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

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).

Changes to legislation: *There are currently no known outstanding effects for the Council Decision (CFSP) 2019/1296. (See end of Document for details)*

(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.

(7) On 21 March and 27 June 2014, the Union and Ukraine signed an Association Agreement[(3)] 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:

***Changes to legislation:** There are currently no known outstanding effects for the Council Decision (CFSP) 2019/1296. (See end of Document for details)*

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.

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

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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

***Changes to legislation:** There are currently no known outstanding effects for the Council Decision (CFSP) 2019/1296. (See end of Document for details)*

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.