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NOTE

from:	General Secretariat of the Council
to:	Working Party on Public Health
No prev doc:	15794/12 SAN 266 PHARM 78 PROCIV 173 CODEC 2580
No Cion prop:	18509/11 SAN 273 PHARM 8 PROCIV 169 CODEC 2404
Subject:	Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health

Following several meetings of the Working Party on Public Health concerning the above proposal (3 July, 3, 19 and 24 September, 8 and 25 October), the Presidency asked delegations for written comments on the last Presidency's proposal in document 15794/12. Written comments have been received from 14 Member States.

On the basis of the text in document 15795/12 and comments received, the Presidency submits new compromise proposals set out in the Annex.

Specific positions of delegations are noted in footnotes. General reservations has been entered by UK, SE and RO. It is also understood that all delegations keep general scrutiny reservation on the text attached.

* * *

The text in the attachment is marked as follows:

Strikethrough	Deletions of the text of the Commission's proposal
<i>bold italics</i>	Additions to the text of the Commission's proposal
<u>Strikethrough underlined</u>	<u>New</u> proposals for deletions of the Commission's proposal, marked with respect to the previous document 15794/12.
<i><u>bold italics underlined</u></i>	<u>New</u> proposals for additions to the Commission's proposal, marked with respect to the previous document 15794/12.

2011/0421 (COD)

Proposal for a
DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on serious cross-border threats to health
(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, paragraphs (4)(c) and (5) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee¹,

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

Having regard to the opinion of the European Data Protection Supervisor³,

Acting in accordance with the ordinary legislative procedure⁴,

¹ OJ C , , p.

² OJ C , , p.

³ OJ C , , p.

⁴ Position of the European Parliament of 5 July 2011 (not yet published in the Official Journal) and decision of the Council of 27 July 2011.

Whereas:

- (1) Article 168 of the Treaty on the Functioning of the European Union states, *inter alia*, that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. Union's action ~~in the field of public health~~, ***which shall complement national policies***, ~~in the field of public health should~~ ***shall*** cover monitoring, early warning of and combating serious cross-border threats to health ~~that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. According to the same provision~~, and Member States ~~***shall***~~ ***must***, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas covered by the Union action in the field of public health⁵.
- (2) By Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998⁶ a network on the epidemiological surveillance and control of communicable diseases in the Community was set up. Experience gained in the implementation of that Decision confirms that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health. However, a number of developments at Union and international level in the past decade make a review of that legal framework necessary.
- (3) Apart from communicable diseases, a number of other sources of danger to health, notably related to other biological agents, chemical agents or environmental events, which include hazards related to climate change, may, by reason of their scale or severity, endanger the health of citizens in the entire Union, lead to the malfunctioning of critical sectors of society and economy and jeopardise individual Member State's capacity to react. Therefore, the legal framework set up under Decision No 2119/98/EC should be extended to cover these other threats and provide for a coordinated wider approach to health security at Union level.

⁵ Alignment of the language with Article 168 of the TFEU.

⁶ OJ L 268, 3.10.1998, p.1.

- (4) An important role in the coordination of recent crises of Union relevance has been played by the Health Security Committee, an informal group composed of high level representatives from Member States and established on the basis of the Presidency Conclusions of 15 November 2001 on bioterrorism⁷. It is necessary to integrate this group into a formalised institutional framework and to assign it a well-defined role avoiding duplications with other Union entities responsible for risk management. ~~; not least that established under Decision No 2119/98/EC.~~
- (5) 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 (ECDC) provides the ECDC with a mandate covering surveillance, detection and risk assessment **and risk communication** of threats to human health from communicable diseases and outbreaks of unknown origin. The ECDC has progressively taken over the epidemiological surveillance of communicable diseases and the operation of the Early Warning and Response System from the Community network set up under Decision No 2119/98/EC. This development is not reflected in Decision No 2119/98/EC, which was adopted before the creation of the ECDC.
- (6) The International Health Regulations (2005) adopted by the Fifty-eighth World Health Assembly on 23 May 2005 reinforced the coordination among States Parties to the World Health Organisation (WHO), which include all the Member States of the Union, of the preparedness for and response to a public health emergency of international concern. The legislation of the Union should take this development into account, including the integrated all-hazards approach of the WHO covering all categories of threats independently of their origin.

⁷ 13826/01.

- (7) This Decision should ~~not apply to the serious cross-border health threats arising from ionizing radiation, as those threats are already covered by Article 2(b) and Chapter 3 of Title II of the Treaty establishing the European Atomic Energy.~~ Moreover, it should apply without prejudice to other binding measures concerning specific activities or setting the standards of quality and safety of some goods, which provide for special obligations and tools for monitoring, early warning and combating specific threats of cross-border nature. ***These include in particular relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, and exposure to ionizing radiation.***
- (7a) The protection of human health is a horizontal aspect defined in numerous Union policies and activities. The Commission should ensure that the structures and mechanisms in place in different sectors and responsible for monitoring, early warning and combating serious cross-border threats to health work in close collaboration in a coherent and consistent way in order to achieve a high level of human health protection, avoiding overlap of performed activities or conflicting actions.***
- (7b) The structures for coordinating responses to serious cross-border health threats established by this Decision, should, in exceptional circumstances, be available to the Member States and the Commission also when the threat is not covered by this Decision and public health measures taken to counter that threat may be insufficient to ensure a high level of protection of the human health. The Health Security Committee should deliberate upon any coordination of response in close cooperation with committees or associations responsible in other areas for the monitoring, early warning or combating of such threats.***
- (8) Preparedness and response planning is an essential element allowing for an effective monitoring, early warning of and combating serious cross-border threats to health. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared 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.

- (9) The International Health Regulations (2005) already require Member States to develop, strengthen and maintain their capacity to detect, assess, notify and respond to a public health emergency of international concern. ~~Coordination~~ **Consultation with a view to coordinate** between the Member States is necessary **in order** to **promote interoperability** ~~achieve a consistent level of preparedness and interoperability~~ between national preparedness plans in view of the international standards, while respecting Member States' competence to organise their health systems.

[Member States should provide the Commission with information on the state of play of their preparedness and response planning. Information provided by the Member States should at least cover the elements that Member States are obliged to report to the WHO in the context of the International Health Regulations (2005). The information should particularly address the cross-border dimension of preparedness and response plans measures foreseen. The Commission should compile the information received and should ensure its exchange of this information among Member States through the Health Security Committee.]

NB: The bracketed part of this recital is related to the discussion on Article 4(2)

- (10) The European Parliament in its resolution of 8 March 2011⁸ and the Council in its Conclusions of 13 September 2010⁹ stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases. With regard to pandemic vaccines, in the context of limited production capacities at global level, such a procedure would increase the availability of those products and ensure fairer access to them among Member States participating in the joint procurement.

⁸ 2010/2153(INI).

⁹ 12665/10.

- (11) Contrary to communicable diseases, whose surveillance at the Union level is carried out on a permanent basis by the ECDC, other serious cross-border threats to health do not currently necessitate a systematic monitoring. A risk-based approach, whereby monitoring ~~networks~~ **is ensured by Member States' monitoring systems and exchange of available information through Early Early Warning and Response System (EWRS)**, ~~are set up ad hoc and on a temporary basis~~, is therefore more appropriate to those other threats¹⁰.
- (12) A system enabling the notification at the Union level of alerts related to serious cross-border threats to health should be put in place in order to ensure that competent public health authorities in Member States and the Commission are duly and timely informed. Therefore, the Early Warning and Response System (EWRS), established under Decision No 2119/98/EC for communicable diseases, should be extended to all the serious cross-border threats to health covered by the present Decision, ***while the operation of the EWRS should remain under the ECDC remit***. The notification of an alert should be required only where the scale and severity of the threat concerned are or may become so significant **that it affects or may affect more than one Member State and it requires or may require a coordinated** ~~the coordination of the~~ ~~response at the Union level is necessary~~. **To avoid duplication, the notification of alerts should be streamlined so that the competent authorities of the Member States do not need to notify the same alert through different systems at Union level. To that end, the Commission should ensure that alert notifications under Early Warning and Response System and other rapid alert systems at Union level are linked to each other.**
- (12a) The Commission should, in liaison with the Member States, ensure coordination and mutual information between the mechanisms and structures established under this Decision and other mechanisms and structures established at Union level whose activities are relevant for the monitoring, early warning, preparedness and response planning, and combating serious cross-border threats to health with a view to ensure the coherence and avoid duplication. In particular the Commission should ensure that relevant information from the various rapid alert and information systems at Union level is gathered and communicated to the Member States through the Early Warning and Response System.***

¹⁰ Recital adapted to changes in Article 7.

- (13) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. This risk assessment should be based on robust scientific evidence and independent expertise and provided by the Agencies of the Union in accordance with their missions or ~~otherwise~~ by expert groups set up by the Commission ***if the risk assessment required*** is totally or partially outside the mandates of the ***Agencies of the Union. In the latter case, the Commission should ask the Member States to propose experts in the required field of expertise and nominate them ad-hoc while ~~to~~ ensuring the highest possible level of expertise, transparency and independence of proceedings of the expert groups and the risk assessment.***¹¹
- (14) Effectively responding to serious cross-border threats to health at national level ***might*** requires a ***consultation*** ~~consistent approach~~ among Member States, in conjunction with the Commission, ***with a view to coordinate national response***, necessitating exchange of information. ~~consultation and coordination of actions~~. Under Decision No 2119/98/EC, the ***Member States*** ~~Commission~~ already ***consult each other in liaison with the Commission with a view to*** coordinates the response at the Union level ~~in collaboration with Member States~~ with regard to communicable diseases. A similar mechanism should apply to all serious cross-border threats to health independently of their origin. It should also be recalled that, independently from this Decision, a Member State may, in case of a major emergency, request assistance under Council Decision of 8 November 2007 establishing a Community Civil Protection Mechanism (2007/779/EC, Euratom)¹².

¹¹ CION: Reservation related to Article 10, paragraphs 2 and 3.

¹² OJ L 314, 1.12.2007, p. 9.

- (15) ~~*Although The Member States have the responsibility to manage public health crisis at national level. However,*~~ measures taken by individual Member States ~~to respond to such threats may~~ ***could*** damage the interests of other Member States if they are ***inconsistent not consistent*** with one another ***and are based on different risk assessments.*** ~~or not based on shared and solid risk assessment. They may also conflict with competences of the Union or with fundamental rules of the Treaty on the Functioning of the European Union.~~ Therefore, the ***aim to coordinate*** ~~coordination of~~ the response at the Union level should ***seek to*** ensure *inter alia* that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty, such as those related to the restriction of travel and trade.
- (16) Inconsistent or confusing communication with the public and stakeholders such as health professionals may have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. Therefore, the coordination of the response ***within the Health Security Committee, assisted by relevant sub-groups,*** ~~at the Union level~~ should encompass ***rapid information exchange on communication messages and strategies and the addressing of communication challenges with the view to coordinate risk and crisis communication,*** ~~shared information campaigns and consistent communication messages to citizens~~ based on robust and independent evaluation of public health risks, ***to be adapted to national needs and circumstances.***

(17) The applicability of some specific provisions of Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council¹³ and Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products¹⁴ depends on the recognition at Union level, in the framework of Decision 2119/98/EC, of an emergency situation or of a pandemic situation with respect to human influenza. Those provisions allow for the accelerated marketing of certain medicinal products in case of urgent needs, by means, respectively, of a conditional marketing authorisation and of the temporary possibility to grant a variation to the terms of a marketing authorisation for a human influenza vaccine even where certain non-clinical or clinical data are missing. However, in spite of the utility of such provisions in the event of a crisis, there is to date no specific procedure for issuing such recognitions at Union level. It is therefore appropriate to provide for such a procedure as part of the standards of quality and safety for medicinal products.

(17a) new

It may be in the interest of the Union to conclude international cooperation agreements with third countries or international organizations to foster the exchange of relevant information from monitoring and alerting systems on serious cross border threats to health. Within the limits of the Union competence, such agreements could include, where appropriate, the participation of such third countries or international organisation in the relevant epidemiological surveillance monitoring network and the Early warning and Response System, exchange of good practice in the areas of preparedness and response planning, public health risk assessment and collaboration on response coordination.

¹³ OJ L 92, 30.3.2006, p.6.

¹⁴ OJ L 334, 12.12.2008, p.7.

- (18) The processing of personal data for the purpose of implementing this Decision should comply with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data¹⁵ and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data¹⁶. In particular, the operation of the Early Warning and Response System should provide for specific safeguards allowing safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level.
- (19) Since the objectives of this Decision cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of those threats and can, therefore, 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 Decision does not go beyond what is necessary in order to achieve those objectives.
- (20) ~~The power to adopt delegated acts in accordance with the Article 290 of the Treaty on the functioning of the European Union should be conferred to the Commission in respect of measures needed to complement the action of the Member States, in very specific and urgent situations, for the transnational aspects of the control of serious cross border threats to health. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, as far as the urgency of the situation allows it. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.~~¹⁷

¹⁵ OJ L 281, 23.11.1995, p. 31.

¹⁶ OJ L 8, 12.1.2001, p. 1.

¹⁷ Related to the deletion of Article 12. CION: Reservation on the deletion.

- (21) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: ~~the procedures for the coordination, the exchange of information and the mutual consultation on preparedness and response planning~~¹⁸; the *establishment and update* adoption of a list of communicable diseases *and special health issues* subject to the network of epidemiological surveillance and the procedures for the operation of such a network; ~~the setting up and termination of ad hoc monitoring networks and the procedures for the operation of such networks~~; the adoption of case definitions for serious cross-border threats to health; the procedures for the operation of the Early Warning and Response System; the procedures for the coordination of the responses of the Member States; the recognition of situations *of public health* emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level. Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹⁹.
- (22) In order to enhance clarity and legal certainty, Decision No 2119/98/EC should be repealed and replaced by this Decision.

¹⁸ CION: reservation on the deletion of the word "coordination".

¹⁹ OJ L 55, 28.2.2011, p.13.

Chapter I

General provisions

Article 1

Subject matter

1. This Decision lays down rules on monitoring, *epidemiological surveillance*, early warning of and combating serious cross-border threats to health, ~~as well as on~~ *including* preparedness and response planning related to those activities, *in order to coordinate and complement national policies*.
2. This Decision aims to support the *cooperation and coordination between the Member States in order to improve the* prevention and control of the spread of severe human diseases across the borders of the Member States, and to *combat other* ~~obviate other major sources of~~ serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.

Article 2

Scope

1. This Decision shall apply *to public health measures* in case of serious cross-border threats to health falling within the following categories:
 - (a) threats of biological origin, consisting of:
 - (i) communicable diseases;
 - (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter ~~referred to as~~ "the related special health issues");
 - (iii) biotoxins or other *harmful* ~~toxic~~ biological agents not related to communicable diseases;
 - (b) threats of chemical origin ~~with the exception of threats arising from ionizing radiation~~;
 - (c) threats of environmental origin; ~~including threats deriving from the effects of climate change~~;

- (d) threats of unknown origin;
- (e) events which may constitute public health emergencies of international concern determined pursuant to the International Health Regulations (2005), provided that they fall under one of the categories of threats set out in points (a) to (d).

1a. This decision shall also apply to the epidemiological surveillance of the communicable diseases and of the related special health issues.

2. The provisions of this Decision are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning, the coordination of preparedness and response planning for and the coordination of combating serious cross border threat to health, This Decision shall apply without prejudice to measures on monitoring, early warning of and combating serious cross-border threats to health as well as the requirements ~~concerning the coordination of~~ preparedness and response planning provided for in other binding Union provisions, including measures setting standards of quality and safety for specific goods and measures concerning specific economic activities.²⁰

2a. In exceptional emergency situations a Member State or the Commission may refer cross-border health threats other than those covered in Article 2(1) for coordination of response to the Health Security Committee in accordance with Article 11, if it is considered that public health measures taken prove insufficient to ensure a high level of protection of the human health.

²⁰ DE: Suggests an alternative wording for paragraph 2 as follows:
"If there is ~~the provisions of this Decision conflict with a provision of~~ another act of the European Union or of the European Atomic Energy Community governing specific aspects of monitoring, early warning, the coordination of preparedness and response planning for and the coordination of combating serious cross-border threats to health, including measures setting standards of quality and safety for specific goods and measures concerning specific economic activities, the provisions of the other Union act shall prevail."
RO: Can support above DE proposal, but without reference to "the European Atomic Energy Community".

3. The Commission shall, ~~where appropriate and~~ in liaison with the Member States, ensure coordination and mutual information between the mechanisms and structures established under this Decision and similar mechanisms and structures established at Union level whose activities ~~are may be~~ relevant for the monitoring, early warning, **preparedness and response planning**, and combating serious cross-border threats to health.

3a. The Commission shall, as part of its reports referred to in Article 19, regularly evaluate the complementarity of mechanisms and structures set up under this Decision with similar structures established at Union Level to efficiently protect public health in order to avoid duplications.

4. **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 Decision, including arrangements foreseen in existing or future bilateral or multilateral agreements or conventions, provided that these arrangements, procedures and measures do not impair the application of this Decision.**

Article 3

Definitions

For the purpose of this Decision, the following definitions shall apply:

- (a) ‘case definition’ means a set of commonly agreed diagnostic criteria that must be fulfilled in order to accurately **identify** ~~detect~~ cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of **unrelated** ~~other similar~~ threats;
- (b) ‘communicable disease’ means an infectious disease caused by a contagious agent which may be transmitted from person to person by direct contact with an affected individual or by an indirect means such as exposure to a vector, **animal**, fomite, product or environment, or exchange of fluid, contaminated with the contagious agent;
- (c) ‘contact tracing’ means measures implemented ~~at national level~~ in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are potentially in danger of developing or have developed a disease;

- (d) ‘epidemiological surveillance’ means the ~~prompt and~~ systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues, ~~including data reflecting the current health status of a community or population, and systematic threat detection for the purpose of directing public health action;~~
- (e) ‘monitoring’ means the continuous observation, ~~surveillance,~~ detection or reviewing of changes in a condition, or situation, or changes 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;
- (f) ‘public health measure’ means a decision or an activity which aims to prevent, *monitor* or control *the spread of* diseases *or contamination*, or to *combat* ~~obviate severe~~ sources of risks to public health or to mitigate their impact on public health;
- (g) ‘serious cross-border threat to health’ means a *life threatening or otherwise serious* hazard *to health* of biological, chemical, environmental or unknown origin which is ~~likely to spread~~ *or entails a significant risk of spreading* across national borders of Member States, and which may ~~cause a potential severe risk to public health necessitate ing~~ a *coordination* ~~ted~~ action at the Union level²¹;
- ~~(h) ‘severe risk to public health’ means a likelihood of a hazard that may result in death, be life-threatening, cause a severe disease in exposed humans, or produce a congenital defect.~~

²¹ DE: Proposes the following definition:

- (g) ‘serious cross-border threat to health’ means a serious hazard public health that may result in death or cause a severe disease in exposed humans and which spreads or entails a significant risk of spreading across national borders of Member States necessitating a coordination at Union level.

Chapter II

Planning

Article 4

Preparedness and response planning

1. Member States *and the Commission* shall ~~, in liaison with the Commission and on the basis of its recommendations,~~ **consult each other** within the Health Security Committee referred to in Article 17 19, ~~coordinate~~ **with a view to coordinating** their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of and response to the serious cross-border threats to health. That ~~coordination~~ **consultation** shall **be aimed at** ~~in particular address the following issues:~~
 - (a) **sharing best practice and experience in preparedness and response planning;**
 - (ab) **promoting** the interoperability of national preparedness plans;
 - (c) **addressing the intersectoral dimension of preparedness and response planning at Union level;**
 - (bd) **supporting** the ~~consistent~~ implementation of core capacity requirements for surveillance and response as referred to in Articles 5 and 13 of the International Health Regulations (2005).

2. For the purpose of paragraph 1, Member States shall **every two years**²² provide the Commission with the following information **on the state of play of non-sensitive elements** ~~concerning the state of play~~ of their preparedness and response planning.

This information shall, where available, consist of the following:

- (i) **identification and state of play of the implementation of the core capacity standards for preparedness and response planning** as determined at national level for the health sector;
[...]

²² CZ/PT: Reservation. Propose the interval of 5 years.

- (ii) Specific mechanisms, *critical elements for planning and implementing solutions* established at national level for the interoperability between the health sector and other critical sectors of society;

[...]

- (iii) *Identification of the sectors considered as critical at national level and general description of the business continuity arrangements put in place for those sectors.*

[...]

- 2a. *Member States may request that the information shall be treated under rules of confidentiality to be adopted by the Health Security Committee in accordance with defined under Article 17(5).*

3. The Commission shall make the information referred to in paragraph 2 available to the members of the Health Security Committee.

4. ~~Before adopting or reviewing their national preparedness plans, Member States shall consult each other and the Commission in relation to the issues referred to in points (a) and (b) of paragraph 1.~~

*For the purpose of paragraph 1, when²³ Before adopting or revising national preparedness plans²⁴, Member States shall **inform** the Commission **in a timely manner of the main aspects of these preparedness plans that are relevant to the objectives referred to in paragraph 1 and to the specific issues referred to in paragraph 2. The Commission shall make this information available to the Health Security Committee.***

²³ CION: Reservation on using "when" instead of "before".

²⁴ CZ: Reservation on the obligation to have national preparedness plans and to share information prior to their adoption. Some MS may not have preparedness plans. This obligation contradicts the principle of subsidiarity. "Planning" needs to be systematically deleted throughout the text.

5.— The Commission shall, by means of implementing acts, *adopt templates to be used by the Member States when providing the information referred to in paragraphs 2 and 4 in order to ensure its relevance to the objectives identified in paragraph 1 and its comparability.*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).²⁵

Article 5²⁶

Joint procurement of medical countermeasures

1. The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to the third subparagraph of Article 91(1) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities²⁷ and Article 125c of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of the Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities²⁸, with a view to the advance purchase of medical countermeasures against serious cross-border threats to health.

²⁵ CIION: Reservation on the deletion of this paragraph
DK/IT/AT/HU/BG/LV/IE: Supported the adoption of implementing acts by the Commission.
LU/DE/UK/ES/BE/EL/CZ/PT/FI/PL/SE/FR/NL/RO: Reservation on the introduction of implementing acts. They preferred that Health Security Committee is in charge, as part of its rules of procedure in accordance with Article 17(5), of necessary procedures for coordination, the exchange of information and the mutual consultation among the Member States and the Commission.

²⁶ SI: Can support deletion of paragraph 5.

FR/PL/BG: Reservation on this Article.

FR: Proposes deletion as the joint procurement of medical countermeasures shall be covered by separate decision.

PL: Current wording hinders participation of Poland in JPA.

²⁷ OJ L 248, 16.9.2002, p.1.

²⁸ OJ L 357, 31.12.2002, p.1.

2. The joint procurement procedure referred to in paragraph 1 shall comply with the following conditions:
 - (a) participation in the joint procurement shall be open to all Member States until the launch of the procedure;
 - (b) rights and obligations of Member States not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;
 - (c) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortions of competition.
 - (d) *the procurement shall not have any direct financial impact on the budget of Member States not participating in the joint procurement.***

3. The joint procurement procedure shall be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, ~~in particular the order of priority for deliveries between the Parties,~~ and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract.

Chapter III

Permanent surveillance and ad hoc monitoring

Article 6

Epidemiological surveillance

1. A network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in **points (i) and (ii) of** Article 2(1)(a) ~~(i) and (ii)~~, is hereby established. ***The network shall be operated and coordinated by the ECDC.***

2. The epidemiological surveillance network shall bring into permanent communication the Commission, the European Centre for Disease Prevention and Control, and the competent authorities responsible at national level for ~~collecting information relating to~~ epidemiological surveillance.

- ~~3. National competent authorities shall collect comparable and compatible data and information in relation to the epidemiological surveillance and without delay communicate them to the epidemiological surveillance network.~~
3. *National competent authorities referred to in paragraph 2 shall communicate the following information to the participating authorities of the epidemiological surveillance network:*
- (a) comparable and compatible data²⁹ and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of Article 2(1)(a);*
 - (b) relevant information concerning the progression of epidemic situations;*
 - (c) relevant information on unusual epidemic phenomena or new communicable diseases of unknown origin, including those in non-Member States.*
4. When reporting information on epidemiological surveillance, the national competent authorities shall, *where available*, use the case definitions adopted in accordance with paragraph 5 for each communicable disease and related special health issue referred to in paragraph 1.

²⁹ SE: Reservation. Proposes "to the extend possible comparable and compatible data".

5. The Commission shall, by means of implementing acts, establish and update:
- (a) in order to ensure ~~an exhaustive~~ coverage *of communicable diseases and special health issues* by the epidemiological surveillance network, the list of communicable diseases *and special health issues* referred to *in points (a)(i) and (ii) of Article 2 (1) of this Decision established according to the criteria set out in the Annex;*
 - (b) in order to ensure at Union level the comparability and compatibility of the collected data, case definitions related to each communicable disease and special health issue subject to epidemiological surveillance;
 - (c) procedures for the operation of the epidemiological surveillance network as developed in application of Articles 5, 10 and 11 of Regulation (EC) No 851/2004.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ~~18~~ 20(2).

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 between the Member States, the Commission may adopt the measures referred to in points (a) and (b) through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article ~~18~~ 20(3).

Article 7

Ad hoc Monitoring Networks

1. Following an alert pursuant to Article 9 concerning a threat to health referred to in points (a)(iii), (b), (c) or (d) of Article 2(1), the 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 and, if the urgency of the situation so allows, through the Health Security Committee* ³⁰ ~~in liaison with the Commission, through an ad hoc monitoring network set up pursuant to paragraph 3~~ as regards the developments of the situation related to the threat concerned at national level.
2. The information transmitted pursuant to paragraph 1, shall include in particular any change in geographic distribution, spread and severity of the threat concerned and of the means of detection, *if available*. ~~It shall be transmitted to the monitoring network by using, where applicable, the case definitions established in accordance with point (d) of paragraph 3.~~
3. The Commission shall, by means of implementing acts:³¹,
 - (a) ~~set up, for the purposes of the cooperation referred to in paragraph 1, an ad hoc monitoring network which shall bring into communication the Commission and the national contact points designated by the Member States in accordance with point (b) of Article 17(1) for the threat concerned;~~
 - (b) ~~terminate the operation of an ad hoc monitoring network when the conditions for notifying an alert in relation to the threat concerned, as laid down in Article 9(1) are no longer met;~~

³⁰ FR: Reservation on the addition of "*and, if the urgency of the situation so allows, through the Health Security Committee*".

There was proposal to change "so allows" into "so requires". PRES keeps "so allows" as the objective is that the information will always be provided via EWRS (it is assumed that HSC members will receive it) and in addition, transmitted directly to HSC members, unless this would not be possible given the urgency of the situation.

³¹ CION: Reservation on the deletion of points (a), (b) and (c).

- ~~(c) adopt generic procedures for the operation of ad hoc monitoring networks;~~
(d) adopt, where necessary, the case definitions to be used for the ad hoc monitoring, in order to ensure at the Union level the comparability and compatibility of the collected data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ~~18~~ 20(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 these case definitions through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 18(3).***

~~set up an ad hoc monitoring network or adopt or update the case definitions referred to in point (d) through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 20(3).~~

Chapter IV

Early warning and response

Article 8

Establishment of an early warning and response system

for serious cross-border health threats

1. A rapid alert system for notifying at the Union level alerts in relation to serious cross-border threats to health, ‘Early Warning and Response System’, is hereby established. This System shall bring into permanent communication the Commission and the competent authorities responsible at national level for alerting, assessing public health risks and determining the measures that may be required to protect public health.

1a. The Commission shall, to the extent possible, ensure that competent national authorities do not need to notify an alert or provide the same information through different systems at Union level³².

³² CION: Reservation on addition of paragraph 1a.

2. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange in order to ensure the proper functioning of the Early Warning and Response System and the uniform implementation of Articles 8 and 9 *and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for 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 18 ~~20~~(2).

Article 9

Alert notification

1. National competent authorities or the Commission shall notify an alert in the Early Warning and Response System where the emergence or development of a serious cross-border threat to health fulfils the following conditions:
 - (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 the Union level.
2. Where the national competent authorities notify to the World Health Organization events that may constitute public health emergencies of international concern in accordance with Article 6 of the International Health Regulations (2005), they shall at the latest simultaneously notify an alert in the Early Warning and Response System, provided that the threat concerned falls within those referred to in Article 2(1) of this Decision.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate ***through the Early Warning and Response System*** any ***available*** relevant information in their possession that may be useful for coordinating the response, ~~in particular on:~~
- (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) personal data necessary for the purpose of contact tracing in accordance with Article ~~16~~ **18**.
 - (j) ***any other information relevant to the given serious cross-border threat to health.***
4. The Commission shall make available to the national competent authorities through the Early Warning and Response System any information that may be useful for coordinating the response ***according to Article 11*** ~~at the Union level~~, including information ***related to serious cross-border threats to health*** ~~on hazards~~ and public health measures related to serious cross-border threats to health transmitted through ~~other Union alert systems~~ ***rapid alert and information systems established under other provisions of Union law.***

Public health risk assessment

1. Where an alert is notified pursuant to Article 9, the Commission shall, where it is necessary for the coordination of the response at Union level, ***upon request of the Health Security Committee or on its own initiative***, make promptly available to the national competent authorities ***and*** to the Health Security Committee ***as*** referred to respectively in Articles 17 & 19, through the Early Warning and Response System, ***a risk assessment of the potential severe risk to public health and of public health measures by:***
- ~~This assessment shall be based:~~
- (a) ~~on the opinion~~ of the European Centre for Disease Prevention and Control in accordance with Article 7(1) of Regulation (EC) No 851/2004 ***in case of a threat referred to in Article 2 (1)(a)(i) and (ii) or Article 2(1)(d)***; and/or
 - (b) ~~on the opinion~~ of the European Food Safety Authority in accordance with Article 23 of 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 safety³⁴ ***in case of a threat referred to in Article 2 and which falls under the mandate of EFSA.***
- ~~;~~ and/or
- (e)2. Where the ***risk*** assessment needed is totally or partially outside the mandates of the ***Agencies referred to in paragraph 1***, ~~on an ad-hoc independent opinion~~, ***the Commission shall, upon request of the Health Security Committee or its own initiative, ask the Member States to propose, through single contact point referred to in Article 15(1)(d), independent experts for and ad-hoc nomination by the Commission to establish a risk assessment.***

³³ CION: Reservation on paragraphs 2 and 3 as the wording is not in line with the institutional autonomy of the Commission to set up expert groups (see also related reservation on recital 13).

³⁴ OJ L 31, 1.2.2002, p.1.

The Commission shall always make the risk assessment promptly available to the national competent authorities through the Early Warning and Response System. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication, and certainly before making it public. It shall also make available to national authorities through the Early Warning and Response System curricula vitae and declarations of interest of nominated experts³⁵.

The abovementioned assessments shall take into account, if available, relevant information provided by other entities, in particular:

- (a) the Scientific Committee on Consumer Safety; the Scientific Committee on Health and Environmental Risks; the Scientific Committee on Emerging and Newly Identified Health Risks in accordance with Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC³⁶; and/or*
 - (b) other European agencies concerned; and/or*
 - (c) the World Health Organization, in particular in case of a public health emergency of international concern.*
- 3. The Commission shall ensure that information from the entities referred to in paragraph 2 that may be relevant for the risk assessment is made available to the national competent authorities through the Early Warning and Response System and to the Health Security Committee.*

³⁵ FR/DE: The curriculum vitae and declarations of interest of nominated experts should be distributed to the HSC members directly and not via EWRS.

³⁶ *OJ L 241, 10.9.2008, p. 21.*

Article 11

Coordination of response

1. Following an alert pursuant to Article 9 ***and without prejudice to each Member State's right not to supply information the disclosure of which is considered ~~by Member States~~ contrary to essential interests of its ~~their~~ security***³⁷, the Member States shall, 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 9 and the*** risk assessments referred to in Article 10, consult each other within the Health Security Committee referred to in Article 17 and in liaison with the Commission ***with a view*** ~~in order~~ to coordinate:
 - (a)*** national responses to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the International Health Regulations (2005) and falls within Article 2 of this Decision;
 - (b)*** ***risk and crisis communication, to be adapted to national needs and circumstances***
[Formerly in paragraph 4.]
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*** consult³⁸ 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, immediately upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.

³⁷ CION: reservation on the addition to paragraph 1.

³⁸ Language "inform and consult" is in line with Article 6(2) of Decision 2119/98/EC.

~~4. — Following an alert pursuant to Article 9, Member States shall inform and consult each other within the Health Security Committee referred to in Article 17 and in liaison with the Commission with a view to coordinate risk and crisis communication, duly taking into account national needs and circumstances.~~

[Paragraph 4 has been merged with paragraph 1.]

4. In the event of a serious cross-border health threat overwhelming the national response capacities, an affected Member State may also request assistance from other Member States through the EU Civil Protection Mechanism established by Council Decision 2007/779/EC, Euratom.
5. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the mutual information, consultation and coordination provided for in *paragraphs 1 to 4* this ~~Article~~.
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18 ~~20~~(2).

Article 12³⁹

Common temporary public health measures

- ~~1. Where the coordination of national responses provided for in Article 11 proves insufficient to control the spread of a serious cross-border threat to health between the Member States or to the Union, and, as a consequence, the protection of the health of the population of the Union as a whole is jeopardised, the Commission may complement the action of the Member States through the adoption, by means of delegated acts in accordance with the procedure provided for in Article ~~21~~ 22, of common temporary public health measures to be implemented by the Member States. These measures may not concern the control of the threat concerned within each Member State.~~
- ~~2. Paragraph 1 shall apply only to serious cross-border health threats which may result in deaths or hospitalisations on a large scale across the Member States.~~

³⁹ CION: Reservation on the deletion of Article 12.

~~3. The measures adopted under paragraph 1 shall:~~

~~(a) 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;~~

~~(b) be proportionate to the public health risks related to that threat, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services;~~

~~(c) be compatible with any applicable international obligation of the Union or of the Member States.~~

Chapter V

Emergency and pandemic influenza situations at the Union level

Article 12 43

Recognition of emergency situations ~~or of pandemic influenza situations~~

1. The Commission may, ~~for the purposes of Article 13~~, where the exceptional conditions laid down in paragraph 2 are met, formally recognise, by means of implementing acts (a) situations ~~of (sanitary) emergency at Union level, including situations of (sanitary) emergency concerning specifically epidemics of human influenza considered as having a pandemic potential~~.

situations ~~pursuant to Article 2 (2) of Regulation (EC) No 507/2006~~ of emergency at Union level; or (b) pre-pandemic situations with respect to human influenza ~~Article 21 of Regulation (EC) No 1234/2008~~ at Union level.

1. **Recognition of a situation of public health emergency at Union level, for the purposes of Article 13, may be declared when the following conditions are met:**

- (a) the Director-General of the World Health Organization *has been consulted and* has not yet adopted a decision declaring the existence of a public health emergency of international concern in accordance with Articles 12 and 49 of the International Health Regulations (2005); **and**
- (b) the serious cross-border health threat at issue:
 - (i) can, by reasons of its nature, be prevented or treated by medicinal products;
 - (ii) is rapidly spreading within and across the Member States and endangers public health at the Union level;
 - (iii) is life-threatening; **and**

- (c) *no satisfactory method of prevention or treatment is authorised in the Union or, even if such a method exists, the medicinal product concerned will not be of major therapeutical advantage to those affected.*

~~the medicinal products, including vaccines, already authorised at Union level in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁴⁰ or in the Member States through the mutual recognition procedure or decentralized procedure referred to in 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 use⁴¹; are not or may not be sufficiently efficient for the prevention or treatment of the threat concerned;~~

- ~~(d) with a view to the formal recognition of a pre-pandemic situation with respect to human influenza at the Union level, the threat concerned is human influenza.~~

2. **The Commission shall formally recognise situations at Union level pursuant to paragraph 1 by means of implementing acts.** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18 20(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 formally recognise situations of emergency at Union level ~~or pre-pandemic situations with respect to human influenza at Union level~~ through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 18 20(3).

3. ***The Director-General of the World Health Organization shall be informed thereof.***

⁴⁰ OJ L 136, 30.4.2004, p. 1

⁴¹ OJ L 311, 28.11.2001, p. 67

Article 13 14

Legal effects of the recognition

~~1.~~ The recognition of a situation of emergency at the Union level pursuant to ~~point (a) of Article 12 13(1)~~, shall have the sole legal effect of ~~triggering~~ **enabling** the applicability of Article 2(2) of Regulation (EC) No 507/2006. *Where this recognition concerns specifically epidemics of human influenza considered as having a pandemic potential, it shall, in addition, ~~trigger~~ enable the applicability of Article 21 of Regulation (EC) No 1234/2008.*

~~2.~~—The recognition of a pre-pandemic situation with respect to human influenza at the Union level pursuant to ~~point (b) of Article 13(1)~~ shall have the sole legal effect of triggering the applicability of Article 2(2) of Regulation (EC) No 507/2006 and of Article 21 of Regulation (EC) No 1234/2008.

Article 14 15

Termination of the recognition

The Commission shall, by means of implementing acts, terminate the recognition of the situations referred to in ~~points (a) and (b) of Article 12 13(1)~~ as soon as one of the **applicable** conditions laid down in ~~points (b), (c) and (d) of Article 12 13(2)~~ is no longer met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18 20(2).

Termination of the recognition in accordance with this Article shall not affect the validity of marketing authorisations granted pursuant to Article 2(2) of Regulation (EC) No 507/2006 or Article 21 of Regulation (EC) No 1234/2008.⁴²

⁴² PRES: It should be clarified that the termination of recognition of the situation of emergency at the Union level does not affect the validity of marketing authorisations already granted.

Chapter VI

International agreements

Article 16

International agreements

- ~~1. The Union may conclude international agreements with third countries or international organisations allowing and organizing its cooperation with those third countries or international organisations on serious cross-border threats to health that pose particular risks of transmission to the population of the Union, in order to cover the following aspects:~~
- ~~(a) exchange of good practice in the areas of preparedness and response planning,~~
 - ~~(b) exchange of relevant information from monitoring and alerting systems, including the participation of the countries or organisations concerned in the relevant epidemiological surveillance or ad hoc monitoring networks and the Early Warning and Response System,~~
 - ~~(c) collaboration on the public health risk assessment of serious cross-border threats to health, with special reference to public health emergencies of international concern declared in accordance with the International Health Regulations (2005),~~
 - ~~(d) collaboration on response coordination, including the occasional participation of the countries or organisations concerned in the Health Security Committee as observers, with special reference to public health emergencies of international concern declared in accordance with the International Health Regulations (2005).~~

Chapter VII

Procedural provisions

Article 15 17

Designation of national authorities and representatives

1. Each Member State shall designate, within ~~six~~ **three** months of the entry into force of this Decision:
 - (a) the competent authorities responsible at national level for ~~collecting information relating to~~ epidemiological surveillance as referred to in Article 6;
 - (b) ~~single contact points for the purpose of the coordination of the ad-hoc monitoring, as referred to in Article 7;~~
 - (be) 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 Articles 8, 9, and 10;
 - (cd) one representative and an alternate⁴³ in the Health Security Committee referred to in Article 17;
 - (d) ***a single contact point for the purpose of the ad-hoc nomination of independent experts as referred to in Article 10(2)⁴⁴.***

2. Member States shall notify the Commission and other Member States of the designations referred to in paragraph 1 ***and of any change thereof. In the case of change, the Commission shall distribute immediately to the Health Security Committee an updated list of the designations as referred to in paragraph 1.***

- ~~3. Each Member State shall notify the Commission and the other Member States of any change in the information provided under paragraph 2.~~

⁴³ FR: Proposes to add "one representative and an alternate **responsible at policy making level**". PRES: it is up to MS to nominate responsible representatives according to their administrative procedures and hierarchical structure. Consistent with the deletion of "high level" in Article 17(1). See also Recital 4.

Article 16 48

Protection of personal data

1. In the application of this Decision, personal data shall be processed in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.
 2. The Early Warning and Response System shall include a selective messaging functionality allowing personal data to be communicated only to national competent authorities concerned by contact tracing measures. *This selective messaging functionality shall be designed and operated so as to ensure safe and lawful exchange of personal data.*
 3. When competent authorities implementing contact tracing measures communicate personal data necessary for contact tracing purposes through the Early Warning and Response System pursuant to Article 9(3), they shall use the selective messaging functionality referred to in paragraph 2 of this Article and communicate the data only to the other Member States concerned by the contact tracing measures.
 4. When circulating the information referred to in paragraph 3, the competent authorities shall refer to the alert communicated previously to the Early Warning and Response System.
 5. Where a ~~national~~ competent authority establishes that a notification of personal data made by it pursuant to Article 9(3) has subsequently proved to be in breach of Directive 95/46/EC because this notification was not necessary for the implementation of the contact tracing measures at issue, it shall inform immediately the Member States to which this notification was transmitted.
- 5a. The records of the personal data exchanged within the selective messaging functionality shall be kept there no longer than one year from the termination of the related contact tracing by the Member States concerned.*

5b. In relation to their responsibilities to notify and rectify personal data in the Early Warning and Response System, the national competent authorities shall be regarded as controllers within the meaning Article 2(d) of Directive 95/46/EC.

In relation to its responsibilities to storage personal data, the Commission shall be regarded as a controller within the meaning of Article 2(d) of Regulation (EC) No 45/2001.

6. The Commission shall adopt:
- (a) guidelines aiming at ensuring that the day-by-day operation of the Early Warning and Response System complies with Directive 95/46/EC and Regulation (EC) No 45/2001;
 - (b) a recommendation providing an indicative list of personal data that may or should be exchanged for the purpose of the coordination of contact tracing measures.

Article 17~~49~~

Health Security Committee⁴⁵

1. A 'Health Security Committee', composed of representatives of *the* Member States **designated under point (c) of Article 15(1)** ~~at a high level~~, is hereby established.
2. The Health Security Committee shall have the following tasks:
 - (a) support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Decision;
 - (b) ~~assist the Commission in providing for the~~ **coordinate *in liaison with the Commission*** ~~ion~~ of the preparedness and response planning efforts of the Member States in accordance with Article 4;
 - (c) ~~assist the Commission in providing for the~~ **coordinate *in liaison with the Commission risk and crisis communication and*** ~~coordination~~ of the responses of the Member States to serious cross-border threats to health, in accordance with Article 11.

⁴⁵ CIION: Reservation on the deletion of "high level" and details in paragraphs 5 and 5c.

3. The Health Security Committee shall be chaired by a representative of the Commission. The Health Security Committee shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.
4. The secretariat shall be provided by the Commission.
5. *The Health Security Committee shall adopt with the majority of two thirds of its members its rules of procedure, which establish the working structure of the Committee, especially:*
 - a) *the procedures for plenary meetings at high level and working groups;*
 - b) *the participation of experts in plenary meetings, the status of observers, including from third countries;*
 - c) *the exchange of classified information;*
 - d) *the possibility for the Committee to end consultations as referred to in Article 11 and to submit relevant information to the body competent under a provision of another act of the European Union or the European Atomic Energy Community;*
 - e) *the procedures for the exchange of information and the mutual consultation referred to in Article 4.*

Article 18 20

Committee on serious cross-border threats to health

1. For the adoption of implementing acts, the Commission shall be assisted by the 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.
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 21⁴⁶

Exercise of the delegation

- ~~1.— The power to adopt the 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 12 shall be conferred on the Commission for a period of five years after [...] ⁴⁷. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.~~
- ~~3.— The delegation of powers referred to in Article 12 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the powers 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 act already in force.~~
- ~~4.— As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.~~

⁴⁶ CION: Reservation on deletion of Article 21.

⁴⁷ OJ: Please insert the date: date of entry into force of this Decision.

~~5.— A delegated act adopted pursuant to Article 12 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and 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 2 months at the initiative of the European Parliament or the Council.~~

~~Article 22~~⁴⁸

~~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 21(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.~~

Article 19²³

Reports concerning this Decision

The Commission shall submit to the European Parliament and the Council every three years a technical report on the activities of the Early Warning and Response System, *on the operation of the epidemiological surveillance network, as well as on* ~~and~~ other activities carried out in the context of the implementation of this Decision, *including how these mechanisms and structures complement each other and efficiently protect public health while avoiding structural duplications. The Commission shall submit the first technical report by [two years after the entry into force of this Decision].*

⁴⁸ CION: Reservation on deletion of Article 22.

Chapter VIII
Final provisions

Article ~~20~~ 24

Repeal of Decision 2119/98/EC

1. Decision No 2119/98/EC is hereby repealed.
2. References to the repealed Decision shall be construed as references to this Decision.

Article 21 ~~25~~

Entry into force

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

Article 22 ~~26~~

Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

Remark:

This are criteria currently set out in the Annex II to the COMMISSION DECISION of 22 December 1999 on the communicable diseases to be progressively covered by the Community Network under Decision No 2119/98/EC of the European Parliament and of the Council (2000/96/EC).

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

- 1. Communicable diseases and special health issues that cause, or have the potential to cause, significant morbidity and/or mortality across the Union Community, especially where the prevention of the diseases requires an global approach to coordination at Union level.*
- 2. Communicable diseases and special health issues where the exchange of information may provide early warning of threats to public health.*
- 3. Rare and serious communicable diseases and special health issues which would not be recognized at national level and where the pooling of data would allow hypothesis generation from a wider knowledge base.*
- 4. Communicable diseases and special health issues for which effective preventive measures are available with a protective health gain.*
- 5. Communicable diseases and special health issues for which a comparison by Member States would contribute to the evaluation of national and Community programmes.*