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NOTE

From:	General Secretariat of the Council
To:	Delegations
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

With a view to the the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices that will take place on 17 May, delegations will find attached a draft text as prepared by the Presidency.

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~strikethrough~~ for deletions.

Draft text

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on serious cross-border threats to health and repealing Decision No 1082/2013/EU

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. In order to address serious cross border threats to health and the consequences thereof, this Regulation lays down rules on:
 - (a) the health security committee
 - (b) preparedness and response planning, including:
 - (i) preparedness plans at Union ~~and national~~ levels;
 - (ii) reporting and **reviewing** ~~auditing~~ on preparedness **at national level**;
 - (c) joint procurement of medical countermeasures;
 - (d) epidemiological surveillance and monitoring;
 - (e) the network for epidemiological surveillance

- (f) the early warning and response system;
- (g) risk assessment;
- (h) coordination of response;
- (i) recognition of a public health emergency situation at Union level.

2. This Regulation establishes:

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

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

Article 2

Scope

1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:

- (a) threats of biological origin, consisting of:
 - (i) communicable diseases;
 - (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter ‘related special health issues’);
 - (iii) biotoxins or other harmful biological agents not related to communicable diseases;

- (b) threats of chemical origin;
- (c) threats of environmental or climate origin;
- (d) threats of unknown origin;
- (e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided that they fall under one of the categories of threats set out in points (a) to (d).
2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.
3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning of, the coordination of preparedness and response planning for, and the coordination of, combatting serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.
4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the 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 Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.

Article 3

Definitions

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

- (1) ‘case definition’ means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;
- (2) ‘communicable disease’ means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent;
- (3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;
- (4) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;
- (5) ‘monitoring’ means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data and analysis on specified indicators relating to serious cross-border threats to health;

- (6) ‘public health measure’ means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health;
- (7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;
- (8) ‘medical countermeasure’ means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council¹ and in Regulation (EU) 2017/745 of the European Parliament and of the Council² or other goods or services for the ~~for the~~ purpose of preparedness and response to a serious cross-border threat to health.
- (9) ‘health systems’ capacity’ means [a definition is under development by the Presidency]**

Article 4

Health Security Committee

1. The Health Security Committee (‘HSC’) is hereby established. It shall be composed of representatives of the Member States, in two working formations:

¹ 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).

² 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).

(a) a high-level **steering** ~~working~~ group to discuss topics of political importance and decisions referred to in point (d) of paragraph ~~2~~ 3 and paragraph 7;

(b) technical working groups to discuss specific topics of technical nature.

2. The HSC shall have the following tasks:

(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;

(b) coordination in liaison with the Commission of the preparedness and response planning **in competence** of the Member States in accordance with Article 10;

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

(d) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health.

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

In the event of a vote, the outcome of the vote shall be decided by simple majority of the members.

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

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

5. The secretariat shall be provided by the Commission.
6. The HSC shall adopt, by a majority of two thirds of its members, its rules of procedure. Those rules of procedure shall establish working arrangements, in particular with regard to:
- (a) the procedures for plenary meetings at high level and technical working groups;
 - (b) the participation of experts in plenary meetings at high level, the status of possible observers, including from third countries;
 - (c) the arrangements for the HSC to examine the relevance to its mandate of a matter submitted to it and the possibility of recommending referral of that matter to a body competent under a provision of another act of the Union or under the Euratom Treaty; those arrangements shall not affect the obligations of the Member States under Articles 10 and 21 of this Regulation.
7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1.

Member States shall notify the Commission and other Member States of the designations and of any change thereof. **In the event of such change, the Commission shall distribute immediately to the HSC an updated list of such designations.**

The Commission shall make publicly available the updated list of the designated members, as well as of the authorities to which the representatives in the HSC belong.

CHAPTER II

PREPAREDNESS AND RESPONSE PLANNING

Article 5

Union preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.
2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6, **and promote effective synergies between the Member States, the Commission, the ECDC and other relevant Union bodies or agencies.**
3. The Union preparedness and response plan shall, in particular, include **provisions of joint** arrangements for governance, capacities and resources for:
 - (a) the timely cooperation between the Commission, the Member States, **the HSC** and the **relevant** Union **bodies or** agencies;
 - (b) the secure exchange of information between the Commission, **the competent authorities responsible at national level, the HSC and the relevant** Union **relevant bodies or** agencies ~~and the Member States~~;
 - (c) the epidemiological surveillance and monitoring;
 - (d) the early warning and risk assessment, **especially regarding interregional preparedness and response**;

- (e) the risk and crisis communication;
- (f) the health preparedness and response and **multi-sectoral** ~~intersectoral~~ collaboration;
- ~~(g) the management of the plan.~~

4. The Union preparedness and response plan shall include interregional preparedness elements to **support** ~~establish~~ **aligned** ~~coherent~~, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.
5. In order to ensure the operation of the Union preparedness and response plan, the Commission, **in collaboration with Member States**, shall conduct stress tests, **simulation** exercises and in-action and after-action reviews ~~with Member States~~, and update the plan as necessary.

Article 6

National preparedness and response plans

1. When preparing national preparedness and response plans ~~each~~ Member States shall **liaise with each other within the HSC and** coordinate with the Commission in order to reach consistency with the Union preparedness and response plan **to the largest possible extent**, **and** also inform without **undue** delay the Commission and the HSC of any substantial revision of the national plan.

Article 7

Reporting on preparedness and response planning

1. Member States shall by the end of November ~~2022~~ 2021 and every ~~3~~ 2 years thereafter provide the Commission **and the ECDC** with a report on their preparedness and response planning and implementation at national level **in relation to the serious cross-border threats to health referred to in Article 2(1).**

That report shall cover the following:

- (a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;
- (b) elements of emergency preparedness, in particular:
 - (i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms, **including in terms of multi-sectoral collaboration;**
 - (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;
 - (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and

- (c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other **serious cross-border threats to health specific issues**.

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

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

The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national level.

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

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

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(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 Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443³ and 2015/444⁴.
5. Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 1 and 2, where it is classified as EU classified information. Those national security regulations shall offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom⁵ and by Council Decision 2011/292/EU⁶.

Article 8

Reviewing Auditing on preparedness and response planning

1. Every ~~4~~ 3 years, the ECDC shall conduct **reviews** ~~audits~~ in the Member States ~~about~~ ~~aimed~~ ~~at ascertaining~~ the state of implementation of the national plans and their **liaison** ~~coherence~~ with the Union plan. Such **reviews** ~~audits~~ shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

³ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁴ 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 OJ L 317, 3.12.2001, p. 1.

⁶ OJ L 141, 27.5.2011, p. 17.

2. Member States shall present **to the Commission and the ECDC** an action plan addressing the proposed recommendations of the **review** ~~audit~~ and the corresponding **improvement** ~~corrective~~ actions and milestones.

~~These actions may, in particular, include:~~

- ~~(a) — review/adjustment of the legislation, if necessary;~~
- ~~(b) — training initiatives;~~
- ~~(c) — overview reports of audits series, which present cases of good practice.~~

3. The Commission shall, **by means of implementing acts, establish** ~~adopt delegated acts in accordance with Article 28 concerning~~ procedures, standards and criteria for the **reviews** ~~audits~~ referred to in paragraph 1.

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

Article 9

Commission report on preparedness and response planning at Union Level

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the **reviews** ~~audits~~ referred to in Article 8, the Commission shall by July **2023** ~~2022~~ and every **4** ~~2~~ years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.
2. The Commission may **complement the action of the Member States through the adoption of** ~~adopt~~ recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.

Article 10

Coordination of preparedness and response planning in the HSC

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

The coordination shall, in particular, be aimed at:

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

Article 11

Training of health care staff and public health staff

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

The Commission shall organise those activities in cooperation with the Member States concerned, **as well as with the ECDC and the WHO.**

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, **and** implement activities to strengthen crisis preparedness and surveillance capacities, **especially regarding the gaps identified**, including the use of digital tools.
3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.
4. The bodies whose staff participates in the training activities organised in accordance with paragraph 1 shall ensure that the knowledge acquired through those activities is disseminated as necessary and is appropriately used in the staff training activities they organised.
5. The Commission **and relevant Union agencies** may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff, **as well as** ~~and~~ for the temporary secondment of staff **between** ~~from one~~ Member States ~~to the other~~ **or Union agencies**.
6. The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5.

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

Article 12

Joint procurement of medical countermeasures

1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council⁷ with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.
2. The joint procurement procedure referred to in paragraph 1, shall comply with the following conditions:
 - (a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States and Union candidate countries, **as well as Andorra, Monaco and San Marino** ~~in accordance with~~ **by way of derogation from** Article 165(2) of Regulation (EU, Euratom) 2018/1046;
 - (b) the rights and obligations of Members States, EFTA States and Union candidate countries not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;
 - (c) Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;
 - (d) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortion of competition;

⁷ 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).

- (e) the joint procurement shall not have any direct financial impact on the budget of Member States, EFTA States and Union candidate countries not participating in the joint procurement.

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

- (a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;
- (b) Regulation (EU) 2016/369;
- (c) the upcoming Pharmaceutical Strategy ;
- (d) the EU4Health Programme established by Regulation (EU) .../... of the European Parliament and of the Council⁸;
- (e) Regulation (EU) No.../... of the European Parliament and of the Council⁹; and
- (f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

⁸ *[Please insert title and OJ reference of the regulation.]*

⁹ Regulation (EU).../... of the European Parliament and of the Council of ... establishing the European Defence Fund (OJ).

CHAPTER III

EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING

Article 13

Epidemiological surveillance

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

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

2. The epidemiological surveillance network shall aim to:
 - (a) monitor trends in communicable diseases over time and across Member States and in third countries to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;
 - (b) detect and monitor any multinational communicable disease outbreaks with respect to source, time, population and place in order to provide a rationale for public health action;

- (c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve those programmes at the national and Union level;
- (d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;
- (e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation and mortality;
- (f) contribute to the assessment of health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;
- (g) contribute to modelling and scenario development for response;
- (h) **contribute to the identification** ~~identify~~ **of** research priorities and needs, and implement relevant research activities;
- (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 epidemiological surveillance network:

- (a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1);
- (b) relevant information concerning the progression of epidemic situations, including for modelling and scenario development;
- (c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;

- (d) molecular pathogen data, if required for detecting or investigating cross-border health threats;
 - (e) health systems ~~system~~ data required for managing cross-border health threats; and
 - (f) information about contact tracing monitoring systems developed at national level.
4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.
5. The Commission and the Member States shall work together to define disease-specific European surveillance standards based on the proposal of the ECDC, in consultation with the relevant surveillance networks.
6. The ECDC shall **liaise with** ~~monitor~~ Member States' **to review the** adherence to these surveillance standards, **supporting Member States with technical and scientific advice to improve the timeliness, completeness and quality of the surveillance data reported.** ~~and share regular monitoring reports with the HSC and the Commission.~~
- ~~The ECDC shall regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC.~~
7. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States. **The HSC may adopt communications and recommendations on surveillance addressed to Member States, the ECDC and the Commission.**
8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.

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

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

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

Article 14

Platform for surveillance

1. The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, 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, in close cooperation with Member States, shall ensure the interoperability with national systems.**
2. The digital platform shall
 - (a) enable the automated collection of surveillance and laboratory data, make use of information from electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;
 - (b) allow for the computerised handling and exchange of information, data and documents.
3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, data and documents transmitted and exchanged through the digital platform.
4. The ECDC shall
 - (a) monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission;
 - (b) regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC and transmitted and exchanged through the digital platform.

5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.
6. The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:
- (a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;
 - (b) the specific rules for the functioning of the platform, including to ensure protection of personal data and security of exchange of information;
 - (c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;
 - (d) the cases where, and the conditions under which the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;
 - (e) the cases where, and the conditions under which the data, information and documents referred to in Article 13 are to be transmitted using the platform and the list of such data, information and documents; and
 - (f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5.

Article 15

EU reference laboratories

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of **specific** ~~certain~~ tests for the uniform surveillance, notification and reporting of diseases by Member States.
2. The EU reference laboratories shall be responsible ~~in particular~~ for the following tasks to coordinate the network of national reference laboratories, in particular, in the following areas:
 - (a) reference diagnostics, including test protocols;
 - (b) reference material resources;
 - (c) external quality assessments;
 - (d) scientific advice and technical assistance;
 - (e) collaboration and research;
 - (f) monitoring, alert and support in outbreak response; and
 - (g) training.
3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, **in cooperation with the WHO Reference Laboratories.**

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly.
- Designations shall establish the responsibilities and tasks of the designated laboratories.

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

5. The laboratories referred to in paragraph 1 shall
- (a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;
 - (b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;
 - (c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
 - (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;
 - (e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and
 - (f) where relevant, be equipped to comply with relevant biosecurity standards.

In addition to the requirements laid down in the first subparagraph, the EU reference laboratories shall also be accredited in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council¹⁰.

¹⁰ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

6. Grants may be awarded to the laboratories referred to in paragraph 1 for the costs that they incur in implementing annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with the EU4Health Programme established by Regulation (EU) .../... of the European Parliament and of the Council¹¹.

Article 16

Network for substances of human origin

1. A network of Member States' services supporting transfusion, transplantation and medically assisted reproduction is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and to monitor, assess and help address disease outbreaks that are relevant to substances of human origin.
2. The network shall be operated and coordinated by the ECDC.
3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting transfusion, transplantation and medically assisted reproduction as referred to in paragraph 1.

Article 17

Ad hoc monitoring

1. Following an alert notified pursuant to Article 19 concerning a serious cross-border threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) or (d) of Article 2(1), Member States shall, in liaison with the Commission and on the basis of the available information from their monitoring systems, inform each other through the 'Early Warning and Response System' ('EWRS') and, if the urgency of the situation so requires, through the HSC about developments with regard to the threat concerned at national level.

¹¹ [Please insert title and OJ reference of the regulation.]

2. The information transmitted pursuant to paragraph 1 shall include in particular any change in geographical distribution, spread and severity of the threat concerned and of the means of detection, if available.
3. The Commission shall, by means of implementing acts, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

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

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

CHAPTER IV

EARLY WARNING AND RESPONSE

Article 18

Early warning and response system

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

2. The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:
 - (a) the processing of personal data of authorised users of the system;
 - (b) the processing of health data and other personal data, in particular, the contact tracing data through the EWRS selective messaging functionality.

Taking into account Member States' opinions, the 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. **The ECDC, in close cooperation with Member States, shall ensure the interoperability with national systems for the purposes of early warning and response.**

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

3. Each Member State shall designate the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of early warning and response.
4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(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, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and
 - (b) it affects or may affect more than one Member State; and
 - (c) it requires or may require a coordinated response at Union level.
2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, they shall at the latest simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.
3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as:
 - (a) the type and origin of the agent;
 - (b) the date and place of the incident or outbreak;
 - (c) means of transmission or dissemination;
 - (d) toxicological data;
 - (e) detection and confirmation methods;

- (f) public health risks;
 - (g) public health measures implemented or intended to be taken at national level;
 - (h) measures other than public health measures;
 - (i) urgent need or shortage of medical countermeasures;
 - (j) requests and offers for cross-border emergency assistance, **including requests for medical evacuation**;
 - (k) personal data necessary for the purpose of contact tracing in accordance with Article 26, **or medical evacuation**;
 - (l) any other information relevant to the serious cross-border threat to health in question.
4. The Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response referred to in Article 21, including information related to serious cross-border threats to health and public health measures related to serious cross-border threats to health already transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.

Article 20

Public health risk assessment

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

- (a) the ECDC in accordance with Article 8a of Regulation (EU) .../... *[OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]]* in the case of a threat referred to in ~~points (i) and (ii)~~ of point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or
- (b) the European Food Safety Authority (EFSA) in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council¹² in the case of a threat referred to in Article 2 of this Regulation where the threat falls under the mandate of the EFSA; and/or
- (c) the European Chemicals Agency (ECHA) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council¹³ in the case of a threat referred to in points (b) and (c) of Article 2(1) where the threat falls under the mandate of the ECHA; and/or
- (d) the European Environment Agency (EEA) in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council¹⁴ in the case of a threat referred to in point (c) of Article 2(1) where the threat falls under the mandate of the EEA; and/or;

¹² 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).

¹³ 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).

¹⁴ Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13).

- (e) the European Centre for Monitoring Centre for Drugs and Drug Addictions (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council¹⁵ in the case of a threat referred to in point (b) of Article 2(1) where the threat falls under the mandate of the EMCDDA.
- (f) The risk assessment shall be carried out in the case of a threat referred to in Article 2(1) in cooperation with the European Police Office (Europol) where the threat is emanating from terrorist or criminal activity **referred to in Article 3 of Regulation (EU) 2016/794**, and in cooperation with the European Medicines Agency ('EMA'), where the threat is linked to medicinal products.
2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information and data at their disposal.
3. Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

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

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.

¹⁵ 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).

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

Article 21

Coordination of response within the HSC

1. **In accordance with the provisions of Article 168 of the Treaty on European Union,**
~~f~~Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall **consult each other and** coordinate within the HSC and in liaison with the Commission:
- (a) national responses, including research needs, to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the IHR and falls within Article 2 of this Regulation;
 - (b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals;
 - (c) 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;
 - (d) support to the EU's integrated political crisis response mechanism (IPCR) in case of its activation.**

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.
3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, **promptly** ~~immediately~~ upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.
4. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1, 2 and 3.

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

Article 22

Recommendations on common temporary public health measures

1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures for Member States.
2. The recommendation for measures adopted under paragraph 1 shall:
 - (a) be based on ~~in particular~~ recommendations of the ECDC **and the WHO** in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;

- (b) respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care;
- (c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.

CHAPTER V

PUBLIC HEALTH EMERGENCY AT UNION LEVEL

Article 23

Recognition of emergency situations

1. The Commission may, based on the expert opinion of the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level.
2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as one of the applicable conditions laid down therein is no longer met.
3. Before recognising a situation of public health emergency at Union level, the Commission **shall** ~~should~~ liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

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

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

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency **at Union level** pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

Article 24

Advisory Committee on public health emergencies

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:
 - (a) whether a threat constitutes a public health emergency at Union level;
 - (b) the termination of a public health emergency at Union level; and
 - (c) advice on response **at Union level**, including:
 - (i) formulation of response measures, including risk and crisis communication, to be addressed to all Member States in line with the different stages of the threat in the Union;

- (ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, non-pharmaceutical countermeasures and public health research needs;
- (iii) prioritisation of health care, civil protection and other resources as well as support measures to be organised or coordinated at Union level;
- (iv) subsequently, recommendation of policy measures for addressing and mitigating long-term consequences of the specific threat.

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

2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring, **and include representatives of the ECDC and the EMA, as well as at least one expert nominated by the Member State(s) within whose territory the threat arises.** The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ~~WHO ECDC and of the EMA~~ participate as observers in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis. **The Member States may propose the appointment of relevant experts to the Commission, according to the specific subject matter.**
3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State.

4. The Advisory Committee shall be chaired by a representative of the Commission.
5. The Secretariat of the Advisory Committee shall be provided by the Commission.
6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of **a public health emergency at Union level** ~~an emergency situation~~, and adoption of recommendations, and voting **and ensuring data protection and privacy**. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.

Article 25

Legal effects of recognition

1. The recognition of **a public health emergency at Union level** ~~an emergency situation~~ pursuant to Article 23 shall have the legal effect of enabling the introduction of:
 - (a) measures, which are applicable during the period of public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) .../... [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]];
 - (b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures;
 - (c) activation of support from the ECDC as referred to in Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force;
 - (d) activation of IPCR mechanism as referred to in Council Decision 2014/415/EU.**

CHAPTER VI

PROCEDURAL PROVISIONS

Article 26

Protection of personal data concerning the EWRS selective messaging functionality

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed and operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.
2. Where competent authorities implementing contact tracing measures communicate through the EWRS personal data necessary for contact tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact tracing measures.
3. When circulating the information referred to in paragraph 2, the competent authorities shall refer to the alert communicated previously through the EWRS.
4. Messages containing personal data shall automatically be erased from the selective message functionality **12+4 months**~~days~~ after the date of their posting.
5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.

6. The Commission shall, by means of implementing acts, adopt:
- (a) detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725;
 - (b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;
 - (c) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact tracing measures;
 - (d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access.

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

Article 27

Committee procedure

1. The Commission shall be assisted by a committee on serious cross-border threats to health. That Committee shall be a committee within the meaning of Article 3(2) of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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

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

Article 28

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(3) shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators].~~
3. ~~The delegation of power referred to in Article 8(3) 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 on Better Law Making of 13 April 2016.~~
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(3) 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 29

Evaluations concerning this Regulation

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.

CHAPTER VII

FINAL PROVISIONS

Article 30

Repeal

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

Article 31

Entry into force

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

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President
