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## **INFORMATION NOTE**

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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 - Outcome of the European Parliament's first reading (Strasbourg, 3 to 6 October 2022)

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### **I. INTRODUCTION**

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure<sup>1</sup>, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

In this context, the Chair of the Committee on the Environment, Public Health and Food Safety (ENVI), Pascal CANFIN (RE, FR), presented on behalf of the Committee a compromise amendment (amendment number 278) to the abovementioned proposal for a Regulation. This amendment had been agreed during the informal contacts referred to above. No other amendments were tabled.

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<sup>1</sup> OJ C 145, 30.6.2007, p. 5.

## II. VOTE

When it voted on 4 October 2022, the plenary adopted the compromise amendment (amendment number 278) to the abovementioned proposal for a Regulation. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto<sup>2</sup>.

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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<sup>2</sup> The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

## **P9\_TA(2022)0333**

### **Serious cross-border threats to health \*\*\*I**

**European Parliament legislative resolution of 4 October 2022 on the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health repealing Decision No 1082/2013/EU (COM(2020)0727 – C9-0367/2020 – 2020/0322(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0727),
  - having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0367/2020),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,
  - having regard to the opinion of the European Economic and Social Committee of 27 April 2021<sup>3</sup>,
  - having regard to the opinion of the Committee of the Regions of 7 May 2021<sup>4</sup>,
  - having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 29 June 2022 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the opinion of the Committee on the Internal Market and Consumer Protection,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0247/2021),
1. Adopts its position at first reading hereinafter set out<sup>5</sup>;

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<sup>3</sup> OJ C 286, 16.7.2021, p. 109.

<sup>4</sup> OJ C 300, 27.7.2021, p. 76.

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>5</sup> This position replaces the amendments adopted on 14 September and 11 November 2021 (Texts adopted, P9\_TA(2021)0377 and P9\_TA(2021)0449).

**P9\_TC1-COD(2020)0322**

**Position of the European Parliament adopted at first reading on 4 October 2022 with a view to the adoption of Regulation (EU) 2022/... of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>6</sup>,

Having regard to the opinion of the Committee of the Regions<sup>7</sup>,

Acting in accordance with the ordinary legislative procedure<sup>8</sup>,

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<sup>6</sup> OJ C 286, 16.7.21, p. 109.

<sup>7</sup> OJ C 300, 27.7.2021, p. 76.

<sup>8</sup> Position of the European Parliament of 4 October 2022

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<sup>9</sup>.<sup>1</sup> Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council<sup>10</sup><sup>1</sup> to strengthen and provide for a more coordinated and wider approach to health security at Union level. The implementation of that legislation confirmed that coordinated Union action on monitoring, early warning of and combatting those threats adds value to the protection and improvement of human health.

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<sup>9</sup> 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).

<sup>10</sup> 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).

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness for and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combatting serious cross-border threats to health, ***including zoonotic-related threats***, as provided for in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis regarding health systems indicators, and with regard to cooperation ***between Member States and Union agencies and bodies, particularly the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO), while taking into account the burden faced by national competent authorities depending on the actual public health situation.***

Moreover, in order to ensure the ***Union's*** effective **■** response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should make it possible to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring **■** of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies, ***while respecting Union legislation on data protection such as Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>11</sup> (GDPR).***

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<sup>11</sup> ***Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).***

- (3) *It is important that public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures for the purpose of preparing for and responding to cross-border threats to health are transparent in accordance with applicable legislation.*
- (4) The Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU, plays an important role in the coordination of **prevention**, preparedness and response planning for serious cross-border threats to health. The HSC should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health, *and to support better coordination between Member States to address those threats. A representative designated by the European Parliament should be able to participate in the HSC as an observer.*



- (5) *In order to increase the effectiveness of the preparedness for and response to serious cross-border threats to health, the Commission including, where relevant, the Health Emergency Preparedness and Response Authority (HERA) established as a Commission service by Commission Decision of 16 September 2021<sup>12</sup>, and the HSC, the ECDC, EMA and other relevant Union agencies and bodies should coordinate and cooperate in relation to such preparedness and response. The coordination between those bodies should build on the participation of relevant stakeholders and aim to avoid any duplication of efforts.*
- (6) In their joint opinion ‘Improving pandemic preparedness and management’, the Group of Chief Scientific Advisors to the Commission, the European Group on Ethics in Science and New Technologies and the Special Advisor to the President of the Commission on the response to COVID-19 recommend establishing a standing EU advisory body for health threats and crises.
- (7) *All recommendations, advice, guidance and opinions mentioned in this Regulation are inherently non-binding on their addressees. Recommendations allow the Commission, the ECDC and the HSC to make their views known and to suggest a line of action without imposing any legal obligation on those to whom such recommendations are addressed.*

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<sup>12</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (OJ C 393 I, 29.9.2021, p. 3).

- (8) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning of and combatting specific threats of a cross-border nature, ***such as the International Health Regulations (IHR) of the WHO adopted in 2005***. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health ***and environmental*** matters, covering goods such as medicinal products, medical devices, ***in vitro diagnostic medical devices***, and foodstuffs, substances of human origin, such as blood, ***plasma***, tissues and cells, and organs, and exposure to ionising radiation.
- (9) ***The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to follow the One Health approach to addressing current and emerging crises.***

- (10) *In line with the One Health and Health in all policies approaches, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. It is crucial that the Union support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage, in addressing the challenges of vulnerable groups and in strengthening the resilience, responsiveness and readiness of healthcare systems as regards addressing future challenges, including pandemics.* In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, **and all relevant stakeholders**, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community ('the Euratom Treaty'), whose activities are relevant to **prevention**, preparedness and response planning, and monitoring, early warning of, and combatting serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (EWRS) set up by Decision No **1082/2013/EU**. **The EWRS is to implement robust, accurate and interoperable data processes with Member States to ensure data quality and consistency. The ECDC should coordinate with Member States throughout such data processes, from assessing the data requirements, transmission, and collection to updating and interpretation, with a view to fostering strong collaboration between the Commission, the ECDC and national and regional competent bodies.**

- (11) ***Prevention, preparedness*** and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' ***prevention, preparedness and response plans*** so as to ensure they are compatible within the regional level structures. ***It is crucial that those Union and national plans be prepared with particular attention paid to cross-border regions in order to enhance their health cooperation. Where appropriate, regional authorities should be able to participate in the drawing up of such national plans.*** To support Member States in this endeavour, ***the Commission and the relevant Union agencies and bodies should provide*** targeted training and ***facilitate the sharing of best practices*** for healthcare staff and public health staff ***to improve their*** knowledge and necessary skills. ***Cross-border elements should also, where relevant, be included in the Union plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised treatment and intensive care across neighbouring regions.*** To ensure the implementation of ***the Union plan***, the Commission should ***facilitate*** stress tests, simulation exercises and in-action and after-action reviews with Member States. ***The Union plan*** should **■** be functional and updated, and have sufficient resources for ***its*** operationalisation. Following **■** reviews of the national plans, ***proposed recommendations*** should be ***addressed in an action plan*** and the Commission should be kept informed of ***any substantial revision of the national plans.***

- (12) Member States should provide the Commission with an update on the latest situation with regard to their *prevention*, preparedness and response planning and implementation at national level, *and where applicable at regional level*. Information provided by the Member States to the Commission should include the elements that Member States are obliged to report to the WHO in the context of the IHR<sup>1</sup>. *Access to timely and complete data is a precondition for prompt risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and a secured network are needed between Union agencies and bodies, the WHO and national competent authorities*. In turn, the Commission should report to the European Parliament and to the Council, every *three* years, on the state of play and progress with *regard to prevention*, preparedness, response planning and implementation at Union level, including on *recommended* actions, to ensure that national *prevention*, preparedness and response plans are adequate. In order to support the assessment of those plans, the ECDC should conduct *assessments* in Member States, in coordination with other Union agencies and bodies. Such planning should include in particular adequate preparedness of critical sectors of society, such as *agriculture*, energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between the health and veterinary sectors for prevention, preparedness and response planning *through the One Health approach*. *The obligations of Member States to provide information under this Regulation do not affect the application of Article 346(1), point (a), of the Treaty on the Functioning of the European Union (TFEU) pursuant to which no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*.

- (13) *Experience from the ongoing COVID-19 pandemic has demonstrated that there is a need for further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions. The national prevention, preparedness and response plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through cross-border training for healthcare staff and coordination exercises for the medical transfer of patients.*
- (14) *Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats to health and contributing to a better understanding on the part of the population of the countermeasures for and risk assessment of different threats. Health education campaigns based on the latest available evidence could help to improve population behaviour in this regard.*

- (15) *Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a public health emergency at Union level would trigger increased coordination and could enable the timely development, stockpiling and joint procurement of medical countermeasures, under Council Regulation (EU) .../...<sup>13+</sup>.*
- (16) *This Regulation should strengthen the tools to safeguard the security of supply of critical medical countermeasures within the Union, while respecting the proper functioning of the internal market in the event that serious cross-border threats to health arise.*

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<sup>13</sup> Council Regulation (EU) 2022/... of .... on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ ....).

<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22 and complete the corresponding footnote.

- (17) *In order to prevent shortages of critical medical countermeasures and protect the security of their supply at Union and national level, as well as to support an effective and strategic stockpile location, the Commission should ensure coordination and information exchange between the entities organising and participating in any action under the different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the framework of measures adopted under Regulation (EU) .../...<sup>+</sup>, and the strategic reserve established under Decision No 1313/2013/EU of the European Parliament and of the Council<sup>14</sup>, taking due account of the accessibility of those medical countermeasures for people in remote, rural and outermost regions.*
- (18) *A Joint Procurement Agreement for medical countermeasures was approved by the Commission on 10 April 2014. That Joint Procurement Agreement provides for a voluntary mechanism for participating countries and the Union institutions to jointly purchase medical countermeasures for different categories of cross-border threats to health including vaccines, antivirals and other treatments. It lays down common rules for the practical organisation of joint procurement procedures.*

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<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22.

<sup>14</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).



*This Regulation should strengthen and extend the framework for joint procurement of medical countermeasures, in accordance with measures concerning monitoring, early warning of and combatting serious cross-border threats to health, laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council<sup>15</sup>. In the event of a serious cross-border threat to health, the joint procurement of medical countermeasures laid down in this Regulation should constitute an effective operational instrument at the Union's disposal, together with other procurement instruments provided for in Union legislation. In particular, contracts under the joint procurement procedure laid down in this Regulation may be concluded or activated in times of crisis, pursuant to Regulation (EU) .../...<sup>+</sup>. In such instances, those contracts should abide by the conditions laid down in the Joint Procurement Agreement, as provided for in this Regulation.* The Commission should ensure coordination and information exchange between the entities organising *and participating in* any action under the different mechanisms established under this Regulation and other relevant Union **acts** related to procurement and stockpiling of medical countermeasures **.**

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<sup>15</sup> 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).

<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22.

**(19) *The Commission should support and facilitate the joint procurement of medical countermeasures by providing all relevant information for the negotiation of such joint procurement, such as information on envisaged prices, manufacturers, delivery time frames and modalities of joint procurement. The Joint Procurement Agreement determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU should also be adapted to provide for an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the Union, a strengthened negotiation position and more efficient action to protect the Union's security of supply. Under the exclusivity clause, participating countries commit to not procuring the medical countermeasure in question through other channels and to not running parallel negotiation processes for that countermeasure. The Commission should facilitate the decision of Member States on participation by providing an assessment, inter alia, of the application of the exclusivity clause, its necessity and the conditions thereof, to be jointly agreed with the participating countries. Member States should decide on their participation in the joint procurement procedure once all the necessary information has been provided to them. In any event, limitations to parallel procurement activities and negotiations should occur only when the participating countries have agreed to such restrictions. Due to the sensitive content of the assessment and its relevance for the financial interests of the Union and the participating Member States during a joint procurement procedure, the possibility of making it public should be duly weighed against the exceptions provided for in Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>16</sup>, and, in particular, Article 4 of that Regulation.***

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<sup>16</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

**(20) *As serious cross-border threats to health are not limited to Union borders, the Union should adopt a coordinated approach, characterised by solidarity and responsibility, in combatting such threats. Therefore, joint procurement of medical countermeasures should be extended to include European Free Trade Association States, Union candidate countries, in accordance with applicable Union legislation, the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046 and in accordance with Article 3(2) of that Regulation. Joint procurement of medical countermeasures is aimed at strengthening the negotiating position of participating countries, contributing to the contracting authorities' security of supply and ensuring equitable access to medical countermeasures against serious cross-border threats to health. Joint procurement procedures should abide by high standards of transparency in relation to Union institutions, including the European Court of Auditors, and Union citizens, in accordance with the principle of transparency as referred to in Article 15 TFEU. While taking into account the protection of commercially sensitive information and the protection of essential national security interests, transparency should also be encouraged in relation to the disclosure of information related to the delivery schedule of the medical countermeasures, terms of liabilities and indemnifications and the number of manufacturing locations. A high degree of transparency should be applied in accordance with Regulation (EC) No 1049/2001. This includes the right of citizens to request access to documents regarding jointly procured medical countermeasures in accordance with Article 2 of Regulation (EC) No 1049/2001. When joint procurement is deployed, in addition to cost, qualitative criteria should be considered in the award process.***

(21) *Prevention is one of the essential steps in the crisis management cycle, according to the WHO. Under the four categories of prevention that have been recognised at the international level, namely primary, secondary, tertiary and quaternary categories, a number of activities constitute a cornerstone for early warning of, monitoring and combatting serious cross-border threats to health. Those activities include the monitoring of vaccination coverage for communicable diseases, surveillance systems for the prevention of communicable diseases and measures to decrease the risk of communicable disease spreading at the personal and community levels, in line with the One Health approach. Investment in prevention activities in relation to serious cross-border threats to health would directly contribute to the objectives of this Regulation. The term ‘prevention’ or ‘disease prevention’ under this Regulation should therefore be understood as covering prevention activities which aim to minimise the burden of communicable diseases and associated risk factors for the purposes of early warning of, monitoring and combatting serious cross-border threats to health.*

(22) *The strengthened Union health framework addressing serious cross-border threats to health should work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, established by Regulation (EU) 2021/522 of the European Parliament and of the Council<sup>17</sup>; the European Structural and Investment Funds (ESIF), namely the European Regional Development Fund and the Cohesion Fund, established by Regulation (EU) 2021/1058 of the European Parliament and of the Council<sup>18</sup>, the European Social Fund Plus, established by Regulation (EU) 2021/1057 of the European Parliament and of the Council<sup>19</sup>, the European Agricultural Fund for Rural Development, established by Regulation (EU) No 1305/2013 of the European Parliament and of the Council<sup>20</sup>, and the European Maritime, Fisheries and Aquaculture Fund, established by Regulation (EU) 2021/1139 of the European Parliament and of the Council<sup>21</sup>; Horizon Europe,*

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<sup>17</sup> Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

<sup>18</sup> Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60).

<sup>19</sup> Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).

<sup>20</sup> Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

<sup>21</sup> Regulation (EU) 2021/1139 of the European Parliament and of the Council of 7 July 2021 establishing the European Maritime, Fisheries and Aquaculture Fund and amending Regulation (EU) 2017/1004 (OJ L 247, 13.7.2021, p. 1).

*established by Regulation (EU) 2021/695 of the European Parliament and of the Council<sup>22</sup>; the Digital Europe Programme, established by Regulation (EU) 2021/694 of the European Parliament and of the Council<sup>23</sup>; the rescEU reserve; the Emergency Support Instrument (ESI), provided for in Council Regulation (EU) 2016/369<sup>24</sup>; and the Single Market Programme (SMP), established by Regulation (EU) 2021/690 of the European Parliament and of the Council<sup>25</sup>.*

- (23) *The decision taken by the World Health Assembly during its Special Session on 1 December 2021 is set to start a global process for a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. In accordance with Council Decision (EU) 2022/451<sup>26</sup>, the Union should engage with the WHO and its Member States to develop a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. The Union will engage with the WHO and its Member States to develop a new legally binding instrument that complements the IHR, thereby strengthening multilateralism and the global health architecture. The Union should also support efforts to strengthen the implementation of and compliance with the IHR.*

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<sup>22</sup> Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

<sup>23</sup> Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021, p. 1).

<sup>24</sup> Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

<sup>25</sup> Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014 (OJ L 153, 3.5.2021, p. 1).

<sup>26</sup> Council Decision (EU) 2022/451 of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005) (OJ L 92, 21.3.2022, p. 1).

(24) *The COVID-19 pandemic has highlighted that major diseases can put severe pressure on the capacities of healthcare systems, with a negative impact, for example, on the provision of healthcare for patients with other communicable or non-communicable diseases, such as the continuity of healthcare, delay of or interruption to treatment for cancer patients and survivors and people with mental health issues. The impact of serious cross-border threats to health may thus pose further challenges in ensuring a high level of human health protection. While respecting the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, it is important to consider the impact of public health emergencies on the provision of healthcare services for other diseases and conditions, in order to safeguard the detection and treatment of other serious diseases and minimise delays or interruptions to such detection and treatment. Hence, the impact an important outbreak of a communicable disease, which absorbs an important part of health system capacities, can have on the continuity of healthcare and on the prevention and treatment of non-communicable diseases and comorbidities needs to be considered.*

- (25) *In times of crisis, ensuring the security of supply within the Union of critical medical countermeasures is paramount, and the experience derived from the COVID-19 pandemic has shown that this could be prejudiced by a number of factors. Union actions to safeguard commitments and protect the supply of medical countermeasures include, among others, an export authorisation mechanism pursuant to Regulation (EU) 2015/479 of the European Parliament and of the Council<sup>27</sup>, enhanced cooperation agreements and procurement activities. Where relevant, actions taken under this Regulation should consider the potential activation of such mechanisms, pursuant to applicable Union legislation.*
- (26) Unlike communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other ■ serious cross-border threats to health do not currently necessitate **systematic** monitoring by Union agencies and bodies. A risk-based approach, whereby monitoring is carried out by Member States' **monitoring systems** and available information is exchanged through the EWRS, is therefore more appropriate **to those** threats.

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<sup>27</sup> Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports (OJ L 83, 27.3.2015, p. 34).



- (27) The Commission should strengthen cooperation and activities with the Member States, the ECDC, EMA, other Union agencies *or bodies*, research infrastructures and the WHO to improve, *through the One Health approach*, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.
- (28) In *the* case of cross-border threats to health *posed by* a communicable disease, the *ECDC should cooperate with* Member States █ to safeguard patients █ in need of *treatment by* substances of human origin from the transmission of such a communicable disease. █ The ECDC should therefore *establish* and operate a network of █ services *supporting the use of substances of human origin*.
- (29) The EWRS, a system enabling the notification at Union level of alerts related to serious cross-border threats to health, *has* been put in place by Decision No *1082/2013/EU* in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All *serious cross-border threats to health* covered by this Regulation are covered by the EWRS.

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

- (30) In order to ensure that the assessment of risks to public health at Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated **and multidisciplinary** manner through appropriate channels or structures, depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies **and bodies** in those risk assessments needs to be broadened according to their speciality in order to ensure an all-hazard approach, via a permanent network of agencies and bodies and relevant Commission services to support the preparation of risk assessments. ***It is important that the Commission, at the request of the HSC or on its own initiative, and in close cooperation with the relevant Union agencies and bodies or Commission services, provide any relevant information, data and expertise at its disposal. Serious cross-border threats to health could require a multidisciplinary approach for their assessment and analysis, and coordination among Union agencies and bodies or Commission services might therefore be essential to ensure a swift and coordinated reaction. Where relevant, such coordination could, in particular, take the form of a multi-source risk assessment under the lead of a particular Union agency or body designated by the Commission. Union agencies and bodies should have adequate financial and human resources to achieve a sufficient degree of expertise and effectiveness in the framework of their mandates.***

- (31) *Member States, the Commission and Union agencies and bodies, while following the One Health approach, should identify recognised public health organisations and experts, and other relevant stakeholders across sectors, which are available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be engaged in the context of Union preparedness and response activities to contribute, where relevant, to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this Regulation, where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.*
- (32) Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect other Member States if they are inconsistent with one another or based on diverging risk assessments. The objective of coordinating the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the TFEU, such as those related to free movement of persons, goods and services.

- (33) The HSC, which is responsible for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for Member States related to the prevention and control of serious cross-border threats to health. Furthermore, should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures. ***In addition, regular dialogue between the HSC and relevant Council bodies should be reinforced in order to ensure better follow-up of the HSC's work at national level.***

- (34) Inconsistent communication with the public and stakeholders, such as healthcare ***and public health*** professionals, can have a negative impact on the effectiveness of the response from a public health perspective, as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and address communication challenges with a view to coordinating risk and crisis communication, based on ***holistic***, robust and independent evaluation of public health risks, to be adapted to national ***and regional*** needs and circumstances ***where relevant***. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. ***To that end, relevant public institutions should contribute to sharing verified information and fighting disinformation.*** Given the cross-sectoral nature of health-related crises, coordination should also be ensured with other relevant constituencies, such as the ***EU Civil Protection Community***.

(35) The recognition of public health emergencies and the legal effects of this recognition provided for in Decision No 1082/2013/EU should be broadened. To that end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of such emergency recognition. The advisory committee should consist of independent experts, ***including representatives of healthcare and social care workers and civil society representatives***, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring. Representatives of the ***Member States***, of the ECDC, of EMA, and of other Union agencies or bodies or of the WHO, should be able to participate as observers. ***All members of the Advisory Committee should provide declarations of interest.*** Recognition of a public health emergency at Union level should provide the basis for introducing operational public health measures for medicinal products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as the ‘EU Health Task Force’.

- (36) Before recognising a public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the outbreak and to inform the WHO of its intention to adopt such a recognition decision. Where such a recognition decision is adopted, the Commission should also inform the WHO thereof.
- (37) The occurrence of an event that corresponds to a serious cross-border threat to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such coordination could require the exchange of personal data, including sensitive information related to health and information about confirmed or suspected human cases of the disease *or infection*, between those Member States directly involved in the contact-tracing measures.

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- (38) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to the Union's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alert systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network, *such as the European Surveillance Portal for Infectious Diseases, operated by the ECDC*, and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response. *Those international cooperation agreements could also facilitate the donation of medical countermeasures, in particular for the benefit of low- and middle-income countries.*

(39) **Any** processing of personal data for the purpose of implementing this Regulation should **be fully compliant** with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>28</sup> **and Directive 2002/58/EC of the European Parliament and of the Council<sup>29</sup>. Processing of personal data should be limited to what is strictly necessary and, whenever possible, those data should be anonymised.** In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact-tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated **where necessary** to relevant authorities involved in contact-tracing measures, **medical evacuation or other cross-border procedures. In the case of cooperation between the health authorities of the Union and third countries, the WHO or other international organisations, transfers of personal data to third countries or international organisations should always comply with the obligations laid down under Regulation (EU) 2018/1725.**

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<sup>28</sup> 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).

<sup>29</sup> Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

- (40) *In order to avoid an administrative burden and the duplication of efforts, overlap of reporting and reviewing activities with existing structures and mechanisms for prevention, preparedness and response planning and implementation at national level in relation to serious cross-border threats to health should be avoided as far as possible. To that end, Member States should not be requested to report data and information if already required by the Commission or other Union agencies and bodies, pursuant to applicable Union legislation. In addition, the Union should further enhance its cooperation with the WHO, in particular under the IHR reporting, monitoring and evaluation frameworks.*
- (41) Since the objectives of this Regulation, namely to address serious cross-border threats to health and the consequences thereof, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (42) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.

- (43) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to: templates to be used when providing the information on preparedness and response planning; the organisation of the training activities and programmes for health-care and public health staff; the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; ■ the functioning of the digital platform for surveillance; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange, for consultation with Member States and for coordination of the responses of the Member States; the recognition of public health emergencies at Union level and the termination of such a recognition; the procedures for the interlinking of the EWRS with contact tracing systems and the procedures necessary to ensure that the processing of data is in accordance with the data protection legislation.

- (44) Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>30</sup>. As the implementing acts provided for in this Regulation concern the protection of human health, the Commission cannot adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with Article 5(4), second subparagraph, point (a), of Regulation (EU) No 182/2011.
- (45) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States, imperative grounds of urgency so require.

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<sup>30</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(46) In order to *supplement certain aspects of this Regulation and to* assess the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of: *the cases and the conditions under which third countries and international organisations can be granted partial access to the functionalities of the digital platform for surveillance, certain data, information and documents which can be transmitted using the platform and the conditions under which the ECDC can participate and be granted access to the health data accessed or exchanged through digital infrastructure, the detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with the data protection regulations, a list of categories of personal data that might be exchanged for the purpose of contact tracing and the* procedures, standards and criteria for the *assessment* of the prevention, preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making <sup>31</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>31</sup> OJ L 123, 12.5.2016, p. 1.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I  
GENERAL PROVISIONS

Article 1  
Subject matter

1. In order to address serious cross border threats to health and the consequences thereof, this Regulation lays down rules on:
  - (a) the *Health Security Committee (HSC)*;
  - (b) *prevention*, preparedness and response planning, including:
    - (i) preparedness plans at Union and national levels;
    - (ii) reporting and *assessing* preparedness *at national level*;
  - (c) joint procurement of medical countermeasures;
  - (d) *emergency research and innovation*;



- (e) epidemiological surveillance and monitoring;
- (f) the network for epidemiological surveillance;
- (g) the Early Warning and Response System (EWRS);
- (h) risk assessment;
- (i) coordination of response;
- (j) recognition of a public health emergency at Union level.

2. This Regulation establishes:

- (a) a network of EU reference laboratories for public health;
- (b) a network for substances of human origin;
- (c) an advisory committee for the occurrence and recognition of a public health emergency at Union level.

3. ***In line with the One Health and Health in all policies approaches, the*** implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

## Article 2

### Scope

1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:
- (a) threats of biological origin, consisting of:
    - (i) communicable diseases, ***including those of zoonotic origin***;
    - (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases ('related special health issues');
    - (iii) biotoxins or other harmful biological agents not related to communicable diseases;

- (b) threats of chemical origin;
- (c) threats of environmental origin, including those due to the climate;
- (d) threats of unknown origin;
- (e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR) ('public health emergencies of international concern'), provided that they fall under one of the categories of threats set out in points (a) to (d).

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.
3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring and early warning of serious cross-border threats to health, and the coordination of *prevention*, preparedness and response planning for, and the coordination of combatting, serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the *HSC* as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.
5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at *international level*, Union level or under the Euratom Treaty, whose activities are relevant for *prevention*, preparedness and response planning for, monitoring, early warning of, and combatting serious cross-border threats to health.
6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the implementation of this Regulation.

### Article 3 Definitions

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

- (1) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, as referred to in Article 2(1), which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;
- (2) ‘case definition’ means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;
- (3) ‘communicable disease’ means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent;
- (4) ‘contact tracing’ means measures ■ to *identify* persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of *being infected or being infectious or who* have developed a *communicable* disease, through manual or other technological means, *with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission*;

- (5) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;
- (6) ‘monitoring’ means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data on and analysis of specified indicators relating to serious cross-border threats to health;
- (7) ***‘One Health’ means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;***
- (8) ***‘Health in All Policies’ means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;***

- (9) ‘public health measure’ means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combatting severe risks to public health or mitigating their impact on public health;
- (10) ‘*medical countermeasures*’ means medicinal products for human use ■ as defined in Directive 2001/83/EC of the European Parliament and of the Council<sup>32</sup> ■, *medical devices as defined in point 12 of this Article and other goods or services that are necessary* for the purpose of preparedness for and response to ■ serious cross-border *threats* to health;

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<sup>32</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11, 2001, p. 67).

- (11) *'International Health Regulations' means the International Health Regulations (IHR) adopted by the World Health Organization (WHO) in 2005;*
- (12) *'medical device' means both a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>33</sup>, read in conjunction with Article 1(2) and Article 1(6), point (a), of that Regulation, and an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>34</sup>;*
- (13) *'health system capacity' means the degree to which a health system maximizes its performance on the following six health system core components or building blocks: (i) service delivery, (ii) health workforce, (iii) health information systems, (iv) access to medical countermeasures, (v) financing, and (vi) leadership/governance; for the purposes of this Regulation, this definition applies only to the parts of health system components or building blocks affected by serious cross-border threats to health .*

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<sup>33</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

<sup>34</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5, 2017, p. 176).



Article 4  
Health Security Committee

1. The HSC is hereby established. It shall be composed of representatives of the Member States at two working *levels*:
  - (a) a *senior* level working group *for regular discussions on serious cross-border threats to health and for the adoption of opinions and guidance as* referred to in paragraph 3, *point (d); and*
  - (b) technical working groups to discuss specific topics *if necessary*.
2. *Representatives of relevant Union agencies and bodies may participate in HSC meetings as observers.*
3. The HSC shall have the following tasks *in cooperation with relevant participating Union agencies and bodies*:
  - (a) enabling coordinated action by the Commission and the Member States for the implementation of this Regulation;

- (b) coordinating in liaison with the Commission *prevention*, preparedness and response planning ■ in accordance with Article 10;
- (c) coordinating in liaison with the Commission the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;
- (d) adopting opinions and guidance, including on specific response measures, for the Member States for the prevention and control of serious cross-border threats to health, *based on the expert opinion of relevant technical Union agencies or bodies*;
- (e) *adopting, on an annual basis, a working programme setting its priorities and objectives.*

4. As far as possible, the HSC shall adopt its guidance *and* opinions by consensus.

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

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

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

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

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

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

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

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

11. *The list setting out the authorities, organisations or bodies to which the HSC participants belong to shall be published on the Commission's website.*
12. *The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's website unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No 1049/2001.*

## CHAPTER II

### **PREVENTION, PREPAREDNESS AND RESPONSE PLANNING**

#### Article 5

##### Union *prevention*, preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies and bodies, *and in accordance with the WHO emergency preparedness and response framework set out in the IHR*, shall establish a Union health crisis and pandemic plan ('the Union *prevention*, preparedness and response plan') to promote an effective and coordinated response to cross-border threats to health at Union level.

2. The Union ***prevention***, preparedness and response plan shall complement the national ***prevention***, preparedness and response plans established in accordance with Article 6, ***and shall promote effective synergies between the Member States, the Commission, the European Centre for Disease Prevention and Control (ECDC) and other relevant Union agencies or bodies.***
3. The Union ***prevention***, preparedness and response plan shall, in particular, include ***provisions on joint*** arrangements for governance, capacities and resources for:
- (a) the timely cooperation between the Commission, the ***Council, the*** Member States, ***the HSC*** and the ***relevant*** Union agencies or ***bodies.*** ***The Union prevention, preparedness and response plan shall take into account the services and support potentially available under the Union Civil Protection Mechanism, and in particular the capacities under the rescEU stockpile as laid down in Commission Implementing Decision (EU) 2019/570<sup>35</sup> or other mechanisms, the capacities and resources made available for its purposes by the Union and the Member States, and the cooperation with the WHO for cross-border threats to health;***
  - (b) the secure exchange of information between the Commission, **█** the Member States, ***in particular the competent authorities or designated bodies responsible at national level, the HSC and the relevant Union agencies or bodies;***

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<sup>35</sup> Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

- (c) the epidemiological surveillance and monitoring;
- (d) the early warning and risk assessment, *especially regarding cross-border interregional preparedness and response*;
- (e) the risk and crisis communication, *including to health professionals and citizens*;
- (f) the health preparedness and response and *multi-sectoral* collaboration, *such as identifying risk factors for disease transmission and the associated disease burden, including social, economic and environmental determinants, following the One Health approach for zoonotic, food and waterborne diseases and relevant other diseases and related special health issues*;
- (g) *the drawing up of an overview of the production capacities for relevant critical medical countermeasures in the Union as a whole to address serious cross-border threats to health as referred to in Article 2*;
- (h) *emergency research and innovation*;

- (i) the management of the plan; *and*
- (j) *support to Member States for the monitoring of the impact of a serious cross-border threat to health on the provision and continuity of healthcare services, including for other diseases and conditions during health emergencies.*

4. The Union *prevention*, preparedness and response plan shall include *cross-border* interregional preparedness elements to *support aligned*, multi-sectoral, cross-border public health measures, in particular considering capacities for *surveillance*, testing, contact tracing, laboratories, *training of healthcare staff* and specialised treatment or intensive care across neighbouring regions. The Union prevention, preparedness and response *plan* shall *take into account national respective circumstances* and include preparedness and response means to address the situation of citizens with higher risks.
5. In order to ensure the implementation of the Union *prevention*, preparedness and response plan, the Commission shall *facilitate, in collaboration with Member States and, when applicable, with relevant Union agencies or bodies or with international organisations*, stress tests, *simulation* exercises and in-action and after-action reviews with Member States, and update the plan as necessary.



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

#### Article 6

##### National *prevention*, preparedness and response plans

1. *Without prejudice to Member States' competences in this area, when preparing national prevention, preparedness and response plans, Member States shall liaise with each other within the HSC and coordinate with the Commission in order to seek coherence with the Union prevention, preparedness and response plan to the largest possible extent.*
2. *National prevention, preparedness and response plans may include elements relating to governance, capacities and resources laid down in the Union prevention, preparedness and response plan as referred to in Article 5.*

3. ***Member States shall also inform without delay the Commission and the HSC of any substantial revision of their national prevention, preparedness and response plan.***
4. ***For the purposes of paragraph 1, Member States may also consult, where relevant, patient organisations, healthcare professionals' organisations, industry and supply chain stakeholders, as well as national social partners.***

#### Article 7

##### Reporting on ***prevention***, preparedness and response planning

1. By ... [12 months from the date of the entry into force of this Regulation] and every three years thereafter, Member States shall provide the Commission ***and relevant Union agencies and bodies*** with ***an updated*** report on ***prevention***, preparedness and response planning and implementation at national level ***and, where appropriate, cross-border interregional levels***.

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

- (a) identification of, and an update on, the status of the implementation of the capacity standards for ***prevention***, preparedness and response planning as determined at national ***and, where appropriate, crossborder interregional*** level for the health sector, as provided to the WHO in accordance with the IHR, ***as well as, where available, the interoperability arrangements between the health sector and other critical sectors in emergency situations;***

- (b) *an update, where necessary, on the* elements of emergency *prevention*, preparedness *and response planning*, in particular:
- (i) governance: including national *and, if appropriate, regional* policies and legislation that integrate emergency *and* preparedness *actions*; plans for emergency *prevention*, preparedness, response and recovery; coordination mechanisms, *including, where relevant, among national, regional or local administrative levels and in terms of multi-sectoral collaboration*;
  - (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; *business continuity measures and arrangements aimed at ensuring continuous* access to diagnostic services, *tools and medicinal products* during emergencies, *where available*; basic and safe gender-sensitive health and emergency services; *an overview of the impact of serious cross-border threats to health on the provision and continuity of healthcare services for other diseases and conditions during public health emergencies*; risk communications; research development and evaluations to inform and accelerate emergency preparedness;


- (iii) resources: including financial resources for emergency preparedness and contingency funding for response; ■ essential supplies for health; ***logistics mechanisms, including for the storage of medical countermeasures;*** dedicated, trained and equipped human resources for emergencies; ■
- (c) implementation of national prevention, preparedness and response plans, including where relevant implementation at the regional and, ***if appropriate,*** local levels, covering epidemic response; antimicrobial resistance, healthcare associated infection, and the other ***serious cross-border threats to health as referred to in Article 2;***
- (d) ***where applicable, consultation with relevant partners on risk assessment and national prevention, preparedness and response plans;***
- (e) ***actions taken to improve gaps found in the implementation of national prevention, preparedness and response plans.***

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

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

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

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

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

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

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

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

4. When receiving classified information transmitted pursuant to paragraph 1, the Commission, *the ECDC* and the HSC shall apply the rules on security regarding the protection of European Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443<sup>36</sup>**■** and (EU, Euratom) 2015/444<sup>37</sup>**■**.

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<sup>36</sup> Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

<sup>37</sup> 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).

5. Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 1 and 2, where it is classified as European Union classified information. Those national security regulations shall offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Decision (EU, Euratom) 2015/444<sup>38</sup> and in Council Decision 2013/488/EU<sup>38</sup>.

#### Article 8

##### *Assessment of prevention, preparedness and response planning*

1. Every three years, the ECDC shall **assess** the Member States' state of implementation of their national prevention, preparedness and response plans and their **relation** with the Union prevention, preparedness and response plan. Such **assessments** shall be **based on a set of agreed indicators and** carried out **in cooperation** with the relevant Union agencies or bodies and shall aim to assess **prevention, preparedness and response planning** at national level with regard to the information referred to in Article 7(1).
2. ***The ECDC shall, if applicable, present to the Member States and to the Commission recommendations based on the assessments referred to in paragraph 1, addressed to Member States, taking into account national respective circumstances.***

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<sup>38</sup> Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

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

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

Those actions may, in particular, include:

- (a) *regulatory actions*, if necessary;
  - (b) training initiatives;
  - (c) an overview ■ of good *practices*.
4. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation concerning procedures, standards and criteria for the *assessments* referred to in paragraph 1 of this Article.



## Article 9

### Commission report on *prevention*, preparedness *and response* planning

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

## Article 10

### Coordination of *prevention*, preparedness and response planning in the HSC

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

The coordination shall, in particular, aim to:

- (a) share best practice and experience in *prevention*, preparedness and response planning;
- (b) promote the interoperability of national *prevention and* preparedness planning and the *multi-sectoral* dimension of *prevention*, preparedness and response planning at Union level;
- (c) support the implementation of capacity requirements for surveillance and response as referred to in the IHR;

- (d) *support the development of the prevention, preparedness and response plans referred to in Articles 5 and 6;*
- (e) *monitor and discuss progress for gaps identified and actions to strengthen prevention, preparedness and response planning, including in the field of research, at cross-border regional, national and Union levels;*
- (f) *facilitate the exchange, outside the joint procurement procedure laid down in Article 12, of information on medical countermeasures, including, where appropriate, on pricing and delivery dates.*

2. *The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations.*

3. *The HSC shall also coordinate, where relevant, response to public health emergencies with the Health Crisis Board, where it is established in accordance with Regulation (EU) .../...<sup>+</sup>, and contribute accordingly to the coordination and information exchange within that body.*

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<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22.

## Article 11

### Training of healthcare staff and public health staff

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

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

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

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with the knowledge and skills necessary, in particular, to develop and implement the national *prevention*, preparedness and response plans, *and* implement activities to strengthen crisis preparedness and surveillance capacities, *especially regarding the gaps identified*, including in relation to the use of digital tools, *and shall be consistent with the One Health approach*.
3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union *in coordination, where possible, with ECDC activities in this area*.
4. Bodies whose staff participate in the training activities referred to in paragraph 1 shall ensure that the knowledge acquired through those activities is disseminated as necessary and is appropriately used in the staff training activities they organise.
5. The Commission *and relevant Union agencies and bodies* may support the organisation of programmes, in cooperation with the Member States *and Union candidate countries*, for the exchange of healthcare staff and public health staff, *as well as* for the temporary secondment of staff *between Member States, Union candidate countries or Union agencies and bodies*. *In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States*.

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

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

## Article 12

### Joint procurement of medical countermeasures

1. The Commission and any of the Member States ■ may engage, *as contracting parties*, in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 with a view to the advance purchase of medical countermeasures for serious cross-border threats to health *within a reasonable time frame*.
2. *A joint procurement procedure as referred to in paragraph 1 ■ shall be preceded by a Joint Procurement Agreement between the parties determining the practical arrangements governing that procedure and the decision-making process with regard to the choice of the procedure, the joint procurement assessment as referred to in paragraph 3, point (c), the assessment of the tenders and the award of the contract.*

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

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

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<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22.

- (c) *before the launch of a joint procurement procedure, the Commission prepares a joint procurement assessment which shall indicate the general envisaged conditions of the joint procurement procedure including as regards possible restrictions to parallel procurement and negotiation activities by the participating countries for the countermeasure in question during the specific joint procurement procedure; that assessment shall take into account the need to ensure security of supply of medical countermeasures concerned to the participating countries. Based on the joint procurement assessment and the relevant information provided therein, such as on envisaged price ranges, manufacturers, delivery time frames and the proposed deadline for decision on participation, the parties to the Joint Procurement Agreement shall express their interest in participating at an early stage. Those parties to the Joint Procurement Agreement which have expressed their interest shall subsequently decide on their participation in the joint procurement procedure under the conditions jointly agreed with the Commission, taking into account the information proposed in the joint procurement assessment;*



- (d) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade and does not cause distortion of competition;
- (e) the joint procurement does not have any direct financial impact on the budget of the countries referred to in point (a) that do not participate in the joint procurement.

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

- (a) stockpiling under rescEU referred to in Article 12 of Decision No 1313/2013/EU;
- (b) Regulation (EU) 2016/369;
- (c) the **■** Pharmaceutical Strategy for Europe;

- (d) the EU4Health Programme established by Regulation (EU) **2021/522**;
- (e) Regulation (EU) 2021/697 of the European Parliament and of the Council<sup>39</sup>; and
- (f) other **programmes and** instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies, **such as measures adopted under Regulation (EU) .../...<sup>+</sup>**.

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

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<sup>39</sup> Regulation (EU) 2021/697 of the European Parliament and of the Council of 29 April 2021 establishing the European Defence Fund and repealing Regulation (EU) 2018/1092 (OJ L 170, 12.5.2021, p. 149).

<sup>+</sup> OJ : please insert the number of the Regulation contained in document st6569/22.

CHAPTER III  
EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC  
MONITORING

Article 13

Epidemiological surveillance

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

**█** *The ECDC shall ensure the integrated operation of the network for epidemiological surveillance as set out in Article 5 of Regulation (EC) No 851/2004 of the European Parliament and of the Council<sup>40</sup>.*

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

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<sup>40</sup> Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

2. **The** network for epidemiological surveillance shall aim to:
- (a) monitor trends in communicable diseases over time, across Member States and in third countries, to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;
  - (b) detect and monitor any **cross-border** communicable disease outbreaks with 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 **and monitor** risk factors for disease transmission, and population groups at risk and in need of targeted prevention measures;

- (e) contribute to the assessment of the burden of communicable diseases on the population, using such data as disease prevalence, complications, hospitalisation and mortality;
- (f) contribute to the assessment of the capacity of health systems to diagnose, prevent and treat specific communicable diseases *with the objective of contributing to patient safety in the context of serious cross-border threats to health*;
- (g) contribute to modelling and scenario development for response;
- (h) *contribute to the identification of* research priorities and needs, and implement relevant research activities *aimed at strengthening public health*;
- (i) support the contact-tracing measures of competent health authorities.

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

4. ***The information communicated by the national competent authorities referred to in paragraph 3, point (a), may be, when available, reported at least at NUTS II level to the European Surveillance Portal for Infectious Diseases operated by the ECDC, on a timely basis.***
5. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 10 for each communicable disease and related special health issue referred to in paragraph 1.
6. The Commission and the Member States shall work together ***to strengthen the data collection and sharing capacity of Member States and*** to define disease-specific European surveillance standards based on the proposal of the ECDC, in consultation with the relevant surveillance networks.
7. The ECDC shall monitor ***and evaluate the epidemiological surveillance activities of dedicated networks on surveillance, including*** adherence to the surveillance standards referred to in paragraph 6; ***support Member States with scientific and technical advice to improve the timeliness, completeness and quality of the surveillance data reported;*** and share regular monitoring reports with the HSC and the Commission. ***The ECDC shall also, where applicable and in accordance with Regulation (EC) No 851/2004, make available its expertise on epidemiological surveillance to third countries.***

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

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

8. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States. *The HSC may adopt communications and recommendations on surveillance addressed to Member States, the ECDC and the Commission.*
9. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.
10. The Commission shall, by means of implementing acts, establish and update:



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

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

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

#### Article 14

##### Digital platform for surveillance

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

2. The digital platform for surveillance shall:
  - (a) enable the automated collection of surveillance and laboratory data, make use of ***relevant non-personal health data from a previously defined and authorised list from*** electronic health records ***and health databases***, and of media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting, ***including statistical reporting***;
  - (b) allow for the computerised handling and exchange of information, data and documents.
3. Member States shall be responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely **■**, complete ***and accurate*** information, data and documents transmitted and exchanged through the digital platform. ***Member States may promote the automation of this process between the national and the Union surveillance systems.***
4. The ECDC shall **■** monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission **■** .

5. For epidemiological *surveillance* purposes, the ECDC shall also have access to relevant health data accessed or made available through digital infrastructure enabling the use of health data for research, policy making *advice* and regulatory purposes.
6. The Commission shall adopt implementing acts for the functioning of the digital platform for surveillance which lay down:
  - (a) the technical specifications of the digital platform for surveillance, including the electronic data exchange mechanism for exchanges with existing *international and national* systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;
  - (b) the specific rules for the functioning of the digital platform for surveillance, including for the protection of personal data and security of exchange of information;
  - (c) contingency arrangements *including secure data backups* to be applied in the event of unavailability of any of the functionalities of the digital platform for surveillance; and
  - (d) *arrangements for promoting standardisation of the infrastructure for storage, processing and analysis of data.*

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

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

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

Article 15  
EU reference laboratories

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

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

2. The EU reference laboratories shall be responsible **■** for coordinating the network of national reference laboratories, in particular, in the following areas:
  - (a) reference diagnostics, including test protocols;
  - (b) reference material resources;
  - (c) external quality assessments;

- (d) scientific advice and technical assistance;
  - (e) collaboration and research;
  - (f) monitoring, alert notifications and support in outbreak response, *including to emerging communicable diseases and pathogenic bacteria and viruses*; and
  - (g) training.
3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, *in cooperation with the WHO reference laboratories. The governance structure of that network shall cover cooperation and coordination with existing national and regional reference laboratories and networks.*
4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period for designation of **four** years, and be reviewed regularly. Such designations shall establish the responsibilities and tasks of the designated EU reference laboratories ■ .
5. The EU reference laboratories referred to in paragraph 1 shall:
- (a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;

- (b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;
- (c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international levels are taken into account in their work;
- (e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and
- (f) where relevant, be equipped to comply with relevant biosecurity standards.

In addition to the requirements laid down in the first subparagraph of this paragraph, the EU reference laboratories shall also be accredited in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>41</sup> .

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

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<sup>41</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).



## Article 16

### Network for substances of human origin

1. A network of Member States' services supporting ***the use of substances of human origin, including*** transfusion ***and*** transplantation, ■ ('the network for substances of human origin') is hereby established to ■ monitor, assess and help address disease outbreaks that are relevant to substances of human origin. ***The network for substances of human origin shall also ensure that any medically assisted reproduction issues in relation to disease outbreaks, if relevant, are addressed.***
2. The network for substances of human origin shall be operated and coordinated by the ECDC.
3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting ***the use of substances of human origin, including*** transfusion ***and*** transplantation, ■ referred to in paragraph 1.

## Article 17

### Ad hoc monitoring

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

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

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

## CHAPTER IV EARLY WARNING AND RESPONSE

### Article 18 Early Warning and Response System

1. The EWRS shall enable the Commission, *the ECDC*, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alert notifications, assessing public health risks and determining the measures that may be required to protect public health.

2. The management and **operational** use of the EWRS shall involve the exchange of personal data in specific cases where the relevant legal instruments so provide. Such management and use shall include:

- (a) the processing of personal data of authorised users of the system; and
- (b) the processing of health data and other personal data **when strictly necessary for the purpose for which those data were transmitted**, through the EWRS selective messaging functionality, **in accordance with Article 28**.

***Taking into account Member States' opinions, the ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space-enabled applications, or other technologies for automated contact tracing, building upon the contact-tracing technologies developed by the Member States or by the Union, used for the purpose of combatting serious cross-border threats to health. The ECDC, in close cooperation with Member States, shall facilitate interoperability with national systems for the purposes of the EWRS.***

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

3. Each Member State shall designate the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of early warning and response ***in accordance with paragraphs 1 and 2 of this Article, as well as Articles 19 and 20.***
  
4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union ***and international*** levels, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid the overlapping of activities or conflicting actions with existing structures and mechanisms for preparedness for, monitoring, early warning of and combatting serious cross-border threats to health, ***in a coordinated One Health approach.***

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

Article 19  
Alert notification

1. National competent authorities or the Commission shall notify an alert in the EWRS where the emergence or development of a serious cross-border threat to health fulfils the following criteria:
  - (a) it is unusual or unexpected for the given place and time, it is causing or may cause significant morbidity or mortality in humans, it is growing rapidly or may grow rapidly in scale, or it is exceeding or may exceed national response capacity;
  - (b) it affects or may affect more than one Member State; and
  - (c) it requires or may require a coordinated response at Union level.
  
2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern, ***and in the absence of full interoperability between the WHO notification system and the EWRS, national competent authorities shall*** ■ simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as:
- (a) the type and origin of the agent;
  - (b) the date and place of the incident or outbreak;
  - (c) means of transmission or dissemination;
  - (d) toxicological data;
  - (e) detection and confirmation methods;
  - (f) public health risks;
  - (g) public health measures implemented or intended to be taken at national level;
  - (h) measures other than public health *measures, including multisectoral* measures;
  - (i) whether there is an urgent need for or shortage of medical countermeasures;

- (j) requests and offers for cross-border emergency assistance, *such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions*;
  - (k) personal data necessary for the purpose of contact tracing in accordance with Article 28;
  - (l) any other information relevant to the serious cross-border threat to health in question.
4. The Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response referred to in Article 21, including information relating to serious cross-border threats to health and public health measures related to serious cross-border threats to health, already transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.
5. *Member States shall update the information referred to in paragraph 3 as new data become available.*



## Article 20

### Public health risk assessment

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or at the 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 one or more of the following Union agencies or bodies:
  - (a) the ECDC in accordance with Article 8a of Regulation (EC) *No* 851/2004 in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), including where it relates to substances of human origin ■ that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of this Regulation;
  - (b) *the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2022/123 of the European Parliament and of the Council<sup>42</sup> where the serious cross-border threat to health is linked to medicinal products and medical devices;*

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<sup>42</sup> *Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).*

- (c) the European Food Safety Authority (EFSA) in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>43</sup> in the case of a *serious cross-border* threat to health referred to in Article 2 of this Regulation where that threat falls under the mandate of EFSA;
- (d) the European Chemicals Agency (ECHA) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>44</sup> in the case of a *serious cross-border* threat to health referred to in Article 2(1), point (b) or (c), of this Regulation where that threat falls under the mandate of the ECHA;
- (e) the European Environment Agency (EEA) in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council<sup>45</sup> in the case of a *serious cross-border* threat to health referred to in Article 2(1), point (c), of this Regulation, where that threat falls under the mandate of the EEA;
- (f) the European Monitoring Centre for Drugs and Drug *Addiction* (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council<sup>46</sup> in the case of a *serious cross-border* threat to health referred to in Article 2(1), point (b), of this Regulation, where that threat falls under the mandate of the EMCDDA.

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<sup>43</sup> 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).

<sup>44</sup> 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).

<sup>45</sup> 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).

<sup>46</sup> 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 be carried out in the case of a threat referred to in Article 2(1) of this Regulation in cooperation with the European Union Agency for Law Enforcement Cooperation (Europol) where the *serious cross-border* threat to health emanates from terrorist or criminal activity *referred to in Article 3 of Regulation (EU) 2016/794 of the European Parliament and of the Council*<sup>47</sup>; and in cooperation with EMA, where the *serious cross-border* threat to health is linked to medicinal products.

2. At the request of the Union agency or body carrying out the risk assessment within its mandate, the Union agencies and bodies referred to in paragraph 1 of this Article shall, without undue delay, provide any relevant information and data at their disposal.  
***Processing of personal data, whenever applicable, shall be carried out in accordance with the data protection requirements as laid down in Article 27.***
3. Where the risk assessment needed is totally or partially outside the mandates of the Union agencies and bodies referred to in paragraph 1, and is considered necessary for the coordination of the response at Union level, the Commission shall, at the request of the HSC or on its own initiative, provide an ad hoc risk assessment.

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<sup>47</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

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

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

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

#### Article 21

##### Coordination of response within the HSC

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

- (a) national responses, including research needs, to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the IHR and falls within Article 2 of this Regulation;
- (b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public **■**, to healthcare professionals *and public health professionals*;
- (c) *the* adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border *threat* to health, *based on the expert opinion of relevant technical Union agencies or bodies*;
- (d) *support for the EU Integrated Political Crisis Response Arrangements (IPCR) as referred to in Council Decision 2014/415/EU<sup>48</sup> in the event of its activation.*

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

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<sup>48</sup> Council Decision 2014/415/EU of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (OJ L 192, 1.7.2014, p. 53).

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, upon adoption, promptly inform the other Member States and the Commission on the nature, purpose and scope of those measures, *especially in cross-border regions*.
4. ***If necessary, in the event of a serious cross-border threat to health, Member States may request assistance from other Member States through the Emergency Response Coordination Centre (ERCC) provided for in Decision No 1313/2013/EU.***
5. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1, 2 and 3 of this Article.

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

## Article 22

### Recommendations on common temporary public health measures

1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures **■** .
2. The recommendations on common temporary public health measures adopted under paragraph 1 shall:
  - (a) be based on, in particular, recommendations of the ECDC *and the WHO*, other relevant Union agencies or bodies, or the Advisory Committee referred to in Article 24;
  - (b) respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care;
  - (c) be *necessary, suitable and* proportionate to the public health risks related to the serious cross-border threat to health in question, avoiding in particular any unnecessary restriction on the free movement of persons, of goods and of services, *and promote coordination of measures between Member States;*
  - (d) *be made available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alert systems; where the recommendation is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless the need is so urgent that the immediate publication of the recommendation is necessary.*

CHAPTER V  
PUBLIC HEALTH EMERGENCY AT UNION LEVEL

Article 23

Recognition of *public health* emergencies *at Union level*

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



4. The Commission shall adopt the measure referred to in paragraphs 1 and 2 of this Article by means of implementing acts.

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

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

#### Article 24

##### Advisory Committee on public health emergencies

1. ***In order to support the decision-making process regarding*** the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission ***or the HSC***, shall advise the Commission or the HSC by providing its views on:
  - (a) whether a threat constitutes a public health emergency at Union level;

- (b) the termination of a public health emergency at Union level; and
- (c) **■** response including:
  - (i) formulation of response measures, including risk and crisis communication, to be addressed to all Member States in line with the different stages of the threat in the Union;
  - (ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, non-pharmaceutical countermeasures and public health research needs;
  - (iii) prioritisation of healthcare, civil protection and other resources as well as support measures to be organised or coordinated at Union level; and
  - (iv) any subsequent recommendation of policy measures for addressing and mitigating the long-term consequences of the specific threat.

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

2. The Advisory Committee shall be composed of independent experts, ***who may include representatives of healthcare and social care workers and civil society representatives***, selected by the Commission according to the fields of expertise and experience of those representatives, which are the most relevant to the specific threat that is occurring, ***and including representatives of the ECDC and EMA as permanent observers***. The Advisory Committee ***shall*** have a multidisciplinary membership so that it can advise on ***public health***, biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ***WHO may also*** participate as observers in the Advisory Committee. The representatives of other Union agencies or bodies relevant to the specific threat ***may*** participate as ***non-permanent*** observers in the Advisory Committee as necessary. The Commission may invite experts with specific expertise with respect to an item on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis, ***in particular from the countries within whose territory the threat arises***. ***The Member States may propose the appointment of relevant experts to the Commission, depending on the specific item.***
3. ***The Commission shall publish information about the Advisory Committee in accordance with the rules of the European Commission on expert groups<sup>49</sup>, including the names of the experts selected to form part of the Advisory Committee and details of the professional or scientific backgrounds that justify their appointment. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment.***

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<sup>49</sup> Commission Decision of 30 May 2016 establishing horizontal rules on the creation and operation of Commission experts groups (not published in the OJ).

4. ***Where applicable, the Advisory Committee shall act in coordination with the Health Crisis Board, where it is established in accordance with Regulation (EU) .../...<sup>+</sup>.***
5. The Advisory Committee shall meet whenever the situation requires, at the request of the Commission, ***the HSC*** or a Member State. **■** ***The Commission shall share all relevant information about the Advisory Committee's meetings with the Member States through the HSC.***
6. ***The Advisory Committee*** shall be chaired by a representative of the Commission.
7. The Secretariat of the Advisory Committee shall be provided by the Commission.
8. The Advisory Committee shall establish its rules of procedure, including on the **■** adoption of ***opinions and*** recommendations, voting rules ***and ensuring data protection and privacy.*** Those rules of procedure shall enter into force upon receipt of a favourable opinion from the Commission. ***The minutes of the Advisory Committee's meetings shall be made public.***

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<sup>+</sup> OJ: please insert the number of the Regulation contained in st6569/22.

## Article 25

### Legal effects of recognition

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

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

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<sup>+</sup> OJ: please insert the number of the Regulation contained in st6569/22.

(d) *activation of the IPCR Arrangements.*

CHAPTER VI  
*FINAL PROVISIONS*

*Article 26*

*Transparency and conflict of interest*

1. *The HSC and the Advisory Committee shall carry out their activities in an independent, impartial and transparent manner and shall undertake to act in the public interest.*
2. *Representatives appointed to the HSC and to the Advisory Committee and, where relevant, observers shall not have any financial or other interests which might be considered prejudicial to their independence.*
3. *The representatives appointed to the HSC and to the Advisory Committee and, where relevant, observers shall make a declaration of their financial and other interests and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve or give rise to a conflict of interest.*

4. *Representatives who participate in meetings of the HSC or of the Advisory Committee and, where relevant, observers, shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda.*
5. *Where the Commission decides that a representative's declared interest constitutes a conflict of interest, that representative shall not take part in any discussions or decisions, nor shall that representative obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.*
6. *Representatives who participate in meetings of the HSC or the Advisory Committee, and, where relevant, observers shall be subject to requirements of professional secrecy, even after their duties have ceased.*

## *Article 27*

### *Personal data protection*

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

## Article 28

Protection of personal data concerning the EWRS selective messaging functionality

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



2. Where national competent authorities implementing contact-tracing measures *or medical evacuation procedures* communicate, through the EWRS, personal data necessary for contact-tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact-tracing *or medical evacuation* measures.
3. When *communicating* the *data* referred to in paragraph 2, the national competent authorities shall refer to the alert communicated previously through the EWRS.
4. *The selective message functionality shall be used solely for the purpose of contact tracing and medical evacuation. It shall only allow national competent authorities to receive data that were sent to them by other national competent authorities. The ECDC shall only access the data required to ensure the proper functioning of the selective message functionality.* Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting *at the latest*.
5. *Where necessary for the purpose of contact tracing, personal* data may also be exchanged using contact-tracing technologies. *The national competent authorities shall not retain the contact data and health data received through the selective message functionality for longer than the retention period applicable* in the context of *their national* contact-tracing activities.

6. The Commission shall adopt **delegated** acts to supplement this Regulation by establishing:
- (a) detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 **including the respective responsibilities of the national competent authorities and of the ECDC**; and
  - (b) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact-tracing measures.
7. **The Commission shall, by means of implementing acts, adopt:**
- (a) **procedures for the interlinking of the EWRS with contact-tracing systems at Union and international levels; and**
  - (b) the modalities for processing **contact-tracing technologies** and their interoperability, as well as the cases where, and the conditions under which, the third countries may be granted access to contact tracing interoperability and the practical arrangements for such access, **in full compliance with the GDPR and the applicable case law of the Court of Justice of the European Union.**

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

## Article 29

### Committee procedure

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

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

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

**Article 30**

**Cooperation with the WHO**

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

Article 31

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in **Article 8(4), Article 14(7) and Article 28(6)** shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of this Regulation].
3. The delegation of power referred to in **Article 8(4), Article 14(7) and Article 28(6)** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to *Article 8(4), Article 14(7) or Article 28(6)* shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 32*  
*Urgency procedure*

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

Article 33

Evaluations concerning this Regulation

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

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

#### Article 34

#### Repeal

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

Article 35

Entry into force

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

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

Done at ...,

*For the European Parliament*

*For the Council*

*The President*

*The President*



## ANNEX I

### *Section 1*

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

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

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

## *Section 2*

### *Criteria for use in the definition and classification of cases:*

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

### *Classification of cases:*

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

### *Section 3*

#### *Procedures for the operation of the network for epidemiological surveillance*

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

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

## ANNEX II

### Correlation table

<b>Decision No 1082/2013/EU</b>	<b>This Regulation</b>
<b>Article 1</b>	Article 1
<b>Article 2</b>	Article 2
<b>Article 3</b>	Article 3
<b>Article 4(1)</b>	Article 6
<b>Article 4(2)</b>	Article 7
<b>Article 5</b>	Article 12
<b>Article 6</b>	Article 13
<b>Article 7</b>	Article 17
<b>Article 8</b>	Article 18
<b>Article 9</b>	Article 19
<b>Article 10</b>	Article 20
<b>Article 11</b>	Article 21
<b>Article 12</b>	Article 23(1), (3), (4)

<b>Article 13</b>	Article 25
<b>Article 14</b>	Article 23(2)
<b>Article 15</b>	---
<b>Article 16(1)</b>	Article 27
<b>Article 16(2) to (8)</b>	Article 28
<b>Article 17</b>	Article 4
<b>Article 18</b>	Article 29
<b>Article 19</b>	Article 33
<b>Article 20</b>	Article 34
<b>Article 21</b>	Article 35
<b>Article 22</b>	---
<b>Annex</b>	Annex I

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