

DECISIONS

COUNCIL DECISION (CFSP) 2019/1296

of 31 July 2019

in support of strengthening biological safety and security in Ukraine in line with the implementation of United Nations Security Council Resolution 1540 (2004) on non-proliferation of weapons of mass destruction and their means of delivery

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) 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 the Proliferation of Weapons of Mass Destruction, Chapter II of which contains a list of measures to combat such proliferation. Such measures need to be taken both within the Union and in third countries.
- (2) The Union is actively implementing that strategy and is giving effect to the measures listed in Chapter III thereof, in particular by releasing financial resources to support specific projects conducted by multilateral institutions, providing States with technical assistance and expertise with regard to a wide range of non-proliferation measures, and fostering the role of the United Nations Security Council (UNSC).
- (3) On 28 April 2004, the UNSC adopted Resolution 1540 (2004) ('UNSCR 1540 (2004)'), which was the first international instrument to deal in an integrated and comprehensive manner with weapons of mass destruction, their means of delivery and related materials. UNSCR 1540 (2004) established binding obligations for all States, and those obligations aimed to prevent and deter non-State actors from obtaining access to such weapons and weapon-related material. The UNSC also decided that all States are to take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical or biological weapons and their means of delivery, including by establishing appropriate controls over related materials.
- (4) On 11 May 2017, the Council adopted Decision (CFSP) 2017/809 ⁽¹⁾ in support of the implementation of UNSCR 1540 (2004). The technical implementation of the activities under Decision (CFSP) 2017/809 is entrusted to the UN Office for Disarmament Affairs (UNODA) in cooperation with relevant regional international organisations, and in particular the Organisation for Security and Cooperation in Europe (OSCE).
- (5) On 11 July 2017, the Council adopted Decision (CFSP) 2017/1252 ⁽²⁾ in support of the strengthening of chemical safety and security in Ukraine in line with the implementation of UNSCR 1540 (2004). The technical implementation of the activities under Decision (CFSP) 2017/1252 is entrusted to the OSCE Secretariat.
- (6) Universal adherence to and full implementation of the Biological and Toxin Weapons Convention (BTWC) and UNSCR 1540 (2004) are among the main priorities of Ukraine in the area of non-proliferation of weapons of mass destruction.

⁽¹⁾ Council Decision (CFSP) 2017/809 of 11 May 2017 in support of the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery (OJ L 121, 12.5.2017, p. 39).

⁽²⁾ Council Decision (CFSP) 2017/1252 of 11 July 2017 in support of the strengthening of chemical safety and security in Ukraine in line with the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery (OJ L 179, 12.7.2017, p. 8).

- (7) On 21 March and 27 June 2014, the Union and Ukraine signed an Association Agreement ⁽¹⁾ which provides, inter alia, for expedited harmonisation of Ukrainian national legislation with relevant Union legislation, including in relation to the elimination of any obstacles to the comprehensive implementation in Ukraine of UNSCR 1540 (2004). Parts of the EU-Ukraine Association Agreement have been provisionally applied since 1 November 2014. The EU-Ukraine Association Agreement entered into force on 1 September 2017.
- (8) According to the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement for the years 2018-2020, Ukraine committed to develop and improve regulations and mechanisms in the field of biological safety and security in line with Ukraine's obligations under the BTWC and UNSCR 1540 (2004) as well as under international norms and standards, and in particular relevant EU legislation.
- (9) In this context, three project proposals were prepared by the OSCE Secretariat in close cooperation with the competent authorities in Ukraine with a view to strengthening overall biological safety and security in Ukraine.
- (10) The OSCE Secretariat should be entrusted with the technical implementation of the projects to be carried out under this Decision.
- (11) The projects should be implemented in line with the respective provisions of the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement. The activities should take into account relevant good practice and lessons learned, identified during the implementation of Decision (CFSP) 2017/1252.
- (12) The OSCE Secretariat should ensure efficient cooperation with relevant international organisations and bodies such as the BTWC Implementation Support Unit, the UNSC Committee established pursuant to UNSCR 1540 (2004), the World Organisation for Animal Health (OIE), and the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction. The OSCE Secretariat should also ensure the complementarity and synergy of projects undertaken further to this Decision with relevant past and ongoing projects and activities in Ukraine supported by individual EU Member States, and with other Union-sponsored programmes in this field including the Instrument contributing to Stability and Peace and the EU Centres of Excellence on Chemical, Biological, Radiological and Nuclear Risk Mitigation,

HAS ADOPTED THIS DECISION:

Article 1

1. For the purpose of promoting peace and security, and effective multilateralism at global and regional levels, the Union shall pursue the following objectives:

- strengthening biological safety and security in Ukraine by improving Ukraine's legislative and regulatory basis and its human and animal health systems, as well as by raising the awareness of life scientists;
- underpinning effective multilateralism at regional level by supporting the action of the OSCE to enhance the capabilities of the competent authorities in Ukraine in the field of biological safety and security in line with obligations under UNSCR 1540 (2004) and the BTWC.

2. In order to achieve the objectives referred to in paragraph 1, the Union shall undertake the following projects:

- harmonization of existing Ukrainian regulations on biosafety and biosecurity with international standards;
- establishing veterinary surveillance system sustainability in Ukraine for diseases related to especially dangerous pathogens ('EDP-related diseases');
- awareness-raising, education and training for life scientists on biosafety and biosecurity.

A detailed description of the projects referred to above is set out in the Annex.

⁽¹⁾ Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part (OJ L 161, 29.5.2014, p. 3).

Article 2

1. The High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') shall be responsible for the implementation of this Decision.
2. The technical implementation of the projects referred to in Article 1(2) shall be carried out by the OSCE Secretariat. It shall perform this task under the control of the High Representative. For this purpose, the High Representative shall enter into the necessary arrangements with the OSCE Secretariat.

Article 3

1. The financial reference amount for the implementation of the projects referred to in Article 1(2) shall be EUR 1 913 900.
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 OSCE Secretariat. That agreement shall stipulate that the OSCE Secretariat is to ensure visibility of the Union's contribution, appropriate to the size of that contribution.
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. The Commission shall inform the Council of any difficulties in that process and of the date of conclusion of the financing agreement.

Article 4

The High Representative shall report to the Council on the implementation of this Decision, and shall do so on the basis of regular reports prepared by the OSCE Secretariat. 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 36 months after the 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 within that period.

Done at Brussels, 31 July 2019.

For the Council
The President
T. TUPPURAINEN

ANNEX

Strengthening Biological Safety and Security in Ukraine in line with UNSCR 1540 (2004)

1. Background

The Ukrainian legislation prohibiting biological weapons is detailed and comprehensive. However, a significant part of this legislation and regulation is outdated and fails to meet international norms and standards. It therefore requires urgent revision and updating to increase harmonisation with the respective world standards.

There is no framework law on biosafety and biosecurity in Ukraine that outlines establishment of a biosafety and biosecurity system and its proper functioning (for example, which would legally identify the central executive body dealing with biosafety and biosecurity and carrying out expert and monitoring functions). Further, there is not currently comprehensive cooperation between all involved ministries, agencies and organizations for preventing and responding to emergency situations related to biological threats.

Mechanisms for state control of adherence to biosecurity requirements during work with biological agents are also absent. There is no register of economic and non-economic actors working with hazardous biological agents in the territory of Ukraine. Furthermore, those actors that work with hazardous biological agents are not obliged by law to have relevant permits. In fact, elimination of the permit system resulted in a situation where there is no reporting and control of adherence to the biosafety and biosecurity requirements in microbiological laboratories, the actual number of which is unknown. A normative document that regulated accounting, transportation, storage and transfer of hazardous biological materials was annulled. The applicable documents pay little attention to other aspects of biosecurity, such as verification of staff reliability and protection of confidential information.

Against the background of the pace of growth of agricultural production, bio-production, transport and external trade relations in the modern world, human and veterinary medicine face many problems specifically associated with the risk of proliferation of biological materials, in particular infectious and parasitic diseases common among people and animals.

Today the main threats relating to biological and food security in Ukraine are associated with African swine fever, bird flu, foot and mouth disease, and multidrug-resistant bacterial pathogens. There are natural focal risks of outbreaks of anthrax, rabies, classical swine fever and tularaemia. Ensuring food and biological security is a sensitive issue that cannot be solved without the involvement of reliable means of monitoring, forecasting and early diagnosis of emergent and economically significant infections of animals, including zoonotic infections. Biological and food security in Ukraine can only be addressed via integration of basic research in genetics and molecular biotechnology in veterinary and human medicine and diagnosis.

Staff of the majority of Ukrainian life sciences laboratories are experienced in handling dangerous biological materials. However, modern biosafety and biosecurity principles and approaches, modern techniques and practices, and codes of conduct linked to modern practices are very rare in laboratories. A number of life science laboratories possess moderate amounts of modern equipment but, due to the lack of operational training on such equipment, the laboratory personnel do not use it or use it in an inappropriate manner. In addition, the existing system of advanced training for some categories of life scientists does not cover all appropriate biosafety and biosecurity issues. All these factors can result in a decrease in the level of biosafety and biosecurity at laboratories where dangerous biological materials are handled.

As a result of the above analysis, three projects have been prepared by the OSCE with a view to strengthening overall biological safety and security in Ukraine. These projects have been developed in cooperation with the relevant Ukrainian authorities. All projects would be implemented in line with the respective provisions of the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement.

The projects would also be implemented taking into account relevant good practice and lessons learned, identified during the ongoing implementation of Decision (CFSP) 2017/1252 in support of the strengthening of chemical safety and security in Ukraine.

2. Objective

The overall objective of this Decision is to support OSCE projects aiming at strengthening biological safety and security in Ukraine in line with Ukraine's obligations under the BTWC and UNSCR 1540 (2004), as well as in accordance with the EU-Ukraine Association Agreement.

3. Description of the projects

3.1. Harmonisation of existing Ukrainian regulations on biosafety and biosecurity with international standards

3.1.1. Objective of the project

- To improve the legislative and regulatory basis of Ukraine on biological safety and security in line with obligations under UNSCR 1540 (2004), namely the adoption and enforcement of appropriate effective laws which prohibit any non-State actor from manufacturing, acquiring, possessing, developing, transporting, transferring or using biological weapons and their means of delivery, in particular for terrorist purposes.

3.1.2. Description of the project

- Specific measures related to legislative and regulatory improvements in the field of biosafety and biosecurity requiring priority implementation and which will be directly supported by this project include:
 - Development and submission to the Verkhovna Rada of Ukraine of the draft Law of Ukraine on Biosafety and Biosecurity;
 - Development and adoption of a resolution of the Cabinet of Ministers of Ukraine on regulation of issues related to control of compliance with the biosecurity and biosecurity requirements in institutions and establishments working with pathogenic microorganisms;
 - Development and adoption of the Biosafety and Biosecurity Concept, the Ukrainian national action plan for responding to outbreaks of dangerous and especially dangerous diseases, and identification of the critical infrastructure that ensures appropriate response to the risks of outbreaks or to outbreaks of dangerous and especially dangerous diseases;
 - Introduction of a uniform system of biological safety of Ukraine as well as plans for protection of biological agents from accidental or deliberate dissemination and for their proper and safe storage and transportation, including their in-house security;
 - Reorganization of the public health and veterinary medicine system to comply with international requirements.

3.1.3. Expected results of the project

- To improve the Ukrainian biosafety and biosecurity system by enhancing the national legislative and regulatory framework in this field;
- To promote collaboration of the different agencies responsible for biosafety and biosecurity;
- To ensure sustainability of the biosafety and biosecurity system in Ukraine.

3.1.4. Project beneficiaries

- Ministry of Health.

3.2. Establishing veterinary surveillance system sustainability in Ukraine for EDP-related diseases

3.2.1. Objective of the project

- To improve biosafety and biosecurity by strengthening human and animal health systems in Ukraine, in line with obligations under UNSCR 1540 (2004), and in particular the enforcement of effective measures to establish domestic controls to prevent the proliferation of biological weapons and their means of delivery, including by establishing appropriate controls over related materials.

3.2.2. Description of the project

- Implementation of effective monitoring of human and animal diseases by establishment of a common use centre for sequencing and genetic characterization of selected agents and equipping of the participating institutions with reverse transcription polymerase chain reaction (RT-PCR) machines;
- Establishing rapid-response measures in emergency situations and the introduction of rapid diagnosis of particularly dangerous animal diseases by development of RT-PCR-based diagnostics tools for PCR-based detection of selected agents (agents of avian influenza, Newcastle disease, multi-resistant tuberculosis, lumpy skin disease, tularemia, African swine fever, classical swine fever, foot-and-mouth disease, brucellosis, multi-resistant salmonellas and anthrax) based on in-house protocols developed in Ukraine;
- Development of safe storage of pathogens, including zoonotic, viral and bacterial pathogens, in laboratories and depositories by development of registration dossiers for RT-PCR-based kits;
- Providing a unified technical policy in the field of conformity assessment for testing laboratories, securing national and international trust, providing conditions for mutual recognition of performance and transparency, and ensuring awareness and competence in the field of biological protection;
- Capacity building in EDP-related disease molecular diagnostics.

3.2.3. Expected results of the project

- Strengthening of national capacity for surveillance and forecasting in veterinary medicine;
- Development of effective national diagnostics and surveillance tools, based on RT-PCR and isothermal PCR instruments (R&D, validation and implementation in the laboratories);
- Implementation of effective monitoring of diseases of animals (including zoonotic diseases);
- Creation of human capacity in molecular diagnostics of EDP-related diseases (PCR techniques laboratory trainings).

3.2.4. Project beneficiaries

- State Service of Ukraine on Food Safety and Consumer Protection;
- Recipient of assistance: National Scientific Center 'Institute for Experimental and Clinical Veterinary Medicine' (Kharkiv, Ukraine).

3.3. Awareness-raising, education and training for life scientists on biosafety and biosecurity

3.3.1. Objective of the project

- Improving biological safety, security and bioethics in Ukraine by raising the awareness of life scientists in the field of biosafety and biosecurity, in line with obligations under UNSCR 1540 (2004), including the enforcement of effective domestic measures to prevent the proliferation of biological weapons and their means of delivery.

3.3.2. Description of the project

- Creation of a team of trainers from different Ukrainian life sciences institutions who will be able to disseminate modern knowledge on biosafety, biosecurity and bioethics principles, best laboratory practices, and techniques and methods for biorisk management in laboratories;
- Improvement of current resources for further dissemination of knowledge and awareness-raising on biosafety, biosecurity and bioethics amongst teachers, students and researchers in life sciences and other relevant stakeholders taking full account of Project P633 of the Science and Technology Center in Ukraine, 'Education and awareness-raising in Ukraine';
- Ensuring sustainability of training capacities after completion of the project.

3.3.3. Expected results of the project

- Increased awareness of national and local stakeholders in the field of biological safety and security;
- Increased capacity of life scientists to safely handle dangerous biological materials;

- Increased capacity of Ukrainian life scientists to reduce risks of possible misuse of materials and equipment being used during their research as well as misuse of their knowledge and results;
- Establishing a strong team of trainers on biosafety and biosecurity for life scientists;
- Improved and sustainable resource for distance knowledge dissemination on biosafety, biosecurity and bioethics.

3.4. Project beneficiaries

- Ministry of Health.

4. Administrative support for the implementation of the projects

Dedicated personnel in the OSCE Secretariat and in the office of the OSCE Project Coordinator in Ukraine will coordinate and manage the implementation of the project activities set out in Section 3 in order to further develop the collaborative framework between the Ukrainian partners, including through the development of relevant new project proposals and national measures.

The supporting personnel will perform the following tasks:

- Managing projects through all steps of the project cycle;
- Carrying out day-to-day financial oversight of the projects;
- Providing technical and legal expertise, supporting larger procurement, engaging with other international organisations, carrying out quality assurance and quality control of the approved projects' deliverables, and reporting to the European Union.

5. Duration

The total estimated duration of the projects will be 36 months.

6. Technical implementing entity

The technical implementation of this Decision will be entrusted to the Conflict Prevention Centre of the OSCE Secretariat and the OSCE Project Coordinator in Ukraine. The OSCE will implement the activities under this Decision in cooperation with other international organisations and agencies, in particular with a view to ensuring effective synergies and avoiding duplication.

7. Reporting

The OSCE Secretariat will prepare regular reports, as well as reports after the completion of each of the activities described. The final reports should be submitted to the European Union no later than six weeks after the completion of the relevant activities.

8. Steering Committee

The Steering Committee for these projects will be composed of a representative of the High Representative and a representative of the implementing entity referred to in section 6 of this Annex. The Steering Committee will review the implementation of this Decision regularly, at least once every 6 months, including through the use of electronic means of communication.

9. Estimated total cost of the projects and European Union financial contribution

The total cost of the projects is EUR 1 913 900.
