

This is one of a series of complementary papers submitted by the EU Member States for the consideration of States Parties. [A reference to the outcome of third country alignment procedure will be added.]

## **EU Paper on BTWC Article X**

### **I. Introduction**

1. The European Union adopted, on 20 March 2006, a Common Position 2006/242/CFSP outlining the objectives and priorities of the EU for the 2006 Review Conference of the Biological and Toxin Weapons Convention (BTWC). The Common Position, in its Article 3, makes reference to specific, practical and feasible proposals for the effective enhancement of the implementation of the BTWC, that the EU will prepare for consideration by States Parties at the Review Conference. This Working Paper is one of the above-mentioned series of proposals and should be considered as one element of an overall EU approach to strengthening the BTWC and its implementation.

### **II. BTWC Article X**

2. BTWC Article X grants the States Parties to the Convention the right to participate in, and the undertaking to facilitate, the exchange of equipment, materials and information for the use of biological agents for peaceful purposes, as well as scientific cooperation in the field. Further, Article X states that the implementation of the BTWC should avoid hampering the development of its States Parties or international cooperation in the field of peaceful biological activities. Previous Review Conferences of the Convention have, when reviewing the implementation of Article X, outlined a number of principles, objectives and measures to enhance implementation.
3. The Sixth Review Conference will, as part of the article by article review of the operation of the Convention, address Article X. Since the Fifth Review Conference, besides the rapid advances in biosciences and biotechnology, a number of developments highly relevant to Article X have taken place at the global, regional and national level. This Working Paper takes stock of relevant developments and discusses possible actions related to Article X to be agreed at the Sixth Review Conference.

### **III. Recent developments relevant to Article X implementation**

4. Given the wide range of peaceful biological activities and the depth of international cooperation on these issues, only a limited number of recent relevant developments are highlighted here:
  - Meeting of States Parties to the BTWC in December 2004, and its preparatory Meeting of Experts in July 2004, that were considered to be highly successful in discussing and promoting common understanding and effective action on surveillance, detection, diagnosis and combating of infectious diseases.

- WHO efforts to enhance its capacities in the area of diseases related to possible biological weapons agents following the adoption, at the World Health Assembly in 2001 and 2002, of the resolutions on global health security and on public health preparedness and response to deliberate use of biological and chemical agents or radionuclear material that affect health, as well as the strengthening of FAO, OIE and IPPC capacities in this field.
  - revision, in 2005, of the International Health Regulations, to be implemented as from 2007.
  - entry into force, in 2003, of the Cartagena Protocol on Biosafety, and the subsequent establishment of a Clearing-House Mechanism, with a capacity-building component, to ensure that all Parties to the Protocol can implement its provisions and facilitate information-sharing on biosafety.
  - other ongoing inter-governmental and non-governmental efforts in the field of biotechnology and biodiversity at global and regional level such as the International Centre for Genetic Engineering and Biotechnology, the International Plant Genetic Resources Institute, related work at UNEP, UNESCO, UNIDO, and the UNDP/UNEP/World Bank Global Environment Facility, OECD biotechnology initiatives, including the possible establishment of a Global Biological Resource Centre Network, as well as the initiatives of several non-governmental organisations and networks.
  - the vigorous efforts of the international community to combat the spread of avian influenza.
  - the rapid growth of international biological and biotechnological cooperation in the private sector, which greatly facilitates opportunities for exchange of technology and information for the prevention of disease or for other peaceful purposes.
5. The European Union, and its Member States, have actively participated in the above-mentioned global endeavours and, in addition, have undertaken a number of specific actions that support the implementation of BTWC Article X, including:
- implementation of the 2002 EU Strategy on Life Sciences and Biotechnology and the related Action Plan, which also covers international cooperation and Europe's responsibilities towards the developing world (see Annex 1).
  - establishment, in 2005, of the European Centre for Disease Prevention and Control whose mandate also covers assistance to third countries.
  - EU development cooperation commitments in several relevant sectors, from health and agriculture to assistance in complying with sanitary and phytosanitary requirements, the EU and its Member States being the biggest provider of development assistance in the world.
  - EU education and research policy, notably cooperation programmes in the field of higher education, international cooperation activities integrated in the EU Framework Programmes for Research, and EU-funded research notably in the fields of biosecurity, infectious diseases and biotechnology.
  - EU assistance in emergency situations, such as the Asian tsunami where 90 000 people were provided with primary health services and more than 880 000 people were provided with safe water and sanitation facilities.
6. The Sixth Review Conference should acknowledge the progress made with Article X implementation, and recognise the contribution of the abovementioned and other ongoing international, regional, bilateral and national efforts towards effective implementation of Article X.

#### IV. Surveillance, detection, diagnosis and combating of infectious diseases

7. The EU welcomes the preparatory work undertaken for, the discussions at, and the conclusions of the 2004 Meeting of States Parties, in particular the Synthesis Paper of the Chair<sup>1</sup> and the background documents provided by the Secretariat<sup>2</sup>.
8. At the Sixth Review Conference, States Parties should reaffirm the conclusions of the Meeting of States Parties of 2004<sup>3</sup> and agree on the following actions:
  - States Parties should continue strengthening existing international organisations and networks, in particular those of the WHO, FAO, OIE and IPPC as well as non-governmental actors working on infectious diseases.
  - States Parties should promote cooperation and complementarity between the above-mentioned organisations, each acting within its mandate.
  - States Parties should reaffirm that the strengthening of WHO, FAO, OIE and IPPC programmes on diseases related to possible biological weapons agents should be undertaken strictly within the mandates of these organisations. States Parties should note that the role of these organisations is limited to the epidemiological and public/animal/plant health aspects of any disease outbreak, but recognise the added value of information exchange with them.
  - While recognising that a well-functioning health services system is the key to ensuring adequate preparedness and response to disease outbreaks, States Parties should continue establishing and/or improving national and regional capabilities to survey, detect, diagnose and combat infectious diseases and integrate these efforts in national emergency and disaster management plans. For specialist capabilities, States Parties should be encouraged to explore innovative arrangements that help to optimise use of scarce resources (as an example, see Annex 2 on the UK's 'Foresight' programme and Annex 3 on the Finnish Centre for Biological Threat Preparedness).
  - States Parties should use existing standards, guidelines, and recommendations wherever possible. In particular, States Parties should endeavour to implement WHO Good Laboratory Practices and Good Clinical Practice, FAO Good Emergency Management Practice and IPPC Good Surveillance Practice.
  - States Parties should work to improve communication on disease surveillance at all levels, including with the WHO, FAO, OIE, IPPC and non-governmental organisations, and among States Parties, also making use of information from civil society sources.
  - States Parties in a position to do so should continue supporting, directly as well as through international organisations, capacity-building in States Parties in need of assistance in the fields of surveillance, detection, diagnosis and combating of infectious diseases and related research.
  - States Parties should promote vaccine development and production, including through international cooperation and public-private partnerships.
  - States Parties should continue exchanging experiences and best practices in the field and, in particular, consider discussing during the BTWC intersessional meeting for the period 2007-10 detection of pathogens and response to epidemics in real time.

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<sup>1</sup> Synthesis of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the presentations, statements, working papers and interventions made by delegations on the topics under discussion at the meeting of experts, BWC/MSP/2004/3, Annex III

<sup>2</sup> BWC/MSP/2004/MX/INF.1, BWC/MSP/2004/MX/INF.2

<sup>3</sup> BWC/MSP/2004/3

## **V. Further actions to enhance implementation of Article X**

9. Earlier Review Conferences of the BTWC have resulted in a broad common understanding on the action needed to implement Article X, reflected, inter alia, in the Final Declaration of the Fourth Review Conference. At the Sixth Review Conference, States Parties should review those understandings with a view to reconfirming them, and pay particular attention to the following:
  - Heightened consciousness of the risks of biological terrorism calls for urgent and vigorous efforts, by all States Parties, to domestically implement BTWC commitments. With a view to the interdependence between strengthening biosecurity and promoting biological sciences and biotechnology, States Parties should recognise that effective national implementation of the Convention worldwide is essential to fully harness the vast potential of biology for peaceful purposes.
  - recognising the important role of the private sector in the transfer of technology and information, States Parties should increasingly engage private sector actors in efforts that enhance the implementation of Article X at the national, regional and international levels.
  - the review of the operation of Article X in subsequent Review Conferences would benefit from more comprehensive information on the implementation of Article X, including needs identified and efforts undertaken by States Parties. States Parties should share this information with other States Parties on a voluntary basis with the Secretariat facilitating this information exchange.

**Life sciences and biotechnology – A Strategy for Europe  
Communication from the Commission to the Council, the European Parliament, the  
Economic and Social Committee and the Committee of the Regions, 27 January 2002  
(COM(2002) 27 final)  
(extract)**

**A EUROPEAN AGENDA FOR INTERNATIONAL COLLABORATION**

Action 24

The Commission should continue to play a leading role in developing international guidelines, standards and recommendations in relevant sectors, based on international scientific consensus and, in particular, push for the development of a consistent, science-based, focused, transparent, inclusive and integrated international system dealing with food safety issues.

Implementer: Commission  
Timeframe: 2002 onwards

**EUROPE'S RESPONSIBILITIES TOWARDS THE DEVELOPING WORLD**

Agriculture

Action 25

The Commission will in co-operation with Member States support:

- a) the redefining of national research towards an appropriate mix of traditional techniques and new technologies, based on priorities developed with local farmers.
- b) the establishment of effective research partnerships between public and private research organisations in developing countries and in the EU, and the adequate capacity and infrastructure for developing countries to enter into such partnerships, in accordance with international commitments under the Conventions.
- c) sub-regional, regional and international organisations, in particular the International Agricultural Research Centres.

Implementer: Member States, Commission  
Timeframe: 2002 onwards

Genetic resources

Action 26

The Commission and the Member States will support the conservation and sustainable use of genetic resources in developing countries and their equitable sharing of benefits arising from their use by:

- a) supporting the development and enforcement of effective measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge, as well as to share

equitably the benefit arising from them, including income generated by intellectual property protection. Support for local communities is vital to conserve indigenous knowledge and genetic resources.

b) supporting the participation of delegates from developing countries in the negotiations of relevant International Conventions.

c) supporting measures to promote greater regional co-ordination in legislation to minimise disparities in access, benefits and also trade in products derived from genetic resources, in accordance with international commitments.

Implementer: Member States, Commission

Timeframe: 2002 onwards

## Health

### Action 27

The Commission and the Member States should work with the international community to concretise the commitment to research to combat HIV/AIDS, malaria, TB and other main poverty-related diseases and also identify effective measures to support developing countries in establishing the structures needed to deploy a health policy.

Implementer: Member States, Commission

Timeframe: 2002 onwards

## Responsible and careful use

### Action 28

The Commission should support:

a) the safe and effective use of modern biotechnologies in developing countries, based on their autonomous choice and on their national development strategies.

b) measures to increase the capacity of developing countries to assess and manage risk for man and the environment, under conditions prevailing in the country.

c) the development of appropriate administrative, legislative and regulatory measures in the developing countries, for the proper implementation of the Cartagena Protocol.

d) that international research on social, economical and environmental impacts are effectively adapted to take into account conditions prevailing in developing countries and that the findings are subsequently disseminated to them in an appropriate format.

e) that the international regulatory requirements remain manageable by developing countries, so as not to impede their trade and production prospects.

Implementer: Commission

Timeframe: 2002 onwards

An example from the UK: **Foresight. Infectious Diseases: preparing for the future**

The 'Foresight' programme is owned by the Office of Science and Innovation in the United Kingdom with the aim of producing challenging visions of the future in order to ensure effective strategies now. It has produced reports in several different areas. One of its most recent projects was on infectious diseases and it aimed to use the best available science to evaluate the threats of infectious diseases in humans, animals and plants over the next 10-25 years; and to produce a vision for their management, specifically through systems for detection, identification and monitoring. The project involved more than 300 scientists, experts and stakeholders from around 30 countries. The project findings, which are available at [http://www.foresight.gov.uk/Detection\\_and\\_Identification\\_of\\_Infectious\\_Diseases/Reports\\_and\\_Publications/Final\\_Reports/E1\\_ID\\_Executive\\_Summary.pdf](http://www.foresight.gov.uk/Detection_and_Identification_of_Infectious_Diseases/Reports_and_Publications/Final_Reports/E1_ID_Executive_Summary.pdf), provide a considerable body of scientific analysis and fresh insights to inform policy development by the relevant stakeholders at both national and international levels.

The project resulted in the development of an action plan, which includes, *inter alia*

- building a more sustained, pro-active and integrated approach to international surveillance for infectious diseases of humans, animals and plants;
- developing effective and sustainable partnerships between richer and poorer countries that help provide infrastructure, technologies and skills to support detection, identification and monitoring activities, specifically the UK and Africa;
- a wide range of stakeholders will need to act together if the benefits are to be realised.

Participants in the action plan include national and international bodies concerned with infectious diseases, and research funders.

Under the auspices of the project a Pan-African Workshop was held in Uganda in August 2005, in collaboration with leading African experts. The project report notes that: *"In August 2005, a ground-breaking workshop was held in Entebbe, Uganda, concerning the future of infectious disease in Africa. This event was unprecedented in Africa and perhaps worldwide, since it brought together leading disease experts spanning plant, animal and human health. The aim was to take a fresh look at this crucial topic and to inject fresh thinking. The event involved experts from 14 African countries, African institutions, and important international organisations such as the World Organisation for Animal Health (OIE), the Food and Agriculture Organisation of the United Nations (FAO), the World Health Organisation (WHO), the Bill and Melinda Gates Foundation, and the Gatsby Foundation. The event generated a wealth of expert advice about the future challenges facing Africa, and options for response."*

### **Finnish Centre for Biothreat Preparedness**

The Finnish Strategy to Secure Vital Functions of Society from November 2003 defined vital functions of Finnish society and established targets and development policies that would guide each administrative branch of the government in dealing with its strategic tasks. The strategy called for cooperation between each government sector in combating new threats towards society. According to the Government Report on Finnish Security and Defence Policy of 2004, terrorism and epidemics caused by infectious diseases were listed as key threats affecting national security.

Based on the above resolutions, the Centre for Biothreat Preparedness started operation in Helsinki in May 2005. The Centre, which will initially employ eight experts, is a centre of excellence for Finnish scientific and laboratory know-how on biological defence, as well as on biothreat assessment and preparedness. The Centre will actively seek domestic and international collaboration. The Centre is composed of two Units; the Biological Defence Unit of the Finnish Defence Forces, and the Biological Threat Unit of the National Public Health Institute, where scientific work will be carried out in a special biological safety laboratory (BSL-3).

The Finnish Defence Forces are developing their Territorial and Operational NBC Defence units for National Defence, as well as a NBC Detachment for the EU Battle Groups and other international tasks. The NBC Detachment will be equipped with a deployable, diagnostic biological and chemical (BC) laboratory. This field laboratory is under development and it will be operational in 2008.

The development of the Deployable BC Field Laboratory is led by Army Staff in cooperation with the Defence Forces Technical Research Centre and the Centre for Biothreat Preparedness, together with the Centre of Military Medicine. One of the Biothreat Centre's initial operational tasks will be to establish the biosafety and microbial identification requirements for the BC laboratory. To achieve this, international collaboration with other countries as well as domestic collaboration between expert organisations is needed. The techniques that are developed for microbial identification are primarily based on molecular amplification of microbial genes to ensure laboratory safety and rapidity of the assays. Early microbiological diagnosis will enable timely medical intervention, before onset of possible severe clinical symptoms of those exposed to deliberate release of selected agents.

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