DECISIONS

COUNCIL DECISION 2013/668/CFSP

of 18 November 2013

in support of World Health Organisation activities in the area of biosafety and biosecurity 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 Articles 26(2) and 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 12 December 2003, the European Council adopted the EU Strategy against Proliferation of Weapons of Mass Destruction ('the EU Strategy'), Chapter III of which contains a list of measures to combat such proliferation.

(2) The Union is actively implementing the EU Strategy and is giving effect to the measures listed in Chapter III thereof, in particular those related to reinforcement, implementation and universalisation of the Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction (BTWC).

(3) At the Sixth (2006) and Seventh (2011) Review Conferences of the BTWC the Union 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.

(4) On 14 April 2008, the Council adopted Joint Action 2008/307/CFSP [1]. That Joint Action was successfully implemented by the World Health Organisation ('WHO') until 31 December 2011.

(5) On 11 December 2008, the Council adopted the 'New lines of Action' to strengthen the EU Strategy. Chapter IV of the EU Strategy sets out the Union's support for a coordinated and complementary approach to biosafety and biosecurity problems guaranteeing optimal management, in particular of biological risks and threats.

(6) On 18 July 2011, the Council adopted Decision 2011/429/CFSP [2] setting out the Union's support for the development of national regulatory frameworks, in particular on biosafety and biosecurity.

(7) The Seventh 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 their transportation, as well as to prevent unauthorised access to such agents and toxins and their unauthorised removal. 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 States Parties. The Conference encouraged such assistance on a regional basis.

(8) The Seventh 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 the alleged use of biological or toxin weapons.

(9) The Seventh 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 WHO, the Food and Agriculture Organisation (FAO), the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC).

[1] Council Joint Action 2008/307/CFSP of 14 April 2008 in support of World Health Organisation activities in the area of laboratory biosafety and bio-security in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction (OJ L 106, 16.4.2008, p. 17).

[2] Council Decision 2011/429/CFSP of 18 July 2011 relating to the position of the European Union for the Seventh 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 (BTWC) (OJ L 188, 19.7.2011, p. 42).

(10) On 15 June 2007, the International Health Regulation ('the IHR') entered into force. It regulates the movement and control of outbreaks of infectious diseases, and the response thereto, regardless of their origin, and requires the WHO Member States to build-up core capabilities in laboratory and surveillance in the field of public health against infectious diseases 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. The WHO biorisk reduction management programme provides guidance on how laboratories should operate through normative guidelines, workshops and training on biosafety practices, laboratory biosecurity and codes of conduct for responsible life science research. It also has 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 biosafety and laboratory biosecurity are encompassed in the WHO Laboratory Biosafety Manual, 3rd edition (2004) and the Biorisk Management, Laboratory Biosecurity Guidance (2006).

(11) The WHO is the only implementing agency with the expertise, deep knowledge, personnel, structure and resources to implement the projects and activities foreseen in this Council Decision.

(12) The Commission is entrusted with the supervision of the proper implementation of the Union's financial contribution,

HAS ADOPTED THIS DECISION:

Article 1

1. For the purpose of giving immediate and practical application to the relevant elements of the EU Strategy, the Union shall contribute to the implementation of decisions made by the States Parties at the Seventh Review Conference of BTWC with the following objectives:

— 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 such agents and toxins and their unauthorised removal,

— promoting biorisk reduction practices and awareness, including biosafety, biosecurity, bioethics and preparedness against intentional misuse of biological agents and toxins, through international cooperation in this area.

2. The projects corresponding to measures of the EU Strategy, are those that aim at the:

— promotion of laboratory biorisk management through national and regional outreach,

— development of national laboratory biorisk management strategies to counter biological risks (a demonstration model for countries).

A detailed description of those projects is set out in the Annex.

Article 2

1. The High Representative of the Union for Foreign Affairs and Security Policy ('the HR') shall be responsible for the implementation of this Decision.

2. The technical implementation of the activities referred to in Article 1 shall be entrusted to the WHO. It shall perform its task under the responsibility of the HR. For this purpose, the HR shall enter into the necessary arrangements with the WHO.

Article 3

1. The financial reference amount for the implementation of the projects referred to in Article 1(2) shall be EUR 1 727 000.

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

3. The Commission shall supervise the proper management of the expenditure referred to in paragraph 1. For that purpose, it shall conclude a financing agreement with the WHO. The financing agreement shall stipulate that the WHO is to ensure the visibility of the Union's contribution, commensurate to its size.

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 Decision. It shall inform the Council of any difficulties in that process and of the date of conclusion of the financing agreement.

Article 4

The HR shall report to the Council on the implementation of this Decision on the basis of regular reports prepared by the WHO. Those reports shall form the basis for the evaluation carried out by the Council. The Commission shall provide information on the financial aspects of the projects referred to in Article 1(2).

Article 5

1. This Decision shall enter into force on the date of its adoption.

2. This Decision shall expire 24 months after the date of the conclusion of the financing agreement referred to in Article 3(3). However, it shall expire 6 months after its adoption if the financing agreement has not been concluded by that time.

Done at Brussels, 18 November 2013.

For the Council
The President
C. ASHTON

ANNEX

1. **General Framework**

The overall objective of this Decision is to support, through the projects described below, the States Parties' implementation of the United Nations Security Council Resolution (UNSCR) 1540 and other related Resolutions, the Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction (BTWC) as well as the International Health Regulations (IHR), and specifically those aspects that relate to the safety and security of biological agents and toxins in laboratories and other facilities, including the period of transit from one place to another, in order to prevent natural, accidental, or deliberate release of biological materials and to better control infections. It is also intended to contribute to raising awareness of biorisk management approaches and encouraging their implementation, ensuring evidence-based and risk-based controls, and promoting exchange of best laboratory practices as well as to help the countries meet the core capacity requirements of laboratory services for priority health threats as defined in IHR.

2. **Project-based specific objectives**

The last several years have seen a growing association of the term 'biosafety' with the term 'biocontainment', with a global upsurge of high containment laboratories. Focus on the construction of sophisticatedly engineered facilities has often resulted in undervaluing the many other critical elements of a comprehensive biorisk management programme, including security, personnel and competency, good microbiological technique, accident and incident investigation, and equipment maintenance. In addition, focus on selected facilities at national level may also have resulted in neglecting many other more conventional laboratories that could also benefit from the implementation of a thorough biorisk management system and provision of essential equipment and supplies that underpin safe and secure operation.

There is a need for awareness and better understanding of the risks encountered in laboratory settings, the need for strategies to address them as well as for legislative and regulatory provisions and for appropriate guidance. The improvement of facilities, the provision of indispensable supplies and the education of staff at all levels are encouraged in order to achieve appropriate and thorough management of laboratory biorisk.

Building upon efforts initiated by the Joint Action 2008/307/CFSP in support of WHO activities in the area of biosafety and biosecurity, this Decision seeks to address some of the abovementioned shortcomings.

Focusing on selected individual countries or sub-region(s), the two following projects are proposed:

2.1. *Project 1: Promotion of laboratory biorisk management through national and regional outreach and replication*

2.1.1. Purposes of the Project 1

(a) To encourage selected individual countries or sub-region(s) to implement laboratory biorisk management (BRM) strategies, addressing biosafety and laboratory biosecurity.

(b) To provide opportunities for the countries in a region to meet and share best practices and lessons learnt. Making the most of this occasion, a needs-based training, possibly including hands-on sessions, will be provided to the national representatives.

(c) To help the countries disseminate the best practices and have them implemented in their own settings.

2.1.2. Expected results of Project 1

(a) Awareness raised on the benefits of the implementation of BRM strategies in laboratories at national and sub-national levels through regional training workshops.

(b) Capacity and capability of stakeholders strengthened to assess biorisk, to define and adopt mitigation strategies in order to reduce them to acceptable levels, to ensure their continuous improvement and to handle infectious agents responsibly, safely, securely and accountably.

(c) A pool of trainers developed to sustain national training programmes and disseminate training opportunities.

2.1.3. Description of Project 1

(a) Provision of regional training opportunities

With the intention of reaching a whole range of stakeholders across the region and in order to meet their various training needs, diverse regional workshops will be proposed, not more than twice, with a participation of up to fifty participants per event. Making the most of the opportunities for the relevant experts and policy-makers in the region to get together, the workshops are also expected to provide a regional forum for each Member State to share the achievement, challenges and good practices with the neighbouring countries.

(b) Multiplication of training sessions at national and/or sub-national levels

Furthermore, a local pool of trainers will be developed through the abovementioned workshops, allowing to multiply training sessions at national and/or sub-national level, and thus address a variety of national stakeholders. Support will be provided in particular to those regional countries, which are not benefitting from Project 2, up to seven times in total, possibly with participation of external experts to support awareness raising among relevant stakeholders and strengthen local technical capacity to implement regionally agreed good practices at central, intermediate and peripheral levels. Wherever possible, the involvement of regional and/or national Biosafety Associations will be considered.

These activities will be carried out in a maximum of seven countries identified as suitable either individually or in combination.

2.2. *Project 2: Development of national laboratory strategies to counter biological risks and to enhance the core capacities (a demonstration model for countries)*

2.2.1. Purposes of Project 2

(a) To engage and connect relevant policy makers (including public health, foreign affairs, animal health, environment, education and research justice and commerce) and laboratory personnel of all levels in establishing, implementing and improving biorisk management policies and practices as well as encouraging the development of a transparent and accountable culture of biosafety and biosecurity.

(b) To assist identified countries to have their key public health laboratories better fitted with equipment and supplies that are indispensable for achieving safe, secure and quality assured diagnostic capabilities. To strengthen the development of specific core capacities under the IHR, with particular focus on laboratories and points of entry.

(c) To raise Nation-wide awareness of internationally agreed normative documents of relevance, namely the European Committee for Standardization (CEN) Workshop Agreement, ISO 15793:2011 Laboratory biorisk management, ISO 15189:2007 Medical laboratories — Particular requirements for quality and competence, ISO 15190:2003 Medical laboratories — Requirements for safety, ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories, ISO 9001:2008 Quality management systems — Requirements, as well as ISO 14001:2004 Environmental management systems — Requirements with guidance for use, involving national health policy makers as well as laboratory managers and staff who are encouraged to commit to a transparent and accountable culture of biosafety, biosecurity and laboratory quality systems.

(d) To strengthen cross-sectoral collaboration and networking trying to engage a variety of national stakeholders and authorities, including the Ministries of Health, Education, Science and Research, Agriculture, Transport, Interior and Foreign Affairs, and customs authorities.

(e) To provide and help develop tools and appropriate guidance to promote the management of laboratory biorisk systems.

2.2.2. Expected results of Project 2

(a) A variety of training opportunities developed and provided as per the identified priority and needs of each national stakeholder.

(b) Biorisk management capacity and capability strengthened to minimise biological risks.

(c) Raising of awareness of national stakeholders and authorities concerned and their engagement in proactive dialogue on the issues related to the safety and security of hazardous biological agents and toxins in laboratories and other facilities. Among national stakeholders, improved understanding and trust to enable a cross-sectoral and cohesive approach to biorisk management.

(d) Standardisation promoted and relevant tools and guidelines developed, allowing to put appropriate mitigation measures in place and continuously improve their performance.

(e) Support provided to strengthen specific core capacities in compliance with IHR.

(f) National policies and strategies reviewed, discussed and developed.

(g) Structural refinement and organisational reform considered and undertaken in an attempt to translate the adopted strategy into action in a sustainable manner.

(h) Physical containment of biological hazards enhanced with the provision of necessary equipment and upgrading of the identified key facility.

(i) Good practices shared with national peers at various tiers and laboratory networking through the organisation of meetings and outreach activities.

(j) Necessary tools developed to assist with effective implementation of the project.

2.2.3. Description of Project 2

For the purposes described under point 2.2.1, the project will be implemented over a period of two years, based on a long-term commitment by the beneficiary countries, the Union and WHO. The project will be implemented in the following two phases:

(a) Preparatory phase

Joint Action 2008/307/CFSP allowed the WHO to assess the biorisk management needs of certain countries, including Indonesia, and to identify a national commitment towards the establishment of a clear political and technical engagement to embark on a joint project aiming at strengthening the management of laboratory biorisk at national level. Further discussions with the Union and the government(s) concerned will allow to identify up to two countries possibly coupled with a small group of neighbouring countries that could benefit from Project 2, taking into consideration Regional technical needs and fast-growing biological diagnostic and research capacities of individual countries and in particular national commitment in harmony with other endeavours of the Union and the WHO. Consideration will be given to the possibility of offering an appropriate training opportunity overseas for the identified nationals so as to nurture core biosafety officer of the countries concerned according to the internationally agreed competence aiming at leading the programme in a better sustainable manner.

As a result of this preparatory process, a memorandum of understanding will be signed by the Union, the WHO and the selected countries.

(b) Implementation phase

In this phase, the selected countries will formulate a national master plan and a strategic action plan describing activities to be implemented in order to achieve the long-term goal of safe, secure and reliable laboratory practices. Those plans will include the completion of a 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 (PHEIC) as defined in the IHR. The planning should be underpinned by genuine national leadership and ownership of the initiative.

Activities will then be implemented and equipment and supplies procured as planned and agreed by all relevant parties. Necessary technical and financial assistance will be provided through this Decision to connect national stakeholders among themselves and with international organisations and other interested parties, so as to sustain their activities and help them become responsible and active global partners in regional professional societies and international networks.

WHO along with the selected countries will prepare progress reports, updating and evaluating the implementation of the national biorisk management enhancement plan as well as national laboratory performance from the biosafety, biosecurity and IHR perspective, and will forward those reports to the Union accordingly.

At the end of the implementation phase, a sub- or Regional workshop will be held for dissemination of the achievement and experience with neighbouring countries.

3. **Duration**

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

4. **Beneficiaries**

The beneficiaries of Project 1 are countries and sub-regions identified in consultation with the Union, in need for improved biorisk management awareness, strategies and practices, possibly including the BTWC signatory States Parties.

The beneficiaries of Project 2 are countries intending to thoroughly strengthen their national capacities and capabilities through this Decision, selected in consultation with the Union and the relevant national authorities for their commitment to improve the management of laboratory biorisk.

5. **Implementing entity**

The projects will be managed and implemented by the WHO in regular consultation with the Union, and with the support, as necessary and appropriate, of external subject-matter experts.

6. **Implementing agency: rational for the choice**

The WHO is the international organisation that provides frameworks, expertise and tools to inform, guide, and support its Member States in protecting the health of people in and around laboratory environments through appropriate biorisk management, standards, rules and procedures. This project fits under the overarching IHR legally-binding agreement that significantly contributes to global public health security. The WHO supports its States Parties by providing a framework for the coordination of the management of events that may constitute a public health emergency of international concern, and will improve the capacity of all countries to detect, assess, notify and respond to public health threats. The WHO has already been in talks with the potential beneficiary countries to seek their agreement. The activities proposed are identified after iterative dialogue with them through WHO's formal channels based on the actual needs and priority in alignment with each national strategy. The Union seeks to continue a fruitful cooperation with the WHO.

7. **Co-financing**

The WHO is not a donor or aid agency but a technical agency and thus a co-financing process with external entities would be extremely complex to deal with particularly in the area of health security where stakeholders have various priorities and regional targets. The WHO will deliver technical expertise and project management but is not in a position to provide funds to joint activities in this context. However, the other concomitant projects conducted by the WHO in the laboratory area will be seen as synergistic, inter-linked and complementing each other.

Although there is no co-financing of the project in the form of funds, the WHO will cover partially or entirely the salaries of staff involved in project implementation, which is considered the contribution-in-kind. Salaries of the Project Officer, Administrative Assistant and of the National Consultant in Bangladesh will be partially covered by the WHO. The salaries of the Financial Officer, Coordinator, Regional advisor and of the Medical officers in Indonesia, Myanmar and Nepal will be covered entirely by the WHO.

8. **Visibility**

The WHO shall take all appropriate measures to publicise the fact that both projects have been entirely funded by the Union. Such measures will be carried out in accordance with the Communication and Visibility Manual for European Union External Actions laid down and published by the Commission, and any other guidelines agreed between the Commission and the WHO.

Particular attention will be paid to branding and publicity highlighting the role of the Union as sole financial supporter of both projects.