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from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health - Outcome of the European Parliament's first reading (Strasbourg, 1 to 4 July 2013)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure ¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

¹ OJ C 145, 30.6.2007, p. 5.

In this context, the rapporteur, Mr Gilles PARGNEAUX (S&D-FR) presented one compromise amendment (amendment 49) to the proposal for Decision, on behalf of the Committee on the Environment, Public Health and Food Safety. This amendment had been agreed during the informal contacts referred to above.

II. VOTE

When it voted on 3 July 2013, the plenary adopted the compromise amendment (amendment 49) to the proposal for a Decision. The Commission's proposal as thus amended and the legislative resolution constitute the European Parliament's position at first reading; it reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the position of the European Parliament. The legislative act would then be adopted in the wording which corresponds to this position.

The text of the amendment adopted and the European Parliament's legislative resolution are set out in the Annex. The amendment is presented in the form of a consolidated text, where changes to the Commission's proposal are highlighted in ***bold and italics***. The symbol "■" indicates deleted text.

Serious cross-border threats to health *I**

European Parliament legislative resolution of 3 July 2013 on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health (COM(2011)0866 – C7-0488/2011 – 2011/0421(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0866),
 - having regard to Article 294(2) and Article 168(4)(c) and 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0488/2011),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 28 March 2012¹,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 28 May 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0337/2012),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 181, 21.6.2012, p. 160.

Position of the European Parliament adopted at first reading on 3 July 2013 with a view to the adoption of Decision No .../2013/EU 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,

* TEXT HAS NOT YET UNDERGONE LEGAL-LINGUISTIC FINALISATION.

¹ OJ C , , p.

² OJ C , , p.

³ OJ C , , p.

⁴ Position of the European Parliament of 3 July 2013.

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, which shall complement national policies, shall cover monitoring, early warning of and combating serious cross-border threats to health and Member States shall***, 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 health.
- (2) By Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998¹ 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.

¹ OJ L 268, 3.10.1998, p. 1.

- (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.
- (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 bioterrorism¹. 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. ■

¹ 13826/01.

- (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 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) This Decision 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, in liaison with the Member States, should ensure coordination and mutual information between the mechanisms and structures established under this Decision and other mechanisms and structures established at Union level and under the Euratom Treaty whose activities are relevant for the monitoring, early warning, preparedness and response planning and combating serious cross-border threats to health in order to achieve a high level of human health protection, avoiding overlap of activities, duplication or conflicting actions. In particular the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System.***

- (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 human health. The Member States should, in liaison with the Commission, coordinate the response within the Health Security Committee in close cooperation with, where applicable, other structures established at Union level and under the Euratom Treaty 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. *In the case of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.*

- (8a) *Cross-border threats to health are often related to pathogenic agents that can be transmitted between individuals. While such transmission cannot be completely prevented, general hygiene measures can make an important contribution by reducing the speed and extent of spreading of the agent and thus reduce the general risk. Such measures could include information on good hygiene measures, such as effective hand washing and drying, in collective settings and in the workplace, and should take into account the existing recommendations of the World Health Organisation.*
- (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. *Consultation with a view to coordinate* between the Member States is necessary *in order to promote* interoperability between national preparedness *planning* in view of the international standards, while respecting Member States' competence to organise their health systems.

Member States should regularly provide the Commission with information on the state of play of their preparedness and response planning at national level. Information provided by the Member States should include 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 planning. The Commission should compile the information received and should ensure its exchange among Member States through the Health Security Committee.

When a Member State decides to substantially revise their national preparedness planning, they should inform the Commission thereof and submit to the Commission the information about the main aspects of such a revision in a timely manner to allow for information sharing and possible consultations within the Health Security Committee.

- (10) The European Parliament in its resolution of 8 March 2011¹ and the Council in its Conclusions of 13 September 2010² 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, ***e.g. by obtaining advantageous prices and order flexibility with regard to a given product.*** With regard to pandemic vaccines, in the context of limited production capacities at global level, such a procedure would ***be undertaken with the aim of enabling more equitable access to vaccines for the Member States involved, to help them better meet the vaccination needs of their citizens, in line with vaccination policies in the Member States.***

¹ 2010/2153(INI).

² 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 ***is ensured by Member States' monitoring systems and available information is exchanged through Early Warning and Response System (EWRS)***, is therefore more appropriate to those other threats.
- (11a) ***The Commission will strengthen cooperation and activities with the ECDC, the Member States, the European Medicines Agency and the WHO to improve the methods and processes through which information related to the coverage of vaccine preventable diseases is provided.***

- (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 response at the Union level.*** ***To avoid duplication, 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 to the extent possible so that the competent authorities of the Member States can avoid to the extent possible to notify the same alert through different systems at Union level.***

- (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 developed in a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. This risk assessment should be provided by the Agencies of the Union in accordance with their missions or by the Commission if the risk assessment required is totally or partially outside the mandates of the Agencies of the Union.

- (13a) ***Taking account of the applicable rules in each case scientific experts should make declarations of interest and declarations of commitments. Such declarations should include any activity, situation, circumstances or other facts potentially involving direct or indirect interest in order to allow identifying those interests which could be considered prejudicial to their independence.***

- (14) Effectively responding to serious cross-border threats to health at national level ***might require consultation*** among Member States, in conjunction with the Commission, ***with a view to coordinate national response and might, necessitate*** exchange of information **■** . Under Decision No 2119/98/EC, the ***Member States already consult each other in liaison with the Commission with a view to coordinating their efforts and*** the response at the Union level **■** 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)¹
- (14a) ***The obligations of Member States to provide information according to this Decision do not affect the application of Article 346(1)(a) of the Treaty on the functioning of the European Union, according to which no Member State shall be obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.***

¹ OJ L 314, 1.12.2007, p. 9

- (15) ***The Member States have the responsibility to manage public health crisis at national level. However, measures*** taken by individual Member States ***could*** damage the interests of other Member States if they are ***inconsistent with one another and if they are based on different risk assessments. Therefore, the aim to coordinate*** 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,*** 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,*** based on robust and independent evaluation of public health risks, ***to be adapted to national needs and circumstances. This exchange of information will facilitate monitoring of the clarity and coherence of messages to the public and to the healthcare professionals.***

- (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 Council¹ 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 products² 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.

¹ OJ L 92, 30.3.2006, p. 6.

² OJ L 334, 12.12.2008, p. 7

- (17a) *In advance of recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share its analysis of the situation of the outbreak and to inform of its intention to issue such a Decision. Where such a Decision is adopted, the Commission should inform the WHO thereof.*
- (17b) *The occurrence of an event that is linked with serious cross-border threats to health and is likely to have Europe-wide consequences may require the Member States concerned to take particular control or contact tracing measures in a coordinated manner to identify those persons already contaminated and those persons exposed to risk. Such cooperation may require the exchange of personal data through the system, including sensitive information related to health, confirmed or suspected human cases, amongst those Member States directly affected by the contact tracing measures.*

- (17c) *The cooperation with third countries and international organisations in the field of public health should be fostered and it is particularly important to ensure the exchange of information with the World Health Organisation on the measures taken in the scope of this Decision. Notably, it may be in the interest of the Union to conclude international cooperation agreements with third countries or international organizations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross border threats to health. Within the limits of the Union 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.*

- (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 data¹ 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 data². 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.

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¹ OJ L 281, 23.11.1995, p. 31

² OJ L 8, 12.1.2001, p. 1.

- (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: ***templates to be used when providing*** the [] information [] on preparedness and response planning; the ***establishment and update*** 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 adoption of case definitions for ***those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other*** serious cross-border threats to health ***subject to ad hoc monitoring***; the procedures for the operation of the Early Warning and Response System; the procedures for the ***information exchange on and the*** coordination of the responses of the Member States; the recognition of situations of ***public health*** emergency at Union level ***and the termination of such a recognition***.

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 powers. ***As the implementing acts foreseen by this Decision concern the protection of the health of humans, the Commission may not adopt a draft implementing act where the Committee delivers no opinion, in accordance with Article 5(4) subparagraph 2, point a) of Regulation (EU) No 182/2011.***

- (22) In order to enhance clarity and legal certainty, Decision No 2119/98/EC should be repealed and replaced by this Decision.
- (22a) ***As there are some Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Decision.***

HAVE ADOPTED THIS DECISION

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, *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 **■** serious cross-border *threats* to health in order to contribute to a high level of public health protection in the Union.
- 2a. *This Decision also clarifies the methods of cooperation and coordination envisaged between the various actors at Union level.*

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 **"the related special health issues"**);
 - (iii) biotoxins or other *harmful* biological agents not related to communicable diseases;
 - (b) threats of chemical origin **"**;
 - (c) threats of environmental origin **"**;

- (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, including measures setting standards of quality and safety for specific goods and measures concerning specific economic activities.***

- 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.*
3. The Commission shall, ■ 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* relevant for the monitoring, early warning, *preparedness and response planning*, and combating serious cross-border threats to health.
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** cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of **unrelated** 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 **■** 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 systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues ;
- (e) ‘monitoring’ means the continuous observation, 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 severe* 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 *spreads or entails a significant risk of spreading* across national borders of Member States, and which may *necessitate coordination at Union level in order to ensure a high level of human health protection*;

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Chapter II Planning

Article 4

Preparedness and response planning

1. Member States **and** the Commission **shall consult each other** within the Health Security Committee referred to in Article 19 **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 ■ serious cross-border threats to health. That **consultation shall be aimed at:**
 - (-a) sharing best practice and experience in preparedness and response planning;**
 - (a) promoting** the interoperability of national preparedness **planning;**
 - (aa) addressing the intersectoral dimension of preparedness and response planning at Union level;**
 - (b) supporting the** 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 ***by [one year after the entry into force of this Decision] and every three years thereafter*** provide the Commission with **■** information ***on*** the state of play of their preparedness and response planning ***at national level.***

This information shall 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, ***as provided to the WHO in accordance with International Health Regulations (2005);***
- (ii) ***description of the measures or arrangements aimed at ensuring*** the interoperability between the health sector and other **■** sectors of society, ***including veterinary sector, identified as critical in case of emergency, in particular:***
 - ***coordination structures in place for cross-sectoral incidents;***
 - ***emergency operational centres (crisis centres).***

- (iii) *description of the business continuity plans, measures or arrangements to ensure the continuous delivery of critical services and products.*

The obligation to provide the information referred to in points (ii) and (iii) only applies if such measures or arrangements are in place or are foreseen as part of the national preparedness and response planning.

- 2a. *When receiving classified information transmitted pursuant to paragraphs 2 and 4 of this Article, the Commission and the Health Security Committee shall apply the rules set out in the Annex to Commission Decision 2011/844/EC.*

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 which handle the information referred to in paragraphs 2 and 4 of this Article. These 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, Euratom and by Council Decision 2011/292/EU of 31 March 2011 on the security rules for protecting EU classified information.

2b. *For the purpose of paragraph 1, when substantially revising national preparedness planning, Member States shall inform the Commission in a timely manner of the main aspects of the revision of their preparedness planning at national level that are relevant to the objectives referred to in paragraph 1 and to the specific issues referred to in paragraph 2.*

3. The Commission shall make the information *received in accordance with paragraphs 2 and 3* available to the members of the Health Security Committee.

On the basis of this information, and for the purpose of paragraph 1, the Commission shall, in a timely manner, initiate discussion in the Health Security Committee, including, where appropriate, on the basis of synthesis or thematic progress reports.

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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 3 *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 20(2).

Article 5
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 **104(1)** of Council Regulation (EC, Euratom) No **966/2012 of the European Parliament and of the Council of 25 October 2012** on the Financial Regulation applicable to the general budget of the **Union and repealing Council Regulation (EC, Euratom) No 1605/2002¹** and Article **133** of Commission **Delegated Regulation (EU, Euratom) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules** applicable to the general budget of the **Union²**, with a view to the advance purchase of medical countermeasures against 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 shall be open to all Member States until the launch of the procedure;

¹ **OJ L 298, 26.10.2012, p. 1-96**

² **OJ L 362, 31.12.2002, p.1-111**

- (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, 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

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)*** , 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 epidemiological surveillance.
- 2a. ***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 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 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.*

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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.
5. The Commission shall, by means of implementing acts, establish and update:
 - (a) in order to ensure ■ 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 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 20(3).

Article 7
Ad hoc Monitoring █

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 requires, through the Health Security Committee*** 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.***
- 2a. ***The Commission shall, by means of implementing acts, 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.***

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Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 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 20(3).

Chapter IV

Early warning and response

Article 8

Establishment of an early warning and response system

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.
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 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 ■ :

- (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 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*, including information *related to serious cross-border threats to health* and public health measures related to serious cross-border threats to health transmitted through *rapid alert and information* systems *established under other provisions of Union law*.

Article 10
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 in Article 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:***
- (a) **█** 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) **█** 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 safety¹ ***in case of a threat referred to in Article 2 and which falls under the mandate of EFSA; and/or***
- (ba) other European agencies concerned.***

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¹ OJ L 31, 1.2.2002, p. 1

2. *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 Health Security Committee or its own initiative provide and ad hoc risk assessment.*

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.

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

3. *The Commission shall ensure that information 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.*

Article 11
Coordination of response

1. Following an alert pursuant to Article 9, ***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, ***the Member States shall*** consult each other within the Health Security Committee referred to in Article 19 and in liaison with the Commission ***with a view*** 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 Member State needs and circumstances, aiming at providing consistent and coordinated information in the EU to the public and to the healthcare professionals.***
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, immediately upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.
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*.

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

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Chapter V Emergency ■

Article 13 Recognition of emergency situations ■

- 1. *The Commission may formally recognise a situation of public health emergency:***
- (a) *for situations of emergency concerning epidemics of human influenza considered as having pandemic potential, the Director-General of the World Health Organization has been informed and has not yet adopted a decision declaring a situation of pandemic influenza in accordance with the applicable rules of the World Health Organization;***
- or***
- (b) *for situations of emergency other than those referred to in point (a), the Director - General of the World Health Organization has been informed and has not yet adopted a decision declaring a public health emergency of international concern in accordance with the International Health Regulations (2005);***

and when

- (i) the serious cross-border health threat at issue endangers public health at the Union level; and*
- (ii) medical needs are unmet in relation to that threat, which means that no satisfactory method of diagnosis, prevention or treatment is authorised in the Union or, even if such a method exists the authorization of a medicinal product could be of major therapeutic advantage to those affected.*

-1a. The Commission shall adopt the measures referred to in paragraph 1 by means of implementing acts.

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Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 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 **public health emergency pursuant to paragraph 1** through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 20(3).

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3. *The Commission shall inform the Director-General of the World Health Organization of the adoption of the measures referred to in paragraph 1.*

Article 14

Legal effects of the recognition

■ The recognition of a situation of emergency ■ pursuant to ■ Article 13(-1), shall have the sole legal effect of **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 enable the applicability* of Article 21 of Regulation (EC) No 1234/2008.

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Article 15
Termination of the recognition

The Commission shall, by means of implementing acts, terminate the recognition of the situations referred to in ■ Article 13(-1) as soon as one of the *applicable* conditions laid down in ■ Article 13(-1a) is no longer met.

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

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Chapter VII

Procedural provisions

Article 17

Designation of national authorities and representatives

1. Each Member State shall designate, within *four* months of the entry into force of this Decision:
 - (a) the competent authorities responsible *within the Member State for* epidemiological surveillance as referred to in Article 6;
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 - (c) 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;
 - (d) one representative and an alternate in the Health Security Committee referred to in Article *19*;

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.*
- 2a. *The Commission shall make publicly available the updated list of the authorities designated in accordance with points a) and b) of paragraph 1, as well as the updated list of the authorities to which the representatives in the Health Security Committee belong.*

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Article 18 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. *In particular, appropriate technical and organisational measures shall be taken to protect this personal data against accidental or illegal destruction, accidental loss, or unauthorised access and against any form of illegal processing.*

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 █ 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. *Messages containing personal data shall automatically be erased from the selective message functionality twelve months after the date of their posting.***
- 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.***

5c. *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 19
Health Security Committee

1. A ‘Health Security Committee’, composed of representatives of ***the*** Member States ***designated under point (c) of Article 17(1)***, 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) ***coordinate in liaison with*** the Commission **■** the preparedness and response planning efforts of the Member States in accordance with Article 4;
 - (c) ***coordinate in liaison with*** the Commission ***risk and crisis communication and*** responses of the Member States to serious cross-border threats to health, in accordance with Article 11.

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 modalities for the Committee to examine the relevance to its mandate of a matter submitted to it and the possibility to recommend referring this matter to a body competent under a provision of another act of the European Union or of the European Atomic Energy Community; these modalities shall not affect the obligations of the Member States under Articles 4 and 11.*

Article 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.
4. ***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.***

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Article 23
Reports concerning this Decision

The Commission shall submit to the European Parliament and the Council ***within two years of the entry into force of this Decision, and subsequently every three years a*** report on the ***implementation of this Decision. The report shall include, in particular, an assessment of the operation of the Early Warning and Response System and of the epidemiological surveillance network, as well as information on how the mechanisms and structures established under this Decision complement other alert systems at Union level and efficiently protect public health while avoiding structural duplications. The Commission may accompany this report with proposals to modify the relevant Union provisions.***

Chapter VIII

Final provisions

Article 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 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 26
Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

Annex to the ANNEX

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, especially where the prevention of the diseases requires an 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.*
-