



EUROPSKI PARLAMENT

2009 - 2014

Dokument s plenarne sjednice

A7-0037/2012

17.10.2012

*****I**

IZVJEŠĆE

o prijedlogu Odluke Europskog parlamenta i Vijeća o ozbiljnim
prekograničnim prijetnjama zdravlju
(COM(2011)0866 – C7-0488/2011 – 2011/0421(COD))

Odbor za okoliš, javno zdravlje i sigurnost hrane

Izvjestitelj: Gilles Pargneaux

Oznake postupaka

- * Postupak savjetovanja
- *** Postupak suglasnosti
- ***I Redovni zakonodavni postupak (prvo čitanje)
- ***II Redovni zakonodavni postupak (drugo čitanje)
- ***III Redovni zakonodavni postupak (treće čitanje)

(Navedeni se postupak temelji na pravnoj osnovi predloženoj u nacrtu akta.)

Izmjene nacрта akta

U amandmanima Parlamenta izmjene nacrtu akta označene su ***podebljanim kurzivom***. Obični kurziv naznaka je tehničkim službama da se radi o dijelovima nacrtu akta za koje se predlaže ispravak prilikom izrade konačnog teksta (na primjer o očitim pogreškama ili izostavcima u danoj jezičnoj verziji). Za predložene ispravke potrebna je suglasnost dotičnih tehničkih službi.

Zaglavljuje svakog amandmana na postojeći akt koji se želi izmijeniti nacrtom akta sadrži i treći redak u kojem se navodi postojeći akt te četvrti redak u kojem se navodi odredba akta na koju se izmjena odnosi. Dijelovi teksta odredbe postojećeg akta koju Parlament želi izmijeniti, a koja je u nacrtu akta ostala nepromijenjena, označeni su ***podebljanim slovima***. Za moguća brisanja u tim dijelovima teksta koristi se oznaka [...].

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NACRT ZAKONODAVNE REZOLUCIJE EUROPSKOG PARLAMENTA

o prijedlogu Odluke Europskog parlamenta i Vijeća o ozbiljnim prekograničnim prijetnjama zdravlju
(COM(2011)0866 – C7-0488/2011 – 2011/0421(COD))

(Redovni zakonodavni postupak: prvo čitanje)

Europski parlament,

- uzimajući u obzir prijedlog Komisije upućen Europskom parlamentu i Vijeću (COM(2011)0866),
 - uzimajući u obzir članak 294. stavak 2. i članke 168. stavak 4. točka (c) i 168. stavak 5. Ugovora o funkcioniranju Europske unije, u skladu s kojima je Komisija podnijela prijedlog Parlamentu (C7-0488/2011),
 - uzimajući u obzir članak 294. stavak 3. Ugovora o funkcioniranju Europske unije,
 - uzimajući u obzir mišljenje Europskog gospodarskog i socijalnog odbora od 28. ožujka 2012.¹,
 - nakon savjetovanja s Odborom regija,
 - uzimajući u obzir članak 55. Poslovnika,
 - uzimajući u obzir izvješće Odbora za okoliš, javno zdravlje i sigurnost hrane (A7-0037/2012),
1. usvaja sljedeće stajalište u prvom čitanju;
 2. traži od Komisije da predmet ponovno uputi Parlamentu ako namjerava bitno izmijeniti svoj prijedlog ili ga zamijeniti drugim tekstom;
 3. nalaže svojem predsjedniku da stajalište Parlamenta proslijedi Vijeću, Komisiji i nacionalnim parlamentima.

Amendment 1

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

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

¹ SL C 181, 21.6.2012., str. 160.

(ECDC) provides the ECDC with a mandate covering surveillance, detection and risk assessment of threats to human health from communicable diseases and outbreaks of unknown origin. The ECDC has progressively taken over the epidemiological surveillance of communicable diseases and the operation of the Early Warning and Response System from the Community network set up under Decision No 2119/98/EC. This development is not reflected in Decision No 2119/98/EC, which was adopted before the creation of the ECDC.

(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 event of a threat that did not arise from a transmissible disease, the ECDC should respond only in cooperation with the competent authority, at the request of that 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.

Justification

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

Amendment 2

Proposal for a decision Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) Cross-border threats to health are also often related to pathogenic agents that can be transmitted between individuals. While such transmission cannot be completely prevented, general hygiene measures can make an important contribution by reducing the speed and extent of spreading of the agent and thus reduce the general risk. Such good hygiene practices should be promoted, especially in sensitive environments and at the work place.

Amendment 3

Proposal for a decision
Recital 10

Text proposed by the Commission

(10) The European Parliament in its resolution of 8 March 2011 and the Council in its Conclusions of 13 September 2010 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 and the Council in its Conclusions of 13 September 2010 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 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 ***is undertaken with the aim of enabling more equitable access to vaccines for the Member States involved, to help them better meet the vaccination needs of their citizens, in line with vaccination policies in the Member States.***

Amendment 4

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.

Justification

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

Amendment 5

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.

Justification

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

Amendment 6

Proposal for a decision Recital 13

Text proposed by the Commission

Amendment

(13) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. This risk assessment should be based on robust scientific evidence and independent expertise and provided by the Agencies of the Union in accordance with their missions, or otherwise by expert groups set up by the Commission.

(13) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. This risk assessment should be based on robust scientific evidence and independent expertise and provided by the Agencies of the Union in accordance with their missions, or otherwise by expert groups set up by the Commission. ***When experts are consulted, they should make a declaration of commitment and a declaration of their interests. The Commission, or the relevant decision-making authorities in the Member States, should verify those declarations.***

Justification

To ensure independence and transparency, conflicts of interest must be prevented by means of declarations of commitments and interests. It is crucial that these declarations should also be checked.

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.***

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

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

(17) The applicability of some specific provisions of Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council and Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, depends on the recognition at Union level in the framework of Decision 2119/98/EC, of an emergency situation or of a pandemic situation with respect to human influenza. Those provisions allow for the accelerated marketing of certain medicinal products in case of urgent needs, by means, respectively, of a conditional marketing authorisation and of the temporary possibility to grant a variation to the terms of a marketing authorisation for a human influenza vaccine even where certain non-clinical or clinical data are missing. However, in spite of the utility of such provisions in the event of a crisis, there is to date no specific procedure for issuing such recognitions at Union level. It is therefore appropriate to provide for such a procedure as part of the standards of quality and safety for medicinal products.
The declaration of an emergency situation at Union level should be without prejudice to the effects of a decision taken by the World Health Organisation to trigger the production of vaccines from seasonal to pandemic.

Justification

The identification of the seed virus necessary for the production of vaccines is a role performed by the WHO. Vaccine manufacturers are dependent on the WHO's undertaking of this task in order to produce influenza (seasonal or pandemic) vaccines. While the EU can

unilaterally alter the marketing authorisation of vaccines, the actual production patterns will still depend on the WHO's declaration and identification of the seed virus.

Amendment 9

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.

Justification

This Recital refers explicitly to contact tracing.

Amendment 10

Proposal for a decision

Recital 20

Text proposed by the Commission

Amendment

(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

(20) The power to adopt acts in accordance with Article 290 of the Treaty on the functioning of the European Union should be ***delegated*** to the Commission in respect of ***the adoption of the procedures for the coordination, the exchange of information and the mutual consultation on preparedness and response planning, the adoption of case definitions for***

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.

serious cross-border threats to health, the adoption of procedures for the operation of the Early Warning and Response System, the adoption of procedures for the coordination of responses 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 *a* simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

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

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

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 recognition of situations

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 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.

of emergency 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.

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 12

Proposal for a decision Recital 22 a (new)

Text proposed by the Commission

Amendment

(22a) As there are various Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, it is crucial to guarantee that national authorities involve the relevant decision-making authorities in the implementation of this Decision in the Member States.

Justification

This is intended as a horizontal amendment applicable to the whole text. In view of its

importance, this point is also explicitly inserted in the amendments to Articles 17 (designation of national authorities and representatives) and 19 (Health Security Committee).

Amendment 13

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 structures at Union level, as well as the methods of cooperation and coordination envisaged between the various institutions.

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 14

Proposal for a decision

Article 2 – paragraph 1 – point a – point i

Text proposed by the Commission

Amendment

(i) communicable diseases;

(i) communicable diseases, ***including human zoonotic infections;***

Amendment 15

Proposal for a decision

Article 2 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. In exceptional emergency situations where a Union mechanism for the coordination of public health measures in case of serious cross-border threats to health other than those covered in Article

2(1) (i.e. threats of biological, chemical and environmental origin) proves insufficient to ensure a high level of human health protection, Member States may refer such threats for a coordinated response to the Health Security Committee in accordance with Article 11, in close coordination with other Union areas, as appropriate.

Amendment 16

Proposal for a decision

Article 3 – paragraph 1 – point a

Text proposed by the Commission

(a) ‘case definition’ means a set of commonly agreed diagnostic criteria that must be fulfilled in order to accurately detect cases of a ***targeted*** serious cross-border threat to health in a given population, while excluding the detection of other similar threats;

Amendment

(a) ‘case definition’ means a set of commonly agreed diagnostic criteria that must be fulfilled in order to accurately detect cases of an ***identified*** serious cross-border threat to health in a given population, while excluding the detection of other similar threats;

Amendment 17

Proposal for a decision

Article 3 – paragraph 1 – point b

Text proposed by the Commission

(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, fomite, product or environment, or exchange of fluid, contaminated with the contagious agent;

Amendment

(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, fomite, ***animal***, product or environment, or exchange of fluid, contaminated with the contagious agent;

Justification

The addition of "animal" makes sure that the proposal also covers zoonoses (infectious diseases that can be transmitted from animal to human).

Amendment 18

Proposal for a decision

Article 4 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the adoption of guidance and other awareness materials on the health and hygiene measures that the public must follow in the event of serious cross-border threats to health. Those measures shall include information on good hygiene measures, such as effective hand washing and drying, in healthcare environments, food establishments, schools and nurseries, entertainment facilities, and also in the working environment, and shall take into account the existing recommendations of the World Health Organisation.

Amendment 19

Proposal for a decision

Article 4 – paragraph 1 – point b b (new)

Text proposed by the Commission

Amendment

(bb) the communication of ‘best practices’.

Amendment 20

Proposal for a decision

Article 4 – paragraph 2 – point i

Text proposed by the Commission

Amendment

(i) minimum core capacity standards determined at national level for the health sector;

(i) minimum core capacity standards determined at national level for the health sector; ***those standards shall also relate to preparations in the field of psychosocial emergency care;***

Amendment 21

Proposal for a decision

Article 4 – paragraph 2 – point ii

Text proposed by the Commission

(ii) specific mechanisms established at national level for the interoperability between the health sector and other critical sectors of society;

Amendment

(ii) specific mechanisms established at national level for the interoperability between the health sector, ***the veterinary sector*** and other critical sectors of society;

Justification

According to the World Health Organisation, more than 60% of human infections are zoonoses originating in animals or animal products. To combat cross-border threats to health as effectively as possible, an holistic ‘One Health’ approach needs to be taken, with coordination and close cooperation between the human health and veterinary sectors being a crucial component of this.

Amendment 22

Proposal for a decision

Article 4 – paragraph 2 – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) specific mechanisms to monitor and report on vaccines coverage in respect of the diseases listed in the Annex to Decision 2119/98/EC.

Justification

Information on communicable disease monitoring and vaccination coverage as set out in Decision 2119/98/EC on epidemiological surveillance will be essential to Commission led preparedness and response planning.

Amendment 23

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 concerning the division of roles and responsibilities among the key actors in preparedness and response planning as well as*** the procedures for the coordination, the exchange of information and the mutual consultation referred to in ***this Article***.

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 24

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 compatibility of the collected data;

Amendment

deleted

Justification

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

Amendment 25

Proposal for a decision

Article 7 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 21 concerning the adoption of 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;

Justification

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

Amendment 26

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

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

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 27

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.

Prior to taking up their duties, they shall make available 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 updated when significant changes occur, and at least once a year. The declarations shall be verified by the Commission for actors at Union level, and by the relevant competent authority for actors at Member State level.

Amendment 28

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.

That 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, 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, in order to organise coordinated, consistent and transparent communication for citizens.

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.

The 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.

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 29

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 concerning the adoption of*** procedures concerning the information exchange in order to ensure the proper functioning of the Early Warning and Response System.

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 30

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 event of
an international public health emergency.***

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 31

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

Text proposed by the Commission

Amendment

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

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 32

Proposal for a decision Article 11 – paragraph 5

Text proposed by the Commission

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.

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 concerning the division of roles and responsibilities among the key actors in the coordination and the** procedures for mutual information, consultation and coordination **referred to** in this Article.

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 33

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

Text proposed by the Commission

Amendment

(ca) be consistent with the recommendations established by the World Health Organisation in the event 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 34

Proposal for a decision

Article 12 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall specify the reasons for adopting those measures.

Justification

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

Amendment 35

Proposal for a decision

Article 13 – title

Text proposed by the Commission

Amendment

Recognition of emergency situations ***or of pandemic influenza situations***

Recognition of emergency situations

Justification

‘Emergency situations’ covers everything. There is no need to specify pandemic influenza situations separately.

Amendment 36

Proposal for a decision

Article 13 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) situations of emergency at Union level;
or

situations of emergency at Union level.

Justification

‘Emergency situations’ covers everything. There is no need to specify pre-pandemic influenza situations separately.

Amendment 37

Proposal for a decision

Article 13 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) pre-pandemic situations with respect to human influenza at Union level. ***deleted***

Justification

‘Emergency situations’ covers everything. There is no need to specify pre-pandemic influenza situations separately.

Amendment 38

Proposal for a decision

Article 13 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

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 20(3).

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 through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 20(3).

Justification

‘Emergency situations’ covers everything. There is no need to specify pre-pandemic influenza situations separately.

Amendment 39

Proposal for a decision

Article 13 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(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. **deleted**

Justification

‘Emergency situations’ covers everything. There is no need to specify pre-pandemic influenza situations separately.

Amendment 40

Proposal for a decision Article 14 – paragraph 2

Text proposed by the Commission

Amendment

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

Justification

‘Emergency situations’ covers everything. There is no need to specify pre-pandemic influenza situations separately.

Amendment 41

Proposal for a decision Article 17 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the **competent** authorities responsible **at national level** for collecting information relating to epidemiological surveillance as referred to in Article 6;

(a) the **relevant decision-making** authorities responsible **within the Member State** for collecting information relating to epidemiological surveillance as referred to in Article 6;

Justification

As there are various Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, it is crucial to guarantee that national authorities involve the relevant decision-making authorities in the implementation of this decision in the Member States.

Amendment 42

Proposal for a decision

Article 17 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The appointment of relevant decision-making authorities and representatives who are part of the Union network established by this Decision shall be made public by the Member States.

Justification

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

Amendment 43

Proposal for a decision

Article 18 - paragraph 5 a (new)

Text proposed by the Commission

Amendment

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

Justification

This decision must recall the confidentiality of personal data.

Amendment 44

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 point (e) of Article 4(1) of Regulation (EC) No 45/2001 and in point (e) of Article 6(1) 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.

Justification

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

Amendment 45

Proposal for a decision

Article 19 – paragraph 1

Text proposed by the Commission

Amendment

1. A ‘Health Security Committee’, composed of representatives of Member States at a high level, is hereby established.

1. A ‘Health Security Committee’, composed of representatives of ***the relevant decision-making authorities in the*** Member States at a high level, is hereby established.

Justification

As there are various Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, it is crucial to guarantee that national authorities involve the relevant decision-making authorities in the implementation of this decision in the Member States.

Amendment 46

Proposal for a decision

Article 19 – paragraph 2 – point c a (new)

(ca) advise the health ministers of the Member States and the Commission on the preparation and coordination of contingency plans.

Amendment 47

Proposal for a decision Article 21

Text proposed by the Commission

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.

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

Amendment

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 4(5), Article 7(3a), Article 8(2), Article 11(5) and Article 12* shall be conferred on the Commission for a period of five years **from** [...]. 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 4(5), Article 7(3a), Article 8(2), Article 11(5) and 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 **power** specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. 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.

Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to *Article 4(5), Article 7(3a), Article 8(2), Article 11(5) and 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.

(The changes in italics in paragraphs 2, 3 and 5 of Article 21 are technical changes introduced by the services as a consequence of amendments 23, 25, 29 and 32.)

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.

Amendment 48

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 the latest 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.

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.

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