



EUROPEAN PARLIAMENT

2009 - 2014

---

*Committee on the Environment, Public Health and Food Safety*

---

**2011/0421(COD)**

20.6.2012

**\*\*\*I**

## **DRAFT REPORT**

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Gilles Pargneaux

***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

***Amendments to a draft act***

In amendments by Parliament, amendments to draft acts are highlighted in bold italics. Highlighting in normal italics is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in bold. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

## CONTENTS

	<b>Page</b>
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION.....	5
EXPLANATORY STATEMENT.....	27



## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**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 Article 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 2012<sup>1</sup>,
  - after consulting the Committee of the Regions,
  - 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 (A7-0000/2012),
1. Adopts the Council position at first reading outlined below;
  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.

**Amendment 1**

**Proposal for a decision  
Recital 3**

*Text proposed by the Commission*

(3) Apart from communicable diseases, a number of other ***sources of danger to***

*Amendment*

(3) Apart from communicable diseases, a number of other ***threats, of biological,***

---

<sup>1</sup> Not yet published in the Official Journal.

*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.

*chemical or environmental origin or arising from defective implantable medical devices or the misuse of medication*, 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 States*' 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.

Or. fr

#### *Justification*

*Through this decision, the Commission hopes to widen the area of application of the Early Warning and Response System to include all serious cross-border threats to health. In this way, the Commission intends to fill the gaps that have been identified in recent years in the health sector regarding notification, monitoring, risk assessment and risk management. Recent events have shown the lack of responsiveness of the European Union with respect to health crises arising from the misuse of medication or the sale of defective medical devices. An effective warning system would certainly have prevented such dramatic events.*

#### **Amendment 2**

##### **Proposal for a decision Recital 5**

###### *Text proposed by the Commission*

(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[28] (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

###### *Amendment*

(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[28] (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. ***In the case of a threat that did not arise from a transmissible disease, the ECDC would have to respond only in cooperation with***

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.

***the competent authority, at the request of this authority.*** 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.

Or. fr

### *Justification*

*The ECDC's mandate, apart from transmissible diseases, should also be defined by this Decision.*

### **Amendment 3**

#### **Proposal for a decision Recital 7**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***

Or. fr

### *Justification*

*Serious cross-border threats to health caused by ionising radiation should be included as part of the global approach advocated by the Commission. The nuclear disaster at Fukushima, Japan, reminds us how crucial it is to be capable of responding rapidly to the health risks arising from such a catastrophe.*

#### **Amendment 4**

##### **Proposal for a decision Recital 10**

###### *Text proposed by the Commission*

(10) The European Parliament in its resolution of 8 March 2011[29] and the Council in its Conclusions of 13 September 2010[30] stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases. With regard to pandemic vaccines, in the context of limited production capacities at global level, such a procedure would increase the availability of those products and ensure fairer access to them among Member States participating in the joint procurement.

###### *Amendment*

(10) The European Parliament in its resolution of 8 March 2011[29] and the Council in its Conclusions of 13 September 2010[30] 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 ***and to obtain, in particular, equal access as well as 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 increase the availability of those products and ensure fairer access to them among Member States participating in the joint procurement.

Or. fr

### *Justification*

*Equal access to vaccines and a certain degree of order flexibility should be guaranteed by the time of the next pandemics.*



**Amendment 5**

**Proposal for a decision  
Recital 10 a (new)**

*Text proposed by the Commission*

*Amendment*

***(10a) Cooperation with the competent international organisations, in particular the World Health Organisation, especially with regard to the classification of threats, should be strengthened.***

Or. fr

*Justification*

*Cooperation with the competent international organisations, in particular the World Health Organisation (WHO), should be emphasised more within this Decision.*

**Amendment 6**

**Proposal for a decision  
Recital 11 a (new)**

*Text proposed by the Commission*

*Amendment*

***(11a) Cooperation with third countries, particularly regarding the emergence or re-emergence of transmissible diseases, should be strengthened.***

Or. fr

*Justification*

*Cooperation with third countries should be emphasised more within this Decision.*

**Amendment 7**

**Proposal for a decision  
Recital 16**

*Text proposed by the Commission*

(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 at *the* Union level should encompass shared information campaigns and consistent communication messages to citizens based on robust and independent evaluation of public health risks.

*Amendment*

(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 at Union level should encompass shared information campaigns and consistent communication messages to citizens based on robust and independent evaluation of public health risks. ***Proper communication strategies would allow the Member States and the Commission to monitor the clarity and coherence of the information content of the message to the public, particularly concerning the nature and characteristics of the threat, the best way of preventing it and the risks and benefits of protection and/or treatment.***

Or. fr

*Justification*

*The E. coli/STEC O104 crisis was a clear example of how a poor communication strategy could hinder the proper management of a crisis and lead to serious economic consequences. This Decision should further stress the importance of implementing a consistent and coordinated communication strategy should a crisis arise.*

**Amendment 8**

**Proposal for a decision  
Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) The occurrence of an event that is linked with serious cross-border threats to health and is likely to have Europe-wide***

*consequences may compel the Member States concerned to take particular control or contact tracing measures in a concerted 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.*

Or. fr

### *Justification*

*This Recital refers explicitly to contact tracing.*

## **Amendment 9**

### **Proposal for a decision Recital 20**

#### *Text proposed by the Commission*

(20) The power to adopt *delegated* acts in accordance with *the* Article 290 of the Treaty on the functioning of the European Union *should be conferred to the Commission* in respect of measures needed to complement the action of the Member States, in very specific and urgent situations, for the transnational aspects of the control of serious cross-border threats to health. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, as far as the urgency of the situation allows it. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

#### *Amendment*

(20) The *Commission should be given the* power to adopt acts in accordance with Article 290 of the Treaty on the functioning of the European Union in respect of *the adoption of the procedures for coordination, the exchange of information and mutual consultation on preparedness and response planning, the adoption of procedures for the operation of the Early Warning and Response System, the adoption of coordination procedures for the response of Member States following an alert notification and the adoption of* measures needed to complement the action of the Member States, in very specific and urgent situations, for the transnational aspects of the control of serious cross-border threats to health. It is of particular importance that the Commission carry out appropriate

consultations during its preparatory work, including at expert level, as far as the urgency of the situation allows it. The Commission, when preparing and drawing up delegated acts, should ensure *the* simultaneous, timely and appropriate transmission of *all* relevant documents to the European Parliament and to the Council.

Or. fr

### *Justification*

*This Decision should offer additional clarification on the procedures for coordination, the exchange of information and mutual consultation on preparedness and response planning as well as the procedures for the operation of the Early Warning and Response System.*

## **Amendment 10**

### **Proposal for a decision Recital 21**

#### *Text proposed by the Commission*

(21) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: ***the procedures for the coordination, the exchange of information and the mutual consultation on preparedness and response planning;*** the adoption of a list of communicable diseases subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the setting up and termination of ad hoc monitoring networks and the procedures for the operation of such networks the adoption of case definitions for serious cross-border threats to health; the procedures for the operation of the Early Warning and Response System; the procedures for the coordination of the responses of the Member States; the

#### *Amendment*

(21) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: the adoption of a list of communicable diseases subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the setting up and termination of ad hoc monitoring networks and the procedures for the operation of such networks the adoption of case definitions for serious cross-border threats to health; the procedures for the operation of the Early Warning and Response System; the procedures for the coordination of the responses of the Member States; the recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level. Those

recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level. Those 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.

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.

Or. fr

### *Justification*

*This Decision should offer additional clarification on the procedures for coordination, the exchange of information and mutual consultation on preparedness and response planning as well as the procedures for the operation of the Early Warning and Response System.*

### **Amendment 11**

#### **Proposal for a decision**

#### **Article 1 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. This Decision defines the roles, duties and responsibilities of the key actors and the structures at Union level as well as the methods of cooperation and coordination envisaged between the various institutions.***

Or. fr

### *Justification*

*This introductory chapter should also address the question of the roles, duties and responsibilities of the key actors as well as the necessary coordination between them. These references are lacking in Article 1.*

**Amendment 12**

**Proposal for a decision  
Article 2 – paragraph 1 – point b**

*Text proposed by the Commission*

b) threats of chemical origin **with the exception of** threats arising from ionising radiation;

*Amendment*

b) threats of chemical origin **including** threats arising from ionising radiation;

Or. fr

*Justification*

*Serious cross-border threats to health caused by ionising radiation should be included as part of the global approach advocated by the Commission. The nuclear disaster at Fukushima, Japan, reminds us how crucial it is to be capable of responding rapidly to the health risks arising from such a catastrophe.*

**Amendment 13**

**Proposal for a decision  
Article 2 – paragraph 1 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

**(da) threats caused by defective active implantable medical devices as per Article 1(2)(c) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices;**

Or. fr

*Justification*

*Through this Decision, the Commission hopes to ‘widen the area of application of the Early Warning and Response System to include all serious cross-border threats to health’. In this way, the Commission intends to fill the gaps that have been identified in recent years in the health sector regarding notification, monitoring, risk assessment and risk management. Recent events have shown the lack of responsiveness of the European Union with respect to health crises arising from the sale of defective medical devices. An effective warning system would certainly have prevented such dramatic events.*

**Amendment 14**

**Proposal for a decision**

**Article 2 – paragraph 1 – point e b (new)**

*Text proposed by the Commission*

*Amendment*

***(db) threats arising from the misuse of medication;***

Or. fr

*Justification*

*Through this Decision, the Commission hopes to ‘widen the area of application of the Early Warning and Response System to include all serious cross-border threats to health’. In this way, the Commission intends to fill the gaps that have been identified in recent years in the health sector regarding notification, monitoring, risk assessment and risk management. Recent events have shown the lack of responsiveness of the European Union with respect to health crises arising from the misuse of medication. An effective warning system would certainly have prevented such dramatic events.*

**Amendment 15**

**Proposal for a decision**

**Article 3 – point g**

*Text proposed by the Commission*

*Amendment*

g) ‘serious cross-border threat to health’ means a hazard of biological, chemical, environmental or unknown origin which is likely to spread across national borders of Member States and which may cause a *potential severe* risk to public health necessitating a coordinated action at the Union level;

(g) ‘serious cross-border threat to health’ means a hazard of biological, chemical, environmental, or unknown origin ***or caused by defective implantable medical devices or the misuse of medication*** which is likely to spread across national borders of Member States and which may cause a *potentially serious* risk to public health necessitating coordinated action at Union level;

Or. fr

### *Justification*

*Through this Decision, the Commission hopes to ‘widen the area of application of the Early Warning and Response System to include all serious cross-border threats to health’. In this way, the Commission intends to fill the gaps that have been identified in recent years in the health sector regarding notification, monitoring, risk assessment and risk management. Recent events have shown the lack of responsiveness of the European Union with respect to health crises arising from the misuse of medication or the sale of defective medical devices. An effective warning system would certainly have prevented such dramatic events.*

### **Amendment 16**

#### **Proposal for a decision Article 4 – paragraph 5 – subparagraph 1**

*Text proposed by the Commission*

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 20(2).**

*Amendment*

5. The Commission shall **be empowered to adopt delegated acts in accordance with Article 21 with regard to the division of roles and responsibilities among the key actors in preparedness and response planning as well as** procedures for coordination, the exchange of information and mutual consultation referred to in **this Article.**

Or. fr

### *Justification*

*The decision should be more precise with regard to the division of roles and responsibilities among the key actors in preparedness and response planning.*

### **Amendment 17**

#### **Proposal for a decision Article 7 – paragraph 3 – subparagraph 1 – point d**

*Text proposed by the Commission*

**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**

*Amendment*

**deleted**



*compatibility of the collected data;*

Or. fr

*Justification*

*This decision must provide more details on the case definitions to be used for ad hoc monitoring.*

**Amendment 18**

**Proposal for a decision  
Article 7 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. The Commission is authorised to adopt delegated acts in accordance with Article 21 regarding the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility of the collected data at Union level;***

Or. fr

*Justification*

*This decision must provide more details on the case definitions to be used for ad hoc monitoring.*

**Amendment 19**

**Proposal for a decision  
Article 8 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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

1. A rapid alert system for notifying at 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, ***the ECDC*** and the competent

at national level for alerting, assessing public health risks and determining the measures that may be required to protect public health.

authorities responsible at national level for alerting, assessing public health risks and determining the measures that may be required to protect public health.

Or. fr

*Justification*

*As a key actor in the Early Warning Response System, the ECDC should be in constant contact with the Commission and the Member States.*

**Amendment 20**

**Proposal for a decision  
Article 8 - paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. The actors in the Early Warning and Response System shall undertake to act independently in the public interest.***

***For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be prejudicial to their independence. Those declarations shall be made annually in writing.***

Or. fr

*Justification*

*This decision refers to the independence of experts in a broad and general manner. Given that the Early Warning and Response System relies heavily on the work of experts, an article should be devoted to the independence and transparency that they must display.*

Proposal for a decision  
Article 8 - paragraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

***1b. The actors in the Early Warning and Response System shall develop their communication strategy in line with the case in hand in order to keep citizens informed of the risk and the measures taken.***

***This communication strategy shall stipulate the content of the message and the time of communication about the problem in question, including the most suitable arrangements for distribution.***

***The strategy shall take into account the specific capacity and responsibilities of each member of the system in order to organise coordinated, consistent and transparent communication for citizens, that is the person responsible for communication in the field of public health risk assessment within the Commission and the person responsible for communication within the Health Security Committee.***

***Member States directly affected by the crisis shall implement all provisions to ensure that their communication is consistent with the communication strategy coordinated by the Health Security Committee.***

***This strategy shall propose in particular the channels of communication that should be used in line with the case in hand, together with the European Parliament, the parties concerned and third countries.***

Or. fr

*Justification*

*The E. coli/STEC O104 crisis was a clear example of how a poor communication strategy can hinder the proper management of a crisis and lead to serious economic consequences. This decision should further stress the importance of implementing a consistent and coordinated communication strategy should a crisis arise. A specific article relating to this issue should be included in this decision.*

**Amendment 22**

**Proposal for a decision  
Article 8 – paragraph 2**

*Text proposed by the Commission*

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 20(2).***

*Amendment*

2. The Commission shall ***be empowered to*** adopt ***delegated acts in accordance with Article 21 with regard to*** information exchange in order to ensure the proper functioning of the Early Warning and Response System.

Or. fr

*Justification*

*This decision should be more precise with regard to how the information exchange needed for the proper functioning of the Early Warning and Response System will take place.*

**Amendment 23**

**Proposal for a decision  
Article 10 - point d (new)**

*Text proposed by the Commission*

*Amendment*

***(d) on the assessment provided by the World Health Organisation in the case of an international public health emergency.***

Or. fr

*Justification*

*Public health risk assessment should also be based on the opinion of the WHO in the case of an international public health emergency.*

**Amendment 24**

**Proposal for a decision  
Article 11 - paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4a. In the case of a serious cross-border threat to health, Member States must coordinate their messages and communication campaigns in order to deliver consistent, harmonised information.***

Or. fr

*Justification*

*The E. coli/STEC O104 crisis was a clear example of how a poor communication strategy can hinder the proper management of a crisis and lead to serious economic consequences. This decision should further stress the importance of implementing a consistent and coordinated communication strategy should a crisis arise.*

**Amendment 25**

**Proposal for a decision  
Article 11 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

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 this Article.

5. The Commission shall ***be empowered to*** adopt ***delegated acts in accordance with Article 21 with regard to the division of roles and responsibilities among the key actors in the coordination and*** procedures for ***reciprocal information***, consultation and coordination ***referred to*** in this Article.

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

*Justification*

*This decision should be more precise with regard to how roles and responsibilities will be divided among the key actors in the Early Warning and Response System.*

**Amendment 26**

**Proposal for a decision  
Article 12 – paragraph 3 - point d (new)**

*Text proposed by the Commission*

*Amendment*

***(d) be consistent with the recommendations established by the World Health Organisation in the case of an international public health emergency.***

*Justification*

*The common temporary measures adopted should be consistent with the recommendations established by the World Health Organisation in the case of an international public health emergency.*

**Amendment 27**

**Proposal for a decision  
Article 12 – paragraph 3 – subparagraph 2 (new)**

*Text proposed by the Commission*

*Amendment*

***The Commission shall specify the reasons for adopting these measures.***

*Justification*

*When adopting common temporary public health measures, the Commission must specify the reasons for adopting these measures.*

**Amendment 28**

**Proposal for a decision  
Article 17 – paragraph 1 – subparagraph 2 (new)**

*Text proposed by the Commission*

*Amendment*

***The appointment of national authorities and representatives who are part of the Community network established by this decision shall be made public by the Member States.***

Or. fr

*Justification*

*This decision should emphasise the public nature of the appointment of structures or authorities which are part of the Community network.*

**Amendment 29**

**Proposal for a decision  
Article 18 - paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5a. Those responsible for processing personal data must take the appropriate technical and organisational measures to protect this data against accidental or illegal destruction, accidental loss, alteration, distribution or unauthorised access and against any form of illegal processing.***

Or. fr

*Justification*

*This decision must recall the confidentiality of personal data.*

**Amendment 30**

**Proposal for a decision  
Article 18 - paragraph 5 b (new)**

*Text proposed by the Commission*

*Amendment*

***5b. In accordance with the provisions on data protection laid down in Article 4(1)(e) of Regulation (EC) No 45/2001 and in Article 6(1)(e) of Directive 95/46/EC, the system shall automatically delete any selective messages containing personal data 12 months after the date on which those messages were sent.***

Or. fr

*Justification*

*This decision should recall the time limit for retaining personal data.*

**Amendment 31**

**Proposal for a decision  
Article 21**

*Text proposed by the Commission*

*Amendment*

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 [...]. 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.

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 12 shall be conferred on the Commission for a period of **three years** after [...]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the **three-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 acts 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 *two* 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 *two* months at the initiative of the European Parliament or the Council.

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 acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify the European Parliament and the Council thereof *simultaneously*.

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 *two* 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 *two* months at the initiative of the European Parliament or of the Council.

Or. fr

#### *Justification*

*The delegation of powers to the Commission should be subject to clear conditions in the case of the delegated acts referred to in Article 12, particularly for common temporary public health measures put in place when the coordination of national responses proves insufficient. The three-year period ensures the better safeguarding of the powers of the European Parliament.*

**Proposal for a decision**  
**Article 23**

*Text proposed by the Commission*

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 and other activities carried out in the context of the implementation of this Decision.

*Amendment*

The Commission shall submit **a report** to the European Parliament and the Council every three years **containing an assessment of the functioning** of the Early Warning and Response System.

***The first report, which shall be submitted within three years of the entry into force of this decision, shall assess the activities of the Early Warning and Response System and other activities carried out in the context of the implementation of this Decision. It shall also include any proposals to amend or adapt this decision as considered necessary by the Commission.***

***Every time common temporary public health measures are adopted under Article 12, and at least two months after the date on which these measures are adopted, the Commission shall submit a detailed report to the European Parliament and the Council on the content of these measures and their contribution to reducing the serious cross-border threat to health.***

Or. fr

*Justification*

*Regular dialogue should be established between the Commission and the European Parliament so that the latter may be informed of the activities and the proper functioning of the Early Warning and Response System. In the case of a health warning, the Commission must, within the two months following the adoption of measures, submit a detailed report to the European Parliament and the Council on the content of these measures and their contribution to reducing the serious cross-border threat to health.*

## EXPLANATORY STATEMENT

### Context

Having learned from recent crises such as the H1N1 ‘pandemic’ in 2009, the volcanic ash cloud in 2010 and the E. coli bacteria in 2011, on 8 December 2011 the Commission submitted a proposal for a decision establishing measures and structures for the effective protection of citizens throughout Europe from a wide range of cross-border threats to health.

### Subject of the proposal for a decision

Based on the Early Warning and Response System set up in 1988 for communicable diseases, the Commission’s proposal presents measures aimed at reinforcing the European Union’s response capacity to prevent serious cross-border threats to health by providing it with resources, networks and structures to complement those already in place in order to combat these threats.

The proposal for a decision is based on the existing structures, reinforcing them using the measures listed below:

- extending the scope of the risk assessment and coordination measures which are currently applied to communicable diseases to all threats to health of biological, chemical or environmental origin.
- strengthening the role of the Health Security Committee with a view to better coordination of measures to combat crises.
- greater preparation in the fight against crises, requiring each Member State to draw up, consolidate and update its national preparation and response plans for dealing with health crises in a coordinated manner, in liaison with the other Member States and the Commission.
- the possibility of recognising a European ‘health emergency’ with the aim of speeding up the provision of the medication needed to combat the crisis.
- the adoption of emergency cross-border measures by the European Commission at European level in exceptional circumstances arising from large-scale deaths or hospitalisations when the Member States’ measures prove insufficient to manage the spread from one country to another.

In the interests of clarity and legal certainty, this decision repeals Decision No 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.

### Rapporteur’s position

Your rapporteur welcomes this proposal for a decision on cross-border threats, particularly in terms of the coordination and efficiency of responses in the event of serious health threats. In order to improve upon this sound legislative basis, your rapporteur proposes to amend the draft decision in the following areas:

## **Scope of the decision**

Through this decision, the Commission hopes to ‘extend the Early Warning and Response System to cover all serious cross-border threats to health’. In this way, the Commission intends to fill the gaps that have been identified in recent years in the health sector regarding notification, monitoring, risk assessment and risk management.

Recent events have shown the lack of responsiveness of the European Union with respect to health crises arising from misuse of medication or the sale of defective medical devices. An effective warning system would certainly have prevented such dramatic events. That is why your rapporteur proposes to extend the scope of this decision to threats arising from misuse of medication or the sale of defective medical devices.

Contrary to the European Commission, your rapporteur believes that serious cross-border threats to health arising from ionising radiation should be an integral part of the global approach advocated in this decision. The nuclear disaster in Fukushima in March 2011 reminds us how crucial it is to be capable of responding rapidly to the health risks arising from such a catastrophe.

## **Communication strategy**

The E. coli/STEC O104 crisis was a clear example of how a poor communication strategy could hinder the proper management of a crisis and lead to serious economic consequences. Your rapporteur believes that this decision should further stress the importance of implementing a consistent and coordinated communication strategy should a crisis arise.

## **Independence of experts**

This decision recalls the independence of experts in a broad and general manner. Given that the Early Warning and Response System relies heavily on the work of experts, an article should be devoted to the independence and transparency that they must display.

## **Protection of personal data**

According to your rapporteur, the exchange of data within the framework of researching contacts should be the subject of a specific paragraph, given the importance that the European Union accords to the protection of personal data. This decision should recall the principles of confidentiality and the time limit for retaining personal data.

## **Mandate of the European Centre for Disease Prevention and Control**

The mandate of the European Centre for Disease Prevention and Control (ECDC), beyond communicable diseases, should also be defined by this decision. The importance of its continued cooperation with the European Commission and the Member States should also be noted.

## **Cooperation with the WHO and third countries**

Cooperation by members of the system with the competent international organisations, in particular the World Health Organisation (WHO), should be emphasised more within this

decision. Cooperation with third countries should also be recalled.

### **Procedures for common purchases of medical countermeasures**

Your rapporteur highlights that equitable access to vaccines and a certain degree of order flexibility should be guaranteed by the time of the next pandemics.

### **Regular dialogue with the European Parliament**

Regular dialogue must be established between the Commission and the European Parliament so that the latter may be informed of the activities and the proper functioning of the Early Warning and Response System. In the case of a health warning, your rapporteur proposes that the Commission should submit a detailed report to the European Parliament and the Council on the content of these measures and their contribution to reducing the serious cross-border health threat within the two months following the adoption of measures.