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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/2370 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 23 November 2022****amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) The Union is committed as a priority to protecting and improving human health through the prevention of disease and by fighting against major cross-border health scourges by means of monitoring, assessing, communicating on, improving preparedness for, providing early warning of and combatting serious cross-border threats to health.
- (2) The European Centre for Disease Prevention and Control (the 'Centre') was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽⁴⁾ as an independent European agency with the mission to identify, assess and communicate current and emerging threats to human health from communicable diseases.
- (3) On 11 March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic. Given the challenges experienced in responding to the pandemic, it became clear that the Union's framework for health crisis preparedness and response should be strengthened to better use the potential of the Union's and Member States' capacities to respond to future pandemics.

⁽¹⁾ OJ C 286, 16.7.2021, p. 109.

⁽²⁾ OJ C 300, 27.7.2021, p. 76.

⁽³⁾ Position of the European Parliament of 4 October 2022 (not yet published in the Official Journal) and decision of the Council of 24 October 2022.

⁽⁴⁾ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

- (4) In its decision of 5 February 2021 in strategic inquiry OI/3/2020/TE, the European Ombudsman identified some important gaps in the effectiveness of the Centre's response to the COVID-19 pandemic, such as regarding complete and comparable data, the level of transparency and communications to the public. Those shortcomings should be addressed in this Regulation.
- (5) The capacity of the Centre to implement new tasks will depend on the level of financial assistance available from the Union, as well as on the internal and external human resources available. In order to be able to fulfil the new tasks entrusted to it as a result of the COVID-19 pandemic, the Centre will need sufficient funding and staffing. Project-oriented funds, such as those allocated under the EU4Health Programme, established by Regulation (EU) 2021/522 of the European Parliament and of the Council ⁽⁵⁾, are not sufficient to respond to the Centre's needs in the future.
- (6) The overexploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to follow the 'One Health' approach to addressing current and emerging crises.
- (7) In their joint opinion 'Improving pandemic preparedness and management', the Group of Chief Scientific Advisors to the Commission, the European Group on Ethics in Science and New Technologies and the Special Advisor to the President of the Commission on the response to COVID-19 recommend establishing 'a standing EU advisory body for health threats and crises'.
- (8) This Regulation should therefore expand the mission and tasks of the Centre in order to enhance the Centre's capacity to provide the required robust and independent scientific expertise, and to support actions which are relevant to the prevention, preparedness and response planning for and the combatting of serious cross-border threats to health in the Union, in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council ⁽⁶⁾.
- (9) The COVID-19 pandemic has highlighted that major communicable diseases can have severe implications for patients with non-communicable diseases, such as delays in or the interruption to treatment for cancer patients and survivors, and for people with mental health issues. The healthcare professionals caring for patients with non-communicable diseases have had the challenge of diagnosing and caring for patients while trying to remain safe themselves. In addition, the diagnoses of certain diseases have been long delayed which has led to those diseases being detected when they are at an advanced stage. Furthermore, much still has to be learned about the effect of communicable diseases on non-communicable diseases, such as post-COVID-19 conditions. The COVID-19 pandemic has also put mental and neurological health in the spotlight. People living with dementia, their carers and family have indicated that the various social distancing and lockdown measures have had a major impact on their well-being, and there are indications that this speeded up the progress of the disease. Hence, the impact which a serious outbreak of a communicable disease can have on the prevention and treatment of non-communicable diseases and comorbidities needs to be considered, given the significant pressure it places on health system capacity.
- (10) The Centre should be tasked with providing timely epidemiological information and analysis of that information, epidemiological modelling, anticipation and forecasting, and with providing timely relevant risk assessments and science-based recommendations, which set out options for the prevention and control of communicable diseases. Risk assessments should be carried out in as short a period as possible, while ensuring that sufficient necessary information is gathered. The Centre's actions should be consistent with the 'One Health' approach, recognising the interconnections between human and animal health and the environment, as many outbreaks of communicable diseases are of zoonotic origin. The Centre should, in close cooperation with Member States, monitor the capacity of Member States' health systems to detect, prevent, respond to and recover from outbreaks of communicable diseases, identify gaps and provide science-based recommendations for the strengthening of health systems. The

⁽⁵⁾ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

⁽⁶⁾ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (see page 26 of this Official Journal).

monitoring of Member States' health system capacity should be based on agreed indicators. The Centre should organise visits to Member States to provide additional support for prevention, preparedness and response planning activities. The Centre should support the implementation of actions that are funded by the relevant Union funding programmes and instruments, and are related to communicable diseases. It should also provide guidelines for case management and support for professional networks to improve guidelines for treatment based on a thorough assessment of the latest evidence. The Centre should support epidemic and outbreak responses in Member States and third countries, including field response and personnel training, and provide the public with timely, objective, reliable and easily accessible information on communicable diseases. The Centre should also establish clear procedures for cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health, such as the WHO, hence contributing to the Union's commitment to reinforcing partners' preparedness and response capacity.

- (11) All recommendations, advice, guidance or opinions provided by the Centre under this Regulation are inherently non-binding on their addressees. Recommendations issued by the Centre allow it to make its views known and to suggest a line of action without imposing any legal obligation on those to whom such recommendations are addressed.
- (12) It is essential that the Centre have access to timely and complete data in order for it to be able to carry out risk assessments in a timely manner and provide relevant recommendations. To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should therefore communicate to the Centre, in a timely manner, comparable data on the surveillance of communicable diseases, such as HIV, viral hepatitis B and C and tuberculosis, as well as on related special health issues, namely antimicrobial resistance and healthcare-associated infections. Member States should also provide available scientific and technical data and information relevant to the Centre's mission, notify the Centre of any serious cross-border threats to health and provide information on prevention, preparedness and response planning and on health system capacity. The Centre and the Member States should agree on timelines, case definitions, indicators, standards, protocols and procedures for the purposes of surveillance. Member States should inform the Centre about any delays in communicating data. In any event, Member States should provide the data required by this Regulation, in so far as it does not conflict with safeguarding national security.
- (13) The Commission, in collaboration with the Centre, the European Environment Agency, the European Chemicals Agency and the European Food Safety Authority, should foster systematic integration of the analysis and assessment of risks associated with environmental, climate and food factors with epidemiological surveillance, taking into consideration the weaknesses of national health systems and the focus on vulnerable groups in the population, in order to work towards a holistic approach to the prevention and early detection of communicable diseases.
- (14) To enhance prevention, preparedness and response planning activities in the Union, the Centre's operation of dedicated networks and networking activities should be broadened to reflect the scope of Regulation (EU) 2022/2371. To this end, the Centre should coordinate with and provide scientific and technical expertise to the Commission, Member States and the Health Security Committee (HSC) established by that Regulation, through dedicated networks of coordinating competent bodies, including by encouraging cooperation within the Union's newly established networks of services supporting the use of substances of human origin.
- (15) With a view to enhancing the effectiveness of epidemiological surveillance in the Union, the Centre should be tasked with the continuous development of secure and interoperable digital platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence and computer modelling and simulation, in the compilation and analysis of data, and with providing Member States with scientific and technical advice to establish integrated epidemiological surveillance systems.
- (16) To strengthen the capacity of the Union and the Member States to assess the epidemiological situation and carry out accurate risk assessment and response, the Centre should, in particular, identify emerging health threats, monitor and report on trends in communicable diseases, support, coordinate and facilitate evidence-based response, provide recommendations for the improvement of communicable disease prevention and control programmes established at

Union and national level, monitor, in close cooperation with Member States, the capacity of national health systems for diagnosis, prevention and treatment of communicable diseases, including in a gender-sensitive way, identify population groups at risk that require specific measures, analyse the correlation of disease incidence with societal, environmental and climate factors, and identify risk factors for transmission and disease severity of communicable diseases as well as research needs and priorities. The Centre should carry out those tasks on the basis of a set of common indicators developed in close collaboration and consultation with Member States. The Centre should work with designated national focal points for surveillance, which form a network that provides strategic advice to the Centre on such matters and would promote the use of enabling sectors, such as EU space data and services. Where possible and in order to minimise duplication of resources and efforts, national focal points should be the same as the national focal points provided for under the International Health Regulations (IHR).

- (17) The Centre should help strengthen the capacity within the Union to diagnose, detect, identify and characterise infectious agents which have the potential to threaten public health, by ensuring the operation of a dedicated network of EU reference laboratories for public health set up in accordance with Regulation (EU) 2022/2371, and that such operation occurs in an integrated manner. That network will be responsible for the promotion of good practice in and alignment of diagnostics, testing methods, training in current and innovative procedures and use of tests, in order to ensure uniform surveillance, notification and standardised procedures for reporting of diseases, as well as improved quality of testing and surveillance.
- (18) In the case of a serious cross-border threat to health posed by a communicable disease, the Centre should cooperate with Member States to safeguard patients in need of treatment using a substance of human origin from the transmission of such a communicable disease. The Centre should therefore establish and operate a network of services supporting the use of substances of human origin.
- (19) With the aim of reducing the occurrence of epidemics and strengthening capacities to prevent communicable diseases in the Union, the Centre should, working in conjunction with Member States so as to take account of their experiences and respective circumstances, develop a framework for the prevention of communicable diseases which addresses such issues as vaccine preventable diseases, vaccine hesitancy, awareness of transmission routes, antimicrobial resistance, health education, health literacy, disease prevention and behaviour change.
- (20) The Centre should enhance preparedness and response capacity at Union and national level by providing scientific and technical expertise to the Member States and the Commission. In this context, the Centre, in close collaboration with Member States and the Commission, should carry out various actions, including contributing to the development of frameworks for Union prevention, preparedness and response plans, regularly reviewing and updating those frameworks, providing science-based recommendations on capacities for prevention of, preparation for and response to disease outbreaks and on the strengthening of national health systems, including by providing training and sharing best practices. The frameworks for Union prevention, preparedness and response plans should be considered to be non-binding instruments. The Centre should broaden its collection and analysis of data in terms of epidemiological surveillance and related special health issues, progression of epidemic situations, unusual epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data and health systems data. To this end, the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and secure data transmission and access, and the Centre should work towards enabling real-time sharing of data, carry out scientific and technical evaluation of prevention and control measures at Union level and work with the WHO, relevant Union agencies and other relevant bodies and organisations operating in the field of data collection.
- (21) Within its mandate, the Centre should respond to the requests of Member States or the Commission in a timely manner.
- (22) Regulation (EU) 2022/2371 provides for the Early Warning and Response System (EWRS) which enables the notification at Union level of alerts related to serious cross-border threats to health and which continues to be operated by the Centre. Given that modern technologies can be of substantial support in combatting health threats and in containing and reversing epidemics, the Centre should work on updating the EWRS to enable the use of

artificial intelligence technologies and interoperable and privacy-preserving digital tools, such as mobile applications, with tracing functionalities identifying at-risk individuals. In carrying out that updating, the Centre should mitigate the risks, such as those related to biased datasets, flawed system design, lack of quality data and overdependence on automated decision-making, and should take into account the importance of establishing safeguards to mitigate those risks during the design and implementation phases of artificial intelligence technologies.

- (23) The Centre should establish appropriate capacities to support international, cross-border interregional and field response, in accordance with Regulation (EU) 2022/2371. Those capacities should enable the Centre to mobilise and deploy outbreak assistance teams, known as the 'EU Health Task Force', to assist in local responses to disease outbreaks and collect field data. The Centre should therefore ensure that it has a permanent capacity to carry out missions in Member States, as well as in third countries, and to provide science-based recommendations on response to health threats. Teams from the EU Health Task Force should also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre. The effective operation of the EU Health Task Force should be based on in-depth country knowledge which can be gained through input from national experts. The Centre should also support the strengthening of preparedness capacities under the IHR in third countries, in order to address serious cross-border threats to health and the consequences thereof. In order to strengthen the operational interface between the Centre and Member States, the Centre should maintain mechanisms for regular secondments between the Centre, the Commission, Member States' experts and international organisations, as well as introduce systematic and permanent working arrangements within the Centre, for example through desk officers.
- (24) The EU Health Task Force to be developed by the Centre to support responses to outbreaks of diseases which can spread within or to the Union should be permanent and be accompanied by a framework for its mobilisation. In addition, it should facilitate the participation of Union field response experts in international response teams in support of and in close coordination with the Union Civil Protection Mechanism. The Centre should enhance the capability of its staff as well as experts from Member States and EEA countries, from candidate countries and potential candidates, as well as from European Neighbourhood Policy countries and partner countries as referred to in Regulation (EU) 2021/947 of the European Parliament and of the Council ⁽⁷⁾, to effectively participate in field missions and crisis management.
- (25) Experts and stakeholders, including civil society organisations, should be engaged in and contribute to the Centre's advisory processes. Compliance with rules on transparency and on conflicts of interest in relation to stakeholder engagement should be ensured.
- (26) The Centre should work in close cooperation with competent bodies and international organisations in the field of public health, in particular the WHO. Such cooperation should take into consideration the need to avoid duplication of efforts.
- (27) The Centre should communicate in an effective and transparent manner about current and emerging health risks to the general public. Scientific studies by the Centre should be accessible.
- (28) In order to assess the effectiveness and efficiency of the legal provisions applicable to the Centre, it is appropriate to provide for a regular evaluation of the performance of the Centre by the Commission.
- (29) This Regulation should not confer any regulatory powers on the Centre.
- (30) The Centre should implement an information system capable of exchanging classified and sensitive non-classified information, in order to ensure that such information is managed with the utmost discretion.

⁽⁷⁾ Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU of the European Parliament and of the Council and repealing Regulation (EU) 2017/1601 of the European Parliament and of the Council and Council Regulation (EC, Euratom) No 480/2009 (OJ L 209, 14.6.2021, p. 1).

- (31) Personal data concerning health are considered to be sensitive data under applicable Union legislation on data protection and therefore enjoy a higher level of protection. Any processing of personal data pursuant to this Regulation by Member States or the Centre is subject to Regulations (EU) 2016/679 ⁽⁸⁾ and (EU) 2018/1725 ⁽⁹⁾ of the European Parliament and of the Council, respectively, and Directive 2002/58/EC ⁽¹⁰⁾ of the European Parliament and of the Council. Processing of personal data under this Regulation should respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Whenever possible, personal data should be anonymised. Where anonymisation would not allow the specific purpose of the processing to be achieved, the personal data should, where possible, be pseudonymised. In the case of cooperation between the health authorities of the Union and third countries, the WHO or other international organisations, transfers of personal data to third countries or international organisations should always comply with the rules laid down in Regulation (EU) 2018/1725.
- (32) In order to ensure uniform conditions for the implementation of this Regulation concerning the rapid mobilisation and responsiveness of the EU Health Task Force, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹¹⁾.
- (33) Since the objectives of this Regulation, namely to expand the mission and tasks of the Centre in order to enhance the Centre's capacity to provide the required scientific expertise and to support actions which combat serious cross-border threats to health in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of the cross-border nature of the health threats and the need for a rapid, better coordinated and coherent response to new emerging health threats, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (34) Regulation (EC) No 851/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 851/2004 is amended as follows:

- (1) Article 2 is replaced by the following:

'Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) "competent body" means any structure, institute, agent or other scientific body recognised by Member States' authorities as providing independent scientific and technical advice or capacity for action in the field of the prevention and control of human disease;

⁽⁸⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽⁹⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁽¹⁰⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

⁽¹¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (2) “coordinating competent body” means a body in each Member State with a designated national coordinator responsible for institutional contacts with the Centre, as well as national focal points and operational contact points responsible for strategic and operational collaboration on scientific and technical issues for specific disease areas and public health functions;
- (3) “dedicated network” means any specific network on diseases, related special health issues or public health functions that is supported and coordinated by the Centre and is intended to ensure collaboration between the coordinating competent bodies of the Member States;
- (4) “communicable disease” means a communicable disease as defined in Article 3, point (3), of Regulation (EU) 2022/2371 of the European Parliament and of the Council (*);
- (5) “serious cross-border threat to health” means a serious cross-border threat to health as defined in Article 3, point (1), of Regulation (EU) 2022/2371;
- (6) “epidemiological surveillance” means epidemiological surveillance as defined in Article 3, point (5), of Regulation (EU) 2022/2371;
- (7) “related special health issues” means related special health issues as referred to in Article 2(1), point (a)(ii), of Regulation (EU) 2022/2371;
- (8) “monitoring” means monitoring as defined in Article 3, point (6), of Regulation (EU) 2022/2371;
- (9) “health system capacity” means health system capacity as defined in Article 3, point (13), of Regulation (EU) 2022/2371.

(*) Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26.).;

- (2) Article 3 is replaced by the following:

‘Article 3

Mission and tasks of the Centre

1. In order to enhance the capacity of the Union and the Member States to protect human health through the prevention and control of communicable diseases in humans and related special health issues, the mission of the Centre shall be to identify and assess current and emerging threats to human health from communicable diseases and related special health issues, to report thereon and, where appropriate, to ensure that information thereon is presented in an easily accessible way. The Centre shall act in collaboration with competent bodies of the Member States or on its own initiative, through a dedicated network. The mission of the Centre shall also be to provide science-based recommendations and support in coordinating the response at Union and national levels, as well as at cross-border interregional and regional level, to such threats, where appropriate. In providing such recommendations, the Centre shall, where necessary, cooperate with Member States and take into account existing national crisis management plans and the respective circumstances of each Member State.

In the case of other outbreaks of diseases of unknown origin that may spread within or to the Union, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak that is clearly not of a communicable disease, the Centre shall act only in cooperation with the coordinating competent bodies and upon their request, and provide a risk assessment.

In pursuing its mission, the Centre shall respect the responsibilities of the Member States, the Commission and other Union bodies or agencies, and the responsibilities of third countries and international organisations active within the field of public health, in particular the WHO, in order to ensure that there is comprehensiveness, coherence and complementarity of action and that actions are coordinated.

The Centre shall support the work of the Health Security Committee (HSC), established by Article 4 of Regulation (EU) 2022/2371, the Council, the Member States and, where relevant, other Union structures, in order to promote effective coherence between their respective activities and to coordinate responses to serious cross-border threats to health, within its mandate.

2. The Centre shall perform the following tasks:

- (a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, using the most effective technologies, such as, where relevant, artificial intelligence, respecting European standards regarding ethical aspects;
- (b) develop, in close collaboration and consultation with Member States, relevant common indicators for standardised data collection procedures and risk assessments;
- (c) provide analyses, scientific and technical advice, opinions, guidelines, science-based recommendations and support for actions by the Union and Member States, to prevent and control communicable diseases and related special health issues, including risk assessments, analysis of epidemiological information, prevention, preparedness and response planning and epidemiological modelling, anticipation and forecasting;
- (d) promote and coordinate the networking of bodies, organisations and experts operating in the Union in the fields relevant to the Centre's mission, including networks arising from public health activities supported by the Commission, and operate dedicated networks on surveillance, while ensuring full compliance with the rules on transparency and conflicts of interest;
- (e) promote and facilitate the exchange of scientific and technical information and expertise and of best practices, including through training, among Member States and other Union agencies and bodies;
- (f) monitor, in close cooperation with Member States, their health system capacity and support the collection of data on their health system capacity to the extent necessary for the management of and response to communicable disease threats and related special health issues, based on the preparedness indicators referred to in Article 5b(2), point (b), of this Regulation and the elements set out in Article 7(1) of Regulation (EU) 2022/2371.
- (g) organise on-site visits in Member States, on a case-by-case basis, in close collaboration with the Member States concerned, to provide additional support to prevention, preparedness and response planning activities as referred to in Article 5b;
- (h) support national monitoring of response to major communicable diseases;
- (i) contribute to defining research priorities and to facilitating the development and implementation of actions funded by relevant Union funding programmes and instruments, including the implementation of joint actions in the area of public health;
- (j) provide, at the request of the Commission or the HSC, or on its own initiative, guidelines, recommendations and proposals for coordinated action for surveillance, monitoring, diagnosis and case management of communicable diseases and related special health issues, and support for professional networks to improve treatment guidelines in cooperation with relevant organisations and associations, national competent bodies and international organisations such as the WHO, while avoiding any duplication of existing guidelines;
- (k) support, for example through the EU Health Task Force referred to in Article 11a, epidemic and outbreak response in Member States, based on in-depth country knowledge, and in third countries in cooperation with the WHO, in a manner that is complementary to, and in close coordination with, other emergency response instruments, in particular the Union Civil Protection Mechanism, and relevant instruments on the stockpiling of medical countermeasures;

- (l) contribute to strengthening preparedness capacities under the IHR, including training, in Member States and in third countries, in particular partner countries, while ensuring that synergies with the work of the WHO are achieved;
- (m) provide, at the request of the Commission or the HSC, or on its own initiative, timely, easily accessible and evidence-based communication messages to the public, in all official languages of the Union, on communicable diseases and threats to health posed by communicable diseases, as well as on the relevant prevention and control measures, with due regard for the competences of the Member States.

3. The Centre, the Commission, the relevant Union bodies or agencies and the Member States shall cooperate in a transparent manner to promote effective coherence and synergies between their respective activities.;

- (3) Article 4 is replaced by the following:

'Article 4

Obligations of Member States

Member States shall coordinate and collaborate with the Centre, in relation to the mission and tasks set out in Article 3, by:

- (a) communicating regularly to the Centre, in accordance with agreed timelines, case definitions, indicators, standards, protocols and procedures, data on the surveillance of communicable diseases, related special health issues and other serious cross-border threats to health undertaken in accordance with Article 13 of Regulation (EU) 2022/2371, and available scientific and technical data and information necessary for the Centre to fulfil its mission referred to in Article 3(2), point (e), of this Regulation, including relevant data on the capacity of health systems for crisis preparedness in relation to detecting, preventing, responding to and recovering from outbreaks of communicable diseases;
- (b) notifying the Centre of any serious cross-border threats to health, as soon as detected, through the Early Warning and Response System (EWRS) provided for under Article 18 of Regulation 2022/2371, and promptly communicating any response measures taken, as well as any relevant information that is useful for coordinating the response as referred to in Article 21 of that Regulation;
- (c) identifying, within the scope of the mission of the Centre, competent bodies and public health experts and organisations that could be available to assist in the Union response to serious cross-border threats to health, such as by undertaking missions to Member States, cross-border regions and third countries in cooperation with the WHO, in order to provide expert advice and carry out field investigations in the event of disease clusters or outbreaks;
- (d) preparing national prevention, preparedness and response plans in accordance with Article 6 of Regulation (EU) 2022/2371 and reporting on prevention, preparedness and response planning and implementation at national level in accordance with Article 7 of that Regulation;
- (e) facilitating the digitalisation of data collection and the data communication process between national and European surveillance systems to provide timely delivery of the necessary information; and
- (f) informing the Centre about any delay in meeting the timelines referred to in point (a).';

- (4) Article 5 is replaced by the following:

'Article 5

Operation of dedicated networks and networking activities

1. The Centre shall support and continuously develop the networking activities of competent bodies through the provision of coordination and scientific and technical expertise to the Commission and Member States and through the operation of dedicated networks.

2. The Centre shall ensure the integrated operation of the network for epidemiological surveillance referred to in Article 13(1) of Regulation (EU) 2022/2371, surveillance of health-related environmental hazards as referred to in Article 2(1), point (c), of that Regulation, and the integrated operation of a network of EU reference laboratories as referred to in Article 15 of that Regulation.

It shall in particular:

- (a) ensure the continuous development of automated digital platforms and applications, including the digital platform for surveillance established under Article 14 of Regulation (EU) 2022/2371, that are subject to human oversight, support epidemiological surveillance at Union level, and support Member States with scientific and technical data and advice to establish integrated surveillance systems enabling real-time surveillance for preparedness, where appropriate and feasible, benefiting from existing Union space infrastructure and services;
- (b) provide quality assurance by monitoring and evaluating the epidemiological surveillance activities of the dedicated networks on surveillance to ensure optimal operation, including by developing surveillance standards and monitoring data completeness and indicators;
- (c) maintain databases for such epidemiological surveillance, coordinate with the hosts of other relevant databases and work towards harmonised approaches to data collection and modelling in order to produce comparable Union-wide data; in carrying out that role, the Centre shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, and shall establish robust procedures for data quality review;
- (d) communicate the results of the analysis of data to the Commission, the HSC and the Member States, make databases accessible to and usable by Member States to support national policymaking and bilateral and multilateral collaboration between Member States, and propose communication messages to Member States to inform the public;
- (e) promote and support harmonised and rationalised operating methodologies for epidemiological surveillance in collaboration with the competent bodies;
- (f) ensure the interoperability of automated applications and other digital tools that support cross-border public health activities, including for contact tracing and warning applications, developed at Union level or national level in close collaboration with Member States;
- (g) ensure the interoperability of the digital platforms for surveillance with digital infrastructure enabling health data to be used for healthcare, research, policy-making and regulatory purposes, and make use of other relevant data, for example environmental factors or phenomena with the potential to have a severe impact on health at Union or cross-border interregional level, or socio-economic risk factors, among others, if useful as regards fulfilling the Centre's mission more effectively.

The digital platforms and applications referred to in the second subparagraph, point (a), shall be implemented with privacy-enhancing technologies taking into account the state of the art.

3. The Centre, through the operation of the network for epidemiological surveillance, shall:

- (a) monitor and report on trends in communicable diseases over time and across Member States and in third countries in cooperation with the WHO, based on agreed indicators, to assess the present situation and facilitate appropriate evidence-based action, including through the identification of specifications for harmonised data collection from Member States;
- (b) detect, monitor and report on serious cross-border threats to health referred to in Article 2(1), points (a)(i) and (a)(ii), of Regulation (EU) 2022/2371, including threats to substances of human origin, or in Article 2(1), point (d), of that Regulation, with regard to source, time, population and place in order to provide a rationale for public health action;

- (c) support the national reference laboratories referred to in Article 15 of Regulation (EU) 2022/2371 in the implementation of the external quality control schemes, including professional testing schemes;
 - (d) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for science-based recommendations to strengthen and improve those programmes at Union and national level;
 - (e) monitor and assess the capacity of health systems to diagnose, prevent and treat major communicable diseases, as well as the resilience of the national health systems in the event of major disease outbreaks, based on preparedness indicators referred to in Article 5b(2), point (b);
 - (f) identify population groups at risk and in need of targeted prevention and response measures, and support Member States in ensuring that those measures also target persons with disabilities;
 - (g) contribute to the assessment of the burden of communicable diseases, such as with regard to disease prevalence, clinical complications, hospitalisation and mortality, by using among other types of data, stratified data on age, gender, disability and other elements, if available;
 - (h) carry out epidemiological modelling, anticipation and scenario development for response, and coordinate such efforts with a view to exchanging best practices, improving modelling capacity across the Union and ensuring international cooperation; and
 - (i) identify risk factors for disease transmission and the associated disease burden, provide analysis of the correlation between disease transmission, on the one hand, and social, economic, climatic and environmental risk factors, on the other, following the 'One Health' approach for zoonotic, food and waterborne diseases and other relevant diseases and special health issues, and identify population groups most at risk, including the correlation between disease incidence and severity with societal and environmental factors, and research priorities and needs.
4. Each Member State shall designate a coordinating competent body and shall also designate a national coordinator, national focal points and operational contact points, as relevant, for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases, as well as for providing support for preparedness and response.

The national focal points shall form networks that provide scientific and technical advice to the Centre.

National focal points and operational contact points designated for disease-specific interactions with the Centre shall form disease-specific or disease-group-specific networks whose tasks shall include the transmission of national surveillance data as well as the submission of proposals for the prevention and control of communicable diseases to the Centre.

Member States shall notify the Centre and other Member States of the designations provided for in this paragraph and of any change thereto.

5. The Centre shall cooperate with the competent bodies, in particular on preparatory work for scientific opinions, scientific and technical assistance, the collection of comparable data based on common formats that allow for ease of aggregation, and the identification of emerging health threats.

6. The Centre shall ensure the operation and coordination of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) 2022/2371, for the purposes of diagnosis, detection, identification, genetic sequencing and characterisation of infectious agents that have the potential to pose a threat to public health.

7. The Centre shall provide scientific and technical assistance to help Member States develop their detection and sequencing capacities, in particular those Member States that do not have sufficient capacities.

8. By encouraging cooperation between experts and reference laboratories, the Centre shall foster the development of sufficient capacity within the Union for the diagnosis, detection, identification and characterisation of infectious agents that have the potential to pose a threat to public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes.

9. The Centre shall ensure the operation and coordination of the network of Member State services supporting the use of substances of human origin, in order to help to ensure that such substances are microbiologically safe, by monitoring, assessing and helping to address relevant disease outbreaks that have the potential to pose serious cross-border threats to health, and to safeguard patients in need of such substances.’;

(5) the following article is inserted:

‘Article 5a

Prevention of communicable diseases

1. The Centre shall support Member States in strengthening their communicable disease prevention and control capacities, and in improving and facilitating the data collection process with interoperable sharing of data.

2. In close collaboration with Member States, the European Medicines Agency (EMA) and other relevant Union bodies and agencies, as well as with international organisations, the Centre shall develop a framework for the prevention of communicable diseases and related special health issues, including socio-economic risk factors, vaccine preventable diseases, antimicrobial resistance, health promotion, health education, health literacy and behaviour change.

3. The Centre may provide guidelines for the creation of communicable disease prevention and control programmes. It shall evaluate and monitor such programmes in order to provide evidence for science-based recommendations for the purposes of coordinating, strengthening and improving such programmes at national, cross-border interregional and Union level, and, where appropriate, at international level.

4. The Centre shall monitor the level of vaccination coverage in respect of major communicable diseases in each Member State, taking into account the specificities of national and regional vaccination schedules.

5. The Centre shall coordinate independent, post-marketing monitoring studies of the effectiveness and safety of vaccines, and shall collect new information, use the relevant data collected by competent bodies, or both. That work shall be conducted jointly with EMA and in particular through a new vaccine monitoring platform.’;

(6) the following article is inserted:

‘Article 5b

Prevention, preparedness and response planning

1. The Centre shall provide science-based recommendations and scientific and technical expertise to the Member States and the Commission, in collaboration with relevant Union bodies and agencies, international organisations and, where relevant, representatives of civil society, such as representatives of patient organisations and public health organisations, in accordance with appropriate working arrangements established with the Commission in the field of prevention, preparedness and response planning.

2. The Centre shall, in close collaboration with the Member States and the Commission:

(a) without prejudice to Member States’ competences in the area of prevention, preparedness and response planning, contribute to the development, regular review and updating of frameworks for national preparedness plans and of threat-specific preparedness plans for adoption by the HSC, and to the development, regular review and updating of the Union prevention, preparedness and response plan in accordance with Article 5 of Regulation (EU) 2022/2371;

- (b) develop preparedness, monitoring and evaluation frameworks, and develop indicators for preparedness based on the IHR, in cooperation with the WHO, which frameworks and indicators are to be discussed within the HSC;
- (c) facilitate self-assessments by Member States of their prevention, preparedness and response planning and external evaluation of such planning, when accepted by the Member State concerned and in a manner that is complementary to the IHR, and contribute to the activities referred to in Articles 7 and 8 of Regulation (EU) 2022/2371;
- (d) ensure assessment of preparedness gaps and the provision of targeted support to Member States and, at their request and in cooperation with the WHO, to third countries that conclude agreements with the Union in accordance with Article 30;
- (e) develop exercises, stress tests, in-action and after-action reviews, and support and complement Member States in those activities, and organise additional actions to address gaps identified in preparedness capacity and capability;
- (f) develop and support specific preparedness activities addressing, amongst other things, vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity, based on identified gaps or at the request of the Member States or the Commission;
- (g) support the integration of research preparedness in the prevention, preparedness and response plans;
- (h) support and complement additional targeted activities addressing at-risk groups and community preparedness;
- (i) based on indicators referred to in Article 3(2), point (b), and in point (b) of this subparagraph, and in close cooperation with the Member States, monitor the capacity of Member States' health systems to detect, prevent, respond to and recover from outbreaks of communicable diseases, identify gaps and provide science-based recommendations for the strengthening of health systems, to be implemented with Union support, as appropriate;
- (j) bolster the modelling, anticipation and forecasting capacity of the Centre; and
- (k) maintain regular secondment mechanisms between the Centre, the Commission, Member States' experts and international organisations, including a EU Health Task Force, which support the activities referred to in points (d), (f), (h) and (i) of this subparagraph and Article 5a(1).

The secondment mechanisms referred to in the first subparagraph, point (k), shall contribute to the strengthening of the operational interface between the Centre and Member States.;

(7) Article 6 is amended as follows:

(a) the following paragraph is inserted:

'1a. The Centre shall provide concrete analyses and independent science-based recommendations for actions to prevent and control communicable diseases and other serious cross-border threats to health, on its own initiative or at the request of the Commission or the Member States through the HSC.;

(b) paragraph 3 is replaced by the following:

'3. The Centre may promote and initiate scientific studies that are necessary for the performance of its mission, and applied scientific studies and projects on the feasibility, development and preparation of its activities. The Centre shall avoid duplication with research and health programmes of the Commission, the Member States, the Union or the WHO, as well as with other relevant programmes, and shall liaise between the public health and research sectors.

To promote and initiate the studies referred to in the first subparagraph, the Centre shall request access to health data made available or exchanged through digital infrastructure and applications, so that such health data can be used for healthcare, health research, policy-making and regulatory purposes linked to public health.

For the purposes of the studies referred to in the first subparagraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors.

3a. The Centre may use its resources and make use of reference laboratories, in order to perform field research, data gathering and data analysis, for the purposes of helping relevant national bodies gather reliable data.;

(c) paragraph 4 is replaced by the following:

‘4. The Centre shall consult with the HSC, the Commission and other relevant Union bodies or agencies with regard to the planning and priority setting of research and public health studies, taking into account the opinion of the Advisory Forum.’;

(8) Article 7 is replaced by the following:

‘Article 7

Procedure for scientific opinions

1. The Centre shall issue a scientific opinion on matters falling within its mission:

- (a) in all cases where Union legislation provides that the Centre is to be consulted;
- (b) at the request of the European Parliament or a Member State;
- (c) at the request of the Commission, the HSC or EMA; and
- (d) on its own initiative.

2. Requests for a scientific opinion as referred to in paragraph 1 shall clearly explain the scientific issue to be addressed and the Union interest concerned, and shall be accompanied by sufficient background information regarding that issue. Where necessary, if scientific opinions are focused on a specific Member State, the Member State concerned shall have the opportunity to contribute with expertise.

3. The Centre shall ensure that it has the ability to anticipate and react quickly in order to issue scientific opinions within a mutually agreed time frame. The Centre’s scientific opinions shall be accessible and shall be operational for policy makers.

4. Where different requests are made on the same issue or where the request does not comply with paragraph 2, the Centre may refuse to issue a scientific opinion or propose amendments to that request in consultation with the institution, committee, agency or Member State that made the request. If the request is refused, the Centre shall provide the institution, committee, agency or Member State that made the request with the reasons for the refusal.

5. Where the Centre has already delivered a scientific opinion on the specific issue covered by a request and it concludes that no scientific elements justify re-examination of the issue, information supporting that conclusion shall be given to the institution, committee, agency or Member State that made the request.

6. The Centre’s internal rules shall specify requirements regarding the format, explanatory background and transparency rules for the publication of a scientific opinion.;

(9) Article 8 is replaced by the following:

‘Article 8

Operation of the Early Warning and Response System

1. The Centre shall support and assist the Commission by operating the EWRS in accordance with Article 18 of Regulation (EU) 2022/2371 and by ensuring, together with the Member States, the capacity to respond to health threats in a coordinated and timely manner.

2. The Centre shall:

- (a) analyse the content of messages it receives via the EWRS;
- (b) provide information, expertise, advice, training and risk assessments to Member States and the Commission; and
- (c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems.

3. The Centre shall work with the Commission, the HSC and Member States to improve the reporting of relevant data through the EWRS, with a view to encouraging digitalisation of that process and its integration into national surveillance systems.
4. The Centre shall work with the Commission and the HSC to continuously update the EWRS, including for the use of modern technologies such as digital mobile applications, artificial intelligence and computer modelling and simulation models, or other technologies for automated contact tracing and warning applications, building upon the contact tracing technologies developed by the Member States, and to define the functional requirements of the EWRS.
5. The Centre shall work with the Commission, the HSC and the eHealth Network and relevant experts in the Member States to further define the functional requirements for contact tracing and warning applications, or, if necessary, other digital tools, and their interoperability, taking into account existing infrastructure and services, such as geolocation services provided by the EU Space Programme.
6. The Centre shall be responsible for ensuring the legality, security and confidentiality of the processing operations of personal data carried out within the EWRS and in the context of the interoperability of contact tracing and warning applications or, if necessary, other digital tools, in accordance with Articles 33 and 36 of Regulation (EU) 2018/1725 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).;

(10) the following article is inserted:

'Article 8a

Public health risk assessment

1. The Centre shall provide risk assessments, in accordance with Article 20 of Regulation (EU) 2022/2371, in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), of that Regulation, including where it relates to substances of human origin that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of that Regulation. Such risk assessments shall be provided in a timely manner.
2. Risk assessments referred to in paragraph 1 shall include general and targeted science-based recommendations and options for response as a basis for coordination in the HSC, such as concerning:
 - (a) a forecast of the evolution of a health crisis and the risk of a health emergency;
 - (b) the Member States' health system capacity to the extent it is necessary for the management of and the response to communicable disease threats and related special health issues, in order to support Member States;
 - (c) identification of vulnerable groups in society;
 - (d) identification of possible protective non-pharmaceutical measures and assessment of their efficacy.
3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of risk assessments, by involving national focal points or Member States' experts, relevant agencies or international organisations such as the WHO, where appropriate.

The Centre shall establish rules of procedure for risk assessments, especially regarding the involvement of experts to ensure that Member State expertise is independent and representative.

4. Where the risk assessment falls outside the mandate of the Centre, and at the request of the agency or body carrying out the risk assessment within its mandate, the Centre shall, without undue delay, provide the agency or body with any relevant information and data that are at its disposal.

5. The Centre shall work together with Member States to improve their risk assessment capacity.;

(11) the following article is inserted:

'Article 8b

Response coordination

1. The Centre shall support response coordination in the HSC as referred to in Article 21 of Regulation (EU) 2022/2371, in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), of that Regulation, including where it relates to substances of human origin that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of that Regulation, in particular by providing science-based recommendations and options for:

- (a) national or cross-border interregional responses to the serious cross-border threat to health;
- (b) the adoption of guidelines for the Member States for the prevention and control of the serious cross-border threat to health.

2. The Centre shall support a Union coordinated response at the request of a Member State, the Council, the Commission, the HSC or Union bodies or agencies.;

(12) Article 9 is amended as follows:

- (a) paragraphs 1, 2 and 3 are replaced by the following:

'1. The Centre shall provide scientific and technical expertise to the Member States, the Commission and other Union bodies or agencies in the development, regular examination and updating of preparedness plans, on training activities and in the development of intervention strategies within the scope of its mission.

2. The Centre may be requested by the Commission, the Member States, the HSC or third countries that conclude agreements with the Union in accordance with Article 30, in particular partner countries, and international organisations, in particular the WHO, to provide scientific or technical assistance in any field within the scope of its mission. The assistance may include aiding the Commission and the Member States to develop technical guidelines on good practice and on protective measures to be taken in response to human health threats, providing expert assistance, mobilising and coordinating investigation teams and assessing the efficiency of response measures. The Centre shall provide evidence-based scientific and technical expertise and assistance within its mandate, and in accordance with the applicable agreements as well as with the appropriate working arrangements established with the Commission with regard to third countries and international organisations.

3. Requests made to the Centre for scientific or technical assistance shall be accompanied by a set deadline, which shall be mutually agreed with the Centre.;

- (b) paragraph 5 is replaced by the following:

'5. The Centre shall inform its Management Board, referred to in Article 14, Member States' authorities and the Commission of any such request and of its outcomes.;

- (c) paragraph 6 is replaced by the following:

'6. The Centre shall, as appropriate, support and coordinate training programmes, in particular in relation to epidemiological surveillance, field investigations, preparedness and prevention, response to public health emergencies, public health research and risk communication. Those programmes shall take into consideration the need for training to be kept up-to-date, take into account the training needs of Member States and shall respect the principle of proportionality.;

(13) Article 11 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Centre shall:

- (a) coordinate standardisation of data collection procedures, and validation, analysis and dissemination of data at Union level;
- (b) seek, where appropriate, the expertise and guidance of the Member States to ensure that there is a correct understanding of the health data made available, their limitations and the national context and information systems.’;

(b) the following paragraph is inserted:

‘1a. The Centre shall collect data and information, and provide links to relevant research data and outputs on:

- (a) epidemiological surveillance;
- (b) the progression of epidemic situations, including for modelling, anticipation and scenario development and the assessment of vulnerable groups;
- (c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries, in cooperation with the WHO;
- (d) pathogen data, including at molecular level, if required for epidemiological surveillance and for detecting or investigating serious cross-border threats to health;
- (e) health systems data required for managing communicable diseases and related special health issues; and
- (f) implementation of the Centre’s recommendations by Member States and the outcomes thereof.’;

(c) paragraph 2 is replaced by the following:

‘2. For the purposes of paragraph 1, the Centre shall:

- (a) develop, together with the competent bodies of the Member States and the Commission, appropriate procedures to facilitate consultation and data transmission and access;
- (b) carry out scientific and technical evaluations of prevention and control measures at Union level;
- (c) work in close cooperation and in a transparent manner with relevant bodies operating in the field of data collection of the Union, third countries, the WHO and other international organisations;
- (d) develop solutions to access relevant health data, whether publicly available or made available or exchanged through digital infrastructure, in order to allow the health data to be used for healthcare, health research, policy-making and regulatory purposes linked to public health; and provide and facilitate controlled and timely access to health data to support public health research.’;

(d) the following paragraphs are added:

‘4. In situations of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, at the request of the Commission, the HSC, EMA, the Member States or on its own initiative, the Centre shall make available epidemiological forecasts as referred to in Article 5(3), point (h). Such forecasts shall be prepared objectively, reliably and on the basis of the best available information, and in cooperation with other institutions and working groups established with Member States’ experts. The forecasts shall be made easily accessible.

5. In situations of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall provide data and easily accessible relevant analyses on the basis of the best available information, as quickly as possible and in accordance with Article 8a(1).’;

(14) the following article is inserted:

'Article 11a

Support for international and field preparedness and response

1. The Centre shall establish a EU Health Task Force and ensure that there is a permanent capacity and an enhanced emergency capacity to mobilise and use it. The EU Health Task Force shall provide assistance with regard to requests for prevention, preparedness and response planning, local responses to outbreaks of communicable diseases and after-action reviews in Member States and in third countries, in cooperation with the WHO. The EU Health Task Force shall include the Centre's staff and experts from Member States, fellowship programmes and international and non-profit organisations.

The Centre shall develop capacities to conduct field epidemiology and research, and gather relevant data, such as on the variants of communicable diseases, using the dedicated network of EU reference laboratories or its own resources.

2. The Centre, in cooperation with the Commission, shall develop a framework to define the organisational structure and the use of the permanent capacity of the EU Health Task Force.

At the joint request of the Commission and Member States, the enhanced emergency capacity of the EU Health Task Force shall be mobilised. The Commission shall, by means of implementing acts, adopt the procedures concerning the mobilisation of the enhanced emergency capacity of the EU Health Task Force. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30a(2).

3. The Centre shall ensure that the EU Health Task Force is coordinated with, complementary to and integrates the capacities of the European Medical Corps, other relevant capacities under the Union Civil Protection Mechanism and mechanisms of international organisations.

4. Through the EU Health Task Force, the Centre shall provide Union field response experts in international response teams mobilised by the WHO Health Emergencies Programme mechanism and the Global Outbreak Alert and Response Network (GOARN), in accordance with appropriate working arrangements established with the Commission.

5. The Centre shall facilitate the development of field response capabilities and crisis management expertise among the Centre's staff and experts from Member States and EEA countries, from candidate countries and potential candidates, as well as from European Neighbourhood Policy countries and partner countries, at the request of the Commission and in collaboration with the Member States.

6. By establishing a mechanism for mobilising and using the EU Health Task Force, the Centre shall maintain the permanent capacity of the EU Health Task Force and enhance the country-specific knowledge necessary to carry out missions to Member States, at the joint request of the Commission and Member States concerned, to provide science-based recommendations on preparedness for and response to threats to health and to carry out after-action reviews, within its mandate.

7. At the request of the Commission and Member States, the Centre shall engage in long-term capacity-building projects aimed at strengthening preparedness capacities under the IHR in non-European third countries, in particular partner countries.;

(15) Article 12 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Centre shall communicate, on its own initiative, information about its activities and the results of its work within the scope of its mission, after having given prior information to the Member States and to the Commission.

The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and easily accessible information with regard to its activities and the results of its work. The Centre shall make scientific information available to the general public, including through a dedicated website, as well as through an active presence on social media or analogous platforms. It shall also publish its scientific opinions, produced in accordance with Article 6, in a timely manner. Information relevant for citizens of the Union shall be made available in all the official languages of the Union to ensure appropriate outreach to citizens of the Union. The Centre shall facilitate the fight against misinformation regarding vaccination and against the causes of vaccine hesitancy.’;

(b) paragraph 3 is replaced by the following:

‘3. The Centre shall cooperate, as appropriate, with the competent bodies in the Member States, the WHO and other interested parties with regard to public information campaigns.’;

(16) Article 14 is amended as follows:

(a) in paragraph 2, the third subparagraph is replaced by the following:

‘Members’ term of office shall be three years and may be extended.’;

(b) in paragraph 5, points (d), (e) and (f) are replaced by the following:

‘(d) adopt, before 31 January each year, the Centre’s work programme for the coming year;

(e) adopt a draft single programming document in line with Article 32 of Commission Delegated Regulation (EU) 2019/715 (*) and the related Commission guidelines for the single programming document; the single programming document shall be adopted where a positive opinion has been given by the Commission and, as regards multiannual programming, after consulting the European Parliament and the Council;

(f) ensure that the Centre’s work programme for the coming year and multiannual programmes are consistent with the Union’s legislative and policy priorities in the area of the Centre’s mission and tasks, and fully take into account the recommendations adopted in the annual Commission opinion on the draft single programming document referred to in Article 32(7) of Delegated Regulation (EU) 2019/715;

(g) adopt, before 31 March each year, the general report on the Centre’s activities for the previous year;

(h) adopt the financial rules applicable to the Centre after the Commission has been consulted;

(i) determine by unanimity of its members, by way of derogation from Article 15(1), the rules governing the languages of the Centre, including the possibility of a distinction between the internal workings of the Centre and the external communication, taking into account the need to ensure access to, and participation in, the work of the Centre by all interested parties in both cases.

The financial rules applicable to the Centre as referred to in the first subparagraph, point (h), of this paragraph shall not derogate from Delegated Regulation (EU) 2019/715, unless specifically required for the Centre’s operation and the Commission has given its prior consent.

(*) Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1).’;

(17) in Article 16(2), point (b) is replaced by the following:

‘(b) drawing up draft work programmes, taking into account the recommendations adopted in the annual Commission opinion on the draft single programming document in accordance with Article 32(7) of Delegated Regulation (EU) 2019/715; the Commission opinion shall be submitted to the Management Board at the earliest possible stage’;

(18) Article 17 is replaced by the following:

‘Article 17

Appointment of the director

1. The director shall be appointed by the Management Board on the basis of a list of at least three candidates proposed by the Commission after an open competition, following publication in the *Official Journal of the European Union* and elsewhere of a call for expressions of interest which has been validated by the Management Board. That appointment shall be for a period of five years, which may be extended once for a further period of up to five years.

2. Before appointment, the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and to answer questions put by members of that institution.’;

(19) Article 18 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. Members of the Advisory Forum shall not be members of the Management Board. Advisory Forum members’ term of office shall be three years and may be extended.’;

(b) in paragraph 4, point (f) is replaced by the following:

‘(f) scientific and public health priorities to be addressed in the work programme; and

(g) key publications under preparation by the Centre, such as forecasting studies.’;

(c) paragraph 8 is replaced by the following:

‘8. The Centre shall engage with public health experts, with representatives of professional or scientific bodies and non-governmental organisations, in particular those having recognised experience in disciplines related to the work of the Centre, as well as in other areas such as environmental protection, with dedicated networks and with the Advisory Forum, to cooperate on specific tasks. In addition, the Commission, the Member States or the Advisory Forum may propose experts, including experts from third countries, or representatives of professional or scientific bodies, or non-governmental organisations to be consulted by the Centre on an ad-hoc basis.’;

(20) in Article 19, paragraph 2 is replaced by the following:

‘2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interest which might be considered prejudicial to their independence or any direct or indirect interest which might be considered prejudicial to their independence. Those declarations shall be made annually in writing and shall be available to the public.’;

(21) Article 20 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint to the Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 230 of the Treaty on the Functioning of the European Union (TFEU), respectively.’;

(b) paragraph 4 is deleted;

(22) the following article is inserted:

‘Article 20a

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 (*) and Directive 2002/58/EC (**) of the European Parliament and of the Council, and to the obligations of Union institutions, bodies, offices and agencies relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.

2. The Centre shall not process personal data except in cases where it is necessary for the fulfilment of its mission. Where appropriate, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

(*) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

(**) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).;

(23) Article 21 is replaced by the following:

'Article 21

Professional secrecy and confidentiality

1. Without prejudice to Article 20, the Centre shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public, if circumstances so require, in order to protect public health. If the confidential information has been submitted by a Member State, that information shall not be disclosed without the prior consent of that Member State.

The Commission's rules on security regarding the protection of EU classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 (*) and (EU, Euratom) 2015/444 (**), shall apply to the work of the Centre and its staff.

2. Members of the Management Board, the director, members of the Advisory Forum, as well as external experts participating in the scientific panels and the staff of the Centre, even after their duties have ceased, shall be subject to the obligation of professional secrecy pursuant to Article 339 TFEU.

3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential.

4. The Centre shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

5. The Centre shall take all necessary measures to facilitate the exchange of information relevant to its tasks with the Commission, the Member States and, where appropriate, other Union institutions, Union bodies, offices and agencies, and international organisations and third countries, in accordance with appropriate working arrangements established with the Commission.

6. The Centre shall develop, deploy and operate an information system capable of exchanging classified and sensitive non-classified information as specified in this Article.

(*) Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

(**) Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).;

(24) Article 22 is amended as follows:

(a) in paragraph 3, point (d) is replaced by the following:

'(d) any voluntary contribution from the Member States; and

(e) any revenue from contribution agreements or grant agreements exceptionally concluded between the Commission and the Centre.';

- (b) the following paragraph is inserted:

‘3a Financing from the Union budget may be awarded to the Centre for the costs that it incurs in implementing its work programme established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with Regulation (EU) 2021/522 of the European Parliament and the Council (*), and the Research and Innovation programmes of the Union. That financing shall not cover expenditure already covered by the general budget of the Union or by any other resource of the Centre set out in paragraph 3 of this Article.

(*) Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).;

- (c) paragraph 5 is replaced by the following:

‘5. Each year, on the basis of a draft drawn up by the director, the Management Board shall produce an estimate of revenue and expenditure for the Centre for the following financial year. That estimate, including a draft establishment plan, shall be included in the draft single programming document provided for in Article 14(5), point (e), of this Regulation. In accordance with Article 40 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (*), by 31 January each year the Centre shall send to the European Parliament, the Council and the Commission its draft single programming document, as endorsed by its Management Board.

(*) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).;

- (d) paragraph 7 is replaced by the following:

‘7. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 314 TFEU.;

- (25) Article 23 is amended as follows:

- (a) paragraph 2 is replaced by the following:

‘2. By 1 March following each financial year, the Centre's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 245 of Regulation (EU, Euratom) 2018/1046.;

- (b) paragraph 4 is replaced by the following:

‘4. On receipt of the Court of Auditors' observations on the Centre's provisional accounts, pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046, the director shall draw up the Centre's final accounts under the director's own responsibility and forward them to the Management Board for an opinion.

The Centre shall inform the Commission without delay of cases of presumed fraud and other financial irregularities, of any completed or ongoing investigations by the European Public Prosecutor's Office (EPPO) or the European anti-Fraud Office (OLAF), and of any audits or controls by the Court of Auditors or the Internal Audit Service (IAS), without endangering the confidentiality of the investigations. That obligation to inform the Commission is without prejudice to Article 24(1) of Council Regulation (EU) 2017/1939 (*).

(*) Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office (‘the EPPO’) (OJ L 283, 31.10.2017, p. 1).;

(c) paragraphs 8 and 9 are replaced by the following:

‘8. The director shall send the Court of Auditors a reply to its observations by 30 September. The director shall also send a copy of that reply to the European Parliament, the Council, the Commission and the Management Board.

9. The director shall submit to the European Parliament, at the latter’s request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 261(3) of Regulation (EU, Euratom) 2018/1046.’;

(26) Article 24 is replaced by the following:

‘Article 24

Application of the Financial Regulation

Article 70 of Regulation (EU, Euratom) 2018/1046 shall apply to the discharge of the Centre’s budget, its audits and accounting rules.’;

(27) Article 25 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council (*) shall apply to the Centre without restriction.

(*) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).’;

(b) paragraph 3 is replaced by the following:

‘3. The decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly indicate that the EPPO may exercise its competences, including its competence to investigate, and that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Centre’s funding and the agents responsible for allocating it, in accordance with their respective legal frameworks.’;

(c) the following paragraph is added:

‘4. Without prejudice to paragraphs 1 to 3, working arrangements with third countries and with international organisations, grant agreements, grant decisions and contracts of the Centre shall grant the necessary rights and access required by the Court of Auditors, OLAF and the EPPO, in the exercise of their respective competences.’;

(28) Article 26 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Centre shall be a body of the Union. It shall have legal personality.’;

(b) the following paragraph is inserted:

‘1a. In each of the Member States, the Centre shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be party to legal proceedings.’;

(c) paragraph 2 is replaced by the following:

‘2. Protocol No 7 on the Privileges and Immunities of the European Union annexed to the Treaties shall apply to the Centre and its staff.’;

(29) in Article 27, paragraph 1 is replaced by the following:

‘1. The contractual liability of the Centre shall be governed by the law applicable to the contract in question. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Centre.’;

(30) Article 28 is replaced by the following:

'Article 28

Examination of legality

1. Member States, members of the Management Board and third parties directly and individually concerned may refer any act of the Centre, whether express or implied, to the Commission for examination of the legality of that act ('administrative appeal').
2. Any administrative appeal shall be made to the Commission within 15 days of the day on which the party concerned first became aware of the act in question.
3. The Commission shall take a decision within one month. If no decision has been taken within that period, the administrative appeal shall be deemed to have been dismissed.
4. An action for annulment of the Commission's explicit or implicit decision referred to in paragraph 3 of this Article to dismiss the administrative appeal may be brought before the Court of Justice of the European Union in accordance with Article 263 TFEU.';

(31) the following article is inserted:

'Article 30a

Committee procedure

1. The Commission shall be assisted by the committee on serious cross-border threats to health established by Regulation (EU) 2022/2371. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).;

(32) Article 31 is replaced by the following:

'Article 31

Review clause

1. By 2025, the Commission shall submit a report to the European Parliament, the Council and the Management Board on the Centre's activities, including an assessment of:
 - (a) how the Centre progressed with implementing the amended mandate in light of the COVID-19 pandemic;
 - (b) the Centre's compliance with the obligations laid down in Regulation (EU) 2022/2371 and other relevant Union legislation;
 - (c) how effectively the Centre's activities address international, Union or national health priorities;
 - (d) the extent to which the work of the Centre is targeted at and affects Member States' capacities.

The report shall reflect the views of the stakeholders, at both Union and national level.

The report shall be accompanied by an independent study commissioned by the Commission.

2. By 2025, and every 5 years thereafter, the Commission shall commission an independent external evaluation of the Centre's performance in relation to its objectives, mandate, tasks and procedures. That independent external evaluation shall be done on the basis of terms of reference, which shall, if necessary, be discussed with the Management Board.

The independent external evaluation shall, in particular, address the possible need to amend the mandate of the Centre and the financial implications of any such amendment. The first evaluation shall examine the feasibility of extending the mandate of the Centre to address the impact of cross-border threats to health on non-communicable diseases.

The Management Board shall examine the conclusions of the independent external evaluation and may issue recommendations, if necessary, to the Commission regarding changes in the Centre, its working practices and the scope of its mission. The Commission shall forward the evaluation report and the recommendations to the European Parliament and the Council.

3. On the basis of the independent external evaluation referred to in paragraph 2 or where it considers that the continued operation of the Centre is no longer justified with regard to its assigned objectives, mandate and tasks, the Commission may propose that the relevant provisions of this Regulation be amended accordingly.

4. The Commission shall report to the European Parliament, to the Council and to the Management Board, where relevant, on the recommendations of the Management Board and on the findings of its evaluations carried out under paragraphs 2 and 3. Those findings shall be made public.'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 23 November 2022.

For the European Parliament
The President
R. METSOLA

For the Council
The President
M. BEK

REGULATION (EU) 2022/2371 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 23 November 2022
on serious cross-border threats to health and repealing Decision No 1082/2013/EU
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) A network for the epidemiological surveillance and control of communicable diseases was set up by Decision No 2119/98/EC of the European Parliament and of the Council ⁽⁴⁾. Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council ⁽⁵⁾ to strengthen and provide for a more coordinated and wider approach to health security at Union level. The implementation of that legislation confirmed that coordinated Union action on monitoring, early warning of and combatting those threats adds value to the protection and improvement of human health.
- (2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness for and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combatting serious cross-border threats to health, including zoonotic-related threats, as provided for in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis regarding health systems indicators, and with regard to cooperation between Member States and Union agencies and bodies, particularly the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO), while taking into account the burden faced by national competent authorities depending on the actual public health situation. Moreover, in order to ensure the Union's effective response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should make it possible to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies, while respecting Union legislation on data protection such as Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽⁶⁾.

⁽¹⁾ OJ C 286, 16.7.2021, p. 109.

⁽²⁾ OJ C 300, 27.7.2021, p. 76.

⁽³⁾ Position of the European Parliament of 4 October 2022 (not yet published in the Official Journal) and decision of the Council of 24 October 2022.

⁽⁴⁾ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

⁽⁵⁾ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

⁽⁶⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

- (3) It is important that public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures for the purpose of preparing for and responding to cross-border threats to health are transparent in accordance with applicable legislation.
- (4) The Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU, plays an important role in the coordination of prevention, preparedness and response planning for serious cross-border threats to health. The HSC should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health, and to support better coordination between Member States to address those threats. A representative designated by the European Parliament should be able to participate in the HSC as an observer.
- (5) In order to increase the effectiveness of the preparedness for and response to serious cross-border threats to health, the Commission including, where relevant, the Health Emergency Preparedness and Response Authority (HERA) established as a Commission service by Commission Decision of 16 September 2021 ⁽⁷⁾, and the HSC, the ECDC, EMA and other relevant Union agencies and bodies should coordinate and cooperate in relation to such preparedness and response. The coordination between those bodies should build on the participation of relevant stakeholders and aim to avoid any duplication of efforts.
- (6) In their joint opinion 'Improving pandemic preparedness and management', the Group of Chief Scientific Advisors to the Commission, the European Group on Ethics in Science and New Technologies and the Special Advisor to the President of the Commission on the response to COVID-19 recommend establishing a standing EU advisory body for health threats and crises.
- (7) All recommendations, advice, guidance and opinions mentioned in this Regulation are inherently non-binding on their addressees. Recommendations allow the Commission, the ECDC and the HSC to make their views known and to suggest a line of action without imposing any legal obligation on those to whom such recommendations are addressed.
- (8) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning of and combatting specific threats of a cross-border nature, such as the International Health Regulations (IHR) of the WHO adopted in 2005. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health and environmental matters, covering goods such as medicinal products, medical devices, in vitro diagnostic medical devices, and foodstuffs, substances of human origin, such as blood, plasma, tissues and cells, and exposure to ionising radiation.
- (9) The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to follow the One Health approach to addressing current and emerging crises.
- (10) In line with the One Health and Health in All Policies approaches, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. It is crucial that the Union support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage, in addressing the challenges of vulnerable groups and in strengthening the resilience, responsiveness and readiness of healthcare systems as regards addressing future challenges, including pandemics. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, and all relevant stakeholders, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community ('the Euratom Treaty'), whose activities are relevant to prevention, preparedness and response planning, and monitoring, early warning of, and combatting serious cross-border

⁽⁷⁾ Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (OJ C 393 I, 29.9.2021, p. 3).

threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (EWRS) set up by Decision No 1082/2013/EU. The EWRS is to implement robust, accurate and interoperable data processes with Member States to ensure data quality and consistency. The ECDC should coordinate with Member States throughout such data processes, from assessing the data requirements, transmission, and collection to updating and interpretation, with a view to fostering strong collaboration between the Commission, the ECDC and national and regional competent bodies.

- (11) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' prevention, preparedness and response plans so as to ensure they are compatible within the regional level structures. It is crucial that those Union and national plans be prepared with particular attention paid to cross-border regions in order to enhance their health cooperation. Where appropriate, regional authorities should be able to participate in the drawing up of such national plans. To support Member States in this endeavour, the Commission and the relevant Union agencies and bodies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to improve their knowledge and necessary skills. Cross-border elements should also, where relevant, be included in the Union plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised treatment and intensive care across neighbouring regions. To ensure the implementation of the Union plan, the Commission should facilitate stress tests, simulation exercises and in-action and after-action reviews with Member States. The Union plan should be functional and updated, and have sufficient resources for its operationalisation. Following reviews of the national plans, proposed recommendations should be addressed in an action plan and the Commission should be kept informed of any substantial revision of the national plans.
- (12) Member States should provide the Commission with an update on the latest situation with regard to their prevention, preparedness and response planning and implementation at national level, and where applicable at regional level. Information provided by the Member States to the Commission should include the elements that Member States are obliged to report to the WHO in the context of the IHR. Access to timely and complete data is a precondition for prompt risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and a secured network are needed between Union agencies and bodies, the WHO and national competent authorities. In turn, the Commission should report to the European Parliament and to the Council, every three years, on the state of play and progress with regard to prevention, preparedness, response planning and implementation at Union level, including on recommended actions, to ensure that national prevention, preparedness and response plans are adequate. In order to support the assessment of those plans, the ECDC should conduct assessments in Member States, in coordination with other Union agencies and bodies. Such planning should include, in particular, adequate preparedness of critical sectors of society, such as agriculture, energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between the health and veterinary sectors for prevention, preparedness and response planning through the One Health approach. The obligations of Member States to provide information under this Regulation do not affect the application of Article 346 (1), point (a), of the Treaty on the Functioning of the European Union (TFEU) pursuant to which no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.
- (13) Experience from the ongoing COVID-19 pandemic has demonstrated that there is a need for further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions. The national prevention, preparedness and response plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through cross-border training for healthcare staff and coordination exercises for the medical transfer of patients.

- (14) Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats to health and contributing to a better understanding on the part of the population of the countermeasures for and risk assessment of different threats. Health education campaigns based on the latest available evidence could help to improve population behaviour in this regard.
- (15) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a public health emergency at Union level would trigger increased coordination and could enable the timely development, stockpiling and joint procurement of medical countermeasures, under Council Regulation (EU) 2022/2372 ⁽⁸⁾.
- (16) This Regulation should strengthen the tools to safeguard the security of supply of critical medical countermeasures within the Union, while respecting the proper functioning of the internal market in the event that serious cross-border threats to health arise.
- (17) In order to prevent shortages of critical medical countermeasures and protect the security of their supply at Union and national levels, as well as to support an effective and strategic stockpile location, the Commission should ensure coordination and information exchange between the entities organising and participating in any action under the different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the framework of measures adopted under Regulation (EU) 2022/2372, and the strategic rescEU reserve established under Decision No 1313/2013/EU of the European Parliament and of the Council ⁽⁹⁾, taking due account of the accessibility of those medical countermeasures for people in remote, rural and outermost regions.
- (18) A Joint Procurement Agreement for medical countermeasures was approved by the Commission on 10 April 2014. That Joint Procurement Agreement provides for a voluntary mechanism for participating countries and the Union institutions to jointly purchase medical countermeasures for different categories of cross-border threats to health including vaccines, antivirals and other treatments. It lays down common rules for the practical organisation of joint procurement procedures. This Regulation should strengthen and extend the framework for joint procurement of medical countermeasures, in accordance with measures concerning monitoring, early warning of and combatting serious cross-border threats to health, laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽¹⁰⁾. In the event of a serious cross-border threat to health, the joint procurement of medical countermeasures laid down in this Regulation should constitute an effective operational instrument at the Union's disposal, together with other procurement instruments provided for in Union legislation. In particular, contracts under the joint procurement procedure laid down in this Regulation may be concluded or activated in times of crisis, pursuant to Regulation (EU) 2022/2372. In such instances, those contracts should abide by the conditions laid down in the Joint Procurement Agreement, as provided for in this Regulation. The Commission should ensure coordination and information exchange between the entities organising and participating in any action under the different mechanisms established under this Regulation and other relevant Union acts related to procurement and stockpiling of medical countermeasures.
- (19) The Commission should support and facilitate the joint procurement of medical countermeasures by providing all relevant information for the negotiation of such joint procurement, such as information on envisaged prices, manufacturers, delivery time frames and modalities of joint procurement. The Joint Procurement Agreement determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU should also be adapted to provide for an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the Union, a strengthened negotiation position and more efficient action to protect the Union's security of supply. Under the exclusivity clause, participating countries commit to not procuring the medical countermeasure in question through other channels and to not running parallel negotiation processes for that countermeasure. The

⁽⁸⁾ Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (see page 64 of this Official Journal).

⁽⁹⁾ Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

⁽¹⁰⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Commission should facilitate the decision of Member States on participation by providing an assessment, *inter alia*, of the application of the exclusivity clause, its necessity and the conditions thereof, to be jointly agreed with the participating countries. Member States should decide on their participation in the joint procurement procedure once all the necessary information has been provided to them. In any event, limitations to parallel procurement activities and negotiations should occur only when the participating countries have agreed to such restrictions. Due to the sensitive content of the assessment and its relevance for the financial interests of the Union and the participating Member States during a joint procurement procedure, the possibility of making it public should be duly weighed against the exceptions provided for in Regulation (EC) No 1049/2001 of the European Parliament and of the Council ⁽¹¹⁾, and, in particular, Article 4 of that Regulation.

- (20) As serious cross-border threats to health are not limited to Union borders, the Union should adopt a coordinated approach, characterised by solidarity and responsibility, in combatting such threats. Therefore, joint procurement of medical countermeasures should be extended to include European Free Trade Association States, Union candidate countries, in accordance with applicable Union legislation, the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046 and in accordance with Article 3(2) of that Regulation. Joint procurement of medical countermeasures is aimed at strengthening the negotiating position of participating countries, contributing to the contracting authorities' security of supply and ensuring equitable access to medical countermeasures against serious cross-border threats to health. Joint procurement procedures should abide by high standards of transparency in relation to Union institutions, including the European Court of Auditors, and Union citizens, in accordance with the principle of transparency as referred to in Article 15 TFEU. While taking into account the protection of commercially sensitive information and the protection of essential national security interests, transparency should also be encouraged in relation to the disclosure of information related to the delivery schedule of the medical countermeasures, terms of liabilities and indemnifications and the number of manufacturing locations. A high degree of transparency should be applied in accordance with Regulation (EC) No 1049/2001. This includes the right of citizens to request access to documents regarding jointly procured medical countermeasures in accordance with Article 2 of Regulation (EC) No 1049/2001. When joint procurement is deployed, in addition to cost, qualitative criteria should be considered in the award process.
- (21) Prevention is one of the essential steps in the crisis management cycle, according to the WHO. Under the four categories of prevention that have been recognised at the international level, namely primary, secondary, tertiary and quaternary categories, a number of activities constitute a cornerstone for early warning of, monitoring and combatting serious cross-border threats to health. Those activities include the monitoring of vaccination coverage for communicable diseases, surveillance systems for the prevention of communicable diseases and measures to decrease the risk of communicable disease spreading at the personal and community levels, in line with the One Health approach. Investment in prevention activities in relation to serious cross-border threats to health would directly contribute to the objectives of this Regulation. The term 'prevention' or 'disease prevention' under this Regulation should therefore be understood as covering prevention activities which aim to minimise the burden of communicable diseases and associated risk factors for the purposes of early warning of, monitoring and combatting serious cross-border threats to health.
- (22) The strengthened Union health framework addressing serious cross-border threats to health should work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, established by Regulation (EU) 2021/522 of the European Parliament and of the Council ⁽¹²⁾; the European Structural and Investment Funds (ESIF), namely the European Regional Development Fund and the Cohesion Fund, established by Regulation (EU) 2021/1058 of the European Parliament and of the Council ⁽¹³⁾, the European Social Fund Plus, established by Regulation (EU) 2021/1057 of the European Parliament

⁽¹¹⁾ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

⁽¹²⁾ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

⁽¹³⁾ Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60).

and of the Council ⁽¹⁴⁾, the European Agricultural Fund for Rural Development, established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽¹⁵⁾, and the European Maritime, Fisheries and Aquaculture Fund, established by Regulation (EU) 2021/1139 of the European Parliament and of the Council ⁽¹⁶⁾; Horizon Europe, established by Regulation (EU) 2021/695 of the European Parliament and of the Council ⁽¹⁷⁾; the Digital Europe Programme, established by Regulation (EU) 2021/694 of the European Parliament and of the Council ⁽¹⁸⁾; the rescEU reserve; the Emergency Support Instrument (ESI), provided for in Council Regulation (EU) 2016/369 ⁽¹⁹⁾; and the Single Market Programme (SMP), established by Regulation (EU) 2021/690 of the European Parliament and of the Council ⁽²⁰⁾.

- (23) The decision taken by the World Health Assembly during its Special Session on 1 December 2021 is set to start a global process for a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. In accordance with Council Decision (EU) 2022/451 ⁽²¹⁾, the Union should engage with the WHO and its Member States to develop a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. The Union will engage with the WHO and its Member States to develop a new legally binding instrument that complements the IHR, thereby strengthening multilateralism and the global health architecture. The Union should also support efforts to strengthen the implementation of and compliance with the IHR.
- (24) The COVID-19 pandemic has highlighted that major diseases can put severe pressure on the capacities of healthcare systems, with a negative impact, for example, on the provision of healthcare for patients with other communicable or non-communicable diseases, such as the continuity of healthcare, delay of or interruption to treatment for cancer patients and survivors and people with mental health issues. The impact of serious cross-border threats to health may thus pose further challenges in ensuring a high level of human health protection. While respecting the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, it is important to consider the impact of public health emergencies on the provision of healthcare services for other diseases and conditions, in order to safeguard the detection and treatment of other serious diseases and minimise delays or interruptions to such detection and treatment. Hence, the impact an important outbreak of a communicable disease, which absorbs an important part of health system capacities, can have on the continuity of healthcare and on the prevention and treatment of non-communicable diseases and comorbidities needs to be considered.

⁽¹⁴⁾ Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).

⁽¹⁵⁾ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

⁽¹⁶⁾ Regulation (EU) 2021/1139 of the European Parliament and of the Council of 7 July 2021 establishing the European Maritime, Fisheries and Aquaculture Fund and amending Regulation (EU) 2017/1004 (OJ L 247, 13.7.2021, p. 1).

⁽¹⁷⁾ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

⁽¹⁸⁾ Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021, p. 1).

⁽¹⁹⁾ Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

⁽²⁰⁾ Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014 (OJ L 153, 3.5.2021, p. 1).

⁽²¹⁾ Council Decision (EU) 2022/451 of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005) (OJ L 92, 21.3.2022, p. 1).

- (25) In times of crisis, ensuring the security of supply within the Union of critical medical countermeasures is paramount, and the experience derived from the COVID-19 pandemic has shown that this could be prejudiced by a number of factors. Union actions to safeguard commitments and protect the supply of medical countermeasures include, among others, an export authorisation mechanism pursuant to Regulation (EU) 2015/479 of the European Parliament and of the Council ⁽²²⁾, enhanced cooperation agreements and procurement activities. Where relevant, actions taken under this Regulation should consider the potential activation of such mechanisms, pursuant to applicable Union legislation.
- (26) Unlike communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other serious cross-border threats to health do not currently necessitate systematic monitoring by Union agencies and bodies. A risk-based approach, whereby monitoring is carried out by Member States' monitoring systems and available information is exchanged through the EWRS, is therefore more appropriate to those threats.
- (27) The Commission should strengthen cooperation and activities with the Member States, the ECDC, EMA, other Union agencies or bodies, research infrastructures and the WHO to improve, through the One Health approach, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.
- (28) In the case of cross-border threats to health posed by a communicable disease, the ECDC should cooperate with Member States to safeguard patients in need of treatment by substances of human origin from the transmission of such a communicable disease. The ECDC should therefore establish and operate a network of services supporting the use of substances of human origin.
- (29) The EWRS, a system enabling the notification at Union level of alerts related to serious cross-border threats to health, has been put in place by Decision No 1082/2013/EU in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS.

In order to foster the effectiveness of alert systems for cross-border threats to health, the Commission should be encouraged to integrate information in an automatic manner from different important databases, such as those comprising environmental data, climate data, water irrigation data and other data relevant to serious cross-border threats to health, which could facilitate understanding and mitigate the risk of potential health threats. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at Union level. The EWRS should be further developed and improved to augment the automation of information collection and analysis, reduce the administrative burden and improve the standardisation of the notifications. To avoid duplication and ensure coordination across Union alert systems, the Commission and the ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are interoperable and, subject to human oversight, automatically linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source. Those national authorities should notify the relevant serious cross-border threats to health events in the EWRS. It allows simultaneous notification to be provided to the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR.

- (30) In order to ensure that the assessment of risks to public health at Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated and multidisciplinary manner through appropriate channels or structures, depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and

⁽²²⁾ Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports (OJ L 83, 27.3.2015, p. 34).

transparency. The involvement of Union agencies and bodies in those risk assessments needs to be broadened according to their speciality in order to ensure an all-hazard approach, via a permanent network of agencies and bodies and relevant Commission services to support the preparation of risk assessments. It is important that the Commission, at the request of the HSC or on its own initiative, and in close cooperation with the relevant Union agencies and bodies or Commission services, provide any relevant information, data and expertise at its disposal. Serious cross-border threats to health could require a multidisciplinary approach for their assessment and analysis, and coordination among Union agencies and bodies or Commission services might therefore be essential to ensure a swift and coordinated reaction. Where relevant, such coordination could, in particular, take the form of a multi-source risk assessment under the lead of a particular Union agency or body designated by the Commission. Union agencies and bodies should have adequate financial and human resources to achieve a sufficient degree of expertise and effectiveness in the framework of their mandates.

- (31) Member States, the Commission and Union agencies and bodies, while following the One Health approach, should identify recognised public health organisations and experts, and other relevant stakeholders across sectors, which are available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be engaged in the context of Union preparedness and response activities to contribute, where relevant, to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this Regulation, where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.
- (32) Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect other Member States if they are inconsistent with one another or based on diverging risk assessments. The objective of coordinating the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the TFEU, such as those related to free movement of persons, goods and services.
- (33) The HSC, which is responsible for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for Member States related to the prevention and control of serious cross-border threats to health. Furthermore, should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures. In addition, regular dialogue between the HSC and relevant Council bodies should be reinforced in order to ensure better follow-up of the HSC's work at national level.
- (34) Inconsistent communication with the public and stakeholders, such as healthcare and public health professionals, can have a negative impact on the effectiveness of the response from a public health perspective, as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and address communication challenges with a view to coordinating risk and crisis communication, based on holistic, robust and independent evaluation of public health risks, to be adapted to national and regional needs and circumstances where relevant. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. To that end, relevant public institutions should contribute to sharing verified information and fighting disinformation. Given the cross-sectoral nature of health-related crises, coordination should also be ensured with other relevant constituencies, such as the EU Civil Protection Community.
- (35) The recognition of public health emergencies and the legal effects of this recognition provided for in Decision No 1082/2013/EU should be broadened. To that end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of such emergency recognition. The advisory committee should consist of independent experts, including representatives of healthcare and social care workers and civil society representatives, selected by the Commission

from the fields of expertise and experience most relevant to the specific threat that is occurring. Representatives of the Member States, of the ECDC, of EMA, and of other Union agencies or bodies or of the WHO, should be able to participate as observers. All members of the Advisory Committee should provide declarations of interest. Recognition of a public health emergency at Union level should provide the basis for introducing operational public health measures for medicinal products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as the 'EU Health Task Force'.

- (36) Before recognising a public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the outbreak and to inform the WHO of its intention to adopt such a recognition decision. Where such a recognition decision is adopted, the Commission should also inform the WHO thereof.
- (37) The occurrence of an event that corresponds to a serious cross-border threat to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such coordination could require the exchange of personal data, including sensitive information related to health and information about confirmed or suspected human cases of the disease or infection, between those Member States directly involved in the contact-tracing measures.
- (38) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to the Union's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alert systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network, such as the European Surveillance Portal for Infectious Diseases, operated by the ECDC, and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response. Those international cooperation agreements could also facilitate the donation of medical countermeasures, in particular for the benefit of low- and middle-income countries.
- (39) Any processing of personal data for the purpose of implementing this Regulation should be fully compliant with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽²³⁾ and Directive 2002/58/EC of the European Parliament and of the Council ⁽²⁴⁾. Processing of personal data should be limited to what is strictly necessary and, whenever possible, those data should be anonymised. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact-tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated where necessary to relevant authorities involved in contact-tracing measures, medical evacuation or other cross-border procedures. In the case of cooperation between the health authorities of the Union and third countries, the WHO or other international organisations, transfers of personal data to third countries or international organisations should always comply with the obligations laid down under Regulation (EU) 2018/1725.

⁽²³⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁽²⁴⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

- (40) In order to avoid an administrative burden and the duplication of efforts, overlap of reporting and reviewing activities with existing structures and mechanisms for prevention, preparedness and response planning and implementation at national level in relation to serious cross-border threats to health should be avoided as far as possible. To that end, Member States should not be requested to report data and information if already required by the Commission or other Union agencies and bodies, pursuant to applicable Union legislation. In addition, the Union should further enhance its cooperation with the WHO, in particular under the IHR reporting, monitoring and evaluation frameworks.
- (41) Since the objectives of this Regulation, namely to address serious cross-border threats to health and the consequences thereof, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (42) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.
- (43) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to: templates to be used when providing the information on preparedness and response planning; the organisation of the training activities and programmes for healthcare and public health staff; the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the functioning of the digital platform for surveillance; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange, for consultation with Member States and for coordination of the responses of the Member States; the recognition of public health emergencies at Union level and the termination of such a recognition; the procedures for the interlinking of the EWRS with contact-tracing systems and the procedures necessary to ensure that the processing of data is in accordance with the data protection legislation.
- (44) Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽²⁵⁾. As the implementing acts provided for in this Regulation concern the protection of human health, the Commission cannot adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with Article 5(4), second subparagraph, point (a), of Regulation (EU) No 182/2011.
- (45) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States, imperative grounds of urgency so require.
- (46) In order to supplement certain aspects of this Regulation and to assess the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of: the cases and the conditions under which third countries and international organisations can be granted partial access to the functionalities of the digital platform for surveillance, certain data, information and documents which can be transmitted using the platform and the conditions under which the ECDC can participate and be granted access to the health data accessed or exchanged through digital infrastructure, the detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with the data protection regulations, a list of categories of personal data that might be exchanged for the purpose of contact tracing and the procedures, standards and criteria for the assessment of the prevention, preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and

⁽²⁵⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽²⁶⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

- (47) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and published formal comments on its website on 8 March 2021.
- (48) This Regulation fully respects the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union.
- (49) Decision No 1082/2013/EU should therefore be repealed and replaced by this Regulation,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. In order to address serious cross-border threats to health and the consequences thereof, this Regulation lays down rules on:
 - (a) the Health Security Committee (HSC);
 - (b) prevention, preparedness and response planning, including:
 - (i) preparedness plans at Union and national levels; and
 - (ii) reporting and assessing preparedness at national level;
 - (c) joint procurement of medical countermeasures;
 - (d) emergency research and innovation;
 - (e) epidemiological surveillance and monitoring;
 - (f) the network for epidemiological surveillance;
 - (g) the Early Warning and Response System (EWRS);
 - (h) risk assessment;
 - (i) coordination of response; and
 - (j) recognition of a public health emergency at Union level.
2. This Regulation establishes:
 - (a) a network of EU reference laboratories for public health;
 - (b) a network for substances of human origin; and
 - (c) an advisory committee for the occurrence and recognition of a public health emergency at Union level.
3. In line with the One Health and Health in All Policies approaches, the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

⁽²⁶⁾ OJ L 123, 12.5.2016, p. 1.

*Article 2***Scope**

1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:
 - (a) threats of biological origin, consisting of:
 - (i) communicable diseases, including those of zoonotic origin;
 - (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases ('related special health issues');
 - (iii) biotoxins or other harmful biological agents not related to communicable diseases;
 - (b) threats of chemical origin;
 - (c) threats of environmental origin, including those due to the climate;
 - (d) threats of unknown origin; and
 - (e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR) ('public health emergencies of international concern'), provided that they fall under one of the categories of threats set out in points (a) to (d).
2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.
3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring and early warning of serious cross-border threats to health, and the coordination of prevention, preparedness and response planning for, and the coordination of combatting, serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.
4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.
5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at international level, Union level or under the Euratom Treaty, whose activities are relevant for prevention, preparedness and response planning for, monitoring, early warning of, and combatting serious cross-border threats to health.
6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the implementation of this Regulation.

*Article 3***Definitions**

For the purposes of this Regulation, the following definitions apply:

- (1) 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, as referred to in Article 2(1), which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

- (2) 'case definition' means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;
- (3) 'communicable disease' means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent;
- (4) 'contact tracing' means measures to identify persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of being infected or being infectious or who have developed a communicable disease, through manual or other technological means, with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission;
- (5) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;
- (6) 'monitoring' means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data on and analysis of specified indicators relating to serious cross-border threats to health;
- (7) 'One Health' means a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;
- (8) 'Health in All Policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;
- (9) 'public health measure' means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combatting severe risks to public health or mitigating their impact on public health;
- (10) 'medical countermeasures' means medicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council ⁽²⁷⁾, medical devices as defined in point 12 of this Article and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health;
- (11) 'International Health Regulations' means the International Health Regulations (IHR) adopted by the World Health Organization (WHO) in 2005;
- (12) 'medical device' means both a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽²⁸⁾, read in conjunction with Article 1(2) and Article 1(6), point (a), of that Regulation, and an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽²⁹⁾;
- (13) 'health system capacity' means the degree to which a health system maximizes its performance on the following six health system core components or building blocks: (i) service delivery, (ii) health workforce, (iii) health information systems, (iv) access to medical countermeasures, (v) financing, and (vi) leadership/governance; for the purposes of this Regulation, this definition applies only to the parts of health system components or building blocks affected by serious cross-border threats to health.

⁽²⁷⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11. 2001, p. 67).

⁽²⁸⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽²⁹⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5. 2017, p. 176).

*Article 4***Health Security Committee**

1. The HSC is hereby established. It shall be composed of representatives of the Member States at two working levels:
 - (a) a senior level working group for regular discussions on serious cross-border threats to health and for the adoption of opinions and guidance as referred to in paragraph 3, point (d); and
 - (b) technical working groups to discuss specific topics if necessary.
2. Representatives of relevant Union agencies and bodies may participate in HSC meetings as observers.
3. The HSC shall have the following tasks in cooperation with relevant participating Union agencies and bodies:
 - (a) enabling coordinated action by the Commission and the Member States for the implementation of this Regulation;
 - (b) coordinating in liaison with the Commission prevention, preparedness and response planning in accordance with Article 10;
 - (c) coordinating in liaison with the Commission the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;
 - (d) adopting opinions and guidance, including on specific response measures, for the Member States for the prevention and control of serious cross-border threats to health, based on the expert opinion of relevant technical Union agencies or bodies; and
 - (e) adopting, on an annual basis, a work programme setting its priorities and objectives.
4. As far as possible, the HSC shall adopt its guidance and opinions by consensus.

In the event of a vote, the outcome of the vote shall be decided by a two-thirds majority of its members.

The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the guidance or opinions.

5. The HSC shall be chaired by a representative of the Commission without the right to vote. The HSC shall meet at regular intervals and whenever the situation requires, at the request of the Commission or a Member State.
6. The secretariat of the HSC shall be provided by the Commission.
7. The HSC and the Commission shall ensure regular consultation with public health experts, international organisations and stakeholders, including healthcare professionals, depending on the sensitivity of the subject.
8. The HSC shall adopt, by a two-thirds majority of its members, its rules of procedure. Those rules of procedure shall establish working arrangements, in particular with regard to:
 - (a) the procedures for plenary meetings;
 - (b) the participation of experts in plenary meetings, the status of possible observers, including from the European Parliament, Union agencies and bodies, third countries and the WHO; and

- (c) the examination by the HSC of the relevance to its mandate of a matter submitted to it and the possibility of recommending referral of that matter to a body competent under a provision of another act of the Union or under the Euratom Treaty.

The working arrangements relating to the first subparagraph, point (c), shall not affect the obligations of the Member States under Articles 10 and 21 of this Regulation.

9. Member States shall designate one representative and not more than two alternate members of the HSC.

Member States shall notify the Commission and other Member States of the designations referred to in the first subparagraph and of any change thereto. In the event of such a change, the Commission shall make available to the HSC's members an updated list of such designations.

10. The European Parliament shall designate a technical representative to participate in the HSC as an observer.

11. The list setting out the authorities, organisations or bodies to which the HSC participants belong shall be published on the Commission's website.

12. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's website unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001.

CHAPTER II

PREVENTION, PREPAREDNESS AND RESPONSE PLANNING

Article 5

Union prevention, preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies and bodies, and in accordance with the WHO emergency preparedness and response framework set out in the IHR, shall establish a Union health crisis and pandemic plan ('the Union prevention, preparedness and response plan') to promote an effective and coordinated response to cross-border threats to health at Union level.
2. The Union prevention, preparedness and response plan shall complement the national prevention, preparedness and response plans established in accordance with Article 6, and shall promote effective synergies between the Member States, the Commission, the European Centre for Disease Prevention and Control (ECDC) and other relevant Union agencies or bodies.
3. The Union prevention, preparedness and response plan shall, in particular, include provisions on joint arrangements for governance, capacities and resources for:
 - (a) the timely cooperation between the Commission, the Council, the Member States, the HSC and the relevant Union agencies or bodies. The Union prevention, preparedness and response plan shall take into account the services and support potentially available under the Union Civil Protection Mechanism, and, in particular, the capacities under the rescEU stockpile as laid down in Commission Implementing Decision (EU) 2019/570 ⁽³⁰⁾ or other mechanisms, the capacities and resources made available for its purposes by the Union and the Member States, and the cooperation with the WHO for cross-border threats to health;

⁽³⁰⁾ Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

- (b) the secure exchange of information between the Commission, the Member States, in particular the competent authorities or designated bodies responsible at national level, the HSC and the relevant Union agencies or bodies;
- (c) the epidemiological surveillance and monitoring;
- (d) the early warning and risk assessment, especially regarding cross-border interregional preparedness and response;
- (e) the risk and crisis communication, including to health professionals and citizens;
- (f) the health preparedness and response and multi-sectoral collaboration, such as identifying risk factors for disease transmission and the associated disease burden, including social, economic and environmental determinants, following the One Health approach for zoonotic, food and waterborne diseases and relevant other diseases and related special health issues;
- (g) the drawing up of an overview of the production capacities for relevant critical medical countermeasures in the Union as a whole to address serious cross-border threats to health as referred to in Article 2;
- (h) emergency research and innovation;
- (i) the management of the plan; and
- (j) support to Member States for the monitoring of the impact of a serious cross-border threat to health on the provision and continuity of healthcare services, including for other diseases and conditions during health emergencies.

4. The Union prevention, preparedness and response plan shall include cross-border interregional preparedness elements to support aligned, multi-sectoral, cross-border public health measures, in particular considering capacities for surveillance, testing, contact tracing, laboratories, training of healthcare staff and specialised treatment or intensive care across neighbouring regions. The Union prevention, preparedness and response plan shall take into account national respective circumstances and include preparedness and response means to address the situation of citizens with higher risks.

5. In order to ensure the implementation of the Union prevention, preparedness and response plan, the Commission shall facilitate, in collaboration with Member States and, when applicable, with relevant Union agencies or bodies or with international organisations, stress tests, simulation exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

6. The Commission may provide technical assistance, at the Member States' request, to support the development of their staffing plans in order to address specific healthcare needs and facilitate exchange of staff between Member States in the event of a serious cross-border threat to health.

7. The reviews of and any subsequent adjustments to the plan shall be published.

Article 6

National prevention, preparedness and response plans

1. Without prejudice to Member States' competences in this area, when preparing national prevention, preparedness and response plans, Member States shall liaise with each other within the HSC and coordinate with the Commission in order to seek coherence with the Union prevention, preparedness and response plan to the largest possible extent.

2. National prevention, preparedness and response plans may include elements relating to governance, capacities and resources laid down in the Union prevention, preparedness and response plan as referred to in Article 5.

3. Member States shall also inform, without delay, the Commission and the HSC of any substantial revision of their national prevention, preparedness and response plan.

4. For the purposes of paragraph 1, Member States may also consult, where relevant, patient organisations, healthcare professionals' organisations, industry and supply chain stakeholders, as well as national social partners.

*Article 7***Reporting on prevention, preparedness and response planning**

1. By 27 December 2023 and every three years thereafter, Member States shall provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness and response planning and implementation at national level and, where appropriate, cross-border interregional levels.

That report shall be succinct, based on agreed common indicators, shall give an overview of the actions implemented in the Member States, and shall cover the following:

- (a) identification of, and an update on, the status of the implementation of the capacity standards for prevention, preparedness and response planning as determined at national and, where appropriate, cross-border interregional level for the health sector, as provided to the WHO in accordance with the IHR, as well as, where available, the interoperability arrangements between the health sector and other critical sectors in emergency situations;
- (b) an update, where necessary, on the elements of emergency prevention, preparedness and response planning, in particular:
 - (i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency and preparedness actions; plans for emergency prevention, preparedness, response and recovery; coordination mechanisms, including, where relevant, among national, regional or local administrative levels and in terms of multi-sectoral collaboration;
 - (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; business continuity measures and arrangements aimed at ensuring continuous access to diagnostic services, tools and medicinal products during emergencies, where available; basic and safe gender-sensitive health and emergency services; an overview of the impact of serious cross-border threats to health on the provision and continuity of healthcare services for other diseases and conditions during public health emergencies; risk communications; research development and evaluations to inform and accelerate emergency preparedness; and
 - (iii) resources: including financial resources for emergency preparedness and contingency funding for response; essential supplies for health; logistics mechanisms, including for the storage of medical countermeasures; dedicated, trained and equipped human resources for emergencies;
- (c) implementation of national prevention, preparedness and response plans, including where relevant implementation at the regional and, if appropriate, local levels, covering epidemic response; antimicrobial resistance, healthcare-associated infection, and the other serious cross-border threats to health as referred to in Article 2;
- (d) where applicable, consultation with relevant partners on risk assessment and national prevention, preparedness and response plans; and
- (e) actions taken to improve gaps found in the implementation of national prevention, preparedness and response plans.

The report shall include, where relevant, cross-border interregional and intersectoral prevention, preparedness and response elements involving neighbouring regions. Such elements shall include coordination mechanisms for the relevant elements of Union and national prevention, preparedness and response plans, including cross-border training and sharing of best practices for healthcare staff and public health staff, and coordination mechanisms for the medical transfer of patients.

2. Every three years, the Commission shall make the information received in accordance with paragraph 1 of this Article available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies.

The report shall include country profiles for monitoring progress and developing action plans, taking into account national respective circumstances, to address identified gaps at national level. For that purpose, the Commission may issue general recommendations, considering the outcomes of the assessment carried out under Article 8.

Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC on the progress and gaps in preparedness, thereby allowing for continuous improvement.

An overview of the recommendations of the report on preparedness for and response to serious cross-border threats to health referred to in Article 2(1) shall be published on the websites of the Commission and the ECDC.

3. The Commission shall, by means of implementing acts, adopt templates to be used by the Member States when providing the information referred to in paragraph 1 of this Article, in order to ensure its relevance to the objectives identified in that paragraph and its comparability, while avoiding any duplication of the information requested and submitted.

The templates shall be designed in collaboration with the HSC and shall be, as far as possible, consistent with templates used under the IHR State Parties reporting framework.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

4. When receiving classified information transmitted pursuant to paragraph 1, the Commission, the ECDC and the HSC shall apply the rules on security regarding the protection of European Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 ⁽³¹⁾ and (EU, Euratom) 2015/444 ⁽³²⁾.

5. Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 1 and 2, where it is classified as European Union classified information. Those national security regulations shall offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Decision (EU, Euratom) 2015/444 and in Council Decision 2013/488/EU ⁽³³⁾.

Article 8

Assessment of prevention, preparedness and response planning

1. Every three years, the ECDC shall assess the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan. Such assessments shall be based on a set of agreed indicators and carried out in cooperation with the relevant Union agencies or bodies and shall aim to assess prevention, preparedness and response planning at national level with regard to the information referred to in Article 7(1).

2. The ECDC shall, if applicable, present to the Member States and to the Commission recommendations based on the assessments referred to in paragraph 1, addressed to Member States, taking into account national respective circumstances.

3. Member States shall, if applicable, present to the Commission and the ECDC in a timely manner within nine months of the receipt of the ECDC conclusions, an action plan addressing the proposed recommendations of the assessment, together with the corresponding recommended actions and milestones.

If a Member State decides not to follow a recommendation, it shall state its reasons for so deciding.

Those actions may, in particular, include:

- (a) regulatory actions, if necessary;
- (b) training initiatives;
- (c) an overview of good practices.

⁽³¹⁾ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁽³²⁾ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

⁽³³⁾ Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

4. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation concerning procedures, standards and criteria for the assessments referred to in paragraph 1 of this Article.

Article 9

Commission report on prevention, preparedness and response planning

1. On the basis of the information provided by the Member States in accordance with Article 7 and the results of the assessment referred to in Article 8, the Commission shall by 27 December 2023 and every three years thereafter, transmit to the European Parliament and to the Council a report on the state of play and progress on prevention, preparedness and response planning at Union level.
2. The Commission report shall include, where applicable, cross-border preparedness and response elements in neighbouring regions.
3. Based on its report, the Commission may support the action of the Member States through the adoption of general recommendations on prevention, preparedness and response planning.

Article 10

Coordination of prevention, preparedness and response planning in the HSC

1. The Commission, relevant Union agencies and bodies and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for monitoring, early warning and assessment of, and response to, serious cross-border threats to health.

The coordination shall, in particular, aim to:

- (a) share best practice and experience in prevention, preparedness and response planning;
 - (b) promote the interoperability of national prevention and preparedness planning and the multi-sectoral dimension of prevention, preparedness and response planning at Union level;
 - (c) support the implementation of capacity requirements for surveillance and response as referred to in the IHR;
 - (d) support the development of the prevention, preparedness and response plans referred to in Articles 5 and 6;
 - (e) monitor and discuss progress for gaps identified and actions to strengthen prevention, preparedness and response planning, including in the field of research, at cross-border regional, national and Union levels; and
 - (f) facilitate the exchange, outside the joint procurement procedure laid down in Article 12, of information on medical countermeasures, including, where appropriate, on pricing and delivery dates.
2. The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations.
 3. The HSC shall also coordinate, where relevant, response to public health emergencies with the Health Crisis Board, where it is established in accordance with Regulation (EU) 2022/2372, and contribute accordingly to the coordination and information exchange within that body.

Article 11

Training of healthcare staff and public health staff

1. The Commission may organise training activities, in close cooperation with the relevant Union agencies and bodies and professional health organisations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States, in particular interdisciplinary One Health training, including on preparedness capacities under the IHR.

The Commission shall organise those activities in cooperation with the Member States concerned, as well as with the ECDC, in particular the EU Health Task Force, and in coordination, where possible, with the WHO. The Commission shall make the fullest use of the potential of distance learning to increase the number of trainees.

In cross-border regions, joint cross-border training, sharing of best practices and familiarity with public health systems for healthcare staff and public health staff shall be promoted.

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with the knowledge and skills necessary, in particular, to develop and implement the national prevention, preparedness and response plans, and implement activities to strengthen crisis preparedness and surveillance capacities, especially regarding the gaps identified, including in relation to the use of digital tools, and shall be consistent with the One Health approach.

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union in coordination, where possible, with ECDC activities in this area.

4. Bodies whose staff participate in the training activities referred to in paragraph 1 shall ensure that the knowledge acquired through those activities is disseminated as necessary and is appropriately used in the staff training activities they organise.

5. The Commission and relevant Union agencies and bodies may support the organisation of programmes, in cooperation with the Member States and Union candidate countries, for the exchange of healthcare staff and public health staff, as well as for the temporary secondment of staff between Member States, Union candidate countries or Union agencies and bodies. In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States.

6. The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

Article 12

Joint procurement of medical countermeasures

1. The Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 with a view to the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable time frame.

2. A joint procurement procedure as referred to in paragraph 1 shall be preceded by a Joint Procurement Agreement between the parties determining the practical arrangements governing that procedure and the decision-making process with regard to the choice of the procedure, the joint procurement assessment as referred to in paragraph 3, point (c), the assessment of the tenders and the award of the contract.

3. The joint procurement procedure referred to in paragraph 1 of this Article shall comply, where it is used to procure medical countermeasures in accordance with this Regulation, including in the framework of Article 8(1) of Regulation (EU) 2022/2372, with the following conditions:

- (a) participation in the joint procurement procedure is open to all Member States, European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046;
- (b) the rights and obligations of the countries referred to in point (a) that do not participate in the joint procurement are respected, in particular those relating to the protection and improvement of human health;

- (c) before the launch of a joint procurement procedure, the Commission prepares a joint procurement assessment which shall indicate the general envisaged conditions of the joint procurement procedure, including as regards possible restrictions to parallel procurement and negotiation activities by the participating countries for the countermeasure in question during the specific joint procurement procedure; that assessment shall take into account the need to ensure security of supply of medical countermeasures concerned to the participating countries. Based on the joint procurement assessment and the relevant information provided therein, such as on envisaged price ranges, manufacturers, delivery time frames and the proposed deadline for decision on participation, the parties to the Joint Procurement Agreement shall express their interest in participating at an early stage. Those parties to the Joint Procurement Agreement which have expressed their interest shall subsequently decide on their participation in the joint procurement procedure under the conditions jointly agreed with the Commission, taking into account the information proposed in the joint procurement assessment;
- (d) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade and does not cause distortion of competition; and
- (e) the joint procurement does not have any direct financial impact on the budget of the countries referred to in point (a) that do not participate in the joint procurement.

4. The Commission shall, in liaison with the Member States, ensure coordination and the exchange of information between the entities organising and participating in any action, including, but not limited to, joint procurement procedures for and development, stockpiling, distribution and donation of medical countermeasures, under different mechanisms established at Union level, in particular under:

- (a) stockpiling under rescEU referred to in Article 12 of Decision No 1313/2013/EU;
- (b) Regulation (EU) 2016/369;
- (c) the Pharmaceutical Strategy for Europe;
- (d) the EU4Health Programme established by Regulation (EU) 2021/522;
- (e) Regulation (EU) 2021/697 of the European Parliament and of the Council ⁽³⁴⁾; and
- (f) other programmes and instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies, such as measures adopted under Regulation (EU) 2022/2372.

5. The Commission shall inform the European Parliament about procedures concerning the joint procurement of medical countermeasures and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall communicate information to the European Parliament regarding sensitive documents in accordance with Article 9(7) of Regulation (EC) No 1049/2001.

CHAPTER III

EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING

Article 13

Epidemiological surveillance

1. The network for the epidemiological surveillance of communicable diseases, including those of zoonotic origin, and related special health issues referred to in Article 2(1), points (a)(i) and (a)(ii), ('the network for epidemiological surveillance') shall ensure permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

⁽³⁴⁾ Regulation (EU) 2021/697 of the European Parliament and of the Council of 29 April 2021 establishing the European Defence Fund and repealing Regulation (EU) 2018/1092 (OJ L 170, 12.5.2021, p. 149).

The ECDC shall ensure the integrated operation of the network for epidemiological surveillance as set out in Article 5 of Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽³⁵⁾.

Whenever relevant, the network for epidemiological surveillance shall work in close cooperation with the competent bodies of the organisations operating in the field of epidemiological surveillance of communicable diseases and of related special health issues, from the Union, third countries, the WHO, and other international organisations.

2. The network for epidemiological surveillance shall aim to:

- (a) monitor trends in communicable diseases over time, across Member States and in third countries, to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;
- (b) detect and monitor any cross-border communicable disease outbreaks with regard to source, time, population and place in order to provide a rationale for public health action;
- (c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve those programmes at the national and Union levels;
- (d) identify and monitor risk factors for disease transmission, and population groups at risk and in need of targeted prevention measures;
- (e) contribute to the assessment of the burden of communicable diseases on the population, using such data as disease prevalence, complications, hospitalisation and mortality;
- (f) contribute to the assessment of the capacity of health systems to diagnose, prevent and treat specific communicable diseases, with the objective of contributing to patient safety in the context of serious cross-border threats to health;
- (g) contribute to modelling and scenario development for response;
- (h) contribute to the identification of research priorities and needs, and implement relevant research activities aimed at strengthening public health; and
- (i) support the contact-tracing measures of competent health authorities.

3. The national competent authorities referred to in paragraph 1 shall communicate the following information, based on agreed indicators and standards, to the participating authorities of the network for epidemiological surveillance:

- (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in Article 2(1), points (a)(i) and (a)(ii);
- (b) relevant information concerning the progression of epidemic situations, including for modelling and scenario development;
- (c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;
- (d) molecular pathogen data, if required for detecting or investigating serious cross-border threats to health;
- (e) health systems data required for managing serious cross-border threats to health; and
- (f) information about contact-tracing monitoring systems developed at national level.

4. The information communicated by the national competent authorities referred to in paragraph 3, point (a), may be, when available, reported at least at NUTS II level to the European Surveillance Portal for Infectious Diseases operated by the ECDC, on a timely basis.

5. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 10 for each communicable disease and related special health issue referred to in paragraph 1.

⁽³⁵⁾ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

6. The Commission and the Member States shall work together to strengthen the data collection and sharing capacity of Member States and to define disease-specific European surveillance standards based on the proposal of the ECDC, in consultation with the relevant surveillance networks.

7. The ECDC shall monitor and evaluate the epidemiological surveillance activities of dedicated networks on surveillance, including adherence to the surveillance standards referred to in paragraph 6; support Member States with scientific and technical advice to improve the timeliness, completeness and quality of the surveillance data reported; and share regular monitoring reports with the HSC and the Commission. The ECDC shall also, where applicable and in accordance with Regulation (EC) No 851/2004, make available its expertise on epidemiological surveillance to third countries.

The ECDC shall regularly provide an overview to the HSC on the timeliness, completeness and quality of the surveillance data reported to it.

The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis for the purposes of paragraph 2.

8. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States. The HSC may adopt communications and recommendations on surveillance addressed to Member States, the ECDC and the Commission.

9. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.

10. The Commission shall, by means of implementing acts, establish and update:

- (a) the list, on the basis of the criteria listed in Section 1 of Annex I, of communicable diseases and related special health issues referred to in Article 2(1), points (a)(i) and (a)(ii), in order to ensure coverage of communicable diseases and related special health issues by the network for epidemiological surveillance;
- (b) case definitions, on the basis of the criteria listed in Section 2 of Annex I, concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ensure the comparability and compatibility at Union level of the collected data; and
- (c) procedures, as set out in Section 3 of Annex I to this Regulation, for the operation of the network for epidemiological surveillance, as developed pursuant to Article 5 of Regulation (EC) No 851/2004.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

11. On duly justified imperative grounds of urgency relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 29(3), for the adoption of case definitions, procedures and indicators for surveillance in Member States in the event of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii). Those indicators for surveillance shall also support the assessment of capacity for diagnosis, prevention and treatment.

Article 14

Digital platform for surveillance

1. The ECDC shall ensure the continued development of the digital platform for surveillance, after conducting data protection impact assessments and having mitigated any risks to the rights and freedoms of the data subjects, as appropriate, through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control. The ECDC shall ensure that the operation of the digital platform for surveillance is subject to human oversight and shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as establish robust procedures for data quality review. The ECDC, in close cooperation with Member States, shall also ensure the interoperability of the digital platform for surveillance with national systems.

2. The digital platform for surveillance shall:

- (a) enable the automated collection of surveillance and laboratory data, make use of relevant non-personal health data from a previously defined and authorised list from electronic health records and health databases, and of media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting, including statistical reporting; and
- (b) allow for the computerised handling and exchange of information, data and documents.

3. Member States shall be responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete and accurate information, data and documents transmitted and exchanged through the digital platform. Member States may promote the automation of this process between the national and the Union surveillance systems.

4. The ECDC shall monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission.

5. For epidemiological surveillance purposes, the ECDC shall also have access to relevant health data accessed or made available through digital infrastructure enabling the use of health data for research, policy-making advice and regulatory purposes.

6. The Commission shall adopt implementing acts for the functioning of the digital platform for surveillance which lay down:

- (a) the technical specifications of the digital platform for surveillance, including the electronic data exchange mechanism for exchanges with existing international and national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;
- (b) the specific rules for the functioning of the digital platform for surveillance, including for the protection of personal data and security of exchange of information;
- (c) contingency arrangements including secure data backups to be applied in the event of unavailability of any of the functionalities of the digital platform for surveillance; and
- (d) arrangements for promoting standardisation of the infrastructure for storage, processing and analysis of data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

7. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation concerning:

- (a) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the digital platform for surveillance and the practical arrangements for such access;
- (b) the cases where, and the conditions under which, the data, information and documents referred to in Article 13 are to be transmitted using the digital platform for surveillance and the list of such data, information and documents; and
- (c) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructure referred to in paragraph 5.

Article 15

EU reference laboratories

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national prevention, preparedness and response plans, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

2. The EU reference laboratories shall be responsible for coordinating the network of national reference laboratories, in particular, in the following areas:

- (a) reference diagnostics, including test protocols;
- (b) reference material resources;
- (c) external quality assessments;
- (d) scientific advice and technical assistance;
- (e) collaboration and research;
- (f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and
- (g) training.

3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with the WHO reference laboratories. The governance structure of that network shall cover cooperation and coordination with existing national and regional reference laboratories and networks.

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period for designation of four years, and be reviewed regularly. Such designations shall establish the responsibilities and tasks of the designated EU reference laboratories.

5. The EU reference laboratories referred to in paragraph 1 shall:

- (a) be impartial, free from any conflict of interest, and, in particular, not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;
- (b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;
- (c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices, and that the latest developments in research at national, Union and international levels are taken into account in their work;
- (e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and
- (f) where relevant, be equipped to comply with relevant biosecurity standards.

In addition to the requirements laid down in the first subparagraph of this paragraph, the EU reference laboratories shall also be accredited in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽³⁶⁾.

6. Grants may be awarded to the EU reference laboratories referred to in paragraph 1 for the costs that they incur in implementing annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with the EU4Health Programme.

Article 16

Network for substances of human origin

1. A network of Member States' services supporting the use of substances of human origin, including transfusion and transplantation, ('the network for substances of human origin') is hereby established to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. The network for substances of human origin shall also ensure that any medically assisted reproduction issues in relation to disease outbreaks, if relevant, are addressed.

⁽³⁶⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

2. The network for substances of human origin shall be operated and coordinated by the ECDC.
3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting the use of substances of human origin, including transfusion and transplantation, referred to in paragraph 1.

Article 17

Ad hoc monitoring

1. Following an alert notified pursuant to Article 19 concerning a serious cross-border threat to health referred to in Article 2(1), point (a)(iii), or in Article 2(1), point (b), (c) or (d), Member States shall, in liaison with the Commission and on the basis of the available information from their monitoring systems, inform each other through the EWRS and, if the urgency of the situation so requires, through the HSC, about developments at national level with regard to the serious cross-border threat to health concerned.
2. The European Surveillance Portal for Infectious Diseases operated by the ECDC shall be used for ad hoc monitoring of a serious cross-border threat to health referred to in Article 2(1), point (a)(iii), or in Article 2(1), point (b), (c) or (d).
3. The information transmitted pursuant to paragraph 1 shall include, in particular, any change in the geographical distribution, spread and severity of the serious cross-border threat to health concerned and in the means of detection, if available.
4. The Commission shall, by means of implementing acts, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt or update the case definitions referred to in the first subparagraph of this paragraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 29(3).

CHAPTER IV

EARLY WARNING AND RESPONSE

Article 18

Early Warning and Response System

1. The EWRS shall enable the Commission, the ECDC, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alert notifications, assessing public health risks and determining the measures that may be required to protect public health.
2. The management and operational use of the EWRS shall involve the exchange of personal data in specific cases where the relevant legal instruments so provide. Such management and use shall include:
 - (a) the processing of personal data of authorised users of the system; and
 - (b) the processing of health data and other personal data when strictly necessary for the purpose for which those data were transmitted, through the EWRS selective messaging functionality, in accordance with Article 28.

Taking into account Member States' opinions, the ECDC shall continuously update the EWRS, allowing for the use of modern technologies such as digital mobile applications, artificial intelligence models, space-enabled applications, or other technologies for automated contact tracing, building upon the contact-tracing technologies developed by the Member

States or by the Union and used for the purpose of combatting serious cross-border threats to health. The ECDC, in close cooperation with Member States, shall facilitate interoperability with national systems for the purposes of the EWRS.

The ECDC shall also provide technical assistance to the competent authorities responsible at national level, including training following updates to the EWRS.

3. Each Member State shall designate the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of early warning and response in accordance with paragraphs 1 and 2 of this Article, as well as Articles 19 and 20.

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union and international levels, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid the overlapping of activities or conflicting actions with existing structures and mechanisms for preparedness for, monitoring, early warning of and combatting serious cross-border threats to health, in a coordinated One Health approach.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

Article 19

Alert notification

1. National competent authorities or the Commission shall notify an alert in the EWRS, where the emergence or development of a serious cross-border threat to health fulfils the following criteria:

- (a) it is unusual or unexpected for the given place and time, it is causing or may cause significant morbidity or mortality in humans, it is growing rapidly or may grow rapidly in scale, or it is exceeding or may exceed national response capacity;
- (b) it affects or may affect more than one Member State; and
- (c) it requires or may require a coordinated response at Union level.

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern, and in the absence of full interoperability between the WHO notification system and the EWRS, national competent authorities shall simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as:

- (a) the type and origin of the agent;
- (b) the date and place of the incident or outbreak;
- (c) means of transmission or dissemination;
- (d) toxicological data;
- (e) detection and confirmation methods;
- (f) public health risks;
- (g) public health measures implemented or intended to be taken at national level;
- (h) measures other than public health measures, including multi-sectoral measures;
- (i) whether there is an urgent need for or shortage of medical countermeasures;
- (j) requests and offers for cross-border emergency assistance, such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions;

- (k) personal data necessary for the purpose of contact tracing in accordance with Article 28;
- (l) any other information relevant to the serious cross-border threat to health in question.

4. The Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response referred to in Article 21, including information relating to serious cross-border threats to health and public health measures related to serious cross-border threats to health, already transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.

5. Member States shall update the information referred to in paragraph 3 as new data become available.

Article 20

Public health risk assessment

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level referred to in Article 21 or at the request of the HSC or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by one or more of the following Union agencies or bodies:

- (a) the ECDC, in accordance with Article 8a of Regulation (EC) No 851/2004, in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), including where it relates to substances of human origin that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of this Regulation;
- (b) the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2022/123 of the European Parliament and of the Council ⁽³⁷⁾, where the serious cross-border threat to health is linked to medicinal products and medical devices;
- (c) the European Food Safety Authority (EFSA), in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽³⁸⁾, in the case of a serious cross-border threat to health referred to in Article 2 of this Regulation where that threat falls under the mandate of EFSA;
- (d) the European Chemicals Agency (ECHA), in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁹⁾, in the case of a serious cross-border threat to health referred to in Article 2(1), point (b) or (c), of this Regulation where that threat falls under the mandate of the ECHA;
- (e) the European Environment Agency (EEA), in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council ⁽⁴⁰⁾, in the case of a serious cross-border threat to health referred to in Article 2(1), point (c), of this Regulation, where that threat falls under the mandate of the EEA;

⁽³⁷⁾ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

⁽³⁸⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽³⁹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽⁴⁰⁾ Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13).

- (f) the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council ⁽⁴¹⁾, in the case of a serious cross-border threat to health referred to in Article 2(1), point (b), of this Regulation, where that threat falls under the mandate of the EMCDDA.

The risk assessment shall be carried out in the case of a threat referred to in Article 2(1) of this Regulation in cooperation with the European Union Agency for Law Enforcement Cooperation (Europol) where the serious cross-border threat to health emanates from terrorist or criminal activity referred to in Article 3 of Regulation (EU) 2016/794 of the European Parliament and of the Council ⁽⁴²⁾; and in cooperation with EMA, where the serious cross-border threat to health is linked to medicinal products.

2. At the request of the Union agency or body carrying out the risk assessment within its mandate, the Union agencies and bodies referred to in paragraph 1 of this Article shall, without undue delay, provide any relevant information and data at their disposal. Processing of personal data, whenever applicable, shall be carried out in accordance with the data protection requirements as laid down in Article 27.

3. Where the risk assessment needed is totally or partially outside the mandates of the Union agencies and bodies referred to in paragraph 1, and is considered necessary for the coordination of the response at Union level, the Commission shall, at the request of the HSC or on its own initiative, provide an ad hoc risk assessment.

4. The Commission shall make risk assessments available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alert systems. Where the risk assessment is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless the immediate publication of the risk assessment is required on grounds of urgency and necessity.

The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.

5. The Commission shall ensure that information that may be relevant for the risk assessment is made available to the national competent authorities through the EWRS and to the HSC.

Article 21

Coordination of response within the HSC

1. Following an alert notification pursuant to Article 19, at the request of the Commission or of a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall consult each other and coordinate within the HSC and in liaison with the Commission with regard to the following:

- (a) national responses, including research needs, to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the IHR and falls within Article 2 of this Regulation;
- (b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public, to healthcare professionals and public health professionals;
- (c) the adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health, based on the expert opinion of relevant technical Union agencies or bodies; and

⁽⁴¹⁾ Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

⁽⁴²⁾ Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

(d) support for the EU Integrated Political Crisis Response Arrangements (IPCR) as referred to in Council Decision 2014/415/EU ⁽⁴³⁾ in the event of its activation.

2. Where a Member State intends to adopt or to terminate public health measures to combat a serious cross-border threat to health, it shall, before adopting or terminating those measures, inform, consult and coordinate with the other Member States, in particular neighbouring Member States, and the Commission on the nature, purpose and scope of those measures, unless the need to protect public health is so urgent that the immediate adoption of those measures is necessary.

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, upon adoption, promptly inform the other Member States and the Commission of the nature, purpose and scope of those measures, especially in cross-border regions.

4. If necessary, in the event of a serious cross-border threat to health, Member States may request assistance from other Member States through the Emergency Response Coordination Centre (ERCC) provided for in Decision No 1313/2013/EU.

5. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1, 2 and 3 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

Article 22

Recommendations on common temporary public health measures

1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures.

2. The recommendations on common temporary public health measures adopted under paragraph 1 shall:

- (a) be based on, in particular, recommendations of the ECDC and the WHO, other relevant Union agencies or bodies, or the Advisory Committee referred to in Article 24;
- (b) respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care;
- (c) be necessary, suitable and proportionate to the public health risks related to the serious cross-border threat to health in question, avoiding, in particular, any unnecessary restriction on the free movement of persons, of goods and of services, and promote coordination of measures between Member States; and
- (d) be made available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alert systems; where the recommendation is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless the need is so urgent that the immediate publication of the recommendation is necessary.

⁽⁴³⁾ Council Decision 2014/415/EU of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (OJ L 192, 1.7.2014, p. 53).

CHAPTER V

PUBLIC HEALTH EMERGENCY AT UNION LEVEL*Article 23***Recognition of public health emergencies at Union level**

1. For serious cross-border threats to health as referred to in Article 2(1), the Commission may, after considering any expert opinion issued by the ECDC, any other relevant Union agencies or bodies or the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level, including pandemic situations where the serious cross-border threat to health in question endangers public health at Union level.
2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as the condition pursuant to paragraph 1 is no longer met.
3. Before recognising a public health emergency at Union level, the Commission shall liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.
4. The Commission shall adopt the measures referred to in paragraphs 1 and 2 of this Article by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise a public health emergency at Union level pursuant to paragraph 1 of this Article through immediately applicable implementing acts in accordance with the procedure referred to in Article 29(3).

*Article 24***Advisory Committee on public health emergencies**

1. In order to support the decision-making process regarding the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission or the HSC, shall advise the Commission or the HSC by providing its views on:
 - (a) whether a threat constitutes a public health emergency at Union level;
 - (b) the termination of a public health emergency at Union level; and
 - (c) response, including:
 - (i) formulation of response measures, including risk and crisis communication, to be addressed to all Member States in line with the different stages of the threat in the Union;
 - (ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, non-pharmaceutical countermeasures and public health research needs;
 - (iii) prioritisation of healthcare, civil protection and other resources as well as support measures to be organised or coordinated at Union level; and
 - (iv) any subsequent recommendation of policy measures for addressing and mitigating the long-term consequences of the specific threat.

The advice on response provided under point (c) shall build upon recommendations of the ECDC, EMA, the WHO and other relevant Union agencies or bodies, as appropriate.

2. The Advisory Committee shall be composed of independent experts, who may include representatives of healthcare and social care workers and civil society representatives, selected by the Commission according to the fields of expertise and experience of those representatives, which are the most relevant to the specific threat that is occurring, and including representatives of the ECDC and EMA as permanent observers. The Advisory Committee shall have a multidisciplinary membership so that it can advise on public health, biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the WHO may also participate as observers in the Advisory Committee. The representatives of other Union agencies or bodies relevant to the specific threat may participate as non-permanent observers in the Advisory Committee as necessary. The Commission may invite experts with specific expertise with regard to an item on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis, in particular from the countries within whose territory the threat arises. The Member States may propose the appointment of relevant experts to the Commission, depending on the specific item.
3. The Commission shall publish information about the Advisory Committee in accordance with the rules of the European Commission on expert groups ⁽⁴⁴⁾, including the names of the experts selected to form part of the Advisory Committee and details of the professional or scientific backgrounds that justify their appointment. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment.
4. Where applicable, the Advisory Committee shall act in coordination with the Health Crisis Board, where it is established in accordance with Regulation (EU) 2022/2372.
5. The Advisory Committee shall meet whenever the situation requires, at the request of the Commission, the HSC or a Member State. The Commission shall share all relevant information about the Advisory Committee's meetings with the Member States through the HSC.
6. The Advisory Committee shall be chaired by a representative of the Commission.
7. The Secretariat of the Advisory Committee shall be provided by the Commission.
8. The Advisory Committee shall establish its rules of procedure, including on the adoption of opinions and recommendations, voting rules and ensuring data protection and privacy. Those rules of procedure shall enter into force upon receipt of a favourable opinion from the Commission. The minutes of the Advisory Committee's meetings shall be made public.

Article 25

Legal effects of recognition

The recognition of a public health emergency at Union level pursuant to Article 23 shall have the legal effect of enabling the introduction of the following non-exhaustive measures:

- (a) measures, which are applicable during a public health emergency, related to medicinal products and medical devices provided for in Regulation (EU) 2022/123;
- (b) mechanisms to monitor shortages of, and to develop, procure, manage and deploy, medical countermeasures, in accordance with Article 12 of this Regulation and with applicable Union legislation, in particular Regulation (EU) 2022/123, and with Regulation (EU) 2022/2372;
- (c) activation of support from the ECDC as referred to in Regulation (EC) No 851/2004 to mobilise and deploy the EU Health Task Force; and
- (d) activation of the IPCR Arrangements.

⁽⁴⁴⁾ Commission Decision of 30 May 2016 establishing horizontal rules on the creation and operation of Commission experts groups (not published in the Official Journal).

CHAPTER VI

FINAL PROVISIONS

*Article 26***Transparency and conflict of interest**

1. The HSC and the Advisory Committee shall carry out their activities in an independent, impartial and transparent manner and shall undertake to act in the public interest.
2. Representatives appointed to the HSC and to the Advisory Committee and, where relevant, observers shall not have any financial or other interests which might be considered prejudicial to their independence.
3. The representatives appointed to the HSC and to the Advisory Committee and, where relevant, observers shall make a declaration of their financial and other interests and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve or give rise to a conflict of interest.
4. Representatives who participate in meetings of the HSC or of the Advisory Committee and, where relevant, observers, shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with regard to the items on the agenda.
5. Where the Commission decides that a representative's declared interest constitutes a conflict of interest, that representative shall not take part in any discussions or decisions, nor shall that representative obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.
6. Representatives who participate in meetings of the HSC or the Advisory Committee, and, where relevant, observers shall be subject to requirements of professional secrecy, even after their duties have ceased.

*Article 27***Personal data protection**

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC, and to the obligations of the Union institutions, bodies, offices and agencies relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.
2. The Commission and, where applicable, other Union institutions, bodies, offices and agencies shall not process personal data except in cases where it is necessary for the fulfilment of their mission. Where appropriate, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

*Article 28***Protection of personal data concerning the EWRS selective messaging functionality**

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to the national competent authorities involved in contact-tracing measures and medical evacuation procedures. That selective messaging functionality shall be designed and operated so as to ensure safe and lawful processing of personal data and to link with contact-tracing systems at Union level.

2. Where national competent authorities implementing contact-tracing measures or medical evacuation procedures communicate, through the EWRS, personal data necessary for contact-tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact-tracing or medical evacuation measures.
3. When communicating the data referred to in paragraph 2, the national competent authorities shall refer to the alert communicated previously through the EWRS.
4. The selective message functionality shall be used solely for the purpose of contact tracing and medical evacuation. It shall only allow national competent authorities to receive data that were sent to them by other national competent authorities. The ECDC shall only access the data required to ensure the proper functioning of the selective message functionality. Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting at the latest.
5. Where necessary for the purpose of contact tracing, personal data may also be exchanged using contact-tracing technologies. The national competent authorities shall not retain the contact data and health data received through the selective message functionality for longer than the retention period applicable in the context of their national contact-tracing activities.
6. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation by establishing:
 - (a) detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, including the respective responsibilities of the national competent authorities and of the ECDC; and
 - (b) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact-tracing measures.
7. The Commission shall, by means of implementing acts, adopt:
 - (a) procedures for the interlinking of the EWRS with contact-tracing systems at Union and international levels; and
 - (b) the modalities for processing contact-tracing technologies and their interoperability, as well as the cases where, and the conditions under which, the third countries may be granted access to contact-tracing interoperability and the practical arrangements for such access, in full compliance with Regulation (EU) 2016/679 and the applicable case law of the Court of Justice of the European Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(2).

Article 29

Committee procedure

1. The Commission shall be assisted by a committee on serious cross-border threats to health. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

*Article 30***Cooperation with the WHO**

The Union shall establish a framework for enhanced cooperation with the WHO, in particular as regards reporting and reviewing activities.

*Article 31***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 8(4), Article 14(7) and Article 28(6) shall be conferred on the Commission for an indeterminate period of time from 27 December 2022.
3. The delegation of power referred to in Article 8(4), Article 14(7) and Article 28(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 8(4), Article 14(7) or Article 28(6) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 32***Urgency procedure**

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 31(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

*Article 33***Evaluations concerning this Regulation**

By 31 December 2024 and every five years thereafter at the latest, the Commission shall carry out an evaluation of this Regulation and present a report on the main findings of that evaluation to the European Parliament and to the Council. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response within the HSC.

The evaluation referred to in the first paragraph shall also include an evaluation of the Commission's work in preparedness and response activities provided for in this Regulation including, where relevant, a review of the implementation of this Regulation by the Health Emergency Preparedness and Response Authority (HERA), as well as an assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response. The Commission shall, if appropriate, present legislative proposals based on that evaluation in order to amend this Regulation or make further proposals.

Article 34

Repeal

1. Decision No 1082/2013/EU is repealed.
2. References to the repealed Decision shall be construed as references to this Regulation and read in accordance with the correlation table in Annex II.

Article 35

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 23 November 2022.

For the European Parliament
The President
R. METSOLA

For the Council
The President
M. BEK

*ANNEX I***Section 1**

Criteria for selection of communicable diseases and related special health issues to be covered by epidemiological surveillance within the network for epidemiological surveillance

Union surveillance shall provide information for public health action at Union level. More specifically, one of the following criteria shall be met:

1. significant morbidity, significant mortality or emerging disease (increasing five-year trend) in a sizeable percentage of Member States;
2. potential to cause cross-border outbreaks;
3. high-threat pathogen (transmissibility and severity);
4. specifically targeted national or Union public health programmes in place that require monitoring and evaluation;
5. Union surveillance adds public health value to national surveillance systems other than what is implied in criteria 1 to 4.

Section 2

Criteria for use in the definition and classification of cases:

1. clinical criteria;
2. laboratory criteria;
3. epidemiological criteria.

Classification of cases:

1. possible case;
2. probable case;
3. confirmed case.

Section 3

Procedures for the operation of the network for epidemiological surveillance

The terms of procedures of the network for epidemiological surveillance shall cover at least the following points:

1. membership and appointment;
 2. terms of reference (detailing responsibilities of the national representatives and the ECDC secretariat of the network, including roles and tasks);
 3. administrative, for example relating to the convening of meetings and decision-making, and technical work procedures, for example relating to data reporting mechanisms, tools and platforms, data analysis and dissemination; and
 4. mechanism for periodic evaluation/review of administrative and technical work procedures.
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ANNEX II

Correlation table

Decision No 1082/2013/EU	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4(1)	Article 6
Article 4(2)	Article 7
Article 5	Article 12
Article 6	Article 13
Article 7	Article 17
Article 8	Article 18
Article 9	Article 19
Article 10	Article 20
Article 11	Article 21
Article 12	Article 23(1), (3), (4)
Article 13	Article 25
Article 14	Article 23(2)
Article 15	–
Article 16(1)	Article 27
Article 16(2) to (8)	Article 28
Article 17	Article 4
Article 18	Article 29
Article 19	Article 33
Article 20	Article 34
Article 21	Article 35
Article 22	–
Annex	Annex I

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2022/2372

of 24 October 2022

on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 122(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The ad-hoc measures taken by the Commission in order to restrict the spread of COVID-19 were reactive, and the Union was not sufficiently prepared to ensure the efficient development, manufacturing, procurement and distribution of crisis-relevant medical countermeasures, especially in the early phase of the COVID-19 pandemic. The pandemic also revealed insufficient oversight of research activities and manufacturing capacities as well as vulnerabilities related to global supply chains.
- (2) The experience gained has shown the need for a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency, in order to enable the Union to take measures that are necessary to ensure the sufficient and timely availability and supply of such countermeasures where that is appropriate to the economic situation. To that effect, this Regulation aims to establish an instrument of economic policy fundamental to avoid the adverse economic consequences of health crises, such as negative growth, unemployment, market disruptions, fragmentation of the internal market, and impediments to swift manufacturing – consequences which have been witnessed on a large scale in the context of the COVID-19 pandemic – with a view to ultimately safeguarding the economic stability of the Union and of its Member States.
- (3) In the event of the recognition of a public health emergency at Union level, it should be possible for the Council, upon a proposal from the Commission pursuant to Article 122(1) of the Treaty on the Functioning of the European Union (TFEU), to decide to activate the framework of measures to the extent that those measures are appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health in accordance with Article 9 TFEU and possible risk of the global disruption of supplies of crisis-relevant medical countermeasures, which could affect the health systems of Member States. The proposal from the Commission should explain the rationale and the need for the proposed activation of an emergency framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency, as established by this Regulation ('the emergency framework'), including for each of the measures proposed, including

an analysis of anticipated impact, subsidiarity, proportionality and financial implications for each of the measures proposed. The use of measures within the emergency framework should be limited in time for a maximum period of six months. It should be possible to prolong the use of such measures in view of the situation. The implementation of such measures should respect the responsibilities of Member States for the organisation and delivery of health services and medical care, including the allocation of the resources at national level, as referred to in Article 168(7) TFEU.

- (4) The emergency framework should include the establishment of a Health Crisis Board on crisis-relevant medical countermeasures to ensure the coordination of approaches at Union level. That is of particular importance given the distribution of responsibilities between Union and national level. To support the Health Crisis Board, the Commission should, on its own initiative or on the proposal of the Health Crisis Board, be able to set up subgroups or ad-hoc working groups, including if needed for industrial aspects. In order to ensure the effective and systematic involvement of Member States in the decisions taken for the implementation of this Regulation, rules for the deliberations of the Health Crisis Board should be laid down. When deliberating, the members of the Health Crisis Board should use their best endeavours to reach a consensus. If a consensus cannot be reached, and in order to ensure a smooth deliberation mechanism, the Health Crisis Board should act by a two-thirds majority, where one vote is given to each Member State. Moreover, it is useful for the effective operation and swift decision-making by the Health Crisis Board that it be supported through preparedness and response planning carried out by the Health Emergency Preparedness and Response Authority (HERA) established by a Commission Decision⁽¹⁾ of 16 September 2021. Such preparedness and response planning is to provide an assessment for the purpose of activating measures pursuant to this Regulation, propose the rules of procedure of the Health Crisis Board, draft negotiating mandates and procedural rules for joint procurements, and provide relevant information for the establishment of an inventory of crisis-relevant medical countermeasure production and production facilities. The involvement of Member States should also contribute to the necessary coordination between the implementation of this Regulation and the operations of the HERA. The Health Crisis Board should be able to also coordinate, where appropriate, with the HERA Board referred to in the Commission Decision of 16 September 2021.
- (5) Member States and the Commission should appoint their representative and alternate representative in the Health Crisis Board.
- (6) The Commission should ensure that a list of crisis-relevant medical countermeasures and raw materials is established and that their supply and demand are monitored. That should provide a comprehensive overview of the needed crisis-relevant medical countermeasures as well as of the Union's capacity to meet that need and to guide relevant decision-making during public health emergencies.
- (7) In view of the mandate of the European Medicines Agency (EMA) and its role as regards monitoring and mitigating potential and actual shortages of medicinal products, medical devices and *in vitro* diagnostic medical devices, including establishing lists of critical medicinal products and critical medical devices, under Regulation (EU) 2022/123 of the European Parliament and of the Council⁽²⁾, close cooperation and coordination between the Commission and EMA should be ensured to implement the measures provided for in this Regulation. When carrying out the tasks set out in Articles 7 to 13 of this Regulation, the Commission, including HERA, should fully respect EMA's responsibilities. A representative of the Executive Steering Group on Shortages of Medical Devices, as established by Article 21 of Regulation (EU) 2022/123, a representative of the Emergency Task Force, as established by Article 15 of that Regulation, and a representative of the Executive Steering Group on Shortages and Safety of Medicinal Products, as established by Article 3 of that Regulation, should be invited, as observers, to the Health Crisis Board. That should complement the smooth transmission of data and information during public health emergencies at Union level, including via integrated IT systems.

⁽¹⁾ Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (OJ C 3931, 29.9.2021, p. 3).

⁽²⁾ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

- (8) With regard to the monitoring of demand and supply of medical countermeasures in the third countries, the Commission should maintain a dialogue with its counterparts to foster international collaboration.
- (9) The measures should also take into account the structures and mechanisms set up by the Union acts on serious cross-border threats to health, namely Regulation (EU) 2022/2371 of the European Parliament and of the Council ⁽³⁾, and on the extended mandate of the European Centre for Disease Prevention and Control (ECDC) laid down by Regulation (EU) 2022/2370 of the European Parliament and of the Council ⁽⁴⁾, in order to ensure response coordination within the Health Security Committee and the Advisory Committee on public health emergencies, as established respectively by Articles 4 and 24 of Regulation (EU) 2022/2371, taking into account input from the ECDC on epidemiological surveillance and monitoring. The Director of the ECDC and a representative of the Advisory Committee on public health emergencies should be invited to attend the meetings of the Health Crisis Board. A member of the Health Security Committee should also be invited, as an observer, to the Health Crisis Board.
- (10) Efficient procurement procedures for crisis-relevant medical countermeasures and raw materials should be ensured. In that regard, the Commission can act as a central purchasing body for participating Member States, under the rules and procedures laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁵⁾, and, where appropriate, Council Regulation (EU) 2016/369 ⁽⁶⁾ as well as joint procurement procedures referred to in Article 12 of Regulation (EU) 2022/2371. In order to allow for speed and efficient procurement during times of crisis, procedural simplifications might be necessary. Moreover, for the purpose of drawing lessons learned from the procurement experience during the COVID-19 pandemic, better involvement of Member States should be ensured in the preparation and award of contracts. Agreements between the Commission and Member States should ensure that all Member States have equal and timely access to all information and that their needs are duly taken into account. Procurements of crisis-relevant medical countermeasures carried out under this Regulation can be exclusive or non-exclusive depending on the agreement of the participating Member States to such restrictions.
- (11) On the basis of the needs of Member States, as advised by the Health Crisis Board, the Commission should seek to ensure that all crisis-relevant medical countermeasures procured or developed under this Regulation meet the relevant Union, and, where applicable, national regulatory requirements, while allowing, as applicable, for any derogations, or other national exemptions.
- (12) Those procurement procedures can be supported by any necessary preparatory steps, including on-site visits at the location of the production facilities of crisis-relevant medical countermeasures. That should allow for the timely procurement and purchase of crisis-relevant medical countermeasures across the Union and promote accessibility across Member States, with the primary objective of securing the speediest possible equitable provision and distribution of the crisis-relevant medical countermeasures in the required quantity needed by each Member State and with all necessary guarantees. The possibility of relocation, redistribution, resale, loan and donation should already be taken into account contractually at the time of purchase.
- (13) In the cases covered by this Regulation, the immediate award and performance of the contracts resulting from procurement procedures carried out for the purposes of this Regulation could be justified given the extreme urgency of the health crisis and resulting economic difficulties. Also, it could be necessary to make adjustments to the contracts that are strictly necessary to adapt them to the evolution of the public health emergency as well as to add contracting authorities during the performance of the contract. For that specific purpose, it is necessary to

⁽³⁾ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

⁽⁴⁾ Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1).

⁽⁵⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

⁽⁶⁾ Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

allow derogations from specific provisions of Regulation (EU, Euratom) 2018/1046 while duly documented by the contracting authority. As those derogations are introduced for the purpose of the emergency framework, they should be temporary and apply solely for the period of the activation of the measure referred to in Article 8 of this Regulation.

- (14) During a public health emergency at Union level, the demand for crisis-relevant medical countermeasures could be greater than the supply. In such a situation, surge production and manufacturing of crisis-relevant medical countermeasures are essential, and the Commission should be entrusted to activate the surge in Union manufacturing capacities for crisis-relevant medical countermeasures, including ensuring resilient supply chains for the needed raw materials and ancillary supplies, such as under the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing ('EU-FAB'). As outlined in the Commission communication of 17 February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants', an EU-FAB project is a network of 'ever-warm', single and/or multi-user, single and/or multi-technology production capacities for vaccine and medicinal products manufacturing at the European level.
- (15) Effective mechanisms should be elaborated and agreed upon at Union level in order to ensure redistribution in cases where the surge of manufacturing has resulted in a situation where supply exceeds demand.
- (16) Appropriate intellectual property tools are needed to mitigate the risks of abandonment of development efforts, or supply issues, concerning crisis-relevant medical countermeasures during a public health emergency, especially where public authorities have provided financial support for the development and production of such countermeasures. The Commission should therefore be able to require the licensing, under fair and reasonable terms, of intellectual property rights and know-how pertaining to such countermeasures, the development and production of which the Commission has financed, in justified exceptional cases, as a safety net and an incentivising element. When facilitating the licensing of intellectual property and know-how pertaining to such countermeasures, the Commission should take into account the upfront financing by the Union or Member States of the development and the production of such countermeasures.
- (17) The activation of emergency research and innovation plans, as well as the repurposing of medicinal products and the activation of clinical trial networks, and conduct of clinical trials, should be ensured to reduce any delays in the development phase of crisis-relevant medical countermeasures. Research and innovation activities should be able to use European digital infrastructures as well as platforms operating under the European Open Science Cloud and other accessible EU digital platforms, in order to get access to (real-world) data for quick analysis. Close coordination of the Commission with the ECDC and the EMA, as the Agency responsible for scientific advice and scientific assessment of new and repurposed medicinal products, should be ensured for those matters, as well as for those related to regulatory aspects concerning the authorisation of medicinal products, including for the establishment of new manufacturing sites for authorised medicinal products, and to guarantee the acceptability of the clinical trials and the evidence they generate for the authorisation of new or repurposed medicinal products. Emergency research can also include diagnostic preparedness. That should allow key actors and relevant infrastructure to be immediately ready for operation in times of public health emergencies, thereby reducing any delays.
- (18) During a public health emergency, detailed overviews of the Union's current and short-term future production capacities of crisis-relevant medical countermeasures are an integral element of demand and supply management. Therefore, an inventory of crisis-relevant medical countermeasure production and production facilities should be established and regularly updated on the basis of the compulsory transmission of information by the relevant economic operators.

- (19) Supply shortages of raw materials, consumables, medical devices, equipment or infrastructure could affect the production of crisis-relevant medical countermeasures. Upon identification of a supply shortage or the risk thereof, the inventory should also cover those elements. That complements the detailed overview of the Union's current and short-term future production capacities, in order to allow for the factoring-in of supply elements that could affect production capacities and to improve demand and supply management of crisis-relevant medical countermeasures at Union level.
- (20) On the basis of the detailed overviews of production capacities, raw materials, consumables, medical devices, equipment and infrastructure, it could transpire that further measures to bolster supply chains and production capacities are needed. Where the market does not, or cannot, ensure adequate supply of needed crisis-relevant medical countermeasures, the Commission should therefore be able to implement measures in those areas that serve to increase the availability and accessibility of crisis-relevant medical countermeasures and raw materials.
- (21) Regulation (EU) 2016/369 provides for a flexible framework for emergency financial support. It allows for the provision of support that cannot be implemented through the existing spending programmes. Such a tool should become available if there is a recognition of a public health emergency at Union level to the extent that is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health. Emergency funding should be provided by the emergency support instrument in line with the appropriate budgetary procedures.
- (22) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁷⁾. The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the public health emergency, imperative grounds of urgency so require.
- (23) Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, such processing should comply with the relevant Union legislation on personal data protection, namely Regulations (EU) 2016/679 ⁽⁸⁾ and (EU) 2018/1725 ⁽⁹⁾ of the European Parliament and of the Council.
- (24) The implementation of the emergency framework should be reviewed by the Commission. During the conduct of the review, the crisis activities of HERA should be considered together with its preparedness activities. Consideration should also be given to relevant learning, from both preparatory and crisis modes, and to the necessity of establishing a distinct entity, such as an agency.
- (25) Since the objective of this Regulation to establish a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the measures necessary to ensure the sufficient and timely availability and supply of such medical countermeasures throughout the Member States, be better achieved at Union level, the Union may adopt a framework of measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

⁽⁷⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽⁸⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

⁽⁹⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency ('the emergency framework').
2. The emergency framework shall include:
 - (a) the establishment of a Health Crisis Board;
 - (b) the monitoring, procurement and purchase of crisis-relevant medical countermeasures and crisis-relevant raw materials;
 - (c) the activation of emergency research and innovation plans, including the use of Union-wide clinical trial networks and data-sharing platforms;
 - (d) emergency Union funding, including under Regulation (EU) 2016/369;
 - (e) measures concerning the production, availability and supply of crisis-relevant medical countermeasures, including the establishment of an inventory of crisis-relevant medical countermeasures production and production facilities, and, as appropriate, of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure, and including measures aimed at increasing their production in the Union.
3. The emergency framework may be activated only to the extent that it is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'monitoring' means monitoring as defined in Article 3, point (6), of Regulation (EU) 2022/2371 ;
- (2) 'public health emergency' means a public health emergency at Union level recognised by the Commission in accordance with Article 23 of Regulation (EU) 2022/2371;
- (3) 'medical countermeasures' means medical countermeasures within the meaning of Article 3, point (10), of Regulation (EU) 2022/2371, including personal protective equipment and substances of human origin;
- (4) 'raw materials' means the materials required in order to produce the required quantities of crisis-relevant medical countermeasures;
- (5) 'real-world data' means data relating to patient health status or the delivery of healthcare from sources other than clinical trials.

Article 3

Activation of the emergency framework

1. In the event of recognition of a public health emergency, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health.
2. Where the Council activates one or several measures set out in Articles 7 to 13, Article 5 shall apply.

3. The Council shall set out in the regulation activating the emergency framework which of the measures set out in Articles 7 to 13 are appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health, and which measures are therefore to be activated.

4. The emergency framework shall be activated for a maximum period of six months. This period may be prolonged in accordance with the procedure set out in Article 4.

5. The regulation activating the emergency framework shall be without prejudice to Decision No 1313/2013/EU of the European Parliament and of the Council ⁽¹⁰⁾ and the overall coordination role of the Emergency Response Coordination Centre under the Union Civil Protection Mechanism (UCPM), both established by that Decision, and the political coordination role of the Integrated Political Crisis Response (IPCR), established under Council Decision 2014/415/EU ⁽¹¹⁾.

Article 4

Prolongation, deactivation and expiry of the period for which the emergency framework is activated

1. No later than three weeks before the expiry of the period for which the emergency framework was activated, the Commission shall submit to the Council a report, drawn up in consultation with the Health Crisis Board, assessing whether that period should be prolonged. The report shall in particular analyse the public health situation and the economic consequences of the public health crisis in the Union as a whole and in Member States, as well as the impact of the measures previously activated under this Regulation.

2. The Commission may propose prolongation to the Council, specifying which of the measures are appropriate for prolongation, when the assessment referred to in paragraph 1 concludes that it is appropriate that the period for which the emergency framework is activated be prolonged. The prolongation shall be for up to six months. The Council may repeatedly decide to prolong the period for which the emergency framework is activated where that is appropriate in view of the economic situation, taking into account the need to ensure a high level of protection of human health.

3. The Commission may propose to the Council to adopt a regulation activating additional measures or deactivating any activated measures set out in Articles 7 to 13, in addition to those measures that it had already activated, where that is appropriate in view of the economic situation, taking into account the need to ensure a high level of protection of human health.

4. Upon expiry of the period for which the emergency framework is activated, the measures taken in accordance with Articles 7 to 13 shall cease to apply.

5. The measures set out in Articles 7 to 13 shall be automatically deactivated where the public health emergency is terminated in accordance with Article 23(2) of Regulation (EU) 2022/2371 .

Article 5

The Health Crisis Board

1. Where the Council activates one or several measures set out in Articles 7 to 13 in accordance with Article 3, the Health Crisis Board shall be established and shall ensure coordination of action by the Council, the Commission, the relevant Union bodies, offices and agencies and Member States to ensure the supply of and access to crisis-relevant medical countermeasures.

⁽¹⁰⁾ Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

⁽¹¹⁾ Council Decision of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (2014/415/EU) (OJ L 192, 1.7.2014, p. 53).

The Health Crisis Board shall assist and provide guidance to the Commission in the preparation and implementation of measures to be taken pursuant to Articles 7 to 13. To that effect, the Commission shall maintain a constant supply of information to the Health Crisis Board on any planned measures or measures that have been taken.

2. The Health Crisis Board shall cease to operate when all of the measures set out in Articles 7 to 13 are deactivated or expire.

3. The Health Crisis Board shall be composed of the Commission and one representative from each Member State. Each Member State shall nominate its representative and alternate representative. The secretariat of the Health Crisis Board shall be ensured by the Commission.

4. The Health Crisis Board shall be co-chaired by the Commission and the Member State holding the rotating presidency of the Council.

The Health Crisis Board shall ensure the participation of all relevant Union institutions, bodies, offices and agencies, including the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), and the Advisory Committee on public health emergencies, as observers. The Health Crisis Board shall invite, as observers, a representative from the European Parliament and a Member State representative of the Health Security Committee and, where relevant, and in line with its rules of procedure, a representative of the World Health Organization (WHO).

5. The Health Crisis Board shall ensure coordination and information exchange with the structures established under:

- (a) Regulation (EU) 2022/123 during the period of the public health emergency, related to medicinal products and medical devices;
- (b) Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽¹²⁾ during the period of the public health emergency;
- (c) Regulation (EU) 2022/2371, in particular the Health Security Committee and the Advisory Committee on public health emergencies;
- (d) Decision No 1313/2013/EU, and in particular the Emergency Response Coordination Centre, for the purpose of bridging operational gaps in accessing crisis-relevant medical countermeasures and raw materials and ensuring, where necessary, corresponding on-site monitoring and coordination tasks.

6. The Health Crisis Board shall ensure information exchange with the IPCR.

7. The co-chairs of the Health Crisis Board may invite experts with specific expertise to take part, as observers, in the work of the Health Crisis Board or subgroups on an ad-hoc basis, with regard to a subject matter on the agenda. Such experts may include: representatives of Union bodies, offices and agencies; representatives of national authorities, including central purchasing bodies and healthcare organisations and associations; representatives of international organisations such as WHO, the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH); and experts from the private sector and from other stakeholders.

8. The Health Crisis Board shall meet whenever the situation requires, upon request from the Commission or a Member State.

9. In the course of the preparation and implementation of the measures set out in Articles 7 to 13, the Commission shall act in close coordination with the Health Crisis Board. In particular, the Commission shall consult the Health Crisis Board in a timely manner, whenever possible before taking action, and shall take the utmost account of the result of deliberations within the Health Crisis Board. The Commission shall report back to the Health Crisis Board on the action taken.

⁽¹²⁾ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

10. The Health Crisis Board may issue opinions, upon the request of the Commission or on its own initiative. Where the Commission does not follow the opinion of the Health Crisis Board, it shall explain the reasons for its action to the Health Crisis Board, without prejudice to the Commission's right of initiative.

11. As far as possible, the Health Crisis Board shall deliberate by consensus. If consensus cannot be reached, the Health Crisis Board shall deliberate by a majority of two thirds of the Member State representatives. Each Member State shall have one vote.

The Health Crisis Board shall adopt its rules of procedure on the basis of a proposal submitted by the Commission. The rules of procedure shall detail when observers are, and are not, to be invited to participate in the deliberations of the Health Crisis Board and how potential conflicts of interest are to be managed.

12. The Commission may, on its own initiative or on the proposal of the Health Crisis Board, set up working groups on an ad hoc basis to support the Health Crisis Board in its work for the purpose of examining specific questions on the basis of the tasks referred to in paragraph 1. The working groups shall deliberate in accordance with the rules set out in paragraph 11. Member States shall nominate experts for the working groups.

13. The Commission shall ensure transparency and provide all Member State representatives with equal access to information, in order to ensure that the decision-making process reflects the situation and the needs of all Member States.

Article 6

Declaration of interest

1. The members of the Health Crisis Board shall undertake to act in the public interest.
2. The members of the Health Crisis Board, as well as observers and external experts participating in the meetings, shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made in writing on the establishment of the Health Crisis Board and at each meeting in order to declare any interests which might be considered prejudicial to their independence in relation to any item on the agenda. If there are interests which might be considered prejudicial to their independence in relation to any item on the agenda, the person concerned shall be excluded from relevant discussions and decisions.

Article 7

Mechanism for monitoring crisis-relevant medical countermeasures

1. Where this measure is activated, the Commission shall, after seeking the advice of the Health Crisis Board, draw up and regularly update, by means of implementing acts, a list of crisis-relevant medical countermeasures and raw materials, as well as a template for monitoring their supply and demand, including production capacity, stockpiles, possible critical aspects or the risk of disruption in the supply chains and purchasing agreements.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 14(3).

2. The list referred to in paragraph 1 shall include a shortlist of specific crisis-relevant medical countermeasures and raw materials for the preparation of measures to be taken in accordance with this Article and Articles 8 to 13, taking into account the information obtained pursuant to:

- (a) Regulation (EU) 2022/123, and in particular Articles 3 to 14 and 21 to 30 thereof, concerning the monitoring and mitigation of shortages of medicinal products and medical devices included in the critical medicines lists and public health emergency critical medical devices list, respectively;
 - (b) Regulation (EC) No 851/2004, and in particular Article 3(2), point (f), thereof, concerning available data on Member States' health system capacity necessary to the management and response to communicable disease threats.
3. Without prejudice to national security interests, Member States shall, where appropriate, provide the Commission with additional information not already collected by Union agencies on the basis of the template referred to in paragraph 1.
4. Without prejudice to national security interests and the protection of commercially confidential information resulting from agreements entered into by Member States, where a Member State intends to adopt at national level measures for the procurement, purchase or manufacturing of crisis-relevant medical countermeasures or raw materials from the list referred in paragraph 1, it may inform the Health Crisis Board in a timely manner.
5. Upon request of the Commission, including on behalf of the Health Crisis Board, EMA shall provide it with information with regard to monitoring of medicinal products and medical devices, including their demand and supply, in accordance with Article 9(2), points (c) and (d), and Article 25(2), points (c) and (d), of Regulation (EU) 2022/123.
6. The Commission shall gather additional information not already collected by Union agencies through a secured IT system and monitor, on the basis of the template referred to in paragraph 1, all relevant information concerning the supply and demand of crisis-relevant medical countermeasures and raw materials within and outside the Union. The Commission shall ensure the interoperability of the IT system with the electronic monitoring and reporting systems developed by EMA pursuant to Article 9(1), point (c), of Regulation (EU) 2022/123.
7. The Commission shall regularly provide information on the results of the monitoring of crisis-relevant medical countermeasures and raw materials to the European Parliament and to the Council.

The Commission shall make available to the European Parliament, to the Council and to the Health Security Committee modelling and forecasts regarding the needs for crisis-relevant medical countermeasures and raw materials with, where appropriate, the support of relevant Union agencies.

The Commission shall subsequently inform the Health Crisis Board of the monitoring and its results.

Article 8

Procurement, purchase and manufacturing of crisis-relevant medical countermeasures and raw materials

1. Where this measure is activated, the Health Crisis Board shall advise the Commission on the appropriate mechanism to purchase crisis-relevant medical countermeasures and raw materials, either through the activation of existing contracts or the negotiation of new contracts, using available instruments, such as Article 4 of Regulation (EU) 2016/369, the joint procurement procedure referred to in Article 12 of Regulation (EU) 2022/2371, or European Innovation Partnerships, established by Regulation (EU) 2021/695 of the European Parliament and of the Council ⁽¹³⁾.

⁽¹³⁾ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

In particular, the Health Crisis Board shall advise the Commission on the need to use a purchasing mode whereby the Commission acts as a central purchasing body on behalf of Member States, either in conjunction with other available instruments or as an autonomous procurement mode.

2. Where appropriate, Member States may mandate the Commission to act as a central purchasing body to procure crisis-relevant medical countermeasures and raw materials on their behalf, under the conditions laid down in this Article.

Member States shall be free to participate in the procurement procedure, including through opt-out mechanisms and, in duly justified cases, through opt-in mechanisms.

The Commission shall, in close coordination with the Health Crisis Board, draw up the proposal for a framework agreement to be signed by Member States that wish to be represented by the Commission ('participating Member States') to act as a central purchasing body for crisis-relevant medical countermeasures.

3. The framework agreement referred to in paragraph 2 shall include procedural rules for the initiation and preparation of procurement procedures set out in this Article, the practical arrangements for Member States' free participation, including the conditions and time frames for possible opt-in and opt-out by Member States, as well as the practical arrangements for the involvement of participating Member States throughout the procurement process as well as allocation procedures of procured crisis-relevant medical countermeasures.

4. Assisted by the Health Crisis Board, the Commission shall carry out the procurement procedures and conclude the resulting agreements with economic operators on behalf of the participating Member States, in accordance with Regulation (EU, Euratom) 2018/1046.

The Commission shall inform the Health Crisis Board, on a regular basis, of the progress made in the procurement process and on the substance of negotiations. The Commission shall take the utmost account of the advice of the Health Crisis Board and of the real needs of Member States. In particular, the Commission shall only consider launching negotiations where a sufficient number of Member States have expressed their support.

5. All participating Member States shall be associated to the procurement process. To that effect, the Commission shall invite participating Member States to nominate representatives to take part in the preparation of the procurement procedures as well as the negotiation of the purchasing agreements. Representatives of participating Member States shall have the status of experts associated to the procurement process, in accordance with Regulation (EU, Euratom) 2018/1046.

Where the Commission intends to conclude a contract containing an obligation to acquire crisis-relevant medical countermeasures, it shall inform the participating Member States of such intention and the detailed terms. The participating Member States shall have the opportunity to express their comments on the draft contracts, that the Commission shall take into consideration. If the opt-out mechanism is applied, participating Member States shall have the right of at least five days to opt out.

6. Procurement referred to in paragraph 2 shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 for its own procurement. When duly justified by the extreme urgency of the health crisis or when strictly necessary in order to adapt to unforeseen circumstances in the evolution of the public health emergency, the following simplifications of procurement procedures may be used:

- (a) by way of derogation from Article 137 of Regulation (EU, Euratom) 2018/1046, possibility to provide, after the signature of the contract, proof or evidence on exclusion and selection criteria, provided that a declaration on honour has been submitted in that regard before the award;
- (b) by way of derogation from Article 172(2) of Regulation (EU, Euratom) 2018/1046, the Commission may modify the contract as necessary to adapt it to the evolution of the public health emergency;

- (c) by way of derogation from Article 165 of Regulation (EU, Euratom) 2018/1046, possibility to add, after the signature of the contract, contracting authorities that are not identified in procurement documents;
- (d) by way of derogation from Article 172(1) of Regulation (EU, Euratom) 2018/1046, the contracting authorities shall be entitled to request the delivery of goods or services from the date on which the draft contracts resulting from the procurement carried out for the purposes of this Regulation are sent, which shall be no later than 24 hours as from the award.

7. In line with the framework agreement referred to in paragraph 2, the Commission may have the ability and responsibility, on behalf of participating Member States and according to their needs, to enter into purchase agreements with economic operators, including individual producers of crisis-relevant medical countermeasures. Those agreements can include a prepayment mechanism for the production or development of such countermeasures in exchange for the right to the result.

In order to enter, on behalf of all participating Member States, into purchase agreements with economic operators, representatives of the Commission, or experts nominated by the Commission, may carry out on-site visits in cooperation with relevant national authorities at the locations of production facilities of crisis-relevant medical countermeasures.

8. The Commission shall have the ability and responsibility to activate the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing (EU-FAB) facilities in order to make available reserved surge manufacturing capacities to ensure the delivery of crisis-relevant medical countermeasures and raw materials, corresponding to the agreed quantities and in accordance with the timing of the EU-FAB contracts. The Commission shall conduct specific procurement procedures for those agreed quantities of crisis-relevant medical countermeasures.

9. Where the Commission provides financing for the production and/or development of crisis-relevant medical countermeasures, the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure their sufficient and timely delivery under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in specific agreements with economic operators.

10. The deployment and use of the crisis-relevant medical countermeasures shall remain the competence of the participating Member States. In cases where the negotiated amounts exceed demand, the Commission, at the request of the Member States concerned, shall elaborate a mechanism for reallocation, resale and donation.

11. The Commission shall ensure that participating Member States are treated equally when carrying out the procurement procedures and when implementing the resulting agreements.

Article 9

Emergency research and innovation aspects of the preparedness and response plans and the use of clinical trial networks and data-sharing platforms

1. Where this measure is activated, the Commission and Member States shall, after consulting the Health Crisis Board, activate the emergency research and innovation aspects of the Union prevention, preparedness and response plan referred to in Regulation (EU) 2022/2371 .

2. The Commission shall support access to relevant data from clinical trials, but also to real-world data. If possible, the Commission shall build upon existing preparedness research initiatives such as Union-wide and international networks for clinical trials as well as observational studies including strategic cohorts, supported by digital platforms and infrastructures, such as high performance computing, enabling the open sharing of findable, accessible, interoperable and reusable (FAIR) data, as well as the activities of the national competent bodies supporting availability and access to data, including health data, in accordance with Article 15.

3. In setting up actions on clinical trials, the Commission shall involve the EMA Emergency Task force established by Regulation (EU) 2022/123 as well as existing networks, such as the European Clinical Research Infrastructure Network, while ensuring compliance with Regulation (EU) No 536/2014 of the European Parliament and of the Council ⁽¹⁴⁾ as well as coordination with ECDC.

4. The participation and contribution of the Union, and that of the Member States, in the emergency research and innovation aspects of the Union prevention, preparedness and response plan shall be in accordance with the rules and procedures of the Multiannual Financial Framework programmes.

Article 10

Inventory of crisis-relevant medical countermeasure production and production facilities

1. Where this measure is activated, the Commission may, by means of implementing acts, draw up and regularly update an inventory of crisis-relevant medical countermeasure production and production facilities and a template for monitoring of production capacity and stocks.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 14(3).

2. The Commission may, using the template referred to in paragraph 1, request the producers of crisis-relevant medical countermeasures to inform the Commission, within five days, of the actual total production capacity, and possible existing stocks of the crisis-relevant medical countermeasures and components thereof, in their Union production facilities and the third-country facilities which they operate, with which they have contracts, or from which they purchase supplies, while fully respecting trade and business secrets. The Commission may also request those producers to transmit to it a schedule of the expected production output for the following three months for each Union production facility.

3. Upon request of the Commission, each producer of crisis-relevant medical countermeasures shall inform the Commission, within a maximum of five days, of any Union crisis-relevant medical countermeasure production facility it operates, including information on its production capacity as regards such countermeasures by means of regular updates. For medicinal products, that information shall comprise facilities related to both finished products and active pharmaceutical ingredients.

4. The Commission shall regularly inform the European Parliament and the Council about the production of crisis-relevant medical countermeasures and the expected production rate within the Union and the production of supplies from third-country facilities, whether the products are finished, intermediates or other components, as well as about the capacity of Union and third-country crisis-relevant medical countermeasure production facilities, while adequately protecting commercially sensitive information of the producers.

Article 11

Inventory of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure

Where this measure is activated, the Commission shall extend the inventory and template provided for in Article 10 to crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure, if it considers that there is a risk of a shortage in supply of crisis-relevant raw materials, consumables, medical devices, equipment or a risk of any problems with infrastructure.

⁽¹⁴⁾ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

*Article 12***Measures to ensure the availability and supply of crisis-relevant medical countermeasures**

1. Where this measure is activated, the Commission may, when it considers that there is a risk of a shortage of crisis-relevant raw materials, consumables, medical and other devices, equipment and infrastructure, implement, as quickly as possible, in agreement with the Member States concerned and after consultation with the economic operators concerned, specific measures to ensure the efficient reorganisation of supply chains and production lines and utilise existing stocks to increase the availability and supply of crisis-relevant medical countermeasures.
2. In particular, the measures referred to in paragraph 1 may include:
 - (a) facilitating the expansion or repurposing of existing, or the establishment of new, production capacities for crisis-relevant medical countermeasures;
 - (b) facilitating the expansion of existing, or the establishment of new, capacities related to activities and the introduction of measures ensuring regulatory flexibility, in order to support the production and placing on the market of crisis-relevant medical countermeasures, while respecting the responsibilities of EMA and national medicines authorities with regard to the evaluation and supervision of medicinal products;
 - (c) implementing procurement initiatives, reserving stockpiles and production capacities to coordinate approaches, and providing critical supply, services and resources for the production of crisis-relevant medical countermeasures;
 - (d) facilitating the collaboration of relevant companies in a joint industry effort to ensure the availability and supply of crisis-relevant medical countermeasures; and
 - (e) facilitating the licensing of intellectual property and know-how pertaining to the crisis-relevant medical countermeasures.
3. The Commission may provide timely financial incentive mechanisms necessary to ensure the rapid implementation of the measures referred to in paragraph 2.

*Article 13***Emergency funding**

Where this measure is activated and the requirements laid down in Regulation (EU) 2016/369 are met, emergency support under that Regulation shall be activated to finance expenditure necessary to address the public health emergency.

*Article 14***Committee Procedure**

1. The Commission shall be assisted by a Health Crisis Implementing Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

3. On duly justified imperative grounds of urgency relating to the public health emergency, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 8 of Regulation (EU) No 182/2011.

*Article 15***Personal data protection**

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC of the European Parliament and of the Council ⁽¹⁵⁾, or the obligations of the Commission and, where appropriate, other Union institutions, bodies, offices and agencies, relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.
2. Personal data shall not be processed or communicated except in cases where it is strictly necessary for the purposes of this Regulation. In such cases, the conditions of Regulations (EU) 2016/679 and (EU) No 2018/1725 shall apply as appropriate.
3. Where processing of personal data is not strictly necessary for the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.
4. The Commission, by means of an implementing act, shall adopt detailed rules to ensure that the requirements provided for by Union legislation concerning the roles of the actors involved in the collection and processing of personal data are fully complied with.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 14(2).

*Article 16***Review**

By 2024 at the latest, the Commission shall carry out a review of this Regulation and present a report on the main findings of that review to the European Parliament and to the Council. That review shall include an evaluation of the work of the Health Preparedness and Emergency Response Authority (HERA) under the emergency framework established by this Regulation, and its relation to the preparedness activities of HERA. That review shall also include an assessment as regards the need to establish HERA as a distinct entity considering relevant agencies or authorities active in the field of health crisis. Member States shall be consulted and their views and recommendations on the implementation of the emergency framework shall be reflected in the final report. The Commission shall, if appropriate, present proposals based on that report in order to amend this Regulation or make further proposals.

*Article 17***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 24 October 2022.

For the Council
The President
A. HUBÁČKOVÁ

⁽¹⁵⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

COUNCIL REGULATION (EU) 2022/2373**of 5 December 2022****amending Regulation (EC) No 1183/2005 concerning restrictive measures in view of the situation in the Democratic Republic of the Congo**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to Council Decision (CFSP) 2022/2377 of 5 December 2022 amending Decision 2010/788/CFSP concerning restrictive measures in view of the situation in the Democratic Republic of the Congo ⁽¹⁾,

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

Whereas:

- (1) Council Regulation (EC) No 1183/2005 ⁽²⁾ gives effect to Council Decision 2010/788/CFSP ⁽³⁾ and provides for certain measures directed against persons acting in violation of the arms embargo with regard to the Democratic Republic of the Congo (DRC), including a freezing of their assets.
- (2) Decision (CFSP) 2022/2377 enlarges the criteria for Union autonomous listings.
- (3) Regulatory action at the Union level is therefore necessary to give effect to Decision (CFSP) 2022/2377 in particular with a view to ensure uniform application by economic operators in all Member States.
- (4) Regulation (EC) No 1183/2005 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1183/2005 is amended as follows:

- (1) in Article 2b, paragraph 1 is replaced by the following:

‘1. Annex Ia shall include the natural or legal persons, entities or bodies designated by the Council on any of the following grounds:

- (a) obstructing a consensual and peaceful solution towards elections in the DRC, including by acts of violence, repression or inciting violence, or by undermining the rule of law;
- (b) planning, directing, or committing acts that constitute serious human rights violations or abuses in the DRC;
- (c) being responsible for sustaining the armed conflict, instability or insecurity in the DRC;
- (d) providing support to natural or legal persons, entities or bodies referred to in point (c);
- (e) inciting violence in connection with the actions mentioned in points (b), (c) and (d);
- (f) exploiting the armed conflict, instability or insecurity in the DRC, including through the illicit exploitation or trade of natural resources and wildlife;
- (g) being associated with natural or legal persons, entities or bodies referred to in points (a), (b), (c), (d), (e) or (f).’;

⁽¹⁾ See page 97 of this Official Journal.

⁽²⁾ Council Regulation (EC) No 1183/2005 of 18 July 2005 concerning restrictive measures in view of the situation in the Democratic Republic of the Congo (OJ L 193, 23.7.2005, p. 1).

⁽³⁾ Council Decision 2010/788/CFSP of 20 December 2010 concerning restrictive measures in view of the situation in the Democratic Republic of the Congo (OJ L 336, 21.12.2010, p. 30).

(2) in Annex Ia, the title is replaced by the following:

'List of natural or legal persons, entities and bodies referred to in Article 2b'.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 December 2022.

For the Council
The President
M. KUPKA

COUNCIL IMPLEMENTING REGULATION (EU) 2022/2374**of 5 December 2022****implementing Regulation (EU) 2020/1998 concerning restrictive measures against serious human rights violations and abuses**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EU) 2020/1998 of 7 December 2020 concerning restrictive measures against serious human rights violations and abuses ⁽¹⁾, and in particular Article 14(4) thereof,

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

Whereas:

- (1) On 7 December 2020, the Council adopted Regulation (EU) 2020/1998.
- (2) Pursuant to Article 14(4) of Regulation (EU) 2020/1998, the Council has reviewed the list of natural or legal persons, entities or bodies subject to restrictive measures set out in Annex I to that Regulation. On the basis of that review, the entries concerning six natural persons and two entities should be updated.
- (3) Annex I to Regulation (EU) 2020/1998 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Council Regulation (EU) 2020/1998 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 December 2022.

For the Council
The President
M. KUPKA

⁽¹⁾ OJ L 410 I, 7.12.2020, p. 1.

Annex I to Regulation (EU) 2020/1998 ('List of natural or legal persons, entities or bodies referred to in Article 3') is amended as follows:

(1) in section A, the entries for the following six natural persons are replaced by the following:

A. Natural persons

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
1.	Alexander (Alexandr) Petrovich KALASHNIKOV	Александр Петрович КАЛАШНИКОВ (Russian spelling)	Position(s): Former director of the Russian Federal Penitentiary Service (FSIN) DOB: 27.1.1964 POB: Tatarsk, Novosibirsk Region/Oblast, Russian SFSR (now Russian Federation)	Alexander Kalashnikov was the director of the Russian Federal Penitentiary Service (FSIN) from 8 October 2019 until 25 November 2021. In that position, he oversaw all activities of the FSIN. In his capacity as director of the FSIN, he was responsible for serious human rights violations in Russia, including arbitrary arrests and detentions.	2.3.2021
			Nationality: Russian Gender: male	In the case of Alexei Navalny, while Mr Navalny was recovering in Germany (September 2020-January 2021) after having been poisoned with a toxic nerve agent of the Novichok group, on 28 December 2020 FSIN demanded that he immediately present himself to a probation officer or face a prison sentence for violating a suspended sentence for fraud conviction. That fraud conviction had been found arbitrary and unfair by the European Court of Human Rights in 2018. On 17 January 2021, acting on the orders of Alexander Kalashnikov, FSIN officers detained Alexei Navalny upon his arrival at Moscow airport.	
				Alexei Navalny's arrest is based on a decision by the Khimki city court, which in turn was issued at the request of FSIN. In late December 2020, FSIN had already requested that a court replace Alexei Navalny's suspended sentence with a prison term. On 17 February 2021, the European Court of Human Rights ordered the Government of Russia to release Alexei Navalny.	

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
6.	WANG Junzheng	王君正 (Chinese spelling)	Position(s): Party Secretary of the Chinese Communist Party (CCP) in the Tibet Autonomous Region (TAR); former Party Secretary of the Xinjiang Production and Construction Corps (XPCC) and Deputy Secretary of the Party Committee of China's Xinjiang Uyghur Autonomous Region; Political commissar of the XPCC and CEO of the China Xinjian Group DOB: May 1963 POB: Linyi, Shandong (China) Nationality: Chinese Gender: male	Party Secretary of the Chinese Communist Party (CCP) in the Tibet Autonomous Region (TAR) since October 2021. Former Party Secretary of the Xinjiang Production and Construction Corps (XPCC) and Deputy Secretary of the Party Committee of China's Xinjiang Uyghur Autonomous Region (XUAR) from April 2020 to October 2021, as well as Political commissar of the XPCC from May 2020 to October 2021. Former Secretary of the Political and Legal Affairs Committee of the XUAR, from February 2019 to September 2020. Wang Junzheng also held other senior posts in the XPCC.	22.3.2021
				The XPCC is a state-owned economic and paramilitary organisation in the XUAR, which exercises administrative authority and controls economic activities in Xinjiang. As Party Secretary and Political commissar of the XPCC, Wang Junzheng was involved in overseeing all policies implemented by the XPCC. In that position, he was responsible for serious human rights violations in China, in particular large-scale arbitrary detentions and degrading treatment inflicted upon Uyghurs and people from other Muslim ethnic minorities, as well as systematic violations of their freedom of religion or belief, linked, inter alia, to the XPCC's implementation of a large-scale surveillance, detention and indoctrination programme targeting Uyghurs and people from other Muslim ethnic minorities.	

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
				He was also responsible for the XPCC's systematic use of Uyghurs and people from other Muslim ethnic minorities as a forced workforce, in particular in cotton fields. As Deputy Secretary of the Party Committee of the XUAR, Wang Junzheng was involved in overseeing all the security policies implemented in Xinjiang, including the aforementioned programme targeting Uyghurs and people from other Muslim ethnic minorities. As Secretary of the Political and Legal Affairs Committee of the XUAR from February 2019 to September 2020, Wang Junzheng was responsible for maintaining internal security and law enforcement in the XUAR. As such, he held a key political position in charge of overseeing and implementing the aforementioned programme.	
9.	JONG Kyong-thaek (a.k.a. CHO'NG Kyo'ng-t'aek)	정경택 (Korean spelling)	Position(s): Director of the General Political Bureau of the Korean People's Army; former Minister of State Security of the Democratic People's Republic of Korea (DPRK) DOB: between 1.1.1961 and 31.12.1963 Nationality: Democratic People's Republic of Korea (DPRK) Gender: male	Jong Kyong-thaek is the Director of the General Political Bureau of the Korean People's Army. He was the Minister of State Security of the Democratic People's Republic of Korea (DPRK) from 2017 until 2022. The Ministry of State Security of the DPRK is one of the leading institutions in charge of implementing the repressive security policies of the DPRK, with a focus on identifying and suppressing political dissent, the inflow of 'subversive' information from abroad, and any other conduct considered a serious political threat to the political system and its leadership.	22.3.2021
				As former Head of the Ministry of State Security, Jong Kyong-thaek is responsible for serious human rights violations in the DPRK, in particular torture and other cruel, inhuman or degrading treatment or punishment, extrajudicial, summary or arbitrary executions and killings, enforced disappearance of persons, and arbitrary arrests or detentions, as well as widespread forced labour and sexual violence against women.	

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
10.	RI Yong Gil (a.k.a. RI Yong Gi, RI Yo'ng-kil, YI Yo'ng-kil)	리영길 (Korean spelling)	Position(s): Minister of National Defence of the Democratic People's Republic of Korea (DPRK) Rank: Vice Marshal DOB: 1955 Nationality: Democratic People's Republic of Korea (DPRK) Gender: male	Ri Yong Gil is the Minister of National Defence of the Democratic People's Republic of Korea (DPRK). He was the Minister of Social Security from January 2021 until June or July 2021. He was Chief of the General Staff of the Korean People's Army (KPA) between 2018 and January 2021. He was promoted to Vice Marshal of the KPA on 14 April 2022. As Minister of National Defence, Ri Yong Gil is responsible for serious human rights violations, including by members of the Military Security Command and other KPA units.	22.3.2021
				The Ministry of Social Security of the DPRK (formerly known as the Ministry of People's Security or Ministry of Public Security) and the Military Security Command are leading institutions in charge of implementing the repressive security policies of the DPRK, including interrogation and punishment of people 'illegally' fleeing the DPRK. In particular, the Ministry of Social Security is in charge of running prison camps and short-term labour detention centres through its Correctional Bureau, where prisoners/detainees are subject to deliberate starvation and other inhuman treatment.	
				As former Head of the Ministry of Social Security, Ri Yong Gil is responsible for serious human rights violations in the DPRK, in particular torture and other cruel, inhuman or degrading treatment or punishment, extrajudicial, summary or arbitrary executions and killings, enforced disappearance of persons, and arbitrary arrests or detentions, as well as widespread forced labour and sexual violence against women. As former Chief of the General Staff of the KPA, Ri Yong Gil is also responsible for the widespread serious human rights violations committed by the KPA.	

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
12.	Abderrahim AL-KANI (a.k.a. Abdul-Rahim AL-KANI, Abd-al-Rahim AL-KANI, Abdel Rahim KHALIFA, Abdel Rahim AL-SHAQAQI)	عبد الرحيم الكاني (Arabic spelling)	Position(s): member of the Kaniyat Militia DOB: 7.9.1997 Nationality: Libyan Passport number: PH3854LY ID number: 119970331820 Gender: male	Abderrahim Al-Kani is a key member of the Kaniyat Militia and brother of the Head of the Kaniyat Militia, Mohammed Khalifa Al-Khani (deceased in July 2021). The Kaniyat Militia exercised control of the Libyan town of Tarhuna between 2015 and June 2020. Abderrahim Al-Kani is in charge of internal security for the Kaniyat Militia. In that capacity, he is responsible for serious human rights abuses in Libya, in particular extrajudicial killings and enforced disappearances of persons between 2015 and June 2020 in Tarhuna. Abderrahim Al-Kani and the Kaniyat Militia fled Tarhuna in early June 2020 to eastern Libya. Since then, several mass graves attributed to the Kaniyat Militia have been discovered in Tarhuna.	22.3.2021
16.	Dimitriy (Dimitry, Dmitri, Dmitry) Valerievich UTKIN	Дмитрий Валерьевич Уткин (Russian spelling)	Position(s): Founder and commander of the Wagner Group Rank: Lieutenant colonel (reserve) Callsign: Vagner, Wagner, The Ninth Wagner Group ID: M-0209 DOB: 1.6.1970 or 11.6.1970 POB: Asbest, Sverdlovsk Oblast, Russian SFSR (now Russian Federation) Nationality: Russian Address: Pskov, Russian Federation Gender: male	Dimitriy Utkin, a former Russian military intelligence (GRU) officer, is the founder of the Wagner Group and responsible for coordinating and planning operations for the deployment of Wagner Group mercenaries across various countries. In his commanding position within the Wagner Group, he is responsible for serious human rights abuses committed by the group, which include torture and extrajudicial, summary or arbitrary executions and killings. This includes the torturing to death of a Syrian deserter by four members of the Wagner Group in June 2017 in the governorate of Homs, Syria. According to a former member of the Wagner Group, Dimitriy Utkin personally ordered the torturing to death of the deserter as well as the filming of the act.	13.12.2021'

(2) in section B, the entries for the following two entities are replaced by the following:

B. Legal persons, entities and bodies

	Name (Transliteration into Latin script)	Name	Identifying information	Reasons for listing	Date of listing
3.	Kaniyat Militia (f.k.a. 7th Brigade, Tarhuna 7th Brigade, Tarhuna Brigade) (a.k.a. 9th Brigade, Al-Kani Militia, Al-Kaniyat, Kani Brigade, Kaniat, Kaniyat, Kanyat)	مليشيا كانيات (Arabic spelling)		The Kaniyat Militia is a Libyan armed militia, which exercised control in the Libyan town of Tarhuna between 2015 and June 2020. Mass graves attributed to the Kaniyat Militia have been discovered in Tarhuna since June 2020, after the militia fled to eastern Libya. The Kaniyat Militia is responsible for serious human rights abuses, in particular extrajudicial killings, and enforced disappearances of persons.	22.3.2021
5.	Wagner Group (a.k.a. Vagner Group, PMC Wagner, Liga, League)	Группа Вагнера (Russian spelling)		The Wagner Group is a Russia-based unincorporated private military entity, which was established in 2014 as a successor organisation of the Slavonic Corps. It is led by Dimitriy Utkin and financed by Yevgeny Prigozhin. Through the setting-up of local entities, and with the support of local governments, the Wagner Group finances and conducts its operations. The Wagner Group is responsible for serious human rights abuses in Ukraine, Syria, Libya, the Central African Republic (CAR), Sudan, Mali and Mozambique, which include torture and extrajudicial, summary or arbitrary executions and killings.	13.12.2021'

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2375**of 29 November 2022****approving Union amendments to the specification for a Protected Designation of Origin or a Protected Geographical Indication ('Bianco di Custoza'/'Custoza' (PDO))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation ⁽¹⁾, and in particular Article 15(2) thereof,

Whereas:

- (1) The Commission has examined the application for the approval of Union amendments to the product specification for the Protected Designation of Origin 'Bianco di Custoza'/'Custoza', forwarded by Italy in accordance with Article 105 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽²⁾ in conjunction with Article 15 of Delegated Regulation (EU) 2019/33. The changes include a change of name from 'Bianco di Custoza'/'Custoza' to 'Custoza'.
- (2) The Commission has published the application for the approval of the Union amendments to the product specification in the *Official Journal of the European Union* ⁽³⁾, as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The Union amendments to the product specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013 in conjunction with Article 15(2) of Delegated Regulation (EU) 2019/33,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the product specification published in the *Official Journal of the European Union* regarding the name 'Bianco di Custoza'/'Custoza' (PDO) are hereby approved.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 9, 11.1.2019, p. 2.

⁽²⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽³⁾ OJ C 295, 2.8.2022, p. 5.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 November 2022.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

DECISIONS

COUNCIL DECISION (CFSP) 2022/2376

of 5 December 2022

amending Decision (CFSP) 2020/1999 concerning restrictive measures against serious human rights violations and abuses

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

- (1) On 7 December 2020, the Council adopted Decision (CFSP) 2020/1999 ⁽¹⁾.
- (2) The measures set out in Articles 2 and 3 of Decision (CFSP) 2020/1999 apply as regards the natural or legal persons, entities and bodies listed in the Annex to that Decision until 8 December 2022.
- (3) On the basis of a review of the Annex to Decision (CFSP) 2020/1999, the measures set out in Articles 2 and 3 of that Decision as regards the natural or legal persons, entities and bodies listed in that Annex should be extended until 8 December 2023. The entries concerning six natural persons and two entities included in that Annex should be updated.
- (4) Decision (CFSP) 2020/1999 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2020/1999 is amended as follows:

- (1) in Article 10, in the second sentence, the date ‘8 December 2022’ is replaced by the date ‘8 December 2023’;
- (2) the Annex is amended as set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 5 December 2022.

For the Council
The President
M. KUPKA

⁽¹⁾ Council Decision (CFSP) 2020/1999 of 7 December 2020 concerning restrictive measures against serious human rights violations and abuses (OJ L 410 I, 7.12.2020, p. 13).

ANNEX

The Annex to Decision (CFSP) 2020/1999 ('List of natural and legal persons, entities and bodies referred to in Articles 2 and 3') is amended as follows:

(1) in section A, the entries for the following six natural persons are replaced by the following:

A. Natural persons

	Names (Transliteration into Latin script)	Names	Identifying information	Reasons for listing	Date of listing
'1.	Alexander (Alexandr) Petrovich KALASHNIKOV	Александр Петрович КАЛАШНИКОВ (Russian spelling)	Position(s): Former director of the Russian Federal Penitentiary Service (FSIN) DOB: 27.1.1964 POB: Tatarsk, Novosibirsk Region/Oblast, Russian SFSR (now Russian Federation) Nationality: Russian Gender: male	Alexander Kalashnikov was the director of the Russian Federal Penitentiary Service (FSIN) from 8 October 2019 until 25 November 2021. In that position, he oversaw all activities of the FSIN. In his capacity as director of the FSIN, he was responsible for serious human rights violations in Russia, including arbitrary arrests and detentions. In the case of Alexei Navalny, while Mr Navalny was recovering in Germany (September 2020-January 2021) after having been poisoned with a toxic nerve agent of the Novichok group, on 28 December 2020 FSIN demanded that he immediately present himself to a probation officer or face a prison sentence for violating a suspended sentence for fraud conviction. That fraud conviction had been found arbitrary and unfair by the European Court of Human Rights in 2018. On 17 January 2021, acting on the orders of Alexander Kalashnikov, FSIN officers detained Alexei Navalny upon his arrival at Moscow airport. Alexei Navalny's arrest is based on a decision by the Khimki city court, which in turn was issued at the request of FSIN. In late December 2020, FSIN had already requested that a court replace Alexei Navalny's suspended sentence with a prison term. On 17 February 2021, the European Court of Human Rights ordered the Government of Russia to release Alexei Navalny.	2.3.2021

6.	WANG Junzheng	王君正 (Chinese spelling)	Position(s): Party Secretary of the Chinese Communist Party (CCP) in the Tibet Autonomous Region (TAR); former Party Secretary of the Xinjiang Production and Construction Corps (XPCC) and Deputy Secretary of the Party Committee of China's Xinjiang Uyghur Autonomous Region; Political commissar of the XPCC and CEO of the China Xinjian Group DOB: May 1963 POB: Linyi, Shandong (China) Nationality: Chinese Gender: male	Party Secretary of the Chinese Communist Party (CCP) in the Tibet Autonomous Region (TAR) since October 2021. Former Party Secretary of the Xinjiang Production and Construction Corps (XPCC) and Deputy Secretary of the Party Committee of China's Xinjiang Uyghur Autonomous Region (XUAR) from April 2020 to October 2021, as well as Political commissar of the XPCC from May 2020 to October 2021. Former Secretary of the Political and Legal Affairs Committee of the XUAR, from February 2019 to September 2020. Wang Junzheng also held other senior posts in the XPCC. The XPCC is a state-owned economic and paramilitary organisation in the XUAR, which exercises administrative authority and controls economic activities in Xinjiang. As Party Secretary and Political commissar of the XPCC, Wang Junzheng was involved in overseeing all policies implemented by the XPCC. In that position, he was responsible for serious human rights violations in China, in particular large-scale arbitrary detentions and degrading treatment inflicted upon Uyghurs and people from other Muslim ethnic minorities, as well as systematic violations of their freedom of religion or belief, linked, inter alia, to the XPCC's implementation of a large-scale surveillance, detention and indoctrination programme targeting Uyghurs and people from other Muslim ethnic minorities. He was also responsible for the XPCC's systematic use of Uyghurs and people from other Muslim ethnic minorities as a forced workforce, in particular in cotton fields. As Deputy Secretary of the Party Committee of the XUAR, Wang Junzheng was involved in overseeing all the security policies implemented in Xinjiang, including the aforementioned programme targeting Uyghurs and people from other Muslim ethnic minorities. As Secretary of the Political and Legal Affairs Committee of the XUAR from February 2019 to September 2020, Wang Junzheng was responsible for maintaining internal security and law enforcement in the XUAR. As such, he held a key political position in charge of overseeing and implementing the aforementioned programme.	22.3.2021
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9.	JONG Kyong-thaek (a.k.a. CHO'NG Kyo'ng-t'aek)	정경택 (Korean spelling)	Position(s): Director of the General Political Bureau of the Korean People's Army; former Minister of State Security of the Democratic People's Republic of Korea (DPRK) DOB: between 1.1.1961 and 31.12.1963 Nationality: Democratic People's Republic of Korea (DPRK) Gender: male	Jong Kyong-thaek is the Director of the General Political Bureau of the Korean People's Army. He was the Minister of State Security of the Democratic People's Republic of Korea (DPRK) from 2017 until 2022. The Ministry of State Security of the DPRK is one of the leading institutions in charge of implementing the repressive security policies of the DPRK, with a focus on identifying and suppressing political dissent, the inflow of 'subversive' information from abroad, and any other conduct considered a serious political threat to the political system and its leadership. As former Head of the Ministry of State Security, Jong Kyong-thaek is responsible for serious human rights violations in the DPRK, in particular torture and other cruel, inhuman or degrading treatment or punishment, extrajudicial, summary or arbitrary executions and killings, enforced disappearance of persons, and arbitrary arrests or detentions, as well as widespread forced labour and sexual violence against women.	22.3.2021
10.	RI Yong Gil (a.k.a. RI Yong Gi, RI Yo'ng-kil, YI Yo'ng-kil)	리영길 (Korean spelling)	Position(s): Minister of National Defence of the Democratic People's Republic of Korea (DPRK) Rank: Vice Marshal DOB: 1955 Nationality: Democratic People's Republic of Korea (DPRK) Gender: male	Ri Yong Gil is the Minister of National Defence of the Democratic People's Republic of Korea (DPRK). He was the Minister of Social Security from January 2021 until June or July 2021. He was Chief of the General Staff of the Korean People's Army (KPA) between 2018 and January 2021. He was promoted to Vice Marshal of the KPA on 14 April 2022. As Minister of National Defence, Ri Yong Gil is responsible for serious human rights violations, including by members of the Military Security Command and other KPA units. The Ministry of Social Security of the DPRK (formerly known as the Ministry of People's Security or Ministry of Public Security) and the Military Security Command are leading institutions in charge of implementing the repressive security policies of the DPRK, including interrogation and punishment of people 'illegally' fleeing the DPRK. In particular, the Ministry of Social Security is in charge of running prison camps and short-term labour detention centres through its Correctional Bureau, where prisoners/detainees are subject to deliberate starvation and other inhuman treatment.	22.3.2021

				As former Head of the Ministry of Social Security, Ri Yong Gil is responsible for serious human rights violations in the DPRK, in particular torture and other cruel, inhuman or degrading treatment or punishment, extrajudicial, summary or arbitrary executions and killings, enforced disappearance of persons, and arbitrary arrests or detentions, as well as widespread forced labour and sexual violence against women. As former Chief of the General Staff of the KPA, Ri Yong Gil is also responsible for the widespread serious human rights violations committed by the KPA.	
12.	Abderrahim AL-KANI (a.k.a. Abdul-Rahim AL-KANI, Abd-al-Rahim AL-KANI, Abdel Rahim KHALIFA, Abdel Rahim AL-SHAQAQI)	عبد الرحيم الكاني (Arabic spelling)	Position(s): member of the Kaniyat Militia DOB: 7.9.1997 Nationality: Libyan Passport number: PH3854LY ID number: 119970331820 Gender: male	Abderrahim Al-Kani is a key member of the Kaniyat Militia and brother of the Head of the Kaniyat Militia, Mohammed Khalifa Al-Khani (deceased in July 2021). The Kaniyat Militia exercised control of the Libyan town of Tarhuna between 2015 and June 2020. Abderrahim Al-Kani is in charge of internal security for the Kaniyat Militia. In that capacity, he is responsible for serious human rights abuses in Libya, in particular extrajudicial killings and enforced disappearances of persons between 2015 and June 2020 in Tarhuna. Abderrahim Al-Kani and the Kaniyat Militia fled Tarhuna in early June 2020 to eastern Libya. Since then, several mass graves attributed to the Kaniyat Militia have been discovered in Tarhuna.	22.3.2021
16.	Dimitriy (Dimitry, Dmitri, Dmitry) Valerievich UTKIN	Дмитрий Валерьевич Уткин (Russian spelling)	Position(s): Founder and commander of the Wagner Group Rank: Lieutenant colonel (reserve)	Dimitriy Utkin, a former Russian military intelligence (GRU) officer, is the founder of the Wagner Group and responsible for coordinating and planning operations for the deployment of Wagner Group mercenaries across various countries.	13.12.2021'

			Callsign: Vagner, Wagner, The Nineth Wagner Group ID: M-0209 DOB: 1.6.1970 or 11.6.1970 POB: Asbest, Sverdlovsk Oblast, Russian SFSR (now Russian Federation) Nationality: Russian Address: Pskov, Russian Federation Gender: male	In his commanding position within the Wagner Group, he is responsible for serious human rights abuses committed by the group, which include torture and extrajudicial, summary or arbitrary executions and killings. This includes the torturing to death of a Syrian deserter by four members of the Wagner Group in June 2017 in the governorate of Homs, Syria. According to a former member of the Wagner Group, Dimitriy Utkin personally ordered the torturing to death of the deserter as well as the filming of the act.	
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(2) in section B, the entries for the following two entities are replaced by the following:

B. Legal persons, entities and bodies

	Name (Transliteration into Latin script)	Name (Arabic spelling)	Identifying information	Reasons for listing	Date of listing
3.	Kaniyat Militia (f.k.a. 7th Brigade, Tarhuna 7th Brigade, Tarhuna Brigade) (a.k.a. 9th Brigade, Al-Kani Militia, Al-Kaniyat, Kani Brigade, Kaniat, Kaniyat, Kanyat)	مليشيا كانيات (Arabic spelling)		The Kaniyat Militia is a Libyan armed militia, which exercised control in the Libyan town of Tarhuna between 2015 and June 2020. Mass graves attributed to the Kaniyat Militia have been discovered in Tarhuna since June 2020, after the militia fled to eastern Libya. The Kaniyat Militia is responsible for serious human rights abuses, in particular extrajudicial killings, and enforced disappearances of persons.	22.3.2021

5.	Wagner Group (a.k.a. Vagner Group, PMC Wagner, Liga, League)	Группа Вагнера (Russian spelling)		The Wagner Group is a Russia-based unincorporated private military entity, which was established in 2014 as a successor organisation of the Slavonic Corps. It is led by Dimitriy Utkin and financed by Yevgeny Prigozhin. Through the setting-up of local entities, and with the support of local governments, the Wagner Group finances and conducts its operations. The Wagner Group is responsible for serious human rights abuses in Ukraine, Syria, Libya, the Central African Republic (CAR), Sudan, Mali and Mozambique, which include torture and extrajudicial, summary or arbitrary executions and killings.	13.12.2021'
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COUNCIL DECISION (CFSP) 2022/2377**of 5 December 2022****amending Decision 2010/788/CFSP concerning restrictive measures in view of the situation in the Democratic Republic of the Congo**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

- (1) On 20 December 2010, the Council adopted Decision 2010/788/CFSP ⁽¹⁾.
- (2) On 12 December 2016, the Council adopted Decision (CFSP) 2016/2231 ⁽²⁾ in response to the obstruction of the electoral process and the related human rights violations in the Democratic Republic of Congo (DRC). Decision (CFSP) 2016/2231 amended Decision 2010/788/CFSP and introduced additional restrictive measures in Article 3(2) of Decision 2010/788/CFSP.
- (3) In view of the gravity of the situation in the DRC, the Council considers that the designation criteria in Decision 2010/788/CFSP should be amended to allow for the application of targeted restrictive measures against natural or legal persons, entities or bodies that sustain, support or benefit from the armed conflict, instability or insecurity in the DRC.
- (4) Decision 2010/788/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2010/788/CFSP is amended as follows:

- (1) in Article 3, paragraph 2 is replaced by the following:

‘2. Restrictive measures as provided for in Articles 4(1) and 5(1) and (2) shall be imposed against natural or legal persons, entities or bodies:

- (a) obstructing a consensual and peaceful solution towards elections in the DRC, including by acts of violence, repression or inciting violence, or by undermining the rule of law;
- (b) involved in planning, directing or committing acts that constitute serious human rights violations or abuses in the DRC;
- (c) responsible for sustaining the armed conflict, instability or insecurity in the DRC;
- (d) providing support to natural or legal persons, entities or bodies referred to in point (c);
- (e) inciting violence in connection with the actions mentioned in points (b), (c) and (d);
- (f) exploiting the armed conflict, instability or insecurity in the DRC, including through the illicit exploitation or trade of natural resources and wildlife;
- (g) associated with natural or legal persons, entities or bodies referred to in points (a), (b), (c), (d), (e) or (f);

as listed in Annex II.’;

⁽¹⁾ Council Decision 2010/788/CFSP of 20 December 2010 concerning restrictive measures in view of the situation in the Democratic Republic of the Congo (OJ L 336, 21.12.2010, p. 30).

⁽²⁾ Council Decision (CFSP) 2016/2231 of 12 December 2016 amending Decision 2010/788/CFSP concerning restrictive measures against the Democratic Republic of the Congo (OJ L 336 I, 12.12.2016, p. 7).

(2) in Annex II, the title is replaced by the following:

'List of natural or legal persons, entities and bodies referred to in Article 3(2)'.

Article 2

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 5 December 2022.

For the Council
The President
M. KUPKA

COMMISSION IMPLEMENTING DECISION (EU) 2022/2378**of 2 December 2022****concerning the extension of the action taken by the Health and Safety Executive of the United Kingdom permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2022) 8678)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof, in conjunction with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

Whereas:

- (1) On 28 April 2022, the Health and Safety Executive of the United Kingdom acting on behalf of the Health and Safety Executive for Northern Ireland ('the UK competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit until 29 October 2022 the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems in the United Kingdom in respect of Northern Ireland ('the action'). The UK competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the UK competent authority, the action was necessary in order to protect public health. Microbiological contamination of aircraft fuel tanks and fuel systems is caused by micro-organisms, such as bacteria, mould and yeast, that grow in the settled water and feed off the hydrocarbons in the fuel at the fuel-to-water interface. If left untreated, the microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The prevention and treatment of microbiological contamination, when detected, are therefore crucial in order to avoid operational problems of aircraft.
- (3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8) as active substances. Biobor JF is a biocidal product of product-type 6, namely 'preservative for products during storage', as defined in Annex V to Regulation (EU) No 528/2012. 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) have not been evaluated for use in biocidal products of product-type 6. As those substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾, they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products, referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to those active substances and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294 10.10.2014, p. 1).

- (4) On 5 August 2022, the Commission received a reasoned request from the UK competent authority to allow the extension of the action in the United Kingdom in respect of Northern Ireland, in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems and the argument that Biobor JF is essential in order to control such microbiological contamination.
- (5) According to the information provided by the UK competent authority the only alternative biocidal product recommended by aircraft and aircraft engine manufacturers for the treatment of microbiological contamination (Kathon™ FP 1.5) was withdrawn from the market in March 2020 due to severe behaviour anomalies in aircraft engines that were noticed after the treatment with that product. Biobor JF is therefore the only available product for that use recommended by aircraft and aircraft engine manufacturers.
- (6) As indicated by the UK competent authority, the alternative procedure for treating an existing microbiological contamination is manual removal in-tank, following defueling and purging of the aircraft. However, that procedure may not always be possible to perform and would expose workers to toxic gases and therefore, it should be avoided.
- (7) According to the information provided to the Commission, the manufacturer of Biobor JF has taken steps towards a future regular authorisation of the product. An application for approval of the active substances that Biobor JF contains is expected to be submitted in mid-2023. The approval of the active substances and subsequent authorisation of the biocidal product would constitute a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.
- (8) As the lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means, it is appropriate to allow the UK competent authority to extend the action in the United Kingdom in respect of Northern Ireland.
- (9) As the action expired on 29 October 2022, this Decision should apply retroactively.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland, may extend until 2 May 2024 the permit for the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems, in the United Kingdom in respect of Northern Ireland.

Article 2

This Decision is addressed to the Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland.

It shall apply from 30 October 2022.

Done at Brussels, 2 December 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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