



Council of the
European Union

Brussels, 28 July 2021
(OR. en)

11093/21

**Interinstitutional File:
2020/0322(COD)**

**SAN 480
PHARM 159
PROCIV 96
COVID-19 322
CODEC 1131**

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee

No. Cion doc.: 12973/20 INIT + ADD 1

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL on serious cross-border threats to health and repealing
Decision No 1082/2013/EU
- Mandate for negotiation with the European Parliament

Delegations will find enclosed the mandate for the negotiations with the European Parliament on the above-mentioned subject as agreed by the Committee of Permanent Representatives at its meeting on 23 July 2021.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on serious cross-border threats to health and repealing Decision No 1082/2013/EU

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² OJ C , , p. .

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.³ Its scope was extended by Decision 1082/2013/EU of the European Parliament and of the Council⁴ to strengthen and provide for a further 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 combating 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 and response to cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the ECDC. Moreover, in order to ensure Union's effective response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats as well as it should provide for the establishment of a network of EU reference laboratories and a network to support monitoring 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.

³ 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

⁴ 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).

- (3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee 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.
- (4) A joint opinion issued by the European Commission's Group of Chief Scientific Advisors (GCSA), the European Group on Ethics in Science and New Technologies (EGE), and the Special Advisor to the President of the European Commission on the response to COVID-19 recommends 'establishing a standing EU advisory body' for health threats and crises.
- (4a) It is understood that all recommendations, advices, guidance and opinions mentioned in this Regulation, are inherently non-binding. A recommendation allows the Commission, ECDC and Health Security Committee to make its views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.
- (5) 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 and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

- (6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. 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, 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), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border 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 2119/98/EC of the European Parliament and of the Council⁵.
- (7) 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 preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided by the Commission and the relevant Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation.

⁵ OJ L 268, 3.10.1998, p. 1.

- (8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)⁶. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, every two years to ensure that national preparedness and response plans are adequate. Such planning should include in particular adequate preparedness of critical sectors of society, such as 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 health and veterinary sectors for preparedness and response planning, through a One Health approach.

⁶ World Health Organization. International Health Regulation (IHR, 2005)
<https://www.who.int/ihr/publications/9789241596664/en/>

- (9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism⁷.
- (9a) It is understood that joint procurement of medical countermeasures can be exclusive or a non-exclusive depending on the agreement of the Member State, participating in the specific procurement. In addition, small countries like Andorra, Monaco, San Marino and the Vatican State City, highly rely on the EU to access medical countermeasures in a health emergency context. By way of derogation from Article 165(2) and in accordance with Article 3(2) of Regulation (EU, Euratom) 2018/1046, joint procurement of medical countermeasures should therefore also be extended to Andorra, Monaco, the Vatican State and San Marino.
- (10) Unlike for 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 a systematic monitoring. A risk-based approach, whereby monitoring is carried out by Member States' monitoring systems and available information is exchanged through EWRS, is therefore more appropriate to those threats.

⁷ OJ L 347, 20.12.2013, p. 924.

- (11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other EU Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.
- (12) In case of cross-border health threats due to a communicable disease, ECDC shall cooperate with Member States to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this purpose.
- (13) 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 2119/98/EC 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. 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 the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are 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.

- (14) In order to ensure that the assessment of risks to public health at the 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 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 transparency. The involvement of Union agencies in these 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 relevant Commission services to support the preparation of risk assessments.
- (15) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate 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 Treaty on the Functioning of the European Union such as those related to free movement of persons, goods and services.
- (16) To this effect, the HSC 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 a 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 HSC's work at national level.

- (17) Inconsistent communication with the public and stakeholders such as healthcare 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 addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the EU Civil Protection Community⁸.
- (18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this 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 situation, 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 advice on public health response measures and views on the termination of this emergency recognition. The advisory committee should consist of independent experts, 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, ECDC, of EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical 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 ‘Health Task Force’.

⁸ OJ L 77I , 20.3.2019, p. 1

- (19) Before recognising a situation of public health emergency at Union level, the Commission should 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. Where such a recognition is adopted, the Commission should also inform the WHO thereof.
- (20) The occurrence of an event that corresponds to serious cross-border threats 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 cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures.
- (21) 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 EU'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 alerting 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 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.

- (22) Any processing of personal data for the purpose of implementing this Regulation should be fully compliant with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council⁹ and with Directive 2002/58/EC on privacy and electronic communications.¹⁰ Processing of personal data should be limited to the strictly necessary and, whenever possible, data should be anonymized. 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 to relevant authorities involved in contact tracing measures. In the case of cooperation with the health authorities of the Union, third countries, WHO or other international organizations, transfers of personal data to third countries or international organizations should always comply with the obligations laid down under Regulation (EU) No 2018/1725.
- (22a) Overlap of reporting and reviewing activities with existing structures and mechanisms on 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 this end, the Union should further enhance its cooperation with the WHO, in particular under the International Health Regulations' reporting, monitoring and evaluation frameworks.

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)

- (23) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States due to the cross-border dimension of serious threats to health but can 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.
- (24) 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.

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update 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 procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation. Furthermore, implementing powers should be conferred on the Commission in order to ensure compliance with the obligations stemming from the EU data protection legal framework, in particular insofar as the roles and responsibilities of the parties involved in the different bodies set up by this Regulation are clearly defined. The European Data Protection Supervisor should be consulted during the preparation of the implementing act, pursuant to Regulation 2018/1725.

- (26) Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹¹. As the implementing acts provided for by this Regulation concern the protection of human health, the Commission may not adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with point (a) of the second subparagraph of Article 5(4) of Regulation (EU) No 182/2011.
- (27) 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.
- (28) [...]
- (29) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725 and has adopted an opinion¹².
- (30) This Regulation fully respects the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union.
- (31) Accordingly, Decision No 1082/2013/EU should therefore be repealed and replaced by this Regulation,

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).

¹² Reference to add once available

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
 - (b) preparedness and response planning, including:
 - (i) preparedness plans at Union levels;
 - (ii) reporting and examining on preparedness at national level;
 - (c) joint procurement of medical countermeasures;

- (d) epidemiological surveillance and monitoring;
- (e) the network for epidemiological surveillance;
- (f) the early warning and response system;
- (g) risk assessment;
- (h) coordination of response;
- (i) recognition of a public health emergency situation 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;
- (c) an advisory committee for the occurrence and recognition of emergency situation at Union level.

3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

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;

- (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter ‘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 (including due to climate) origin;
 - (d) threats of unknown origin;
 - (e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), 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, early warning of, the coordination of 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 Health Security Committee 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 Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating 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 application of this Regulation.

Article 3

Definitions

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

- (1) ‘case definition’ means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;
- (2) ‘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;
- (3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;

- (4) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;
- (5) ‘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 and analysis on specified indicators relating to serious cross-border threats to health;
- (6) ‘public health measure’ means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health;
- (7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin 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;
- (8) ‘medical countermeasure’ means any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in this Regulation;

- (9) ‘health systems’ capacity’ means the degree to which a health system maximizes its performance on 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 purpose of this regulation, the definition shall apply only to the parts of health system components or building blocks affected by the serious cross-border threats to health outlined in Article 2(1).
- (10) ‘One Health concept’ means a multi-dimensional approach to health, which recognises that human, animal and environmental health are interconnected.

Article 4

Health Security Committee

1. The Health Security Committee (‘HSC’) is hereby established. It shall be composed of representatives of the Member States, in two working levels:
 - (a) a steering panel;
 - (b) technical working groups to discuss specific topics if necessary.
2. The HSC shall have the following tasks:
 - (a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation, in cooperation with, where applicable, other structures;
 - (b) coordination in liaison with the Commission of the preparedness and response planning in accordance with Article 10 and without prejudice to the competences of Member States;

- (c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;
- (d) adoption of 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 bodies or agencies.

3. As far as possible, the group shall adopt its guidance or opinions by consensus.

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

4. The HSC shall be co-chaired by a representative of the Commission and a representative of the Member States. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

5. The secretariat shall be provided by the Commission.

6. The HSC shall adopt, by a majority of two thirds 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 third countries and WHO;
 - (c) the arrangements for the HSC to examine 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; those arrangements shall not affect the obligations of the Member States under Articles 10 and 21 of this Regulation.
7. 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 and of any change thereof. In the event of such change, the Commission shall distribute immediately to the HSC's members an updated list of such designations.

CHAPTER II

PREPAREDNESS AND RESPONSE PLANNING

Article 5

Union preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies, and in accordance with the WHO emergency preparedness and response framework set out by the International Health Regulations (IHR), shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.
2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6, and promote effective synergies between the Member States, the Commission, the ECDC and other relevant Union bodies or agencies.
3. The Union preparedness and response plan shall, in particular, include provisions of 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 bodies or agencies. The plan shall take into account the possible services and support provided under the EU Civil Protection Mechanism, or other mechanisms, the capacities and resources made available for its purposes by the EU and the Member States and the cooperation with the WHO for cross-border threats to health;

- (b) the secure exchange of information between the Commission, the competent authorities or designated bodies responsible at national level, the HSC and the relevant Union bodies or agencies;
 - (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;
 - (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 a one health approach for zoonotic, food and water borne diseases and relevant other diseases and special health issues.
4. The Union 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, capacities and structures for contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall take into account national circumstances and preconditions and include preparedness and response means to address the situation of those citizens with higher risks.
5. In order to ensure the operation of the Union preparedness and response plan, the Commission may, in collaboration with Member States and, when applicable, with relevant Union bodies or agencies or with international organizations, conduct stress tests, simulation exercises and in-action and after-action reviews, and update the plan as necessary.

Article 6

National preparedness and response plans

1. Without prejudice to Member States competences in this area, when preparing national 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 preparedness and response plan to the largest possible extent, Member States shall also inform without delay the Commission and the HSC of any substantial revision of the national plan.

Article 7

Reporting on preparedness and response planning

1. Member States shall by the end of November 2022 and every 3 years thereafter provide the Commission and the ECDC with a report on their preparedness and response planning and implementation at national level in relation to the serious cross-border threats to health referred to in Article 2(1).

That report shall cover the following:

- (a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;

- (b) elements of emergency preparedness, in particular:
 - (i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms, including, where relevant, among administrative levels (national, regional and/or local) 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; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;
 - (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and
- (c) implementation of national response plans, including where relevant implementation at the regional level, covering epidemic response, related special health issues and other serious cross-border threats to health.

The report shall include, whenever relevant, cross-border interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.

2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 3 years.

The report shall include country profiles for monitoring progress and developing action plans, taking into account national circumstances and preconditions, to address identified gaps at national level.

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

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

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, in order to ensure its relevance to the objectives identified in that paragraph, and its comparability.

The templates shall be based on the opinion of the HSC and shall be, as far as possible, based on/consistent with templates used under the International Health Regulations State Parties reporting framework in order to avoid double reporting activities for Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

4. In the performance of their obligations pursuant to this Article, Member States shall not be required to disclose information in the report that would harm their essential national security interests.

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 Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443¹³ and 2015/444¹⁴.

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 EU 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 Commission Decision 2001/844/EC, ECSC, Euratom¹⁵ and by Council Decision 2011/292/EU¹⁶.

Article 8

Examining on preparedness and response planning

1. Every 4 years, the ECDC shall examine the Member States state of implementation of the national plans and their relation with the Union plan. Such examinations shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

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

¹⁴ 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).

¹⁵ OJ L 317, 3.12.2001, p. 1.

¹⁶ OJ L 141, 27.5.2011, p. 17.

- 1a. The ECDC shall, if applicable, present to the Member States and the Commission recommendations of the examinations referred to in paragraph 1 addressed to Member States, taking into account national circumstances and preconditions.
2. Member States shall, if applicable, present to the Commission and the ECDC an action plan addressing the proposed recommendations of the examination, with the corresponding improvement actions and milestones, or reasoning if the proposed recommendations of the examination are not considered.
3. The Commission shall, by means of implementing acts, establish procedures, standards and criteria for the examinations referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 9

Commission report on 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 examine referred to in Article 8, the Commission shall by July 2023 and every 3 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.
2. Based on the report referred to in paragraph 1, the Commission may complement the action of the Member States through the adoption of general recommendations on the preparedness and response planning.

Article 10

Coordination of preparedness and response planning in the HSC

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

The coordination shall, in particular, be aimed at:

- (a) sharing best practice and experience in preparedness and response planning;
- (b) promoting the interoperability of national preparedness planning and the multi-sectoral dimension of preparedness and response planning at Union level;
- (c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;
- (d) supporting the development of the preparedness and response plans referred to in Articles 5 and 6;
- (e) monitoring and discussing progress, gaps identified and actions to strengthen preparedness and response planning at national and Union levels.

Article 11

Training of health care staff and public health staff

1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.

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 the WHO.

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, and implement activities to strengthen crisis preparedness and surveillance capacities, especially regarding the gaps identified, including the use of digital tools.
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.
4. The bodies whose staff participates in the training activities organised in accordance with 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 organised.
5. The Commission and relevant Union agencies may support organising 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.

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 27(2).

Article 12

Joint procurement of medical countermeasures

1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council¹⁷ with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.
 - 1a. The joint procurement procedure 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 assessment of the tenders and the award of the contract.

¹⁷ 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).

2. The joint procurement procedure referred to in paragraph 1, shall comply with the following conditions:
- (a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States and Union candidate countries, as well as Andorra, Monaco, San Marino and the State of Vatican City, 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) not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;
 - (d) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortion of competition;
 - (e) the joint procurement shall not have any direct financial impact on the budget of Member States, EFTA States and Union candidate countries not participating in the joint procurement.

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:
- (a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;
 - (b) Regulation (EU) 2016/369;
 - (c) the Pharmaceutical Strategy ;
 - (d) the EU4Health Programme established by Regulation (EU) .../... of the European Parliament and of the Council¹⁸;
 - (e) Regulation (EU) No.../... of the European Parliament and of the Council¹⁹; and
 - (f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

¹⁸ [Please insert title and OJ reference of the regulation.]

¹⁹ Regulation (EU).../... of the European Parliament and of the Council of ... establishing the European Defence Fund (OJ ...).

CHAPTER III

EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING

Article 13

Epidemiological surveillance

1. The network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance. The ECDC shall ensure the integrated operation of the network as set out in Article 5 of Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]].

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

2. The epidemiological surveillance network shall aim to:
 - (a) monitor trends in communicable diseases over time and 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 respect 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 level;
- (d) identify risk factors for disease transmission, 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 health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases ~~as well as patients' safety~~;
- (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;
- (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, taking into account the actual public health situation, to the participating authorities of the epidemiological surveillance network:

- (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1);
- (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 cross-border health threats;
 - (e) health systems ~~system~~ data required for managing cross-border health threats; and
 - (f) information about contact tracing monitoring systems developed at national level.
4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.
 5. The Commission and the Member States shall work together to strengthen the data collection 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.
 6. The ECDC shall liaise with Member States to examine the adherence to these surveillance standards, supporting Member States with technical and scientific advice to improve the timeliness, completeness and quality of the surveillance data reported.
 7. 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.
 8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.

9. The Commission shall, by means of implementing acts, establish and update:
- (a) the list of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1), in order to ensure coverage of communicable diseases and related special health issues by the epidemiological surveillance network;
 - (b) case definitions 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;
 - (c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

10. On duly justified imperative grounds 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 Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption of case definitions, procedures and indicators for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1). The indicators mentioned above shall also support the assessment of capacity for diagnosis, prevention and treatment.

Article 14

Platform for surveillance

1. The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, in order to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control, in particular in the frame of the European Health Data Space, pursuant to point (g) of Article 5(2) of Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]]. The ECDC, in close cooperation with Member States, shall also ensure the interoperability with national systems.
2. The digital platform shall
 - (a) enable the automated collection of surveillance and laboratory data, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;
 - (b) allow for the computerised handling and exchange of information, data and documents.
3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, that is available in the Member States, data and documents transmitted and exchanged through the digital platform.

4. For the purposes of this Article, the ECDC shall
 - (a) monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission;
 - (b) regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC and transmitted and exchanged through the digital platform.
5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making advice and regulatory purposes.
- 5a. Any processing of personal data for the purposes of this Article shall be carried out, whenever applicable, in accordance with the data protection requirements as laid down in Article 25a .
6. The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:
 - (a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing 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 platform, including to ensure protection of personal data and security of exchange of information;
 - (c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;

- (d) 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 platform and the practical arrangements of such access;
- (e) the cases where, and the conditions under which the data, information and documents referred to in Article 13 are to be transmitted using the platform and the list of such data, information and documents; and
- (f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures 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 plans referred to in Article 6, the Commission may, by means of implementing acts, define specific selection criteria and 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 specific tests for the uniform surveillance, notification and reporting of diseases by Member States.
2. The EU reference laboratories shall be responsible for the following tasks to coordinate 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 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.
4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 3 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

5. The 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 level 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, the EU reference laboratories shall also be accredited in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council²⁰.

- 6. Grants may be awarded to the 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 established by Regulation (EU) .../... of the European Parliament and of the Council²¹.

Article 16

Network for substances of human origin

- 1. A network of Member States' services supporting transfusion and transplantation to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. The network shall ensure to address any medically assisted reproduction issues in relation with disease outbreak, if relevant.

²⁰ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

²¹ [*Please insert title and OJ reference of the regulation.*]

2. The network 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 transfusion and transplantation as 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 point (iii) of point (a) of Article 2(1) and in points (b), (c) or (d) of Article 2(1), 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 ‘Early Warning and Response System’ (‘EWRS’) and, if the urgency of the situation so requires, through the HSC about developments with regard to the threat concerned at national level.
2. The information transmitted pursuant to paragraph 1 shall include in particular any change in geographical distribution, spread and severity of the threat concerned and of the means of detection, if available.
3. 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 27(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 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

CHAPTER IV

EARLY WARNING AND RESPONSE

Article 18

Early warning and response system

1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.
2. The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:
 - (a) the processing of personal data of authorised users of the system;
 - (b) the processing of health data and other personal data when strictly necessary for the purpose of contact tracing, through the EWRS selective messaging functionality, in accordance with Article 26.

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, provided that these technologies ensure an equivalent protection of personal data. The ECDC, in close cooperation with Member States, shall ensure the interoperability with national systems for the purposes of the early warning and response system.

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

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, 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 level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating 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 27(2).

For the purposes of this Article, any processing of personal data shall be carried out in accordance with data protection requirements, pursuant to Article 25a.

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, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and
 - (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 in accordance with Article 6 of the IHR, they shall at the latest 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;
 - (i) urgent need or shortage of medical countermeasures;
 - (j) requests and offers for cross-border emergency assistance, including requests for medical evacuation;
 - (k) personal data necessary for the purpose of contact tracing in accordance with Article 26;
 - (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 related 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.

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 or upon request of the HSC referred to in Article 21 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:

- (a) the ECDC in accordance with Article 8a of Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]] in the case of a threat referred to in point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or
- (b) the European Food Safety Authority (EFSA) in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council²² in the case of a threat referred to in Article 2 of this Regulation where the threat falls under the mandate of the EFSA; and/or
- (c) the European Chemicals Agency (ECHA) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council²³ in the case of a threat referred to in points (b) and (c) of Article 2(1) where the threat falls under the mandate of the ECHA; and/or
- (d) the European Environment Agency (EEA) in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council²⁴ in the case of a threat referred to in point (c) of Article 2(1) where the threat falls under the mandate of the EEA; and/or;

²² 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).

²³ 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).

²⁴ 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).

- (e) the European Centre for Monitoring for Drugs and Drug Addictions (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council²⁵ in the case of a threat referred to in point (b) of Article 2(1) where the threat falls under the mandate of the EMCDDA.
 - (f) The risk assessment shall be carried out in the case of a threat referred to in Article 2(1) in cooperation with the European Police Office (Europol) where the threat is emanating from terrorist or criminal activity referred to in Article 3 of Regulation (EU) 2016/794, and in cooperation with the European Medicines Agency ('EMA'), where the threat is linked to medicinal products.
2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 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 data protection requirements as laid down in Article 25a.
3. Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless grounds of urgency and necessity require the need is so urgent that the immediate publication of the risk assessment is necessary.

²⁵ 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).

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.

4. 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, on a request from the Commission or 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:
 - (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 and to healthcare 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 threats to health, based on the expert opinion of relevant technical Union bodies or agencies;
 - (d) the support to the EU's integrated political crisis response mechanism (IPCR) in case of its activation.

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the 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, promptly upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.
4. 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.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(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 at Union level.
2. The recommendation for measures adopted under paragraph 1 shall:
 - (a) be based on recommendations of the ECDC and the WHO in particular, other relevant 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 proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services;
- (d) be made available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alerts 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.

CHAPTER V

PUBLIC HEALTH EMERGENCY AT UNION LEVEL

Article 23

Recognition of public health emergency situations at Union level

1. For serious cross-border threats to health referred to in Article 2(1), the Commission may, based on the expert opinion of the ECDC, any other relevant Union agencies or bodies and 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 the Union level.
2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as one of the applicable conditions pursuant to paragraphs 1 and 4 are no longer met.

3. Before recognising a situation of 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 define specific criteria for a public health emergency at Union level by means of implementing acts.
5. The Commission shall adopt the decisions referred to in paragraphs 1 and 2 by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(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 situations of public health emergency at Union level pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

Article 24

Advisory Committee on public health emergencies

1. To support 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, shall advise the Commission 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) advice on response at Union level, 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 health care, civil protection and other resources as well as support measures to be organised or coordinated at Union level;
 - (iv) subsequently, recommendation of policy measures for addressing and mitigating long-term consequences of the specific threat.

The advice on response provided under point (c) of this paragraph shall build upon recommendations of the ECDC, the WHO and other relevant agencies or bodies, accordingly.

2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring, and include representatives of the ECDC and the EMA, as well as at least one expert nominated by each of the Member States within whose territory the threat arises, if applicable. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the WHO may participate as observers in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat may participate as non-permanent members in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis. The Member States may propose the appointment of relevant experts to the Commission, according to the specific subject matter.
3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State. The Commission shall share all relevant information on Advisory Committee's meetings with the Member States through the HSC.
4. The Advisory Committee shall be chaired by a representative of the Commission.
5. The Secretariat of the Advisory Committee shall be provided by the Commission.
6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of a public health emergency at Union level, adoption of recommendations, ~~and~~ voting and ensuring data protection and privacy. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.

Article 25

Legal effects of recognition

1. 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 the period of public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) .../... [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]];
 - (b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures, in accordance with the applicable Union legislation, in particular Regulation (EU) .../... [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]], and Article 12;
 - (c) activation of support from the ECDC as referred to in Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force;
 - (d) activation of IPCR mechanism as referred to in Council Decision 2014/415/EU.

CHAPTER VI

GENERAL PROVISIONS

Article 25a

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) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission, the ECDC and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.
2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of this Regulation. In such cases, the conditions of Regulation (EU) No 2016/679 and Regulation (EU) No 2018/1725 shall apply as appropriate.
3. Where processing of personal data is not strictly necessary to 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.

These implementing acts shall be adopted in accordance with the examination procedure referred to Article 27(2).

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 national competent authorities involved in the contact tracing measures concerned. 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 competent authorities implementing contact tracing measures 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 measures. Where the national competent authority notifying the alert can identify all the Member States concerned, based on the data at its disposal, it shall transmit data only to the national competent authorities of those Member States.
3. When circulating the information referred to in paragraph 2, the competent authorities shall refer to the alert communicated previously through the EWRS.
4. The selective message functionality shall not store the contact data or health data. It shall only allow national competent authorities to receive data that were sent to them by other national competent authorities for the sole purpose of contact tracing. The ECDC shall only access the data for ensuring the good functioning of the selective message functionality.
5. 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, by means of implementing acts, adopt:
- (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 competent authorities at national level and the ECDC;
 - (b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;
 - (c) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact tracing measures;

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 27

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 Article 3(2) 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 the third subparagraph of Article 5(4) 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 27a

Cooperation with WHO

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

Article 28

[...]

Article 29

Evaluations concerning this Regulation

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. 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 with the HSC.

CHAPTER VII

FINAL PROVISIONS

Article 30

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 the Annex.

Article 31

Entry into force

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,

For the European Parliament
The President

For the Council
The President
