

III

(Acts adopted under the EU Treaty)

ACTS ADOPTED UNDER TITLE V OF THE EU TREATY

COUNCIL JOINT ACTION 2008/307/CFSP

of 14 April 2008

in support of World Health Organisation activities in the area of laboratory bio-safety and bio-security in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 14 thereof,

Whereas:

- (1) On 12 December 2003, the European Council adopted the EU Strategy against the Proliferation of Weapons of Mass Destruction (hereinafter referred to as the EU Strategy), Chapter III of which contains a list of measures to combat such proliferation.
- (2) The European Union is actively implementing the EU Strategy and is giving effect to the measures listed in Chapter III thereof, in particular those related to the reinforcement of the Biological and Toxin Weapons Convention (hereinafter referred to as the BTWC), including support for the national implementation of the BTWC through, *inter alia*, Council Joint Action 2006/184/CFSP of 27 February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction⁽¹⁾ and the EU Action Plan on biological and toxin weapons, complementary to the EU Joint Action in support of the BTWC⁽²⁾.
- (3) On 20 March 2006, the Council of the European Union adopted Common Position 2006/242/CFSP relating to the 2006 Review Conference of the Biological and Toxin Weapons Convention (BTWC)⁽³⁾, with the

objective of further strengthening the universality of the BTWC and promoting a successful outcome of the Review Conference (hereinafter referred to as the Sixth Review Conference). At the Sixth Review Conference, held in December 2006, the EU promoted full compliance with the provisions of the BTWC by all States Parties and the strengthening, where necessary, of national implementation measures, including penal legislation, and the control over pathogenic micro-organisms and toxins in the framework of the BTWC. The EU also put forward working papers, including on bio-safety and bio-security.

- (4) The Sixth Review Conference reaffirmed the commitment of States Parties to take the necessary national measures under Articles I, III and IV of the BTWC in order to ensure the safety and security of microbial or other biological agents or toxins in laboratories and other facilities, and during transportation, as well as to prevent unauthorised access to and removal of such agents and toxins. The Conference also urged States Parties with relevant experience in legal and administrative measures for the implementation of the provisions of the BTWC to provide assistance on the request of other State Parties. The Conference encouraged such assistance on a regional basis.
- (5) The Sixth Review Conference decided to discuss, in 2008, and promote common understanding and effective action on, *inter alia*, national, regional and international measures to improve bio-safety and bio-security, including laboratory safety and security of pathogens and toxins.
- (6) The Sixth Review Conference also noted, in the context of Article VII of the BTWC, that the States Parties' national preparedness contributes to international capabilities for responding to, investigating and mitigating outbreaks of disease, including those due to alleged use of biological or toxin weapons.

⁽¹⁾ OJ L 65, 7.3.2006, p. 51.

⁽²⁾ OJ C 57, 9.3.2006, p. 1.

⁽³⁾ OJ L 88, 25.3.2006, p. 65.

- (7) The Sixth Review Conference encouraged the States Parties, in the context of Article X of the BTWC, to continue strengthening existing international organisations and networks, in particular those of the World Health Organisation (WHO), the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC), called upon States Parties to continue supporting and/or improving national and regional capacities to survey, detect, diagnose and combat infectious diseases and also other possible biological threats, and urged States Parties in a position to do so to continue supporting, directly as well as through international organisations, capacity-building activities in States Parties in need of assistance in the fields of surveillance, detection, diagnosis and combat of infectious diseases, and related research.
- (8) On 15 June 2007, the International Health Regulation (hereinafter referred to as the IHR) entered into force. It regulates the movement and control of and response to outbreaks of infectious diseases regardless of their origin, and requires the WHO Member States to build-up core capabilities in laboratory and surveillance to allow for the implementation of the IHR. The WHO Secretariat is committed to supporting WHO Member States to implement their IHR national plans through the WHO headquarters and regional offices, including the WHO Office in Lyon. The WHO bio-risk reduction management programme provides guidance on how laboratories should operate through normative guidelines, workshops and training on bio-safety practices, laboratory bio-security and codes of conduct for responsible life science research. It has also a role in establishing UN guidelines on the transportation of infectious substances. Under the IHR, public health laboratories have a role in being prepared to address biological, chemical, radiological and nuclear threats. The definitions for bio-safety and laboratory bio-security are encompassed in the WHO Laboratory Bio-safety Manual, third edition (2004) and the Bio-risk Management, Laboratory Bio-security Guidance (2006).
- (9) The implementation of this Joint Action shall be performed in accordance with the Financial and Administrative Framework Agreement (hereinafter referred to as 'the Framework Agreement') concluded between the European Commission, on the one hand, and the UN, on the other hand, which sets out a framework for the UN and the European Commission for enhancing their cooperation, including operational partnership,

HAS ADOPTED THIS JOINT ACTION:

Article 1

1. For the purpose of giving immediate and practical application to the relevant elements of the EU Strategy, the EU shall

contribute to the implementation of decisions made by the States Parties at the Sixth Review Conference of BTWC, with the following objectives:

- (a) ensuring the safety and security of microbial or other biological agents or toxins in laboratories and other facilities, including during transportation as appropriate, in order to prevent unauthorised access to and removal of such agents and toxins;
- (b) promoting bio-risk reduction practices and awareness, including bio-safety, bio-security, bioethics and preparedness against intentional misuse of biological agents and toxins, through international cooperation in this area.

2. To achieve the objectives referred to in paragraph 1, the EU shall introduce projects consisting of the following measures:

- (a) organisation of outreach workshops, consultations and training for competent authorities in the relevant sectors and for laboratory managers/staff at the national, sub-regional and regional 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;
- (b) assistance to a selected country to review public health response capacity in the context of enhancing national biological preparedness, to develop and implement a bio-risk reduction management plan, particularly concerning laboratory practice and safety, and to harmonise it with integrated national preparedness plans, and to strengthen the performance and sustainability of national laboratories by connecting them with regional and international networks.

A detailed description of these projects is set out in the Annex to this Joint Action.

Article 2

1. The Presidency, assisted by the Secretary-General/High Representative (hereinafter referred to as the SG/HR), shall be responsible for the implementation of this Joint Action. The Commission shall be fully associated.

2. The technical implementation of the measures referred to in Article 1(2) shall be carried out by the WHO, which includes the WHO Office in Lyon.

The WHO shall perform its tasks under the control of the SG/HR assisting the Presidency. For this purpose, the SG/HR shall enter into the necessary arrangements with the WHO.

3. The Presidency, assisted by the SG/HR, and the Commission shall keep each other regularly informed about the implementation of this Joint Action, in conformity with their respective competences.

Article 3

1. The financial reference amount for the implementation of the measures referred to in Article 1(2) shall be EUR 2 105 000, to be funded from the general budget of the European Union.

2. The expenditure financed by the amount stipulated in paragraph 1 shall be managed in accordance with the Community procedures and rules applicable to the general budget of the European Union.

3. The Commission shall supervise the proper management of the expenditure referred to in paragraph 2, which shall take the form of a grant. For this purpose, the Commission shall conclude a financing agreement with the WHO. The financing agreement shall stipulate that the WHO is to ensure that the visibility of the EU contribution is appropriate to its size, including by participation of EU experts.

4. The Commission shall endeavour to conclude the financing agreement referred to in paragraph 3 as soon as possible after the entry into force of this Joint Action. It shall inform the Council of any difficulties in that process and of the date of conclusion of the financing agreement.

Article 4

The Presidency, assisted by the SG/HR, shall report to the Council on the implementation of this Joint Action on the basis of quarterly reports prepared by the WHO. These reports will form the basis for the evaluation carried out by the Council. The Commission shall be fully associated. It shall report to the Council on the financial aspects of the implementation of this Joint Action.

Article 5

This Joint Action shall enter into force on the day of its adoption.

It shall expire 24 months after the date of conclusion of the financing agreement referred to in Article 3(3), or six months after the date of its adoption if no financing agreement has been concluded by then.

Article 6

This Joint Action shall be published in the *Official Journal of the European Union*.

Done at Luxembourg, 14 April 2008.

For the Council

The President

I. JARC

ANNEX

DESCRIPTION OF THE PROJECTS TO BE FINANCED**1. General objectives**

The overall objective of this Joint Action is to support, through the projects described below, the implementation of the BTWC, in particular those aspects that relate to the safety and security of microbial or other biological agents and toxins in laboratories and other facilities, including during transportation as appropriate, in order to prevent unauthorised access to and removal of such agents and toxins.

It is also to contribute to raising awareness of bio-risk management practices and to promote, especially through Project 2, the harmonisation of good national laboratory practices and biological agent response with overall national biological preparedness.

2. Project-based specific objectives

The projects described below will address three areas of major concern in the accidental and deliberate spread of diseases:

1. The risk of terrorists or other criminals having access to dangerous biological pathogens/toxins. The intention of terrorists to acquire and to use the disease as a weapon must be contained. Such events as the anthrax spore-laden letters in the US in 2001 have the potential to create huge political and economic disturbances.
2. A considerable increase in new laboratories in general, but in particular in high-level containment laboratories which lag behind in respecting adequate bio-safety and bio-security standards. In recent years, a considerable number of countries, including countries which have limited resources, have allocated funds to construct high level containment laboratories. While this should allow the country's scientists to gain experience in the handling of dangerous pathogens like the SARS coronavirus, or viral hemorrhagic fever viruses, it may also bring about risks, especially in countries which are not able to reserve sufficient funds for the long-term maintenance of their facilities and do not provide adequate training for staff.
3. The occurrence of laboratory incidents and accidental releases of highly dangerous bio-materials due to inadequate bio-safety and bio-security practices in laboratories and other facilities, and lack of compliance with the UN infectious substance packaging and shipping regulations. Three separate SARS laboratory accidents in Asia in 2003 and 2004 and the recent death from laboratory acquired Ebola haemorrhagic fever infection in Russia as well as deficiencies in bio-safety practices leading to laboratory acquired infections (tularemia and melioidosis) in the US are examples demonstrating the associated risks involved in inadequate bio-safety and laboratory bio-security, the improvement of which requires stronger commitment through management practices and the training of staff irrespective of the type of laboratory environment (human, animal or agricultural) in which the worker operates.

2.1. Project 1: Promotion of bio-risk reduction management through regional and national outreach**Purpose of the project**

The purpose of this project is to encourage States to assume responsibility for developing programmes to avoid accidental exposure or release and to prevent deliberate misappropriation or misuse of bio-agents in the laboratories. The project will involve national health policy makers as well as laboratory managers and laboratory staff to encourage their commitment to a bio-safety/bio-security culture. The project will also contribute to the development of bio-risk reduction programmes at national, regional and international levels, including through the networking of laboratories and through a harmonised bio-safety and laboratory bio-security definition in the countries of the region, with the aim of promoting transparency and commitment to bioethics (including the promotion of non-proliferation). Particular attention will be given to cross-sector networking between public health and other sectors such as animal health and the environment, to ensure a coordinated and comprehensive approach to bio-risk reduction.

Results of the project

- (i) Regions and countries will become engaged in active dialogue on the issues related to the safety and security of dangerous bio-agents and toxins in laboratories and other facilities.
- (ii) Existing laboratory bio-safety and bio-security practices will be mapped.
- (iii) The development of national plans will be supported, in particular in compliance with IHR, pathogen regulations and control measures to enhance safety and security in the handling of highly infectious materials.

- (iv) Training curricula will be developed, designed to keep policy makers, laboratory managers and laboratory staff engaged in bio-risk reduction practices. (They will include bio-ethics and the promotion of the Codes of Conduct).
- (v) Means will be provided for connecting national stakeholders among themselves and with international organisations (including the FAO, the OIE and the IPPC), so as to sustain their activities and help them become responsible global partners in regional professional societies and international networks.

Description of the project

- (a) Regional outreach workshops to raise bio-risk reduction management awareness and to envisage concrete country-focused operational initiatives in the field of bio-safety and bio-security

In 2006, the WHO organised bio-risk reduction management awareness-raising workshops in Central and South America, Eastern Mediterranean countries and English-speaking African countries. It will complete this first general awareness-raising cycle of outreach in the remaining regions, and will ensure a follow-up to these efforts through more focused outreach to respond to specific needs of the countries in the selected regions, including on bio-ethics and the Codes of Conduct. In order to avoid duplication of effort and to coordinate and harmonise approaches, the WHO will consult with relevant stakeholders and donors (international actors and non-governmental organisations) on the ongoing projects and needs for assistance.

Five regional workshops are planned, which may target the following regions: sub-Saharan Africa, South America, South and Southeast Asia, East Asia/Western Pacific, Central Asia and Eastern European countries (including Russia).

- (b) Consultations with relevant competent authorities to commit them to bio-risk reduction management in the health sector

The WHO will consult with the competent authorities in the relevant sectors and with the managers of the reference libraries to encourage their commitment to bio-risk reduction management. At least four visits are planned. The countries to be visited will be selected through a consultation process within the Steering Committee, and the selection of the countries will reflect their commitment to the implementation of the non-proliferation policy.

- (c) In-depth topic specific workshops on bio-risk reduction practices

The WHO will arrange at least two regional workshops to discuss specific topics aimed at deepening the understanding of the elements of bio-risk reduction practices, with health policy makers as well as laboratory managers and staff. Issues relating to legislation and management will be addressed, as well as how to plan for sustainability of the programmes through networks, seminars and professional societies. The seminars will target primarily Eastern Mediterranean and Eastern European countries, or other countries relevant for the selection process in Project 2.

2.2. *Project 2: Strengthening the security and laboratory management practices against biological risks (a demonstration model for countries)*

Purposes of the project

- (i) To map and assess public health response capacity, in particular in respect of biological agents and toxins, in the context of enhancing national biological preparedness by connecting the health sector with the sectors of foreign affairs, justice, environment, commerce, agriculture (and animal health), intelligence.
- (ii) To develop a forum to keep the relevant national actors informed and connected with regard to public health preparedness and response capacity.
- (iii) To develop a bio-risk reduction management plan, particularly concerning laboratory practice and safety, and to harmonise it with integrated national preparedness plans.
- (iv) To implement the national bio-risk reduction management plan, in particular concerning laboratory practice and safety.
- (v) To map and strengthen the performance, capacity and sustainability of national laboratories by connecting them with regional and international laboratory networks.

Results of the project

- (i) The programme of the selected country will be strengthened, to minimise biological risks.
- (ii) Among national stakeholders, there will be improved understanding of and trust created in the role of the public health sector in biological incident response.
- (iii) The bio-laboratory component will be connected with national stakeholders in biological incident response.
- (iv) Improved laboratory safety, quality and performance.
- (v) Continuance of recognised laboratory quality and connectivity will be assured through regional and international validation.
- (vi) The country will be provided with meeting laboratory core capacity in compliance with the IHR.

Description of the project

For the purposes described above, the project will be implemented over an appropriate period which requires a long-term commitment by both the applicant country and the EU. The project will be implemented in phases. An EU-sponsored seconded expert should be appointed as a country project leader.

Preparatory phase

The WHO will identify a number of candidate countries for the project, with a view to recommending to EU Member States a suitable candidate through the Steering Committee. The selection criteria will reflect as a priority non-proliferation concerns. The WHO and the Presidency, assisted by the SG/HR, will conduct exploratory discussions with the candidate countries. Based on the progress of those discussions, the WHO will conduct preliminary country pre-assessment visits, relevant for the next phase of the project. The WHO will appoint a project officer, who shall be a national of one of the EU Member States.

As a result of this preparatory process, a memorandum of understanding will be signed by the EU (represented for this purpose by the Presidency, assisted by the SG/HR), the WHO and the selected country.

Assessment phase

In the assessment phase, the WHO will conduct an assessment of national biological activities and assets in the selected country, and will assist with their harmonisation with national preparedness for and response to biological incidents. This will include the completion of the bio-incidents evaluation exercise and of the coordination plan to inform all stakeholders of the status of national preparedness against biological incidents, and the initiation of the harmonisation of public health responsibilities in the national preparedness plan for biological threats and/or incidents as well as public health emergencies of international concern.

Technical assistance phase

In this phase, the aim is to strengthen laboratory practices to respond to a public health event of international concern and to ensure that laboratory performance is safe and its results are validated at the national, regional and international levels. To achieve these goals, training will be provided for the responsible stakeholders in the public health area and in the biological response. Laboratory infrastructure plans will be developed and country bio-safety professionals will be connected with international networks, including through participation in the annual meetings and conferences of the international bio-safety associations.

Evaluation phase

The WHO will prepare, on a quarterly basis and in cooperation with the selected country, reports evaluating the implementation of national biological preparedness plans as well as national laboratory performance from the bio-safety and bio-security perspective, and will forward these evaluation reports to the Presidency, assisted by the SG/HR, and to the Commission.

3. Duration

The total estimated duration of the implementation of this Joint Action is 24 months.

4. Beneficiaries

The beneficiaries are States Parties to the BTWC or States which have initiated the ratification/accession process. The Joint Action targets primarily countries and regions which are vulnerable because of unsafe practices in biological laboratories, contributing to an increased risk of the loss, theft and misuse of high-consequence micro-organisms and their products.

5. Implementing entity

The Presidency, assisted by the SG/HR, is responsible for the implementation and supervision of the implementation of the Joint Action. The Presidency is to entrust the technical implementation to the WHO.

The projects will be implemented by WHO staff in cooperation, as appropriate, with (experts from) WHO Member States, in particular the EU Member States. Where recruiting new staff for the implementation of the project, preference should be given to nationals of the EU Member States. The implementation of the Joint Action will be supervised by a Steering Committee consisting of representatives of the WHO, the EU Presidency assisted by the SG/HR and the Commission. The Steering Committee will hold meetings as necessary, but at least twice a year, in order to review progress and to discuss issues relating to implementation. This is to ensure harmonisation of the overall project implementation and evaluation reports. The Steering Committee will also serve as a mechanism for the selection of countries for Project 1(b) and Project 2.
