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NOTE

from: Presidency
to: Permanent Representatives Committee (Part 1)/Council
Subject: **Preparation** for the Employment, Social Policy, **Health** and Consumer Affairs
Council Meeting on 22 June 2012

Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health (Legislative deliberation) (First reading)
- *Orientation debate*

1. With a view to preparing the Council (Employment, Social policy, **Health** and Consumer Affairs) meeting on 22 June 2012, Delegations will find attached the note from the Presidency on the abovementioned subject as a basis for the ministerial interventions on this item.
2. After discussion of the proposal at 8 meetings of the Working Party on Public Health, the Presidency wishes to invite ministers to have an orientation debate in order to advance and guide the discussions on some of the key outstanding issues and with a view to a speedy adoption of the proposal.

3. A Presidency compromise proposal for the Health Security Initiative that reflects the work carried out at Working Party level so far is included in the ANNEX as background information for the debate.
4. The Commission considers that:
 - Scope: the scope of the proposal should consist of a list of categories of serious cross-border threats to health, which combined with a specific definition of such threats described in Article 3(f) of the legal act, provides for more legal certainty and clarity in comparison with a rather broad definition suggested instead.
 - Preparedness: the coordination of preparedness planning needs to be strengthened instead of maintaining the current situation based on a voluntary approach. Incoherent and inconsistent preparedness among Member States may weaken the overall response capabilities of the Union.
 - Risk assessment: there is a necessity to guarantee evidence based and independent scientific expertise when providing risk assessment of serious cross-border threats to health, and the Commission also points out that it is important to separate such expertise from risk management.
 - Common measures: the Commission does not agree with the deletion of the provisions on common temporary public health measures and international agreements. Common temporary public health measures would provide for a safety net in case the coordination of national responses proves insufficient to cope with an extreme emergency situation and when as a consequence the protection of the population of the Union as a whole is jeopardised.
 - International agreements: International agreements would foster the cooperation with third countries and international organisations competent in the field of serious cross-border threats to health.
5. The Presidency proposes to structure the debate around the questions set out in the Annex to this note.

NOTE FROM THE PRESIDENCY

**Proposal for European Parliament and Council Decision
on serious cross-border threats to health, 2011/0421 (COD)**

Orientation debate - Questions

In any public health crisis situation the level of preparedness, the quality of risk assessment and the appropriate response are decisive in terms of coping efficiently with the situation. Member States are in charge of preparedness planning, crisis management and of the organisation of response and recovery at national level. At the same time, cross-border events need to be addressed in a coordinated manner at EU level.

In its conclusions on the Health Security Committee¹ of 22 February 2007, the Council called on the Commission to come forward with a proposal for a long-term solution for the Community framework for health security.

In its conclusions on Health Security² of 17 December 2008, the Council invited the Member States and the Commission to strengthen their coordination in facing public health emergencies of international concern within the EU, as defined in the International Health Regulations (IHR) 2005.

The Council also invited the Commission to take into account the inter-sectoral dimension of preparing for pandemic influenza, to develop the monitoring, preparation, early warning and response at European level to adapt it to the challenges of cross border public health emergencies and to consider providing the HSC with a legal basis. It also requested a long-term solution for the Community framework for health security.

¹ Doc. 6226/07 (Presse 23).

² Doc. 16515/08 SAN 303.

In its conclusions on Lessons to be learned from the A/H1N1 pandemic - Health security in the EU³ of 13 September 2010, the Council invited the Commission to review pandemic preparedness at EU level taking into account lessons learned and evaluations from and in coherence with the international framework. In this context attention should be given to inter-sectoral preparedness.

On 8 December 2011 the Commission adopted a proposal for European Parliament and Council Decision on serious cross-border threats to health, 2011/0421 (COD).

Preparedness (Article 4 of the Commission proposal)

Discrepancies in preparedness planning across the EU can lead to incoherent strategies and could potentially weaken and delay response capacity at EU and national level and negatively impact the situation in affected Member States as well as in neighbouring countries.

Question:

Would Delegations agree to strengthen common approaches on preparedness planning, in particular, would they agree to:

- *consult with other Member States and the Commission on preparedness by exchanging information and consulting each other within the Health Security Committee prior to updating their planning?*
- *delegate powers to the Commission to implement procedures necessary for the coordination, the exchange of information and the mutual consultation that would improve preparedness?*

³ Doc. 12665/10 SAN 158

Measures in extremely dangerous situations for public health (Article 12 of the Commission proposal)

Questions:

- 1. Do Delegations support the proposal of the Presidency to delete Article 12 of the Commission proposal which foresees the adoption of binding common temporary public health measures at EU level?*
- 2. As there may be dangerous situations where national responses are not sufficient to control the spread of a serious cross border health threat between the Member States, could Member States envisage other mechanisms for enhanced coordination at EU level to control a public health crisis?*

Composition of the Health Security Committee (Articles 17 and 19 of the Commission proposal)

The Health Security Committee (HSC) is currently the instrument which exists at EU level to discuss the management of health crisis caused by chemical, biological and environmental events. However, it is informal and has no legal mandate.

In its conclusions of 13 September 2010 the Council invited the Commission to present, in 2011, a proposal for a long-term solution for health security taking into account the outcome of the examination of the options for the legal basis of the HSC referred to above and the existing structures in all relevant sectors and the need to avoid duplication of work, and in the interim, to ensure that the Council is regularly updated on the work of the HSC.

Question:

Do Member States see the HSC as a standing committee of (high level) representatives nominated by national public health authorities or as a flexible body composed of representatives from different national authorities and at different levels depending on the category of threat?

* * *

The text below 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
<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

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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,

[...]

Whereas:

[...]

(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 in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and food stuffs.

(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) In exceptional circumstances, where it is necessary to complement public health measures in case of serious cross-border threats to health not covered by this Decision, and in order to ensure a high level of human health protection, Member States may decide to coordinate their public health responses within the Health Security Committee in accordance with Article 11, in liaison with the Union structures concerned, subject to the agreement of this Committee.

[...]

(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. 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 the coordination of the response at the Union level is necessary.

(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. 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.

[...]

(16a) The communication activities of the Health Security Committee should be strengthened. Its Communicators network, designed to exchange information rapidly and to address communication challenges, should continue to develop common communication strategies in a compatible manner and should be maintained as the appropriate channel for coordinating risk and crisis communication issues.

[...]

HAVE ADOPTED THIS DECISION

Chapter I

General provisions

Article 1

Subject matter

1. This Decision lays down rules on monitoring, 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).

2. 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.

2a. In exceptional emergency situations where public health measures in case of serious cross-border threats to health other than those covered in Article 2(1) prove insufficient to ensure a high level of human health protection, Member States may refer such threats for coordination of response within the Health Security Committee in accordance with Article 11, in close coordination with other Union sectors, as appropriate.

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.

4. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the field covered by this Decision, including arrangements foreseen in existing or future bilateral or multilateral agreements or conventions, provided that they respect their obligations under 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 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 hazard 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 *result in death, be life-threatening, or cause a severe disease in exposed humans* ~~cause a potential severe risk to public health and which necessitates a coordination ted action at the Union level;~~
- ~~(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.~~

Chapter II

Planning

Article 4

Preparedness and response planning

1. Member States shall *coordinate*, in liaison with the Commission and ~~on the basis of its recommendations,~~ within the Health Security Committee referred to in Article ~~17~~ 19, ~~coordinate~~ 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 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 EU 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 provide the Commission with ~~the following information~~ *on non-sensitive elements concerning the state of play* of their preparedness and response planning, *including available information on:*
 - (i) ~~minimum~~ core capacity standards *as* determined at national level for the health sector;
 - (ii) specific mechanisms established at national level for the interoperability between the health sector and other critical sectors of society;
 - (iii) business continuity arrangements in critical sectors of society.

2a. Member States may request that the information shall be treated under rules of confidentiality to be 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. ***When adopting or revising*** ~~Before adopting or reviewing their national preparedness plans,~~ Member States shall ***inform*** ~~consult~~ each other and the Commission in relation to the issues referred to in ~~points (a) and (b)~~ of paragraph 1 ***in a timely manner***.

5. The Commission shall, by means of implementing acts, determine the procedures necessary for the coordination, the exchange of information and the mutual consultation referred to in paragraphs 1 to 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ~~18~~ 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 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 Communities⁴ 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 Communities⁵, with a view to the advance purchase of medical countermeasures against serious cross-border threats to health.

⁴ OJ L 248, 16.9.2002, p.1

⁵ 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 s-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 Article 2(1)(a)(i) and (ii), is hereby established.
- 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 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.

4. When reporting information on epidemiological surveillance, the national competent authorities shall 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 ~~an exhaustive~~ coverage by the epidemiological surveillance network, the list of communicable diseases referred to in Article 2 (1) (a)(i);

(b) the criteria for selection of communicable diseases of special areas to be covered by epidemiological surveillance within the network;

~~(cb)~~ 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;

~~(de)~~ 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 ~~1820~~(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 ~~1820~~(3).

~~6new.~~ *(deleted)*

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, *within the Health Security Committee, through the Early Warning and Response System*, ~~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. ~~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,

- ~~(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;~~
- ~~(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 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.

2new. (deleted)

3new. (deleted)

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.

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 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**.

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 17 ~~19~~, through the Early Warning and Response System, an independent risk assessment of the potential severe risk to public health and of public health measures by:** ~~through the Early Warning and Response System and to the Health Security Committee referred to respectively in Articles 8 and 19 an assessment of the risks to public health.~~

~~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 safety⁶~~ **in case of a threat referred to in Article 2 and which falls under the mandate of EFSA**; ~~and/or~~.

⁶ OJ L 31, 1.2.2002, p.1

(e)2. ~~W~~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 for an ad-hoc nomination of independent experts according to Article 15(1)(e). The Commission shall entrust the nominated experts with establishing a risk assessment and make it promptly available to the national competent authorities through the Early Warning and Response System.*

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/EC⁷; 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.*

4new. (deleted)

⁷ OJ L 241, 10.9.2008, p. 21.

Article 11

Coordination of response

1. Following an alert pursuant to Article 9, the Member States shall, 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 19 and in liaison with the Commission *with a view* ~~in order~~ to coordinate 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.

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. *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.*

5new. (deleted)

45. 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.

~~56.~~ 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 12

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.~~

~~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~~ 13

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 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.~~

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).

2. The Commission may adopt the measures referred to in paragraph 1 only when all 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);
- (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;

- (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 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 Agency⁸ 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 use⁹, 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.~~

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 the applicability of Article 2(2) of Regulation (EC) No 507/2006 and 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~~ 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 conditions laid down in ~~points (b), (c) and (d) of Article 12~~ 13(2) is no longer met.

⁸ OJ L 136, 30.4.2004, p. 1

⁹ OJ L 311, 28.11.2001, p. 67

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

Chapter VI

International agreements

Article 16

International agreements

~~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 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) the authority or authorities responsible at national level for the purposes of Article 17 one representative and an alternate in the Health Security Committee referred to in Article 19.~~
- (d) a single contact point for the purpose of the ad-hoc nomination of independent experts as referred to in Article 10(2).**

2. Member States shall notify the Commission and other Member States of the designations 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.

4. The Commission shall distribute immediately to the Health Security Committee an updated list of the designated competent authorities and single contact points as referred to in paragraph 1.

Article ~~16~~ 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.

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.

4a. The processing of personal data for the purpose of contact tracing shall be subject to the following conditions:

(a) this personal data:

- is necessary for the purpose of contact tracing,

- is limited to information indispensable for the identification and location of persons exposed to that threat,

- is related to an alert already notified pursuant to Article 8,

- is exchanged only between Member States concerned by a contact tracing;

(b) the contact tracing relies on the exchange of this personal data between the Member States and is proportionate to the risk to public health.

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 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 and the processing of personal data involved therein, 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 and the processing of personal data involved therein, 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~~ 19

Health Security Committee

1. A 'Health Security Committee', composed of representatives of *the* Member States *designated under point (b) 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.

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 its rules of procedure.***

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 21

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 [...]¹⁰. 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.

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.

¹⁰ — OJ: Please insert the date: date of entry into force of this Decision

Article 22

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 ~~19~~ 23

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 [DATE].***

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
