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.

254. 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.

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

256. 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. Background

257. The United States is firmly committed to fulfilling all of its obligations under the Biological and Toxin Weapons Convention (BWC), including those under Article X. The United States places great importance on Article X implementation and continues to invest significant resources in these efforts. The Seventh Review Conference confirmed the importance of implementation of Article X and requested States Parties to report on their fulfillment of their Article X obligations, in order to produce a more complete picture of its implementation.

258. The United States and the international community have worked together collectively to pursue mutual goals related to Article X, including, *inter alia*:

- (a) Contributing to the advancement of life sciences for peaceful purposes;
- (b) Building sound, appropriate regulatory and oversight systems at all levels to ensure the safe and peaceful application of dual-use materials and technologies;
- (c) Effectively implementing our obligations under the BWC and United Nations Security Council Resolution (UNSCR) 1540;

(d) Advancing educational and collaborative opportunities for the international scientific community; and

(e) Improving global health security through preventing, detecting, and responding effectively to infectious disease, whether naturally occurring, deliberate, or accidental.

## **B. General perspectives on the implementation of Article X**

259. Although the United States Government has supported, and will continue to support, capacity building and other forms of assistance for those countries seeking it, formal “assistance” programs comprise only a part of a much larger undertaking. In the United States, activities and programs to promote exchange, cooperation, and assistance in fulfilment of its Article X commitments are undertaken not only by the United States Government, but also by individuals, industry, foundations, academia, and other non-governmental organizations. Many projects are multi-sectoral and involve collaboration between the United States Government and other organizations.

260. While the large number of U.S. programs and the wide range of efforts underway contribute to the implementation of Article X, such efforts do not take place solely in the BWC forum. The programs and activities conducted by the United States, which are many and varied, are undertaken for their own intrinsic value, whether to advance our understanding of the life sciences, promote developmental and humanitarian objectives, improve global health, or all of the above. Providing programs and initiatives through a broad range of institutions, stakeholders, and fora allows for the advancement of all of these objectives.

261. The breadth and scope of U.S. contributions and assistance precludes a comprehensive listing of each and every program in its entirety, but this paper provides a selection of examples designed to illustrate the range and diversity of activities and demonstrate the full commitment of the United States to the letter and spirit of Article X.

262. The remainder of this report is organized around the three basic commitments contained in Article X: (1) to facilitate the fullest possible exchange of information, equipment, and materials for peaceful purposes; (2) to contribute to the advancement and application of the life sciences; and (3) to implement the BWC in ways that avoid hampering the economic and technological development of States Parties.

## **C. Bilateral, regional, and multilateral efforts to facilitate the fullest possible exchange of biological equipment, materials, and information for peaceful purposes**

263. The United States engages actively through bilateral, regional, and multilateral channels and, through these interactions, works to facilitate the exchange of biological equipment, materials, and information and the application of life science advances for peaceful purposes. The United States Government, in particular, provides support that enables scientists to participate in and foster the exchange of ideas that advance knowledge sharing in the life sciences.

### **1. Trade promotion**

264. The United States is one of the largest economies in the world and the second-largest exporter of goods and services. In 2015, U.S. businesses exported \$1.5 trillion of goods. Specifically in the life sciences sector, the United States is a leader in the healthcare,



pharmaceutical, and medical devices markets. In 2010, the United States launched the National Export Initiative (NEI), which sought to improve the private sector's ability to export goods and services; in May 2014, the U.S. Department of Commerce launched the second phase of the NEI program, NEI/NEXT, which aims to streamline the export/import process and negotiate new access, enforce existing agreements, and build the capacity of developing countries. Such measures, along with others to enhance the international trade system, promote investment, trade, and economic growth, and help firms to work with our international partners abroad and provide them with equipment and other products.

## 2. International collaboration and exchange programs for scientific research

265. The United States views programs that promote science education, train young scientists, and provide opportunities for international researcher-to-researcher collaborations as essential to the fulfillment of our Article X obligations. Such programs are mutually beneficial for all participating countries and contribute to the furtherance of scientific progress.

266. The Department of State's Office of Science and Technology Cooperation (OSTC) implements capacity-building programs and engages with partner nations in dialogue on a range of scientific policy issues. More than 50 bilateral and multilateral science and technology agreements provide a framework for international collaboration on scientific endeavors. Among other efforts, OSTC implements the Science Envoy Program, through which eminent U.S. scientists and engineers build peer-to-peer connections with the scientific communities in partner countries, promote science education, and identify opportunities for ongoing bilateral cooperation.

267. The National Academies of Sciences, Engineering, and Medicine, in cooperation with sponsoring federal laboratories and other research organizations, conducts the National Research Council Research Associateship Programs, which have supported the research of more than 14,000 scientists and engineers since their establishment in 1954. The goal of these programs is to provide advanced training and collaborative research opportunities for highly qualified postdoctoral and visiting scientists, while enhancing the research conducted in federal laboratories and affiliated institutions.

268. The Department of Health and Human Services supports multiple international training and exchange programs for scientific research, including, *inter alia*:

(a) The National Institute of Health (NIH)/National Institute for Allergies and Infectious Disease's International Centers of Excellence in Research program, which develops research programs in disease-endemic countries through partnerships with local scientists and provides training opportunities to young researchers both in-country and at NIH;

(b) The NIH Visiting Program, which provides opportunities for foreign scientists to train and conduct collaborative research at the NIH;

(c) The NIH/Fogarty International Center, which supports promising research initiatives in the developing world through grants and fellowships and develops new partnerships between U.S. scientists and their counterparts abroad;

(d) The NIH/National Cancer Institute (NCI)'s Short Term Scientist Exchange Program, which facilitates scientific interactions between non-U.S. scientists and researchers at NCI; and

(e) The Food and Drug Administration (FDA)'s Foreign National Training Program, which enables researchers from foreign countries to initiate and conduct research that complements projects at the FDA's National Center for Toxicological Research.

269. The Department of Defense provides an opportunity for U.S. military and civilian scientists to conduct research in foreign government laboratories and for foreign military and civilian scientists to work in U.S. Department of Defense laboratories through the Engineer and Scientist Exchange Program. The Department has signed formal international agreements with 16 countries for reciprocal working arrangements for scientists in governmental and defense organizations.

270. The United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) offers international trade and scientific exchange programs that help partner countries strengthen their capacities for agricultural productivity, food security and participation in international trade. These FAS programs link U.S. and foreign scientists and policymakers to address mutual priorities for disease prevention, surveillance, detection and diagnosis in plant and animal health, and food safety systems. For example, recent participants in the USDA Norman E. Borlaug International Agricultural Science and Technology Fellowship Program and Cochran Fellowship Program have worked on combating aflatoxin, African swine fever, anthrax, brucellosis, foot-and-mouth disease, highly pathogenic avian influenza, Rift Valley fever, tuberculosis, and additional diseases and pests of economic importance. FAS capacity-building programs also promote international cooperation on other beneficial applications of life sciences, such as molecular genetic techniques for developing improved crop varieties.

271. American colleges and universities also engage in joint research collaborations with colleagues across the globe and educate many of the world's emerging scientists through undergraduate, graduate, and post-graduate training. During the 2014/2015 academic year, the number of international students at U.S. colleges and universities increased to a record high of 974,926, 44 percent of whom were studying science, technology, engineering, and math (STEM) fields.

272. Additionally, many nongovernmental organizations and foundations based in the United States promote engagement among scientists from around the world. Some of these entities explicitly sponsor the scientific development of foreign researchers; for example, the Howard Hughes Medical Institute distributes International Student Research Fellowships, which are intended to facilitate the research training of outstanding international predoctoral students in the biomedical and related sciences. Other nongovernmental organizations host scientific exchanges and fora to bring scientists together to share best practices and lessons learned, and to highlight the role of science in society. One noteworthy example is the Intel International Science and Engineering Fair (ISEF), a program of the Society for Science and the Public. ISEF is the world's largest pre-college science competition. Each year it enables more than 1,700 high school students from more than 75 countries, regions, and territories to display their independent research and compete for \$4 million in awards. The American Society for Microbiology (ASM) also has a robust program to engage international partners and foster collaboration and partnership; its premier event, ASM Microbe, is the largest gathering of microbiologists from across the globe and provides a forum to explore the full scope of microbiology. ASM also regularly hosts conferences focusing on specialized areas, including clinical virology, biodefense, and emerging infectious diseases.

### **3. Open access and online training courses**

273. Many United States institutions support "open access" — the principle of making research results broadly available, free of charge. Open access databases promote collaboration and facilitate the spread of expertise throughout the globe, and diminish the costs associated with distributing scientific information and sharing results. In February 2013, the White House Office of Science and Technology Policy directed all federal departments and agencies to develop plans to make published results of federally funded

research freely available to the public within one year of publication. In accordance with this directive, the Departments of Agriculture, Defense, and Health and Human Services, the Department of Energy's Office of Science, the National Aeronautics and Space Administration, the National Institute of Standards and Technology, the National Oceanic and Atmospheric Administration, and the National Science Foundation have all released plans to enhance public access to the results of research funded by these entities.

274. In addition, many U.S. colleges and universities have adopted open access policies requiring researchers to make their publications available free of charge. In some cases, these policies may apply only to graduate theses or faculty members in specific fields, or may allow researchers to opt in; some, however, apply broadly to all the research conducted at that institution. A growing number of major U.S. institutions are also making undergraduate and even some graduate courses freely available online. Yale University, the Massachusetts Institute of Technology, Stanford University, and the Johns Hopkins Bloomberg School of Public Health are among the U.S. universities providing free and open access to a variety of courses through their own websites or through online platforms such as Coursera or edX.

275. The TrainingFinder Real-time Affiliate Integrated Network (TRAIN) is funded in part by the Centers for Disease Control and Prevention (CDC) and managed by the Public Health Foundation (PHF), a private, non-profit organization. TRAIN is a web-based learning network for agencies and organizations that deliver, track, and share trainings for professionals who protect the public's health. The national TRAIN network is currently made up of 26 state health departments and three federal agencies (CDC, Medical Reserve Corps, and Veteran's Health Administration). Each has its own doorway into the national TRAIN network that allows these agencies to share courses with a growing learning system of more than one million registered learners. TRAIN offers health professionals access to courses on a wide array of public health topics in a variety of formats, including classroom training, webinars, and online self-study options. Such online and distance learning opportunities enable the exchange of information between public health professionals and organizations and promote the development of the public health workforce.

#### **D. Contributions to the development and application of scientific discoveries in the life sciences**

276. The United States is a world leader in life sciences research and development (R&D), accounting for more than a quarter of global investment in the field. Much of this work is undertaken by industry, academia and non-profit organizations, although the federal government remains the largest funder of life sciences research at U.S. colleges and universities; state and local governments also provide some funding to academic institutions. This makes the United States one of the foremost engines driving both basic science and its application, from universities to government institutes to biotech companies to amateur biologist.

277. When the BWC was negotiated, many scientists believed that antibiotics, vaccines, and other medical developments had led to the imminent demise of infectious disease; today, however, the number of outbreaks and the number of emerging and reemerging infectious diseases are both on the rise. Strengthening capabilities to prevent, detect, and treat naturally-occurring infectious diseases is therefore a vitally important application of the life sciences. Moreover, measures to limit vulnerability to infectious diseases, such as bolstering health care infrastructure, strengthening diagnostic capabilities, and developing new medical therapies, would be beneficial in the event of a deliberate attack with a biological weapon as well as in the case of a naturally occurring outbreak. Improved disease surveillance, meanwhile, can help public health officials to identify outbreaks that

are caused deliberately, because unusual events can be more easily recognized if there is sufficient background data on the usual pattern of naturally occurring diseases. Thus, helping other States Parties strengthen their national capacities to prevent, identify, and respond to infectious disease outbreaks is a direct contribution to the object and purpose of the BWC, including Article X obligations.

278. To this end, the United States has provided a wide range of assistance to international partners, including, *inter alia*, the following examples designed to reduce threats; improve global detection of disease; enhance capacity to investigate, diagnose, prevent, and respond to disease outbreaks; and improve global health.

#### **1. Threat Reduction**

279. The U.S. Department of State's Biosecurity Engagement Program (BEP) works in partnership with countries in the Middle East and North Africa, South Asia, Southeast Asia, sub-Saharan Africa, and Eastern Europe to promote safe, secure, and sustainable bioscience throughout the world. Specific activities planned for the coming year include conducting surveillance and laboratory diagnostic testing for emerging diseases in Southeast Asia; enhancing physical security of West African laboratories that house large numbers of Ebola samples; promoting One Health collaborations in East Africa; and supporting a biorisk management and genomics training center in the Middle East that serves as a regional training hub for biosecurity, biosafety, and molecular diagnostics.

280. The Department of State also leads U.S. interagency participation in the G7 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, an initiative aimed at preventing terrorists from acquiring or developing weapons of mass destruction.

281. The Department of Defense Cooperative Biological Engagement Program (CBEP) implements projects with the objectives of reducing threats posed by pathogens of security concern and related materials and expertise, as well as other emerging infectious disease risks. CBEP works to enhance partner-country and regional capabilities to 1) identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens; and 2) rapidly and accurately survey, detect, diagnose, and report outbreaks of security concern in accordance with international reporting requirements and in support of international nonproliferation agreements. CBEP also works to establish and enhance international research partnerships between U.S. and partner country scientists. CBEP programs are supported in partnership with countries throughout Africa, South and Southeast Asia, East and Central Europe, and the Middle East.

282. CBEP continues to support training programs in partner countries focused on enhancing the skills essential for effective biosurveillance programs; promoting a culture of safe, secure, and responsible life science research; emergency response skills; and multi-sectoral cooperation between health and security forces to enhance response capacity to a deliberate biological attack. CBEP has also helped partner countries to implement specific projects. For example, the program provided diagnostic laboratory support in several West African countries, and partnered with countries in the Caucasus to implement an electronic disease surveillance system to facilitate rapid detection, diagnosis, and reporting of infectious disease outbreaks.

#### **2. Disease Surveillance, Detection, and Response**

283. The CDC, as the nation's primary agency and worldwide leader for disease detection, has worked in partnership with countries to develop sustainable capacities to support disease surveillance and response activities. Through the Global Disease Detection program (GDD), CDC partners with host countries to identify new health threats and

reduce the burden of infectious disease. GDD has established 10 regional Centers to work directly with more than 50 ministries of health to provide technical support and scientific collaboration. By enhancing laboratory systems, increasing preparedness and communication activities, and conducting public health research, among other activities, GDD works with partner countries to build and strengthen public health capacity. From 2006-2015, GDD Centers responded to over 1,900 disease outbreaks and other public health emergencies, with nearly two-thirds of responses initiated within 24 hours of receiving a request for assistance. GDD Centers have discovered 12 pathogens that were new to the world and detected 61 pathogens that were new to the region in which they were discovered.

284. The U.S. Agency for International Development (USAID)'s Emerging Pandemic Threats (EPT) program seeks to aggressively preempt or combat emerging diseases that could spark future pandemics. The EPT program is composed of five complementary projects (ONE HEALTH WORKFORCE, PREDICT, PREPAREDNESS & RESPONSE, FAO, WHO) operating in 32 countries in Africa, Asia, and the Middle East in coordination with CDC and DoD. These projects focus on identifying zoonotic viruses at interfaces involving humans and livestock, domestic animals, or wildlife; characterizing and mitigating risk for disease transmission between animals and people; strengthening laboratory capacity to diagnose and report human and animal pathogens; workforce training to include strengthening outbreak response capacity; and enhancing mechanisms and policies related to One Health and prevention, detection, and response for infectious disease in animals and people. EPT works with governments, universities, and other key in-country, regional, and global partners to strengthen country-level capacities for routine infectious disease detection and outbreak response. EPT supports the One Health concept by integrating multisectoral and multidisciplinary approaches in strategic planning and implementation.

285. The USDA Agricultural Research Service (ARS) is actively engaged in implementing research programs that help prevent, detect, or improve surveillance of plant and animal diseases, including emerging disease and zoonotic agents that pose a threat to human health. ARS also actively collaborates with international partners worldwide on research projects dedicated to support disease surveillance programs for transboundary animal diseases. ARS is one of the founding members of the Global Foot-and-Mouth Research Alliance (GFRA) and the African Swine Fever Research Alliance (GARA), and is an active member of the global network of expertise on animal influenza (OFFLU), which supports the FAO and OIE global efforts to control and eradicate transboundary animal diseases that affect the health of animals and people worldwide. ARS also partners with the American Biosafety Association (ABSA) to conduct biosafety training relevant to agriculture to many national and international participants at a biennial symposium.

286. The Armed Forces Health Surveillance Branch's Global Emerging Infections Surveillance Section (AFHSB-GEIS) enhances health protection of the armed forces through an integrated worldwide military laboratory network that conducts emerging infectious disease surveillance. GEIS provides direction, funding, and oversight to this laboratory network that works with more than 50 international partners based in all regions of the world. These partners conduct disease surveillance and rapid outbreak response, perform innovative pathogen discovery activities, and enhance coordination and collaboration efforts between DoD agencies and international partners to facilitate information sharing and early detection of emerging infectious disease threats. The GEIS program communicates information from its surveillance activities to support health protection decisions for forces assigned in the DoD Geographic Combatant Commands' regions of interest. Additionally, GEIS information is used to increase public awareness and understanding of global health security issues and inform public health decisions among the United States Government and international agencies. GEIS encourages its partners to

present and publish their findings in medical journals, global health security publications, and at scientific meetings, and to comply with the International Health Regulations.

287. In fiscal year 2016, GEIS distributed more than \$56 million to support a range of emerging infectious disease surveillance projects, including expanding Zika virus surveillance worldwide. This enhanced Zika virus surveillance involves 10 projects in 18 countries and territories by four laboratory partners based in the United States and five located overseas.

### 3. Capacity Enhancement and Global Health Security

288. In addition to the efforts above, the United States further supports the WHO's International Health Regulations (2005) (IHR), which, *inter alia*:

(a) Provide a framework for WHO alert and response activities that are implemented in collaboration with countries to control international outbreaks and other public health risks and emergencies;

(b) Allow the WHO to provide support for the implementation of national capacities for epidemic preparedness and response, including laboratory capacities and early warning alert and response systems; and

(c) Standardize approaches for readiness and response during a public health emergency of international concern, allowing the International Health Regulations Emergency Committee to issue travel and trade recommendations based on the best evidence available.

The United States coordinates and works with multiple domestic and international partners to strengthen core public health capacities and capabilities globally in line with the IHR.

289. In partnership with more than 50 other nations, international organizations, and public and private stakeholders, the United States is implementing the Global Health Security Agenda (GHSA), with the intent to prevent and reduce the likelihood of disease outbreaks, detect infectious disease threats early to save lives, and rapidly respond to outbreaks with coordinated multi-sectoral engagement. The GHSA aims to ensure that participants are fully prepared to detect and respond to disease threats, as well as spur progress on compliance with the IHR and other global health security frameworks, such as the World Organization for Animal Health (OIE) standards and guidelines for veterinary services and animal health systems.

290. In July 2015, the United States Government announced its intent to invest more than \$1 billion in resources to expand the GHSA and support partner countries in achieving its targets. Meeting these targets will expand our ability to prevent or mitigate the impact of naturally-occurring outbreaks and intentional or accidental releases of dangerous pathogens; detect and report outbreaks when they occur; and respond and control outbreaks before they become epidemics. The United States has partnered with 32 international partners to undergo independent external assessments and establish a five-year roadmap to achieve and sustain the targets of the GHSA in each country. To do so, the United States Government, through the United States Agency for International Development, the CDC and other agencies of the Department of Health and Human Services, the Department of Defense, the Department of Agriculture and others, is working with ministries of health, agriculture, environment and other key stakeholders to detect viruses with pandemic potential, improve laboratory capacity to support surveillance, strengthen national and local capacities to respond, and provide education on biosafety and biosecurity. The Department of State leads a robust interagency effort to engage with non-governmental stakeholders to encourage their participation in capacity-building activities under the GHSA.

291. The Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services manages cooperative agreements with partner countries and international organizations to strengthen core public health emergency preparedness and response capacities abroad. ASPR works through these partnerships to strengthen emergency preparedness and response by building surveillance networks, strengthening laboratory diagnostic capacity, training personnel, and improving communication capacities within the Ministries of Health of partner countries.

292. ASPR leads U.S. engagement in the Global Health Security Initiative (GHSI). GHSI is an informal network formed in 2001 to ensure health-sector exchange and coordination of practices in confronting risks to global health posed by chemical, biological and radio-nuclear threats, as well as by pandemic influenza. The member countries/organizations of the GHSI are Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the European Commission; the WHO serves as a technical advisor. The GHSI partners hold an annual meeting of Health Ministers to foster dialogue on topical policy issues and promote collaboration. Other initiatives involving senior health officials as well as policy, technical, and scientific personnel take place on a regular basis, focused on risk management; communications; chemical events; radio-nuclear threats; pandemic influenza; and global laboratory cooperation.

#### **4. Other Improvements in Global Health**

293. The United States Government is the largest funder and implementer of global health programs worldwide; funding for global health has grown to more than \$9 billion in fiscal year 2016. The United States is a major contributor to the Global Fund for AIDS, Tuberculosis, and Malaria, a multilateral organization aimed at fighting the three diseases worldwide, as well as several other multilateral health organizations, including UNAIDS, WHO, the International AIDS Vaccine Initiative (IAVI), and the GAVI Alliance, among others.

294. Meanwhile, through bilateral arrangements, the United States provides direct support in the area of global health to more than 60 low- and middle-income countries. In 2015, the CDC responded upon request to 319 disease outbreaks worldwide and supported more than 1,400 deployments to 28 countries.

### **E. Efforts to avoid hampering economic or technological development or international cooperation in the life sciences for peaceful purposes**

#### **1. Export controls**

295. The United States Government's export licensing system is designed to be fast, transparent, and effective in fulfilling Article III and United Nations Security Council Resolution (UNSCR) 1540 obligations to guard against the risks of proliferation and terrorism. In coordination with several other departments and agencies, the Department of Commerce's Bureau of Industry and Security (BIS) administers and enforces controls on the export of items with chiefly commercial uses that can also be used in conventional arms, weapons of mass destruction, terrorist activities, or human rights abuses.

296. In 2009, President Barack Obama directed the agencies involved in administering the U.S. export control system to conduct a broad-based review of export controls in order to enhance national security. This review led to the Export Control Reform (ECR) initiative. This three-phase plan will eventually consolidate the current system into a single control list, a single licensing agency, a single primary enforcement coordinating agency, and a single information technology system. As of 2016, Phase I is finished and Phase II is

nearly complete. The ECR effort will make the process of export licensing easier, cheaper, and faster, while protecting U.S. interests in national and international security.

297. To accomplish its objectives, BIS administers and enforces controls on the export of items through the Export Administration Regulations (EAR). In FY 2015, BIS approved 29,283 license applications valued at \$505 billion. Of these, 1,161 licenses, valued at \$16.6 million, were for biological materials and handling equipment controlled by Australia Group regulations. In contrast, BIS rejected only two license applications for biological equipment, representing only 0.17 percent of the total trade in bio-related items. Moreover, much U.S. trade, including exports of biological items, operates under our no license required provisions. Therefore, consistent with our obligations under Article X of the BWC, these regulations have a minimal impact on overall trade.

298. The Department of State's Export Control and Related Border Security (EXBS) Program seeks to prevent the proliferation of weapons of mass destruction (WMD) and destabilizing accumulations and irresponsible transfers of conventional weapons by helping to build effective national strategic trade control systems in countries that possess, produce, or supply strategic items, as well as in countries through which such items are most likely to transit. To achieve this goal, the EXBS Program works with partner governments to identify regulatory and institutional gaps and strengthen partner countries' legal authorities and institutional capabilities. The EXBS Program provides a wide range of technical assistance, from executive exchanges to training workshops to the provision of detection equipment and specialized training for border control and enforcement agencies.

299. The EXBS program is active in more than 60 countries and draws on the expertise and cooperation of a range of U.S. government departments and agencies, the private sector, and domestic and international nongovernmental organizations to provide legal, licensing, and enforcement training, along with information systems and equipment. By strengthening the capacity of their trade and border control systems, the program helps partner countries adhere to the guidelines of multilateral export control regimes and meet their obligations and commitments to important international initiatives, including Article III, UNSCR 1540, and the Proliferation Security Initiative.

## **2. Oversight of dual-use research of concern**

300. In 2012, the United States Government issued its "Policy for Oversight of Life Sciences Dual Research of Concern," which established a regular review of United States Government-funded or -conducted research with certain high-consequence pathogens and toxins to identify dual-use research of concern (DURC) and implement risk mitigation measures where applicable. In 2014, a complementary policy, the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," was issued to address institutional oversight of DURC. These policies aim to preserve the benefits of life sciences research, while minimizing the risk of misuse.

301. The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee chartered to provide advice, guidance, and leadership, as requested by the U.S. Government, regarding biosecurity oversight of dual-use research — defined as biological research with legitimate scientific purpose that may be misused to pose a threat to public health or national security. Supported by the Office of Science Policy at NIH, the NSABB seeks to identify approaches to the issue of oversight of dual-use research that will assure that potential concerns are assessed and evaluated, while at the same time protecting scientific freedom and the progress of the scientific enterprise. The NSABB has recommended a framework for the oversight of dual-use research, developed strategies for raising awareness of dual-use issues, and provided guidance for strengthening the culture of responsibility within the life sciences research community. The Board has also been active



in domestic and international engagement, seeking to raise awareness about dual-use research and related issues.

### **3. Overcoming impediments to ongoing exchanges and international cooperation**

302. The United States believes that partnerships for capacity-building and other forms of assistance to partner nations, whether by governments, international organizations, academic institutions, or private industry, benefit both parties in terms of economic and scientific development and fulfilling commitments under the BWC. However, there are a number of obstacles to successful implementation of Article X that countries receiving assistance could reduce in order to further promote the fullest possible exchange of equipment, materials, and information.

303. Recognized, effective, and predictable intellectual property right (IPR) regulations provide an important incentive for investments in innovation and facilitate exports around the world. The lack of effective protection and enforcement for IPR can dissuade those holding the IPR from investing in a country and collaborating with their institutes or academics. Strengthening IPR regulations by ensuring that relevant laws are enforced and include rigorous penalties can deter potential traffickers, provide patent holders tools for defending against infringement, lower costs for manufacturers, and provide incentives for those holding the IPR to enter new markets.

304. Comprehensive and uniform regulations support long-term research and development collaborations. Unfortunately, regulatory agencies in many States lack adequate training and resources to review patent and other regulatory applications in a timely and consistent manner, creating enormous backlogs, approval uncertainty, and market access delays. Predictable and robust legal and regulatory regimes are critical to promote investment.

305. High tariffs, taxes, and other fees also present significant market access barriers. These markups often increase the end-user price of medicine significantly, sometimes by more than 80 percent. A recent study put the average global markup at almost 20 percent, but tariff rates can sometimes reach 50 percent or more. Not only do such expenses unnecessarily increase drug costs to patients, but they also often slow product delivery. Non-tariff measures, such as customs delays or rules of origin, are less visible impediments that can also impose great barriers to trade and cooperation.

306. Customs delays can also make it difficult for the pharmaceutical or biotechnology industry or academic or government programs to provide equipment or materials to support collaborative efforts. The need to invest time and effort to address such delays can be a significant deterrent to ongoing commitment to providing assistance and resources to certain countries.

## **F. Conclusion**

307. International cooperation and exchange in the life sciences and in combating disease will continue to be a core objective for the United States of America, consistent with our obligations under Article X of the Biological Weapons Convention. International cooperation to support the advancement of biological sciences for peaceful purposes; assistance to improve global population health through the prevention, detection, and mitigation of disease; and the development of capacity and collaborative opportunities for scientists across the globe are all areas in which the United States will continue to commit programs and resources. Furtherance of these aims has broad support across the range of U.S. institutions, including the United States Government, non-governmental institutions, industry, the scientific community, civil society, and the American people.

