Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Decision	2011/0421(COD)
Serious cross-border threats to health Repealing Decision 2119/98/EC 1996/0052(COD) Repealed by 2020/0322(COD) Subject 4.20 Public health 4.20.01 Medicine, diseases	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		10/01/2012
	S&D PARGNEAUX Gilles	
	Shadow rapporteur	
	PPE FJELLNER Christofer	
	ALDE TAYLOR Rebecca	
	Verts/ALE BREPOELS Frieda	
	ECR CABRNOCH Milan	
	EFD CYMAŃSKI Tadeusz	

Committee for opinion	Rapporteur for opinion	Appointed
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meeting	Date
Justice and Home Affairs (JHA)	3260	07/10/2013
Employment, Social Policy, Health and Consumer Affairs	3206	06/12/2012
Employment, Social Policy, Health and Consumer Affairs	3177	21/06/2012

European Commission

Commission DG	Commissioner
Health and Food Safety	BORG Tonio

European Economic and Social Committee

European Committee of the Regions

Key events

08/12/2011	Legislative proposal published	COM(2011)0866	Summary
17/01/2012	Committee referral announced in		

	Parliament, 1st reading		
21/06/2012	Debate in Council	3177	Summary
10/10/2012	Vote in committee, 1st reading		
17/10/2012	Committee report tabled for plenary, 1st reading	A7-0337/2012	Summary
06/12/2012	Debate in Council	3206	Summary
02/07/2013	Debate in Parliament		
03/07/2013	Results of vote in Parliament		
03/07/2013	Decision by Parliament, 1st reading	T7-0311/2013	Summary
07/10/2013	Act adopted by Council after Parliament's 1st reading		
22/10/2013	Final act signed		
22/10/2013	End of procedure in Parliament		
05/11/2013	Final act published in Official Journal		

Technical information

Procedure reference	2011/0421(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
	Repealing Decision 2119/98/EC 1996/0052(COD) Repealed by 2020/0322(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 168-p5
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/08163

Documentation gateway

Legislative proposal		COM(2011)0866	08/12/2011	EC	Summary
Document attached to the procedure		SEC(2011)1519	08/12/2011	EC	
Document attached to the procedure		SEC(2011)1520	08/12/2011	EC	
Document attached to the procedure		N7-0082/2012 OJ C 197 05.07.2012, p. 0021	28/03/2012	EDPS	Summary
Economic and Social Committee: opinion, report		CES0827/2012	28/03/2012	ESC	
Committee draft report		PE491.305	20/06/2012	EP	
Amendments tabled in committee		PE496.383	18/09/2012	EP	

Amendments tabled in committee		PE496.640	09/10/2012	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0337/2012	17/10/2012	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0311/2013	03/07/2013	EP	Summary
Commission response to text adopted in plenary		SP(2013)625	24/09/2013	EC	
Draft final act		00029/2013/LEX	23/10/2013	CSL	
Follow-up document		COM(2015)0617	07/12/2015	EC	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Decision 2013/1082
OJ L 293 05.11.2013, p. 0001 Summary

Corrigendum to final act 32013D1082R(01)
OJ L 231 04.09.2015, p. 0016

Serious cross-border threats to health

PURPOSE: establish a European initiative to combat serious cross-border threats to health.

PROPOSED ACT: Decision of the European Parliament and of the Council.

BACKGROUND: many activities related to preparedness and response planning and risk assessment for communicable diseases but also for chemical threats to health and events caused by climate change have been supported at European level, in particular the current Community network for the epidemiological surveillance and control of communicable diseases (see Decision No 2119/98/EC of the European Parliament and the Council establishing a network for the epidemiological surveillance and control of communicable diseases in the Community). The EU already has policies, mechanisms and instruments in place for the prevention and control of serious cross-border threats and for the development of capacities to manage crises. A non-exhaustive list includes the EU Civil Protection Mechanism, the Cohesion and Solidarity Funds, the EU action plan on chemical, biological, radiological and nuclear security, and European alert networks, such as ECURIE.

In order to avoid overlaps with these areas and duplicating existing disaster prevention and control structures, a gap analysis has been carried out to assess how far these existing systems cover the monitoring of threats to health, their notification, risk assessment and crisis management capacities and structures from the public health perspective. This gap analysis revealed that the existing structures and mechanisms at EU level do not address these threats sufficiently as far as public health is concerned.

The lack of public health risk assessment at EU level leads to discrepancies in evaluating the danger of a given threat, duplication of assessments between Member States and inconsistent measures at EU level. Such a situation can also lead to inefficient use of the limited resources currently available.

Although the Member States have the responsibility to manage public health crises at national level, no country can tackle a cross border public health crisis on its own. At EU level, the legal basis for addressing serious cross-border health threats has been reinforced with the Lisbon Treaty. The EU can now take action in this field that complement and support national policies and encourage cooperation between Member States.

This is the reason why it is proposed to create a new instrument to step up cooperation and strengthen coordination in the area of the notification and risk assessment.

The aim is to streamline and strengthen European Union capacities and structures for effectively responding to serious cross-border health threats. These threats can be events caused by communicable diseases, biological agents responsible for non-communicable diseases, and threats of chemical, environmental, or unknown origin, as well as threats deriving from the effects of climate change.

IMPACT ASSESSMENT:

The Commission has carried out detailed analysis of three options:

- Option 1: status quo: maintaining the current level of activities;
- Option 2: separate and different handling of serious cross-border threats to health - enhanced EU cooperation through the use of soft instruments based on a voluntary approach;
- Option 3: establishing a common EU legal framework covering all serious cross-border threats to health through improved cooperation and legally binding measures.

The results of the analysis led to the conclusion that option 3 has the strongest positive health impacts as it improves the protection of citizens against serious cross-border threats to health.

LEGAL BASIS: Article 168, paragraphs (4)(c) and (5) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: this proposal lays down the rules on monitoring, early warning of and combating serious cross-border threats to health, as well as on preparedness and response planning related to those activities. It aims to support the prevention and control of the spread of severe human diseases across the borders of the Member States, and to obviate other major sources of serious cross-border threat to health in order to contribute to a high level of public health protection in the Union.

Scope: the proposal applies in case of serious cross-border threats to health falling within the following categories:

- threats of biological origin, consisting of: (i) communicable diseases; (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases; (iii) biotoxins or other toxic biological agents not related to communicable diseases;
- threats of chemical origin with the exception of threats arising from ionizing radiation;
- threats of environmental origin, including threats deriving from the effects of climate change;
- threats of unknown origin;
- events which may constitute public health emergencies of international concern determined pursuant to the International Health Regulations (2005).

General structure: the monitoring system revolves around the following four fields:

1) preparedness and response planning: the proposal provides for the coordination of the efforts of the Member States in terms of improved preparedness and capacity building. To this end, the Commission will ensure coordination between national planning and between key sectors such as transport, energy and civil protection, and will support Member States in setting up a joint procurement mechanism for medical countermeasures, e.g. vaccines against influenza, which would enable the EU to be better prepared for future pandemics;

2) establishment of an epidemiological monitoring network: to provide the relevant information and data for risk assessment and monitoring of emerging threats, an ad hoc network will be set up in situations where a Member State has raised an alert on a serious threat other than a communicable disease. Communicable diseases will continue to be monitored as they are today;

3) the use of the existing Early Warning and Response System to cover all serious threats to health, and not only communicable diseases as is the case today;

4) coordinated development of national or European public health risk assessments for threats of biological, chemical, environmental or unknown origin in a crisis situation.

EU response to a public health crisis: the proposal sets up a coherent framework for the EU response to a public health crisis. In concrete terms, by formalising the existing Health Security Committee, the EU will be in a better position to coordinate national crisis responses in a public health emergency. A procedure for the mobilisation and coordination of the European response to a serious cross-border risk is proposed. Thus, if a Member State intends to adopt public health measures to combat a serious cross-border health risk, it shall, before adopting any measures consult the other Member States and the Commission on the nature, purpose and scope of the measures. The measures taken shall be decided by means of implementing acts.

Provision is also made for the following specific measures:

- Common temporary public health measures to control the spread of a serious cross-border threat to health between the Member States or to the Union as a whole;
- Emergency and pandemic influenza situations at the Union level;
- International agreements with third countries or international organisations.

BUDGETARY IMPACT: this legal proposal does not impact on decentralised agencies. In addition, the current EU health programme already covers some activities in relation to monitoring, alerting and risk assessment of some health threats. After 2013, the Commission intends to cover these activities under the proposed Health for growth programme 2014-2020. The cost is included in the proposed envelope of the new programme.

DELEGATED ACTS: in accordance with Article 290 of the TFEU, the Commission should be empowered to adopt delegated acts 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. 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 recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level.

Serious cross-border threats to health

Opinion of the European Data Protection Supervisor on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health

The Proposal aims at replacing Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable

diseases in the Community, which is the current legal basis for the Early Warning and Response System (EWRS). The latter has been the subject of a prior check Opinion of the EDPS.

The EDPS welcomes the references to Regulation (EC) No 45/2001 and Directive 95/46/EC in Article 18 of the proposal and the fact that the reference to the applicable data protection legislation inArticle 18 now encompasses all personal data processing under the scope of the proposal. He also welcomes the specific data protection safeguards for contact tracing set forth, or required to be adopted by the Commission, under Article 18.

However, the following elements of the Proposal still require, or would benefit from, clarification, further detail or other improvements from the point of view of data protection:

- contact tracing,
- ad hoc surveillance,
- controller-processor relationship,
- retention period, and
- security measures.

The EDPS notes that several aspects of the proposal are not elaborated in the text itself, but will be the subject of delegated and implementing acts, such as the list of communicable diseases to which the proposal shall apply and the procedures for the information exchange in the EWRS. Other aspects will be clarified in guidelines and recommendations to be adopted by the Commission, such as the data protection guidelines for the EWRS.

Whilst details can of course be regulated in delegated and implementing acts, and such additional provisions are certainly of great benefit, the EDPS recommends that the proposal itself also provide more guidance on some of the points mentioned above.

Recommendations: in general, the EDPS recommends that some essential elements, including certain essential data protection safeguards, should be also included in the text of the proposal itself. In addition, some clarifications are also necessary due to the expansion of the scope of the proposal to additional health threats beyond communicable diseases, which have not been subject to the prior checking procedure and also not discussed in the guidelines.

More particularly, the EDPS recommends that the Proposal should:

- provide a clearer definition for contact tracing, including also its purposes and scope, which might be different for communicable diseases and other heath threats;
- define more clearly how the individuals used for contact tracing will be determined, which sources might be used to obtain contact details and how these individuals will be informed of the processing of their personal data;
- include criteria to be used when assessing whether contact tracing measures are necessary and proportionate;
- specify at least the main categories of data to be processed for contact tracing;
- for the system of ad hoc surveillance, specify the kinds of data to be processed and take measures to minimise the processing of personal data, for example by using appropriate anonymisation techniques and restricting the processing to aggregate data as far as possible;
- clarify the relationship between ad hoc surveillance networks and the EWRS;
- clarify the role of the ECDC in ad hoc surveillance networks;
- clarify the tasks and responsibilities of all actors involved from the data protection point of view in order to obtain legal certainty on the issue of controllership;
- establish legally binding retention periods at least for contact tracing;
- include in Article 18 a more specific reference to the requirements on data security and confidentiality.

Serious cross-border threats to health

Ministers held an orientation debate on a draft decision aimed at strengthening EU capacities and structures for effectively responding to serious cross-border health threats.

State of play: Member states stressed the importance of preparedness against serious cross-border threats to health, and considered that it could be achieved through coordination and the exchange of information between member states within the health security committee (HSC), rather than an obligation for prior consultations or recommendations by the Commission. This was regarded important in order to respect national competencies in the field of health and to be in line with article 168 of the Treaty on the Functioning of the EU.

Ministers supported the Commission proposal to provide a legal mandate to the health security committee. As regards the composition of this committee, most ministers argued for a standing committee of high representatives nominated by public health authorities with the possibility of inviting experts on a case-by-case basis.

Member states confirmed their wish to delete article 12 of the Commission proposal which envisages the possibility of binding common temporary public health measures at EU level. Instead they shared the view that member states should deal with urgent cases of cross-border health threats through the HSC.

The discussion gave guidance for future work on this file that will continue during the incoming Cyprus presidency.

The Commissions point of view on the Councils compromise text: the Commission considers that:

- Scope: the scope of the proposal should consist of a list of categories of serious crossborder threats to health, which combined with a specific definition of such threats described in Article 3(f) of the legal act, provides for more legal certainty and clarity in comparison with a rather broad definition suggested instead.
- Preparedness: the coordination of preparedness planning needs to be strengthened instead of maintaining the current situation based on a voluntary approach. Incoherent and inconsistent preparedness among Member States may weaken the overall response

capabilities of the Union.

- Risk assessment: there is a necessity to guarantee evidence based and independent scientific expertise when providing risk assessment of serious cross-border threats to health, and the Commission also points out that it is important to separate such expertise from risk management.
- Common measures: the Commission does not agree with the deletion of the provisions on common temporary public health measures and international agreements. Common temporary public health measures would provide for a safety net in case the coordination of national responses proves insufficient to cope with an extreme emergency situation and when as a consequence the protection of the population of the Union as a whole is jeopardised.
- International agreements: International agreements would foster the cooperation with third countries and international organisations competent in the field of serious crossborder threats to health.

Serious cross-border threats to health

The Committee on the Environment, Public Health and Food Safety adopted the report by Gilles PARGNEAUX (S&D, FR) on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health.

The committee recommends that the European Parliaments position adopted at first reading, under the ordinary legislative procedure, should amend the Commission proposal as follows:

Subject matter: Members consider that this Decision should define 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.

This Decision shall apply in case of threats of biological origin, consisting of communicable diseases, including human zoonotic infections.

Preparedness and response planning: Member States shall, in liaison with the Commission and on the basis of its recommendations, within the Health Security Committee, address the following issues: (i) 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; (ii) the communication of best practices.

Members also stress that 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.

Recalling that according to the World Health Organisation, more than 60% of human infections are zoonoses originating in animals or animal products, the report highlights that an holistic approach needs to be taken, with coordination and close cooperation between the human health and veterinary sectors being a crucial component of this.

The Health Security Committee shall advise the health ministers of the Member States and the Commission on the preparation and coordination of contingency plans.

Communication strategy: Members consider that this decision should further stress the importance of implementing a consistent and coordinated communication strategy should a crisis arise. They propose introducing a specific article stipulating that 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.

Risk assessment and common public health measures: public health risk assessment should also be based on the opinion of the WHO in the case of an international public health emergency. 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. When adopting common temporary public health measures, the Commission must specify the reasons for adopting these measures.

Recognition of emergency situations: Members state that the term emergency situations should cover everything. There is no need to specify pandemic influenza situations separately.

National authorities and representatives: as there are various Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, Members consider it crucial to guarantee that national authorities involve the relevant decision-making authorities in the implementation of this decision in the Member States. They stress that the public nature of the appointment of structures or authorities which are part of the Community network should be emphasised. Measures as regards the confidentiality of personal data should be strengthened.

Political dialogue: Members state that 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.

Serious cross-border threats to health

The Council took stock of progress made on a draft decision aimed at strengthening EU capacities and structures for effectively responding to serious cross-border health threats, and gave the Irish Presidency a basis on which to start negotiations.

Under the Cypriot Presidency, good progress has been achieved and the draft decision has been amended in line with Member States' comments. The changes proposed by the Cypriot Presidency:

- ensure notably Member States' autonomy in preparedness and response planning as well as the non mandatory character of preparedness planning at European level;
- give the Health Security Committee a key role in consultations among Member States and with the Commission. The Health Security

Committee should be a central body for consultations among the Member States and the Commission with a view to coordinating their capacities for monitoring, early warning and response to serious cross-border health threats.

However, the Commission considers that its proposal has been weakened in several respects, which makes it difficult for the Commission to accept the direction in which the consensus among the Member States is moving.

This is in particular the case as regards preparedness planning and the possibility to provide a "safety net" via "temporary public health measures". The Commission has therefore reserved its position on related articles.

A few issues still remain open and further discussions are needed in order to reach agreement in the Council ahead of possible negotiations with the European Parliament with a view to a first reading agreement. The main changes introduced during the Cypriot Presidency, also focusing on the open questions, are described below:

Scope: it has been clarified that it does not include threats from ionizing radiation as these are sufficiently covered by the Treaty establishing the European Atomic Energy Community. In the event of exceptional emergencies, the structures to be established by the draft Decision should also be available to the Member States and the Commission for threats that are not covered by the scope of this draft Decision.

Preparedness and response planning: the question of empowering the Commission to adopt implementing acts to determine the procedures necessary for the exchange of information and mutual consultation among Member States in accordance with Article 4 has been extensively debated. The Presidency is now proposing to delete Article 4(5) and to instruct the HSC in Article 17(5) (e) to adopt those procedures. This is supported by a majority of the Member States, while some Member States are opposed to this proposal.

Joint procurement of medical countermeasures: the introduction of a voluntary system for joint procurement of medical countermeasures, especially pandemic vaccines, should contribute to fairer access to them for the Member States participating. Nevertheless, a few Member States cannot agree to this article and are calling for the Commission to propose a separate decision.

Epidemiological surveillance: in line with the judgment of the Court of Justice of the EU, the criteria for the selection of communicable diseases and special health issues to be covered by the Community Network as currently set out in Annex II to Commission Decision 2000/96/EC have been stipulated in the Annex to the draft decision.

Ad hocmonitoring: the Commission's proposal to set up an ad hoc monitoring network by means of implementing acts for health threats other than communicable diseases and special health issues permanently monitored by the Union's Early Warning and Response System (e.g. threats of chemical, environmental or unknown origin), has not received support.

Public health risk assessment: according to the current version of the article, the Commission shall, upon request of the Health Security Committee, or on its own initiative, ask the Member States to propose through single contact points independent experts for an ad hoc nomination by the Commission to establish risk assessment where expertise beyond the mandate of the EU agencies is needed.

Coordination of response: this article, which was largely agreed on during the Danish Presidency, was subject to an addition stipulating that Member States shall not be obliged to submit information the disclosure of which they consider contrary to essential interests of their security.

Recognition of emergency situations: the text now states that a recognition of emergency, applicable only to the EU, can be made by the Commission if the WHO has not yet reacted, the cross-border health threat is rapidly spreading across the Union and can be prevented by medicinal products.

Conclusion of international agreements: a recital has been added to clarify that conclusion of international cooperation agreements may be in the interest of the Union in order to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health.

Establishment of the Health Security Committee (HSC): the composition of the HSC has been the subject of repeated discussions. It has finally been agreed that the HSC should be composed of one designated representative of each Member State and one alternate, who should meet in plenary meetings. Membership of the HSC will therefore be nominative and will not generally be ensured by authorities of Member States.

Serious cross-border threats to health

The European Parliament adopted by 678 votes to 21, with 4 abstentions, a legislative resolution on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health.

Parliament adopted its position at first reading, under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between the European Parliament and the Council. They amend the Commission proposal as follows:

Subject matter: the decision should define 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. It shall apply to public health measures in case of serious cross-border threats to health falling within the categories outlined in the decision. It lays down rules on monitoring, epidemiological surveillance, early warning of and combating serious cross-border threats to health. It aims to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.

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

Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Decision.

Preparedness and response planning: Member States shall, in liaison with the Commission and on the basis of its recommendations, within the Health Security Committee, address the following issues: (i) sharing best practice and experience in preparedness and response planning; (ii) promoting the interoperability of national preparedness planning; (iii) addressing the intersectoral dimension of preparedness and response

planning at Union level.

Exchange of information: Member States should regularly provide the Commission with information on the state of play of their preparedness and response planning at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the WHO in the context of the International Health Regulations (2005). The information should particularly address the cross-border dimension of preparedness and response planning. The Commission should compile the information received and should ensure its exchange among Member States through the Health Security Committee.

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

Risk assessment and common public health measures: public health risk assessment should also be based on the opinion of the WHO in the case of an international public health emergency. 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. When adopting common temporary public health measures, the Commission must specify the reasons for adopting these measures.

Epidemiological surveillance: there are provisions to strengthen cross-border epidemiological surveillance through a mutual information system on epidemics and the development of epidemic phenomena. A list of diseases to be monitored is provided in the annex to the decision.

A procedure is also provided in case of specific disease outbreaks (early warning and ad hoc epidemiological surveillance system). To this end, a specific rapid alert could be triggered in the event of serious cross-border threats to health originating from a zoonotic infection.

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

Common procedure for purchasing vaccinations: the resolution stresses the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases, e.g. by obtaining advantageous prices and order flexibility with regard to a given product.

Authorities and national representatives: as there are some Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Decision.

Provisions are regards confidentiality and data protection have been enhanced.

Independence of experts: scientific experts should make declarations of interest and declarations of commitments. Such declarations should include any activity, situation, circumstances or other facts potentially involving direct or indirect interest in order to allow identifying those interests which could be considered prejudicial to their independence.

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

Annex: a new Annex has been introduced laying down the criteria for selection of communicable diseases and special health issues to be covered by epidemiological surveillance within the network.

Serious cross-border threats to health

PURPOSE: to strengthen the capacities and structures of the EU to respond effectively to serious cross-border threats to health.

LEGISLATIVE ACT: Decision No 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 2119/98/EC
CONTENT: the decision lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, in order to coordinate and complement national policies.
The decision applies to serious cross-border threats to health such as threats of biological origin (for example, communicable diseases such as the pandemic flu H1N1 in 2009), antimicrobial resistance, biotoxins (for example, the outbreaks of E Coli infection in 2011) or threats of chemical origin, or unknown or environmental (for example, the volvanic ash cloud in 2010).
Preparedness and response planning: the decision confers a legal base on the Health Security Committee (HSC) which currently exists informally and whose role in strengthened.
The decision stipulates that the Member States and the Commission should consult each other within the HSC with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health.

That consultation should be aimed at in particular sharing best practice and experience in preparedness and response planning and promoting the interoperability of national systems of preparedness planning.

Member States should, by 7 November 2014, and every three years thereafter, provide the Commission with an update on the latest situation with regard to their preparedness and response planning at national level.

Joint procurement of medical countermeasures: the decision allows the institutions of the Union and any Member States which so desire to engage in a joint procurement procedure with a view to the advance purchase of medical countermeasures (in particular, vaccines) for serious

cross-border threats to health.

Epidemiological surveillance and ad hoc monitoring: the decision institutes a network for the epidemiological surveillance of the communicable diseases and of the related special health issues.

The epidemiological surveillance network shall bring into permanent communication the Commission, the European Centre for Disease Prevention and Control (ECDC), and the competent authorities responsible at national level for epidemiological surveillance. The network shall be operated and coordinated by the ECDC.

A list of diseases to be monitored is set out in the Annex to the decision.

Following an alert concerning a threat to health, the Member States should inform each other through the Early Warning Response System (EWRS) and, if the urgency of the situation so requires, through the HSC, about developments with regard to the threat concerned at national level.

Establishment of an early warning and response system: the EWRS, created on an informal basis in 1998, is strengthened and its scope extended to all cross-border threats to health to enable coordination and response at the EU level.

The EWRS should enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

National competent authorities or the Commission should notify an alert in the EWRS where the emergence or development of a serious cross-border threat to health fulfils the following criteria:

- the threat is unusual or unexpected for the given place and time, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and
- the threat affects or may affect more than one Member State; and
- the threat requires or may require a coordinated response at Union level.

Recognition of emergency situations: the decision introduces the possibility for the Commission to recognise a situation of public health emergency to accelerate the availability of medicines to combat the health crisis.

Before recognising a situation of public health emergency at Union level, the Commission should liaise with the World Health Organisation (WHO) in order to share the Commissions analysis of the situation of the outbreak and to inform the WHO of its intention to issue such a decision. Where such a decision is adopted, the Commission should also inform the WHO thereof.

The occurrence of an event that is linked to serious cross-border threats to health and is likely to have Europe-wide consequences could require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner to identify those persons already contaminated and those persons exposed to risk.

Independent experts: the new decision introduces a clause on independence and transparency which applies to experts involved in the system. The EWRS experts must also declare the presence or absence of any interests, direct or indirect, which could be considered prejudicial to their independence.

ENTRY INTO FORCE: 06/11/2013.

Serious cross-border threats to health

The Commission presents a report on the implementation of Decision No 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health. The report is, in particular, to include an assessment of the operation of the Early Warning and Response System (EWRS) and of the epidemiological surveillance network, as well as information on how the established mechanisms and structures complement other alert systems at Union level while not duplicating them.

The report notes that Decision 1082/2013/EU, in force since 6 November 2013, has improved health security in the European Union and the protection of the Union's citizens from communicable diseases, and other biological, chemical and environmental events.

Established mechanisms and structures: the preparedness of Member States as well as the mechanisms to notify an alert, assess the risk and manage a cross-border threat through the coordination of response at EU level has been systematically tested during health events of comparatively low and medium severity for the EU.

The report notes that in all cases, the established mechanisms and structures, namely the EWRS, the epidemiological surveillance network, the European Centre for Disease Prevention and Control (ECDC), and the Health Security Committee (HSC) have proven to operate effectively and up to the quality level required in case of a serious cross-border threat to health. These structures have operated successfully during the Ebola outbreak, the Middle East Respiratory Syndrome caused by coronavirus (MERS CoV) and the poliomyelitis threat.

An important measure successfully carried out during the outbreak has been the medical evacuation to the EU of health workers infected or suspected to be infected with the Ebola virus. In addition, measures were put in place to facilitate entry screening of travellers coming to the EU from the Ebola-affected countries.

The EWRS was used to notify alerts and the measures taken by Member States. The selective exchange functionality was crucial for the transmission of personal data to support the medical evacuation of Ebola patients from the affected countries into the EU.

These systems have been shown to complement other EU rapid alert systems that cover other areas (e.g. food, animal health, etc.) but may have a severe impact on public health without duplicating them. Complementarity has been ensured by:

- upgrading the EWRS informatics tool to allow access to the information for users responsible for other sectors and
- creating operational arrangements in order to share the notifications circulated through the EWRS with Commission services responsible for food safety, animal health, medical devices and medicines, and other sectors potentially impacted by serious cross-border threats to health.

Lessons learned from the Ebola crisis: the recent Ebola epidemic has not only been a devastating crisis for the West African countries affected but also had significant repercussions for Europe. The initial reaction was to protect the EU and only later the attitude changed to recognise that crucial help was needed from Europe and the international community in order to manage the Ebola outbreak at source. A major conclusion from the Ebola outbreak is that there is scope for improving the implementation of provisions whereby Member States are to co-ordinate their national responses. Ad-hoc consultations within the HSC have proven very useful to share options to plan and implement a coherent EU response to specific threats.

However, there is currently lacking an evidence-based evaluation on how the Member States have used the technical guidelines, options for actions, advice to travellers, and other technical documents provided by the Commission. The report recommends encouraging this kind of assessment in the future to have evidence based appreciation of the impact and the use of such materials at national level with a view to identifying possible measures to improve their impact.

The report concludes that the cooperation between the relevant Commission services and the collaboration with the Commission agencies and Member States to implement the framework provided by Decision 1082/2013/EU has worked well during the period. There is currently no need to introduce any changes in this respect.

International Health Regulations (IHR): Article 4(2) of Decision 1082/2013/EU requires Member States to provide the Commission, by 7 November 2014 and three years thereafter, with an update on the latest situation on their preparedness and response planning at national level. The information to be provided is to cover the implementation of the International Health Regulations (IHR), interoperability between the health sector and other sectors, and business continuity plans.

The information provided revealed a number of strengths and weaknesses. As regards the strengths, the majority of the respondents indicated that they have implemented the IHR core capacities and that they involved other sectors in the preparedness and response planning activities covering a wide range of serious cross-border threats to health. As regards weaknesses, a number of respondents indicated incomplete implementation of the IHR core capacities.

In their replies to the survey, Member States proposed actions that the Commission, the EU agencies or Member States should take to ensure that the IHR core capacities are maintained and strengthened in the future including regular follow-up with all Member States, training and exercises, sharing experiences, guidelines and procedures, and technical support and expertise with preparedness and response planning.