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2011/0421 (COD)

Proposal for a

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on serious cross-border threats to health**

(Text with EEA relevance)

{SEC(2011) 1519 final}

{SEC(2011) 1520 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSED ACT

#### 1.1. Reasons for and objectives of the proposal

The aim of the proposed Decision 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<sup>1</sup>. Threats deriving from the effects of climate change (i.e. heat waves, cold spells) are included in the scope of this Decision and covered under the same heading as environmental threats.

Health threats of radiological or nuclear origin causing exposure to ionising radiation are not covered by this proposal because they are already dealt with by the provisions of the Treaty establishing the European Atomic Energy Community (Articles 2(b) and 30-39), which constitutes the '*lex specialis*' in relation to Article 168 of the Treaty on the Functioning of the European Union.

Based on lessons learnt from recent public health emergencies and building on existing EU-level instruments related to health threats, this proposal will set up a coherent framework for crisis response.

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. In the current financial turmoil it is more important than ever to focus on actions in areas where the added value is evident, such as minimising the negative effects of a potential public health crisis. Recent cross-border events such as the H1N1 pandemic in 2009, the volcanic ash cloud and toxic red sludge in 2010, or the outbreak of *E. coli* STEC O104 in 2011, had significant effects on society and demonstrated that none of the impacts of these emergencies can be confined to only one sector. Therefore, through improved multi-sectoral cooperation at EU level other sectors need to be equally prepared to manage the impacts of a public health crisis.

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, except for any harmonisation of the laws and regulations of the Member States. Also, the Treaty stipulates that the EU must complement and support national policies and encourage cooperation between Member States, without superseding their competence in that field.

So far, EU legislation in this area only addresses threats related to communicable diseases<sup>2</sup>. The EU network for surveillance and control of communicable diseases has specific mechanisms for monitoring communicable diseases, giving alerts and coordinating the EU response. Because its scope is limited to communicable diseases, however, the network no longer meets the current standards or needs for an improved EU response to all serious cross-border health threats and will therefore be replaced by this Decision. The Decision covers all

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<sup>1</sup> Including threats of malicious intentional origin

<sup>2</sup> Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1)

serious cross-border threats to health except for those caused by radiological or nuclear exposure.

The objectives of the proposed Decision are as follows:

Firstly, in the area of preparedness planning, the Decision 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.

Secondly, in order 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.

Thirdly, the Decision expands 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.

Fourthly, the proposal introduces coordinated development of national or European public health risk assessments for threats of biological, chemical, environmental or unknown origin in a crisis situation.

Finally, the Decision 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.

## **1.2. General context**

The proposal will help implement the European Health Strategy<sup>3</sup> and also contribute to Europe 2020<sup>4</sup> by promoting health as an integral part of the smart and inclusive growth objectives. The proposal will also contribute to implementing the Internal Security Strategy in its crises and disasters management component<sup>5</sup>, notably the overall objective to establish a coherent risk management policy linking threat and risk assessment to decision making. The Health Security Initiative will appropriately take into account the EU external cooperation activities for health crises prevention and responses with third countries and activities supported under the Union's programmes for research, and explore synergies with the numerous bilateral EU assistance and cooperation programmes with a significant health component.

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 by the previous and current health programme. It is planned that

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<sup>3</sup> White Paper of 23 October 2007 — Together for Health: A Strategic Approach for the EU 2008-2013, COM(2007) 630 final

<sup>4</sup> Communication from the Commission of 3 March 2010 — Europe 2020: A strategy for smart, sustainable and inclusive growth, COM(2010) 2020 final

<sup>5</sup> EU Internal Security Strategy in Action: Five steps towards a more secure Europe, 22.11.2010 - COM(2010) 673 final – Objective 5: Increase Europe's resilience to crises and disasters – Action 2: an all-hazards approach to threat and risk assessment

for important elements of the initiative, specific actions will be supported by the future Health programme currently under development<sup>6</sup>.

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<sup>7</sup>, and European alert networks such as ECURIE<sup>8</sup>.

In addition, to support the EU security framework and to protect citizens against serious cross-border threats, different alert, information and management systems, scientific committees and agencies are already operating to ensure food and feed safety, animal and plant health, medical products safety, and consumer protection. Systems have been put in place to control chemical accidents and radiological events, for border security and for protection against crime and terrorism.

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<sup>9</sup> as far as public health is concerned. For example, there is a variety of monitoring and alert systems for different threats at EU level, but these are not systematically linked to EU public health institutions. In addition, the International Health Regulations (IHR) (2005)<sup>10</sup> — an international treaty for the coordination of all health emergencies — stipulate that Member States must notify the World Health Organisation of any event that may constitute a public health emergency of international concern, independently of its origin (including biological, chemical or environmental). But there are no similar notification obligations at EU level under any of the existing structures.

As regards risk assessment, national public health risk assessments exist, but may not be comprehensive and consistent when considered from the EU perspective, and there is currently no mechanism for a coordinated approach at EU level. 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 and may delay appropriate public health measures, potentially putting at risk the overall response at EU level. The absence of a comprehensive or proper evaluation of risks may lead to unclear communication and may undermine public confidence in measures proposed or taken by public health authorities in Member States.

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<sup>6</sup> [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF;http://ec.europa.eu/health/programme/docs/prop\\_prog2014\\_en.pdf](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF;http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf)

<sup>7</sup> Communication from the Commission of 24 June 2009 to the European Parliament and the Council on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan COM(2009) 273 final

<sup>8</sup> European Community Urgent Radiological Information Exchange (ECURIE).

<sup>9</sup> Please refer to the impact assessment report for further details, in particular Appendix 2 ‘Structures for preparedness and response to cross-border health threats’.

<sup>10</sup> <http://www.who.int/ihr/en/>

Apart from the instruments in the area of radiological protection, existing mechanisms do not provide a comprehensive basis for decisions on public health measures for the population where there is a severe health impact such as contamination or poisoning caused by chemical, biological or environmental events. This has led to a situation where today there is no possibility for a coordinated EU response with public health measures or agreements on prophylaxis and treatment. These kinds of cross-border public health emergencies are addressed case by case on an ad hoc basis. Therefore, the proposal will build on the existing instruments, step up cooperation and strengthen coordination in the area of notification and risk assessment.

As regards preparedness planning, during the H1N1 influenza pandemic in 2009, Member States procuring pandemic influenza vaccines individually were competing with each other for limited amounts of available vaccine, which weakened their purchasing power. Contractual confidentiality clauses often prevented Member States from exchanging information, leading – as shown in an independent evaluation<sup>11</sup> – to considerable variations between Member States as regards contractual conditions, particularly regarding liability for side effects being transferred from the manufacturers to the Member States. In addition, the lack of flexibility in contracts to include conditions under which the reserved amount of doses could be changed or excess vaccines could be returned resulted in a huge waste of resources. The Member States that could not accept those unfavourable conditions had no guarantee of being able to obtain pandemic influenza vaccines, thus weakening the preparedness across the EU for such a cross-border health threat. This could have had very serious health consequences if the pandemic had proved more virulent and deadly.

Furthermore, in the aftermath of the H1N1 pandemic in 2009, the European Parliament in its resolution of 8 March 2011 and the Council in its conclusions of 13 September 2010<sup>12</sup> 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 purchases.

This proposal provides a legal basis for an EU mechanism for the joint procurement of medical countermeasures in which contracting parties<sup>13</sup> could participate on a voluntary basis in order to purchase medical countermeasures, such as pandemic influenza vaccines, thereby improving preparedness for future pandemics.

In relation to crisis management, and in view of the lessons learnt from recent emergencies, health ministers have repeatedly called for a review of the health security framework, including options for a legal basis for the Health Security Committee, and stressed the need to review pandemic preparedness planning.

The Health Security Committee is currently an informal structure at EU level for the coordination of public health risk assessment and the management of serious cross-border threats to health. It was set up by the EU health ministers in the aftermath of the 11 September 2001 terrorist attacks in the United States. At the beginning, its mandate was limited to

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<sup>11</sup> [http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_vaccine\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf)

<sup>12</sup> Council Conclusions of 13 September 2010 on lessons learned from the A/H1N1 pandemic — health security in the European Union (12665/10).

<sup>13</sup> Potential contracting parties: Member States and the European Commission (the latter procuring medical countermeasures on behalf of all interested EU institutions for coverage of staff)

tackling bioterrorism<sup>14</sup>, but it has subsequently been extended to cover all types of public health-related crisis<sup>15</sup>. It is composed of representatives of the Member States' health authorities and chaired by the Commission.

Due to the informal nature of the Committee, the involvement and commitment of Member States is voluntary and there is insufficient coordination of public health responses and no cross-sectoral interlinking of decision-making processes in public health. The Commission can prepare and table recommendations and advice. By formalising the Health Security Committee, it can be expected that public health preparedness planning and crisis management can be taken forward in a more consistent and comprehensive manner at EU level. In addition, Member States will benefit from pooling scarce resources related to risk assessment or crisis management, for example.

### **1.3. Existing European Union and international provisions in this area**

The Community network for the epidemiological surveillance and control of communicable diseases established under Decision No 2119/98/EC comprises the epidemiological surveillance of communicable diseases and the Early Warning and Response System (EWRS). 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<sup>16</sup> (ECDC) provides the ECDC with a mandate covering surveillance and risk assessment of threats to human health from communicable diseases and illnesses of unknown origin. In this context, the ECDC has taken over the epidemiological surveillance of communicable diseases and the operation of the EWRS from the Community network. For this reason the proposed Decision repeals Decision No 2119/98/EC.

The Treaty on the Functioning of the European Union (TFEU) covers several aspects of health security, including EU disaster prevention and control. Mechanisms related to EU disaster prevention, response and control are dealt with under civil protection (Article 196 TFEU), the solidarity clause (Article 222 TFEU), EU financial assistance to Member States (Article 122 TFEU), and humanitarian aid to third countries (Article 214 TFEU).

In addition, some health security aspects are already addressed within areas of common safety concern in public health matters (such as food safety, animal and plant health, the quality and safety of pharmaceuticals and medical devices, or organs and substances of human origin, blood and blood derivatives), consumer protection, health and safety at work, the environment, transport safety and security, respectively covered by Articles 168(4), 169, 153-156, 191-193, 141 and 91 of the TFEU. Furthermore, an information system will be put in place by 1 June 2015 by the Directive 2010/65/EU. It will help Member States to improve the monitoring and early warning of threats deriving from sea vessels. The Directive includes provisions permitting an electronic exchange of data notified in the dangerous goods declaration and the marine declaration of health.<sup>17</sup>

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<sup>14</sup> Presidency Conclusions of 15 November 2001 on bioterrorism (13826/01)

<sup>15</sup> Council Conclusions of 22 February 2007 on the transitional prolongation and extension of the mandate of the HSC (6226/07)

<sup>16</sup> OJ L 142, 30.4.2004, p. 1

<sup>17</sup> Directive 2010/65/EU of the European Parliament and of the Council of 20 October 2010 on reporting formalities for ships arriving in and/or departing from ports of the Member States and repealing Directive 2002/6/EC, OJ L 283, 29.10.2010, p. 1

Furthermore, EU secondary legislation establishes specific rules for monitoring, giving early warning of and combating serious cross-border threats to health (e.g. the Seveso II Directive<sup>18</sup> and the CAFE Directive<sup>19</sup>) and requires in a few instances Member States to develop joint activities to address transboundary air pollution including recommended behaviour (CAFE Directive). For these reasons this Decision does not impinge on the provisions that already exist but seeks to close the gaps in relation to notifications, monitoring, risk assessment and crisis management from the public health perspective. Therefore, the Decision extends the Early Warning and Response System to cover all serious cross-border threats to health (except radio nuclear), adds a monitoring requirement in a crisis for threats to health other than communicable diseases and provides for a crisis management structure for addressing health threats, as these are not covered under other legislation.

The International Health Regulations (2005) already require Member States to develop, strengthen and maintain the capacity to detect, assess, notify and respond to public health emergencies of international concern. Under this agreement, the World Health Organisation is empowered to declare public health emergencies of international concern and to issue recommendations including health measures. The proposed Decision aims to support the consistent and coordinated implementation of the International Health Regulations by the EU Member States. In particular, it will ensure adequate coordination between the Member States to achieve a consistent level of preparedness and interoperability between national preparedness plans, while respecting the Member States' responsibility for the organisation of their health systems.

Against this background, the Decision should apply without prejudice to other legally binding provisions relating to health security, not least as regards preparedness, monitoring, alerting, assessment and management of serious cross-border threats to health. However, where gaps have been identified in relation to monitoring, alerting, risk assessment or crisis management these are addressed in the Decision. In order to address the gaps, the Decision requires the Member States to coordinate their preparedness efforts, extends the early warning and response system to cover all serious cross-border threats to health, provides for coordinated public health risk assessment by bringing together risk assessments and stressing their public health aspects, adds monitoring requirements in a crisis for threats to health other than communicable diseases and, finally, provides for a crisis management structure for addressing health threats.

## **2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES**

### **2.1. Consultation with interested parties and use of expertise**

The open stakeholder consultation on health security in the European Union took place between 4 March and 31 May 2011. In all 75 responses to the online questionnaire were received: 21 on behalf of national, regional or local authorities, 31 on behalf of organisations and 23 from individual citizens<sup>20</sup>.

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<sup>18</sup> Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13)

<sup>19</sup> Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L152, 11.6.2008, p.1)

<sup>20</sup> Report on the Stakeholder Consultation on Health Security in the European Union:  
[http://ec.europa.eu/health/preparedness\\_response/docs/healthsecurity\\_report\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/healthsecurity_report_en.pdf)

The key outcome of these stakeholder consultations is that most stakeholders are strongly in favour of having all serious cross-border health threats included in the EU health security policy<sup>21</sup>.

The Health Security Committee was consulted six times on the initiative. The EWRS network discussed the health security initiative at their meeting in February 2011. The European office of the World Health Organisation is represented on both committees as an observer. In addition, bilateral meetings with six Member States were held at their request and the initiative was also presented to the EU Health Policy Forum on 19 May 2011.

Adding to the expertise of the Member States, the European Centre for Disease Prevention and Control provided useful input as regards the scientific risk assessment issues.

## **2.2. 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. It proposes a comprehensive framework for health security structures and systems including obligations on Member States in terms of preparedness and response planning.

The EU added value will be increased through streamlining and coordinating all aspects of preparedness and response planning, risk assessment and risk management by setting up strategic and technical-level cooperation on health security at EU level. This would be guaranteed by the establishment of a sound legal basis for all serious cross-border health threats. By also providing a legal basis for operating a joint procurement mechanism for medical countermeasures, this option would help strengthen the preparedness and response capacity to deal with cross-border health threats across the EU.

In the Member States, administrative savings in public health risk management will also be achieved through enhanced coordination under the Health Security Committee, which allows pooling and exchange of expertise.

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<sup>21</sup> Please see the outcome of the consultation in the impact assessment report



### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **3.1. Legal basis**

With the entry into force of the Lisbon Treaty, the Union has been empowered to support, coordinate or supplement the action of Member States in the area of the protection and improvement of human health (Article 6(a) TFEU). The Treaty also states that Union action must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health; in particular, it must cover ‘monitoring, early warning of and combating serious cross-border threats to health’ (Article 168(1) TFEU). EU action should, however, exclude any harmonisation of the laws and regulations of the Member States and respect their responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care.

Furthermore, the Union should take into account requirements linked to a high level of protection of human health while defining and implementing its policies and activities (Article 9 TFEU). The principle of ‘health in all policies’ is particularly relevant in the multi-sectoral context due to the transnational dimension of serious cross-border threats to health.

At international level, a comprehensive framework on health security exists since 15 June 2007 in the form of the International Health Regulations which have been ratified by all Member States.

#### **3.2. Subsidiarity**

Serious cross-border threats to health and public health emergencies of international concern have, by their nature, transnational implications. In a globalised society, people and goods are moving across borders and illnesses and contaminated products can circulate within hours across the globe. Public health measures therefore need to be consistent with each other and coordinated to contain further spread and minimise the consequences of such threats.

Measures taken by an individual Member State to respond to such threats may touch upon the competences of the EU or other national governments, and can therefore damage the interests of Member States and run counter to the fundamental principles and goals of the EU if they are not consistent with each other and are not based on shared scientifically objective and comprehensive risk assessment. As an example, the lack of coordination at EU level in the *E. coli* outbreak in 2011 led to loss of life and economic loss for the food industry and also had consequences for trade. With respect to the H1N1 pandemic in 2009, there was a drastic drop in medication compliance for pandemic vaccines, potentially endangering the health of citizens, including health care workers, and jeopardising the capacity of the health sector to efficiently respond to that crisis. In addition, the pandemic led to economic losses for the Member States’ budgets due to unused vaccines, resulting from the different public perceptions both about the severity of the threat and the safety and efficacy of those products. Furthermore, measures that are effective from a public health standpoint (e.g. isolation, quarantine, social distancing, workplace and school closures, travel advice and border controls) can have adverse consequences for civil liberties and the internal market. Therefore, the coordination of the response at Union level should ensure that measures taken at national level are proportionate and limited to public health risks related to serious cross-border health threats, and do not conflict with obligations and rights laid down in the Treaty, such as those relating to the restriction of travel and trade. Preparedness measures would need to pay particular attention to protecting workers potentially exposed to the threat.

Since the objectives of the action to be taken cannot be sufficiently achieved by the Member States alone due to the cross-border aspects of those threats and can therefore, for reasons of effectiveness, be better achieved at EU level, the EU may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, the proposed Decision does not go beyond what is necessary in order to achieve those objectives.

The proposal builds on positive experience with coordination in the field of communicable diseases, and proposes extending the existing systems and applying the lessons learnt to ensure that citizens enjoy equal protection against all health hazards.

For the purpose of achieving the objectives, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union, in order to supplement or amend certain non-essential elements of the basic act.

In order to achieve uniform conditions for the implementation of the basic act, particularly with regard to the procedures for information sharing, consultation and coordination of preparedness and response, the Commission should be empowered to adopt implementing acts in accordance with Article 291 of the Treaty on the Functioning of the European Union.

#### **4. BUDGETARY IMPLICATIONS**

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.

The joint procurement, as a voluntary mechanism, may have a budgetary impact in case the EU Institutions were to participate as a Contracting Authority for the procurement of medical countermeasures to cover EU staff. Member States remain responsible for procuring medical countermeasures to cover their citizens.

The budgetary implications for EU institutions are difficult to forecast as it depends on the type of medical countermeasure that is procured, the staff coverage pursued, and, in the case of pandemic influenza, the unknown characteristics of the next pandemic influenza virus in terms of whether 1 or 2 vaccine doses will be required to achieve immunity. The expenditure should be covered within the medical expenditure foreseen by each institution.

During the 2009 influenza H1N1 pandemic, 10,000 doses of pandemic influenza vaccine were bought by the EU institutions at a price of 6 euro per dose. For Commission staff 5,000 doses were reserved of which 3,000 were administered (vaccination was offered on a voluntary basis). The Medical Service envisages a similar approach for an eventual future influenza pandemic. In the case of a serious pandemic where a higher number of staff may wish to get vaccinated, it is envisaged that staff is vaccinated through the health care services of the host country. In conclusion, it is expected that the budgetary implication of vaccine procurement for a future pandemic will be similar to the situation in 2009.

Proposal for a

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on serious cross-border threats to health**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168, paragraphs (4)(c) and (5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Having regard to the opinion of the European Data Protection Supervisor<sup>3</sup>,

Acting in accordance with the ordinary legislative procedure<sup>4</sup>,

Whereas:

- (1) Article 168 of the Treaty on the Functioning of the European Union states, *inter alia*, that the Union's action in the field of public health should cover monitoring, early warning of and combating serious cross-border threats to health, and that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. According to the same provision, Member States must, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas covered by the Union action in the field of public health.
- (2) By Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998<sup>5</sup> a network on the epidemiological surveillance and control of communicable diseases in the Community was set up. Experience gained in the

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<sup>1</sup> OJ C , , p.

<sup>2</sup> OJ C , , p.

<sup>3</sup> OJ C , , p.

<sup>4</sup> Position of the European Parliament of 5 July 2011 (not yet published in the Official Journal) and decision of the Council of 27 July 2011

<sup>5</sup> OJ L 268, 3.10.1998, p.1

implementation of that Decision confirms that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health. However, a number of developments at Union and international level in the past decade make a review of that legal framework necessary.

- (3) Apart from communicable diseases, a number of other sources of danger to health, notably related to other biological agents, chemical agents or environmental events, which include hazards related to climate change, may, by reason of their scale or severity, endanger the health of citizens in the entire Union, lead to the malfunctioning of critical sectors of society and economy and jeopardise individual Member State's capacity to react. Therefore, the legal framework set up under Decision No 2119/98/EC should be extended to cover these other threats and provide for a coordinated wider approach to health security at Union level.
- (4) An important role in the coordination of recent crises of Union relevance has been played by the Health Security Committee, an informal group composed of high level representatives from Member States and established on the basis of the Presidency Conclusions of 15 November 2001 on bioterrorism<sup>6</sup>. It is necessary to integrate this group into a formalised institutional framework and to assign it a well-defined role avoiding duplications with other Union entities responsible for risk management, not least that established under Decision No 2119/98/EC.
- (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<sup>7</sup> (ECDC) provides the ECDC with a mandate covering surveillance, detection and risk assessment of threats to human health from communicable diseases and outbreaks of unknown origin. The ECDC has progressively taken over the epidemiological surveillance of communicable diseases and the operation of the Early Warning and Response System from the Community network set up under Decision No 2119/98/EC. This development is not reflected in Decision No 2119/98/EC, which was adopted before the creation of the ECDC.
- (6) The International Health Regulations (2005) adopted by the Fifty-eighth World Health Assembly on 23 May 2005 reinforced the coordination among States Parties to the World Health Organisation (WHO), which include all the Member States of the Union, of the preparedness for and response to a public health emergency of international concern. The legislation of the Union should take this development into account, including the integrated all-hazards approach of the WHO covering all categories of threats independently of their origin.
- (7) This Decision should not apply to the serious cross-border health threats arising from ionizing radiation, as those threats are already covered by Article 2(b) and Chapter 3 of Title II of the Treaty establishing the European Atomic Energy. Moreover, it should apply without prejudice to other binding measures concerning specific activities or setting the standards of quality and safety of some goods, which provide for special obligations and tools for monitoring, early warning and combating specific threats of cross-border nature.

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<sup>6</sup> 13826/01

<sup>7</sup> OJ L 142, 30.4.2004, p.1

- (8) Preparedness and response planning is an essential element allowing for an effective monitoring, early warning of and combating serious cross-border threats to health. Such planning should include in particular adequate preparedness of critical sectors of society such as energy, transport, communication or civil protection which rely, in a crisis situation, on well-prepared public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level.
- (9) The International Health Regulations (2005) already require Member States to develop, strengthen and maintain their capacity to detect, assess, notify and respond to a public health emergency of international concern. Coordination between the Member States is necessary to achieve a consistent level of preparedness and interoperability between national preparedness plans in view of the international standards, while respecting Member States' competence to organise their health systems.
- (10) The European Parliament in its resolution of 8 March 2011<sup>8</sup> and the Council in its Conclusions of 13 September 2010<sup>9</sup> 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.
- (11) Contrary to communicable diseases, whose surveillance at the Union level is carried out on a permanent basis by the ECDC, other serious cross-border threats to health do not currently necessitate a systematic monitoring. A risk-based approach, whereby monitoring networks are set up *ad hoc* and on a temporary basis, is therefore more appropriate to those other threats.
- (12) A system enabling the notification at the Union level of alerts related to serious cross-border threats to health should be put in place in order to ensure that competent public health authorities in Member States and the Commission are duly and timely informed. Therefore, the Early Warning and Response System (EWRS), established under Decision No 2119/98/EC for communicable diseases, should be extended to all the serious cross-border threats to health covered by the present Decision. The notification of an alert should be required only where the scale and severity of the threat concerned are or may become so significant that the coordination of the response at the Union level is necessary.
- (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.

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<sup>8</sup> 2010/2153(INI)

<sup>9</sup> 12665/10

- (14) Effectively responding to serious cross-border threats to health at national level requires a consistent approach among Member States, in conjunction with the Commission, necessitating exchange of information, consultation and coordination of actions. Under Decision No 2119/98/EC, the Commission already coordinates the response at the Union level in collaboration with Member States with regard to communicable diseases. A similar mechanism should apply to all serious cross-border threats to health independently of their origin. It should also be recalled that, independently from this Decision, a Member State may, in case of a major emergency, request assistance under Council Decision of 8 November 2007 establishing a Community Civil Protection Mechanism (2007/779/EC, Euratom)<sup>10</sup>.
- (15) Measures taken by individual Member States to respond to such threats may damage the interests of other Member States if they are not consistent with one another, or not based on shared and solid risk assessment. They may also conflict with competences of the Union or with fundamental rules of the Treaty on the Functioning of the European Union. Therefore, the coordination of the response at the Union level should ensure *inter alia* that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty, such as those related to the restriction of travel and trade.
- (16) Inconsistent or confusing communication with the public and stakeholders such as health professionals may have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. Therefore, the coordination of the response 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.
- (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<sup>11</sup> 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<sup>12</sup>, 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.

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<sup>10</sup> OJ L 314, 1.12.2007, p. 9.

<sup>11</sup> OJ L 92, 30.3.2006, p.6

<sup>12</sup> OJ L 334, 12.12.2008, p.7

- (18) The processing of personal data for the purpose of implementing this Decision should comply with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>13</sup> and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>14</sup>. In particular, the operation of the Early Warning and Response System should provide for specific safeguards allowing safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level.
- (19) Since the objectives of this Decision cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of those threats and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.
- (20) The power to adopt delegated acts in accordance with the Article 290 of the Treaty on the functioning of the European Union should be conferred to the Commission in respect of measures needed to complement the action of the Member States, in very specific and urgent situations, for the transnational aspects of the control of serious cross-border threats to health. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, as far as the urgency of the situation allows it. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (21) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: the procedures for the coordination, the exchange of information and the mutual consultation on preparedness and response planning; the adoption of a list of communicable diseases subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the setting up and termination of ad hoc monitoring networks and the procedures for the operation of such networks; the adoption of case definitions for serious cross-border threats to health; the procedures for the operation of the Early Warning and Response System; the procedures for the coordination of the responses of the Member States; the recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level. Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>15</sup>.

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<sup>13</sup> OJ L 281, 23.11.1995, p. 31

<sup>14</sup> OJ L 8, 12.1.2001, p. 1.

<sup>15</sup> OJ L 55, 28.2.2011, p.13

- (22) In order to enhance clarity and legal certainty, Decision No 2119/98/EC should be repealed and replaced by this Decision.

HAVE ADOPTED THIS DECISION

## Chapter I General provisions

### Article 1 **Subject matter**

1. This Decision lays down rules on monitoring, early warning of and combating serious cross-border threats to health, as well as on preparedness and response planning related to those activities.
2. This Decision 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.

### Article 2 **Scope**

1. This Decision shall apply in case of serious cross-border threats to health falling within the following categories:

(a) threats of biological origin, consisting of:

(i) communicable diseases;

(ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter referred to as "the related special health issues");

(iii) biotoxins or other toxic biological agents not related to communicable diseases;

(b) threats of chemical origin with the exception of threats arising from ionizing radiation;

(c) threats of environmental origin, including threats deriving from the effects of climate change;

(d) threats of unknown origin;

(e) events which may constitute public health emergencies of international concern determined pursuant to the International Health Regulations (2005), provided that they fall under one of the categories of threats set out in points (a) to (d).

2. This Decision shall apply without prejudice to measures on monitoring, early warning of and combating serious cross-border threats to health as well as the requirements concerning preparedness and response planning provided for in other binding Union provisions, including



measures setting standards of quality and safety for specific goods and measures concerning specific economic activities.

3. The Commission shall, where appropriate and in liaison with the Member States, ensure coordination and mutual information between the mechanisms and structures established under this Decision and similar mechanisms and structures established at Union level whose activities may be relevant for the monitoring, early warning and combating serious cross-border threats to health.

### Article 3 Definitions

For the purpose of this Decision, the following definitions shall apply:

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

(b) ‘communicable disease’ means an infectious disease caused by a contagious agent which may be transmitted from person to person by direct contact with an affected individual or by an indirect means such as exposure to a vector, fomite, product or environment, or exchange of fluid, contaminated with the contagious agent;

(c) ‘contact tracing’ means measures implemented at national level in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are potentially in danger of developing or have developed a disease;

(d) ‘epidemiological surveillance’ means the prompt and systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues, including data reflecting the current health status of a community or population, and systematic threat detection for the purpose of directing public health action;

(e) ‘monitoring’ means the continuous observation, surveillance, detection or reviewing of changes in a condition, or situation, or changes in activities, including a continuous function that uses systematic collection of data and analysis on specified indicators relating to serious cross-border threats to health;

(f) ‘public health measure’ means a decision or an activity which aims to prevent or control diseases, or to obviate sources of risks to public health or to mitigate their impact on public health;

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

(h) ‘severe risk to public health’ means a likelihood of a hazard that may result in death, be life-threatening, cause a severe disease in exposed humans, or produce a congenital defect.

## Chapter II Planning

### Article 4

#### **Preparedness and response planning**

1. Member States shall, in liaison with the Commission and on the basis of its recommendations, within the Health Security Committee referred to in Article 19, coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of and response to the serious cross-border threats to health. That coordination shall in particular address the following issues:

(a) the interoperability of national preparedness plans;

(b) the consistent implementation of core capacity requirements for surveillance and response as referred to in Articles 5 and 13 of the International Health Regulations (2005).

2. For the purpose of paragraph 1, Member States shall provide the Commission with the following information concerning the state of play of their preparedness and response planning:

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

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

(iii) business continuity arrangements in critical sectors of society.

3. The Commission shall make the information referred to in paragraph 2 available to the members of the Health Security Committee.

4. Before adopting or reviewing their national preparedness plan, Member States shall consult each other and the Commission in relation to the issues referred to in points (a) and (b) of paragraph 1.

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).

### Article 5

#### **Joint procurement of medical countermeasures**

1. The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to the third subparagraph of Article 91(1) of

Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>16</sup> and Article 125c of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of the Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>17</sup>, with a view to the advance purchase of medical countermeasures against serious cross-border threats to health.

2. The joint procurement procedure referred to in paragraph 1 shall comply with the following conditions:

(a) participation in the joint procurement shall be open to all Member States until the launch of the procedure;

(b) rights and obligations of Member States not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;

(c) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortions of competition.

3. The joint procurement procedure shall be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, in particular the order of priority for deliveries between the Parties, and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract.

### Chapter III

#### Permanent surveillance and ad hoc monitoring

##### Article 6

##### **Epidemiological surveillance**

1. A network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in Article 2(1)(a)(i) and (ii), is hereby established.

2. The epidemiological surveillance network shall bring into permanent communication the Commission, the European Centre for Disease Prevention and Control, and the competent authorities responsible at national level for collecting information relating to epidemiological surveillance.

3. National competent authorities shall collect comparable and compatible data and information in relation to the epidemiological surveillance and without delay communicate them to the epidemiological surveillance network.

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<sup>16</sup> OJ L 248, 16.9.2002, p.1

<sup>17</sup> OJ L 357, 31.12.2002, p.1

4. When reporting information on epidemiological surveillance, the national competent authorities shall use the case definitions adopted in accordance with paragraph 5 for each communicable disease and related special health issue referred to in paragraph 1.

5. The Commission shall, by means of implementing acts, establish and update:

(a) in order to ensure an exhaustive coverage by the epidemiological surveillance network, the list of communicable diseases referred to in Article 2 (1) (a)(i);

(b) in order to ensure at Union level the comparability and compatibility of the collected data, case definitions related to each communicable disease and special health issue subject to epidemiological surveillance;

(c) procedures for the operation of the epidemiological surveillance network as developed in application of Articles 10 and 11 of Regulation (EC) No 851/2004.

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

On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt the measures referred to in points (a) and (b) through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 20(3).

#### Article 7

#### **Ad hoc Monitoring Networks**

1. Following an alert pursuant to Article 9 concerning a threat to health referred to in points (a)(iii), (b), (c) or (d) of Article 2(1), the Member States shall, on the basis of the available information from their monitoring systems, inform each other, in liaison with the Commission, through an ad hoc monitoring network set up pursuant to paragraph 3 as regards the developments of the situation related to the threat concerned at national level.

2. The information transmitted pursuant to paragraph 1, shall include in particular any change in geographic distribution, spread and severity of the health threat concerned and of the means of detection. It shall be transmitted to the monitoring network by using, where applicable, the case definitions established in accordance with point (d) of paragraph 3.

3. The Commission shall, by means of implementing acts:

(a) set up, for the purposes of the cooperation referred to in paragraph 1, an ad hoc monitoring network which shall bring into communication the Commission and the national contact points designated by the Member States in accordance with point (b) of Article 17(1) for the threat concerned;

(b) terminate the operation of an ad hoc monitoring network when the conditions for notifying an alert in relation to the threat concerned, as laid down in Article 9(1) are no longer met;

(c) adopt generic procedures for the operation of ad hoc monitoring networks;

(d) adopt, where necessary, the case definitions to be used for the ad hoc monitoring, in order to ensure at the Union level the comparability and compatibility of the collected data.

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

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may set up an ad hoc monitoring network or adopt or update the case definitions referred to in point (d) through immediately applicable implementing acts in accordance with the urgency procedure referred to in Article 20(3).

## Chapter IV Early warning and response

### Article 8

#### **Establishment of an early warning and response system**

1. A rapid alert system for notifying at the Union level alerts in relation to serious cross-border threats to health, ‘Early Warning and Response System’, is hereby established. This system shall bring into permanent communication the Commission and the competent authorities responsible at national level for alerting, assessing public health risks and determining the measures that may be required to protect public health.

2. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange in order to ensure the proper functioning of the Early Warning and Response System and the uniform implementation of Articles 8 and 9.

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

### Article 9

#### **Alert notification**

1. National competent authorities or the Commission shall notify an alert in the Early Warning and Response System where the emergence or development of a serious cross-border threat to health fulfils the following conditions:

(a) it is unusual or unexpected for the given place and time, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity, and

(b) it affects or may affect more than one Member State, and

(c) it requires or may require a coordinated response at the Union level.

2. Where the national competent authorities notify to the World Health Organization events that may constitute public health emergencies of international concern in accordance with Article 6 of the International Health Regulations (2005), they shall at the latest simultaneously

notify an alert in the Early Warning and Response System, provided that the threat concerned falls within those referred to in Article 2(1) of this Decision.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate any relevant information in their possession that may be useful for coordinating the response, in particular on:

- (a) the type and origin of the agent,
- (b) the date and place of the incident or outbreak,
- (c) means of transmission or dissemination,
- (d) toxicological data,
- (e) detection and confirmation methods,
- (f) public health risks,
- (g) public health measures implemented or intended to be taken at national level,
- (h) measures other than public health measures,
- (i) personal data necessary for the purpose of contact tracing in accordance with Article 18.

4. The Commission shall make available to the national competent authorities through the Early Warning and Response System any information that may be useful for coordinating the response at the Union level, including information on hazards and public health measures related to serious cross-border threats to health transmitted through other Union alert systems.

#### Article 10

#### **Public health risk assessment**

Where an alert is notified pursuant to Article 9, the Commission shall, where it is necessary for the coordination of the response at Union level, make promptly available to the national competent authorities through the Early Warning and Response System and to the Health Security Committee referred to respectively in Articles 8 and 19 an assessment of the risks to public health.

This assessment shall be based:

- (a) on the opinion of the European Centre for Disease Prevention and Control in accordance with Article 7(1) of Regulation (EC) No 851/2004; and/or
- (b) on the opinion the European Food Safety Authority in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the

European Food Safety Authority and laying down procedures in matters of food safety<sup>18</sup>; and/or

(c) where the assessment needed is totally or partially outside the mandates of the above-mentioned Agencies, on an ad hoc independent opinion.

## Article 11 **Coordination of response**

1. Following an alert pursuant to Article 9, the Member States shall, on the basis of the available information, including risk assessments referred to in Article 10, consult each other within the Health Security Committee referred to in Article 19 and in liaison with the Commission in order to coordinate national responses to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the International Health Regulations (2005) and falls within Article 2 of this Decision.

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.

4. In the event of a serious cross-border health threat overwhelming the national response capacities, an affected Member State may also request assistance from other Member States through the EU Civil Protection Mechanism established by Council Decision 2007/779/EC, Euratom.

5. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the mutual information, consultation and coordination provided for in this Article.

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

## Article 12 **Common temporary public health measures**

1. Where the coordination of national responses provided for in Article 11 proves insufficient to control the spread of a serious cross-border threat to health between the Member States or to the Union, and, as a consequence, the protection of the health of the population of the Union as a whole is jeopardised, the Commission may complement the action of the Member States through the adoption, by means of delegated acts in accordance with the procedure

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<sup>18</sup> OJ L 31, 1.2.2002, p.1

provided for in Article 22, of common temporary public health measures to be implemented by the Member States. These measures may not concern the control of the threat concerned within each Member State.

2. Paragraph 1 shall apply only to serious cross-border health threats which may result in deaths or hospitalisations on a large scale across the Member States.

3. The measures adopted under paragraph 1 shall:

(a) respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care;

(b) be proportionate to the public health risks related to that threat, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services;

(c) be compatible with any applicable international obligation of the Union or of the Member States.

## Chapter V Emergency and pandemic influenza situations at the Union level

### Article 13

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

1. The Commission may, where the exceptional conditions laid down in paragraph 2 are met, formally recognise, by means of implementing acts:

(a) situations of emergency at Union level; or

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

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

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may formally recognise situations of 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).

2. The Commission may adopt the measures referred to in paragraph 1 only when all the following conditions are met:

(a) the Director-General of the World Health Organization has not yet adopted a decision declaring the existence of a public health emergency of international concern in accordance with Articles 12 and 49 of the International Health Regulations (2005);

(b) the serious cross-border health threat at issue:

(i) can, by reasons of its nature, be prevented or treated by medicinal products;



(ii) is rapidly spreading within and across the Member States and endangers public health at the Union level;

(iii) is life-threatening;

(c) the medicinal products, including vaccines, already authorised at Union level in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>19</sup> or in the Member States through the mutual recognition procedure or decentralized procedure referred to in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>20</sup>, are not or may not be sufficiently efficient for the prevention or treatment of the threat concerned;

(d) with a view to the formal recognition of a pre-pandemic situation with respect to human influenza at the Union level, the threat concerned is human influenza.

#### Article 14

##### **Legal effects of the recognition**

1. The recognition of a situation of emergency at the Union level pursuant to point (a) of Article 13(1), shall have the sole legal effect of triggering the applicability of Article 2(2) of Regulation (EC) No 507/2006.

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.

#### Article 15

##### **Termination of the recognition**

The Commission shall, by means of implementing acts, terminate the recognition of the situations referred to in points (a) and (b) of Article 13(1) as soon as one of the conditions laid down in points (b), (c) and (d) of Article 13(2) is no longer met.

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

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<sup>19</sup> OJ L 136, 30.4.2004, p. 1

<sup>20</sup> OJ L 311, 28.11.2001, p. 67

## Chapter VI International agreements

### Article 16 **International agreements**

The Union may conclude international agreements with third countries or international organisations allowing and organizing its cooperation with those third countries or international organisations on serious cross-border threats to health that pose particular risks of transmission to the population of the Union, in order to cover the following aspects:

- (a) exchange of good practice in the areas of preparedness and response planning,
- (b) exchange of relevant information from monitoring and alerting systems, including the participation of the countries or organisations concerned in the relevant epidemiological surveillance or ad hoc monitoring networks and the Early Warning and Response System,
- (c) collaboration on the public health risk assessment of serious cross-border threats to health, with special reference to public health emergencies of international concern declared in accordance with the International Health Regulations (2005),
- (d) collaboration on response coordination, including the occasional participation of the countries or organisations concerned in the Health Security Committee as observers, with special reference to public health emergencies of international concern declared in accordance with the International Health Regulations (2005).

## Chapter VII Procedural provisions

### Article 17 **Designation of national authorities and representatives**

1. Each Member State shall designate, within three months of the entry into force of this Decision:

- (a) the competent authorities responsible at national level for collecting information relating to epidemiological surveillance as referred to in Article 6;
- (b) single contact points for the purpose of the coordination of the ad hoc monitoring, as referred to in Article 7;
- (c) the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of Articles 8, 9, and 10;
- (d) one representative and an alternate in the Health Security Committee referred to in Article 19.

2. Member States shall notify the Commission and other Member States of the designations referred to in paragraph 1.

3. Each Member State shall notify the Commission and the other Member States of any change in the information provided under paragraph 2.

## Article 18

### **Protection of personal data**

1. In the application of this Decision, personal data shall be processed in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.

2. The Early Warning and Response System shall include a selective messaging functionality allowing personal data to be communicated only to national competent authorities concerned by contact tracing measures.

3. When competent authorities implementing contact tracing measures communicate personal data necessary for contact tracing purposes through the Early Warning and Response System pursuant to Article 9(3), they shall use the selective messaging functionality referred to in paragraph 2 of this Article and communicate the data only to the other Member States concerned by the contact tracing measures.

4. When circulating the information referred to in paragraph 3, the competent authorities shall refer to the alert communicated previously to the Early Warning and Response System.

5. Where a national competent authority establishes that a notification of personal data made by it pursuant to Article 9(3) has subsequently proved to be in breach of Directive 95/46/EC because this notification was not necessary for the implementation of the contact tracing measures at issue, it shall inform immediately the Member States to which this notification was transmitted.

6. The Commission shall adopt:

(a) guidelines aiming at ensuring that the day-by-day operation of the Early Warning and Response System complies with Directive 95/46/EC and Regulation (EC) No 45/2001;

(b) a recommendation providing an indicative list of personal data that may or should be exchanged for the purpose of the coordination of contact tracing measures.

## Article 19

### **Health Security Committee**

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

2. The Health Security Committee shall have the following tasks:

(a) support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Decision;

(b) assist the Commission in providing for the coordination of the preparedness and response planning efforts of the Member States in accordance with Article 4;

(c) assist the Commission in providing for the coordination of the responses of the Member States to serious cross-border threats to health, in accordance with Article 11.

3. The Health Security Committee shall be chaired by a representative of the Commission. The Health Security Committee shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

4. The secretariat shall be provided by the Commission.

#### Article 20

##### **Committee on serious cross-border threats to health**

1. For the adoption of implementing acts, the Commission shall be assisted by the Committee on serious cross-border threats to health. That Committee shall be a committee within the meaning of Article 3(2) of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

#### Article 21

##### **Exercise of the delegation**

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

2. The power to adopt delegated acts referred to in Article 12 shall be conferred on the Commission for a period of five years after [...] <sup>21</sup>. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Article 12 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated act already in force.

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

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<sup>21</sup> OJ: Please insert the date: date of entry into force of this Decision

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.

#### Article 22

#### **Urgency procedure**

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 21(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

#### Article 23

#### **Reports concerning this Decision**

The Commission shall submit to the European Parliament and the Council every three years a technical report on the activities of the Early Warning and Response System and other activities carried out in the context of the implementation of this Decision.

### Chapter VIII

### Final provisions

#### Article 24

#### **Repeal of Decision 2119/98/EC**

1. Decision No 2119/98/EC is hereby repealed.
2. References to the repealed Decision shall be construed as references to this Decision.

#### Article 25

#### **Entry into force**

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Article 26  
**Addressees**

This Decision is addressed to the Member States.

Done at Brussels,

*For the European Parliament  
The President*

*For the Council  
The President*

## ANNEX

### LEGISLATIVE FINANCIAL STATEMENT

#### 5. FRAMEWORK OF THE PROPOSAL/INITIATIVE

##### 5.1. Title of the proposal/initiative

Draft Decision of the European Parliament and of the Council on serious cross-border threats to health

Policy area(s) concerned in the ABM/ABB structure<sup>1</sup>

Union action in the field of health (17 03 06)

Programme of the European Union action in the field of health — Expenditure on administrative management (17 01 04)

External staff and other management expenditure in support of the 'Health and consumer protection' policy area – Other management expenditure (17 01 02 11)

Administrative expenditure of the 'Commission's administration' policy area – Personnel policy and management - Medical service (26 01 50 01)

##### 5.2. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**<sup>2</sup>
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**

##### 5.3. Objectives

###### 5.3.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

###### HEALTH SECURITY

The general objectives of this initiative are to improve the protection of the citizens of the European Union from serious cross-border threats and to ensure a high level of human health protection in defining and implementing EU policies and activities. Capacities and structures

<sup>1</sup> ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

<sup>2</sup> As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

will be strengthened and measures concerning monitoring, early warning of and combating serious cross-border threats to health as set out in Article 168 of the TFEU are envisaged.

5.3.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

The specific objective of this initiative is to strengthen the response to all serious cross-border threats to health (other than those associated with radio nuclear events) based on a comprehensive and coherent approach to preparedness and response planning, risk monitoring and assessment, as well as risk management including risk communication.

Specific objective No. 1:

As regards **preparedness and response planning**, the specific objective is to develop a common approach to preparedness planning at EU level for all serious cross-border threats to health, ensuring coherence and interoperability among sectors at EU level and between Member States. This includes improving equitable access to medical countermeasures (e.g. pandemic influenza vaccines).

ABM/ABB activity(ies) concerned

Union action in the field of health (17 03 06)

Programme of the European Union action in the field of health — Expenditure on administrative management (17 01 04)

Administrative expenditure of the 'Commission's administration' policy area – Personnel policy and management - Medical service (26 01 50 01)<sup>3</sup>

Specific objective No. 2:

In the area of **risk monitoring and assessment** the specific objective is to create conditions to ensure a coherent and comprehensive identification and notification of health threats and evaluation of their risks to health, especially in the case of health-related crises with a multidisciplinary dimension.

ABM/ABB activity(ies) concerned

Union action in the field of health (17 03 06)

Programme of the European Union action in the field of health — Expenditure on administrative management (17 01 04)

Specific objective No. 3:

In the area of **risk management** the specific objective is to create conditions to strengthen and enhance coordination between Member States, the international level and the Commission in

<sup>3</sup> Participation in the joint procurement of pandemic influenza vaccines for Commission staff.



order to ensure a coherent and consistent policy approach to effectively manage responses to serious cross-border threats to health across the EU.

ABM/ABB activity(ies) concerned

Union action in the field of health (17 03 06)

External staff and other management expenditure in support of the ‘Health and consumer protection’ policy area – Other management expenditure (17 01 02 11)

Specific objective No. 4:

As regards **risk and crisis communication**, the aims of the initiative will be to create and facilitate shared communication strategies and messages in order to avoid conflicting or inaccurate information being released to the public.

ABM/ABB activity(ies) concerned

Union action in the field of health (17 03 06)

Programme of the European Union action in the field of health — Expenditure on administrative management (17 01 04)

### 5.3.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

Public health impact. The protection of EU citizens against serious cross-border health threats and the effectiveness of public health security structures and mechanisms at EU level would be considerably improved. This would allow coherent preparedness planning based on shared and common mandatory standards and a better coordinated and balanced response to all types of serious cross-border health threats. For example, all Member States would need to have preparedness plans in place that would cover both health measures and other critical sectors, and structures and capacities would need to be set up in compliance with agreed check lists. This option would also result in a more coherent and comprehensive approach to the identification, notification and assessment of serious cross-border health threats. By setting up a legal basis allowing joint procurement, this option would considerably improve equitable access to medical countermeasures by Member States, thereby ensuring a higher level of protection of EU citizens across the Union. Furthermore, inter-sectoral cooperation would be improved in the event of cross-border health threats, also contributing to better public health protection.

Social impact. A coordinated approach to access to medical countermeasures would raise confidence in measures undertaken by public health authorities, as they would rely on a robust legal instrument. For those Member States that had opted to participate in joint procurement, the mechanism would lead to a higher level of protection for vulnerable groups by ensuring a guaranteed supply and would promote solidarity between the Member States by providing common minimum coverage for vulnerable groups of society.

Economic impact. The setting-up of a joint procurement mechanism for medical countermeasures would boost the supply of medical products and encourage development of new products based on long-term contracts agreed with the public health sector.

Financial impact. As regards preparedness, additional costs could be expected, particularly in relation to human resources and the provision of technical equipment in the Member States and at EU level. In order to cover gaps in risk assessment, additional financial resources in the region of EUR 500,000 annually would be needed from the EU health programme to establish a framework contract so as to gain access to expert knowledge when needed. The aim would be to establish permanent networks of national correspondents between health authorities and agencies competent in assessing specific threats. However, proposed measures relating to enhanced cooperation would have no substantial financial impacts, because they would be based on the existing mechanisms and structures in place.

Administrative burden. Governance in public health risk management would be significantly improved, as only one expert committee would need to be operated.

Impact at international level. Better coordination in the EU of implementation of the International Health Regulations (2005)<sup>4</sup> by the Member States and closer collaboration between the EU and the WHO on preparedness for and response to public health emergencies of international concern would contribute to enhancing global health security.

#### 5.3.4. *Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

For the systematic follow-up of the policy measures in the field of preparedness and response planning, risk assessment and risk management, monitoring and evaluation of the implementation of the legislative instrument will be carried out as follows:

The Commission will submit to the European Parliament and the Council regular reports evaluating the implementation of the legal act. The first report will be submitted following an evaluation which will be carried out within four years after the entry into force of the legal act.

Evaluation of the effective operation of the structures and mechanisms provided for by the Health Security Initiative will be based on information from Member States supplied annually, with scientific support from specialised agencies and organisations such as the ECDC or EMA to provide a basis for comparison and consistency in Commission reporting.

The main instrument for gathering data for the purpose of such an evaluation will be a reporting system that will be approved and implemented by the new health committee. The competent authorities in the Member States, the European Centre of Disease Prevention and Control and the Commission will cooperate closely to develop the required tools and instruments. Involvement of other international bodies such as the World Health Organisation and the Global Health Security Initiative (GHSI)<sup>5</sup> may be considered where appropriate.

Reporting will cover information on cooperation mechanisms established, key sectors involved and websites in place to share information on best practices. Key indicators for the monitoring as well as the evaluation of policy implementation and outcomes are set out below:

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<sup>4</sup> <http://www.who.int/ihr/en/>

<sup>5</sup> More information on the Global Health Security Initiative can be found in the Commission Staff Working Document on Health Security in the European Union and Internationally, available at: [http://ec.europa.eu/health/preparedness\\_response/docs/commission\\_staff\\_healthsecurity\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf)

## Monitoring the implementation of suggested actions

### Impact Indicators

Specific Objectives	Result Indicators	Source of Information
1. Improved protection of citizens of the EU from serious cross-border threats to health	More rapid and effective defeat of cross-border threats to the health of EU citizens (morbidity, mortality, Quality Adjusted Life Years Saved)	External and independent evaluation four years after implementation of the legal basis
2. Public health security structures and systems: Effectiveness <sup>48</sup> , efficiency <sup>49</sup> and coherence <sup>50</sup> as regards the objectives described in this initiative		
2.1 Coherent and comprehensive <u>overall approach</u> for all serious cross-border threats to health (preparedness and response planning, risk monitoring and assessment as well as risk management including risk communication)	Legal proposal for Health Security Initiative adopted	Regular evaluations as legal requirement (article in the legislative text), first evaluation after four years of implementation of the legal base
<p>2.2. <u>preparedness and response planning</u>, common approach at EU level for <i>all</i> serious cross-border threats to health</p> <p>a. generic and specific preparedness</p> <p>b. ensuring coherence and interoperability among critical sectors of society</p> <p>c. common core capacities for preparedness / EU tailor-made criteria for notification (to address IHR with a common approach)</p>	<p>a. number of new preparedness plans established at EU and national level further developed generic preparedness principles (possible detailed provisions for specific threats)</p> <p>b. number of preparedness and response planning in critical sectors of society</p> <p>c. number of agreements on minimum core capacities and shared standards at EU level to address IHR</p> <p>d. adoption of the proposal to set up a joint procurement mechanism and its implementation: number of countries</p>	<p>annual reports of competent authorities in Member States based on an agreed questionnaire</p> <p>continuous ECDC assessment of preparedness at national level for communicable diseases</p> <p>synthesis reports by the Commission every two years with a qualitative evaluation of the implementation by the Member States</p>

<sup>48</sup> Effectiveness = the extent to which options achieve the objectives of the proposal

<sup>49</sup> Efficiency/cost effectiveness = the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)

<sup>50</sup> Coherence = the extent to which options are coherent with the overarching objectives of EU policy, and the extent to which they are likely to limit trade-offs across the economic, social and environmental domain

d. equitable access to medical countermeasures	participating, amount of medical counter-measures purchased through this mechanism	
<ul style="list-style-type: none"> <li>• <u>2.3. risk monitoring and assessment</u>: coherent and comprehensive approach for <ul style="list-style-type: none"> <li>• - identification and notification of health threats, based on improved linkage between existing monitoring and notification mechanisms and structures</li> <li>- improved capacities for robust, reliable, and rapid public health risk assessment for serious cross-border threats to health</li> </ul> </li> </ul>	<p>standard operation procedures in place and memoranda of understanding agreed with relevant sectors to closer link existing notification structures</p> <p>EU tailor-made criteria implemented for notification of health threats agreed at EU level</p> <p>number and types of threats detected and reported links to IHR established</p> <p>strengthened capacities in place for assessment of health threats, regardless of their cause (number of networks in place and number of types of threats covered)</p> <p>number of risk assessments, type of threats assessed, structures that assessed the risk and quality of risk assessments requested and performed</p>	Report from the Commission
<ul style="list-style-type: none"> <li>• <u>2.4. risk management</u>: improved coordination –</li> <li>• - sustainable structure at EU level for any serious cross-border public health crisis;</li> <li>• - clear mandate for this structure with strong commitment of Member States</li> </ul>	<p>Sustainable mechanism (operational EU health group) and structure in place for EU wide crisis management</p> <p>Standard Operation procedures for crisis management agreed with Member States</p> <p>internal rules of procedures established for a unique structure (level of participation of Member States, number and quality of recommendations issued)</p>	Report from the Commission
<u>2.5.crisis communication</u> : improved conditions for crisis communication	<p>Agreement on reinforced operating procedures for risk and crisis communication (who, why, when, where, how, what)</p> <p>Number of campaigns implemented, number of exercises carried out, number of common press statements, number and quality of communication tools, brochures, guidance documents, posters etc;</p>	Communication strategies and coordination of messages put in practice

A more detailed inventory of existing capacities, measures and plans in terms of preparedness, risk assessment and risk management at the level of each Member State and for all threats other than communicable diseases is currently being drawn up. It will allow indicators to be further defined and serve as the benchmark against which progress will to be measured after approval of the legal initiative.

#### **5.4. Grounds for the proposal/initiative**

##### *5.4.1. Requirement(s) to be met in the short or long term*

The aim of the Health Security Initiative (HSI) is to streamline and strengthen capacities and structures on health security in order to improve the protection of the citizens of the European Union (EU) from all serious cross-border threats that may affect public health. These threats can be events caused by communicable diseases, biological agents causing diseases that are not communicable<sup>51</sup>, and threats of chemical, environmental or unknown origin, or caused by climate change. Threats emerging from the effects of climate change (i.e. heat waves, cold spells) are covered by environmental threats throughout the initiative.

Due to the cross-border nature of these threats and to their potential severe consequences on the EU population, a coordinated public health approach at the EU level is necessary. The health security initiative aims to establish such a common EU framework on health security.

The health security initiative intends to offer European citizens the same level of protection as already exists for communicable diseases and to complement and add value to actions between Member States through coherent and more efficient governance of health threats. It will seek to reinforce the coordination of the EU risk management and will strengthen the existing structures and mechanisms in the public health area.

The legal basis for the initiative is provided by the Lisbon Treaty which introduced a new competence for the EU to set up measures in the area of serious cross-border health threats.<sup>52</sup> This impact assessment will examine a range of policy options to improve the crisis management cycle from the public health perspective. Its scope covers the following key areas:

- the coordination at EU level of the preparedness and response planning for serious cross-border threats to health, including equitable access to medical countermeasures such as vaccines and improved preparedness for all critical sectors in society.
- the monitoring and scientific assessment at EU level of risks from these potential threats as independent expertise with sound scientific advice on emerging health threats is required to respond appropriately to a health emergency;

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<sup>51</sup> Biological events can be caused by communicable diseases and by harmful substances produced by micro-organisms (such as ricin). These harmful substances are typically found in nature, but can be produced, modified or manipulated to cause illness intentionally in a criminal or terrorist attack.

<sup>52</sup> See annex 1 for article 168 of the Lisbon Treaty

- the public health aspects of crisis management and the public health measures required under such circumstances to prevent or limit the spread of public health threats and mitigate the effects of such events.<sup>53</sup>. In this context, the impact assessment will also elaborate on the status of the Health Security Committee<sup>54</sup> (HSC) and will look into ways to ensure effective communication.

#### 5.4.2. *Added value of EU involvement*

The EU added value would be increased across all aspects of preparedness and response planning, risk assessment and risk management by setting up strategic and technical cooperation on health security at EU level. This would be guaranteed by the establishment of a robust legal instrument for all serious cross-border health threats. By also providing a legal basis for operating a joint procurement mechanism for medical countermeasures this option could add value to strengthening preparedness and response capacity to deal with cross-border health threats across the EU.

#### 5.4.3. *Lessons learned from similar experiences in the past*

Recent cross-border events such as the H1N1 pandemic in 2009/2010, the volcanic ash cloud in 2010, or the outbreak of the *E. coli*/STEC O104 in 2011 have had significant impacts on society and demonstrated that none of these emergencies can be confined to a specific sector. It is not only public health that is concerned but also civil protection, food safety, international trade, travel and/or law enforcement, depending on the nature of the threat.

**Pandemic influenza H1N1** in 2009 and 2010 caused 2900 deaths within the EU and 18,000 worldwide; the pandemic put heavy pressure on the health services, including intensive care, required contact tracing, huge investments in vaccines and antivirals and had Member States competing for better conditions for procurement of vaccines. The economic and societal disruptions, particular in Mexico and the United States, where schools were e.g. closed, lead to disruption for tourism and travel.

The management of Pandemic Influenza H1N1 was thoroughly evaluated<sup>55</sup>.

Lessons learnt at EU level and key messages endorsed by the Health Security Committee include the following<sup>56</sup>: Member States, the Commission and EU Agencies continue to

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<sup>53</sup> Measures include medical countermeasures (masks, medicines) and containment of the event and decontamination (reduction or removal of chemical agents from persons or places which have been contaminated) A health measure will not address issues that are wider than public health and hence will not include law enforcement or civil protection measures.

<sup>54</sup> To avoid confusing this committee with a committee as established under Article 3 of Regulation (EU) No 182/2011 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:055:0013:0018:EN:PDF>) it would be appropriate to change its name and avoid the term 'committee'. Another name, such as 'EU High level Group for Health Security' may better reflect the true nature of this body.

<sup>55</sup> [http://ecdc.europa.eu/en/healthtopics/pandemic\\_preparedness/pandemic\\_2009\\_evaluations/Pages/pandemic\\_2009\\_evaluations.aspx](http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/pandemic_2009_evaluations/Pages/pandemic_2009_evaluations.aspx) provides an overview of all evaluations on H1N1

<sup>56</sup> Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009 covering the period 24 April 2009 – 31 August 2009: [http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_response\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_response_en.pdf);

evaluate pandemic preparedness for sectors and services identified as potentially at risk, (health and cross-sectoral), particularly as not all sectors experienced similar levels of pressure. Member States, the Commission and EU Agencies refine and publicise estimates of pandemic planning assumptions for a new pandemic as early as possible to enable other sectors to prepare, and ensure that these are reviewed as the pandemic progresses. Member States incorporate planning for the provision of mutual aid as part of generic business continuity planning for health services, including health sector supply and support services.

Many improvements are needed, for example the experience drawn from Pandemic H1N1 2009, and endorsed in the recent ECDC-WHO-Euro led workshops (Sept 2011) shows that it is necessary to undertake a risk-based approach so as to make responses more proportionate and tailored to the specific features of a particular pandemic, which may differ considerably.

Under the current EU communicable disease legislation EU surveillance and a case definition for H1N1 were agreed rapidly on the basis of ECDC and WHO advice. However, the statements by the Health Security Committee on vaccination coverage<sup>57</sup>, on travel advice<sup>58</sup> and on school closures<sup>59</sup> during the pandemic were hard to reach, slow to be agreed, and not always followed up by the Member States, given the informal nature of that committee. It was also not possible, owing to regulatory and contractual limitations, to rapidly come up with a mechanism for ensuring a supply of antivirals and vaccines<sup>60</sup>.

During the H1N1 pandemic in 2009, some Member States were unable to procure enough pandemic influenza vaccines and the vaccines when they arrived did so at very different dates across the EU countries. Non-equitable access to pandemic influenza vaccines during the H1N1 (2009) pandemic was due to weak purchasing power of Member States<sup>61</sup>. This contrasted with what happened in parts of Latin America and the Caribbean where countries participating in the Pan American Health Organisation routine joint vaccine procurement mechanism received pandemic vaccines at approximately the same time, according to a pre-agreed plan and with more advantageous conditions than EU Member States negotiated.

Member States wishing to secure pandemic influenza vaccines were pitched against each other and had to accept disadvantageous contractual conditions. Evidence that was gathered for the Commission in an independent evaluation<sup>62</sup> shows the considerable variations in contractual conditions, particularly regarding liability for side effects being transferred from the manufacturers to the Member States. In addition, the lack of flexibility in contracts to include conditions under which the reserved amount of doses could be changed or excess vaccines could be returned resulted in an enormous waste of resources. The Member States that could

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<sup>57</sup> HSC/EWRS statement on Influenza A(H1N1) 2009: target and priority groups for vaccination, 25 August 2009

[http://ec.europa.eu/health/archive/ph\\_threats/com/influenza/docs/hsc\\_ewrs\\_statement\\_en.pdf](http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/hsc_ewrs_statement_en.pdf)

<sup>58</sup> HSC/EWRS statement on Influenza A(H1N1) 2009 Symptomatic individuals travelling, 13 August 2009

[http://ec.europa.eu/health/archive/ph\\_threats/com/influenza/docs/statement\\_travel\\_en.pdf](http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_travel_en.pdf)

<sup>59</sup> HSC/EWRS statement on School closures, 13 August 2009:

[http://ec.europa.eu/health/archive/ph\\_threats/com/influenza/docs/statement\\_school\\_en.pdf](http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_school_en.pdf)

<sup>60</sup> [http://ec.europa.eu/health/preparedness\\_response/docs/council\\_lessonsh1n1\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf)

<sup>61</sup> Assessment report on EU wide pandemic vaccine strategies of 25.8.2010

[http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_vaccine\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf)

<sup>62</sup> [http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_vaccine\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf)



not accept those unfavourable conditions had no guarantee at all of being able to obtain pandemic influenza vaccines, thus weakening the preparedness across the EU against such cross-border health threat. This could have had very serious health consequences if the pandemic had proved more virulent and deadly.

There were difficulties in communicating with health professionals and the public on the need for pandemic vaccination in the 2009 H1N1 pandemic.<sup>63</sup>

Due to the huge interruption of transport during the **Volcanic ash cloud** from Iceland in 2010 e.g. organ transplants had to be postponed due to delays in the delivery of organs, there were also problems of medicines for people stranded abroad without their usual medicines and without any prescription and of course, respiratory problems especially for people with medical conditions.

The recent **E.coli/STEC O104** outbreak made 3910 people ill and caused 46 deaths within 2 months only. It led to overflowing intensive care units in Germany, shortages of medical equipment e.g. for dialysis, extreme pressure on laboratory capacity needed to examine the samples and to lack of public confidence in health measures. This epidemic had a huge impact on the vegetable/agriculture sector in the EU. A EUR 227 million compensation scheme was established by the import ban of Russia during 2 months for EU fresh vegetables lead to additional extrapolated costs of EUR 100 million.

The experience with E.coli/STEC O104 clearly demonstrated how insufficient preparedness, inadequate response or communication strategies in one Member State have led to more severe negative impacts on others.

Premature communication to the general public and to the press on the source of the outbreak was made at various levels. Certain national/regional announcements were not backed by sound scientific evidence or risk assessment. This leads to difficulties in the efficient management of the crises and important economic impacts.

Citizens and external States stopped eating/importing fresh vegetables. This had devastating consequences for the producers of the vegetables in question (salad, cucumbers, sprouts), in particular in the South of Europe.

The estimation of the economic operators' losses in the first two weeks of the crisis is at least of EUR 812.6 million, according to farmers' organizations. These data may represent an underestimation, since it does not cover the whole period of the crisis and does not include figures from all EU countries. Losses caused by several trade restrictions adopted by third states (ban of imports) have also to be taken in account (e.g. Russia banned vegetables import with losses estimated in EUR 600 million).

The Commission played an active role in order to reduce the financial burden incurred by this crisis. A EUR 210 million aid package was immediately adopted and further EUR 75.1 million

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[http://ec.europa.eu/health/communicable\\_diseases/docs/assessment\\_response\\_en.pdf](http://ec.europa.eu/health/communicable_diseases/docs/assessment_response_en.pdf) (chapter 12)

of shared aids with MS are aimed to the promotion of agricultural products in the next three years.

Communication with the public on risks arising from E. coli STEC O104 in 2011 was difficult due to inconsistent and uncoordinated messages at regional, national and EU level, as well as those originating from the WHO.

Following several terrorist attacks involving **chlorine** in Iraq in March 2007, Europol urgently requested to the Commission to assess the potential of chlorine to become a common terrorist weapon and, more particularly, the possibility of this substance being used in Europe. There is no EU body which could deal with such a risk assessment and therefore the Commission had to collect information from different sources, such as the Chemical Working Group of the HSC, from the representatives of funded projects on the subject from the Health Programme and by means of joint efforts with ECHA and JRC. The absence of a mechanism to mobilise appropriate expertise led to delay in making a risk assessment, despite the existence of assessments aimed at law enforcement or civil protection.

There was also a problem concerning public risk assessment in relation to the **melamine** milk contamination event in 2008.<sup>64</sup> Based on their knowledge, the food safety authorities did not see a risk for adults in Europe. However, public health authorities had to address citizen's concerns about longer term effects, particularly for travellers returning from China who had been at risk of having consumed contaminated milk and composite products. There was no possibility to have a comprehensive and rapid public health risk assessment and also no possibility to enable surveillance of exposed persons in the short, medium or long term.

Concerning **chemical events**, a series of table top exercises have been run in 2011 ("Iridium") to simulate incidents caused by dangerous chemicals, based on real life events. For example, a leaking container on a ferry on the Baltic Sea caused illness in passengers and ship workers that came in contact with the chemical, but they had to travel on to their destinations. They presented unusual and non-specific symptoms<sup>65</sup>.

It became apparent during the exercises that there is a gap in the mechanisms currently in place at EU level to trigger and alert or to provide notification of the impact that an unfolding chemical incident could have or has on public health, in order to make an early risk assessment or to develop an EU case definition to control and contain the impact on public health of a chemical incident. Standard operating procedures for public health impact of a chemical event at EU level, and possibly proposal of new provisions would provide a stronger basis for addressing the public health aspects of chemical incidents.

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<sup>64</sup> Melamine accumulates in the body and causes toxicity problems. Products across the globe containing contaminated milk have been imported from China in 2008. According to WHO, more than 51 900 infants and young children in China were hospitalized for urinary problems, possible renal tube blockages and possible kidney stones related to the consumption of melamine contaminated infant formula and related dairy products. Six deaths among infants have been confirmed in mainland China.

<sup>65</sup> [http://ec.europa.eu/health/preparedness\\_response/docs/iridium\\_1\\_2011\\_frep\\_en.pdf](http://ec.europa.eu/health/preparedness_response/docs/iridium_1_2011_frep_en.pdf)

There were difficulties in managing cross-border chemical events, as shown in the Iridium exercise report. (Sectors concerned were chemicals, transport, health, and maritime transport).

There was an absence of management measures at EU level to tackle the **heat waves** in 2003 when people died due to the heat; no discussion of coordinated measures, for example on sharing of hospital capacities across national borders.

The absence of adequate coordination of measures at EU level and of the follow up to the **spill of aluminium sludge** in Hungary, affecting the Danube River in 2010 (Environment, chemicals, health and civil protection was another example).

#### 5.4.4. *Coherence and possible synergy with other relevant instruments*

In a more general strategic framework, the health security initiative will help implement the European Health Strategy<sup>66</sup> and also contribute to the objectives of Europe 2020<sup>67</sup> by promoting health as an integral part of the smart and inclusive growth objectives. Furthermore, it will contribute to the overall European Security context and will build on existing instruments and strategies related to disaster prevention and control.

Several principle areas under the TFEU are dealing with EU disaster prevention and control. Mechanisms related with EU disaster prevention and control cover civil protection (Article 196), solidarity clause (Article 222), EU financial assistance (Article 122), humanitarian aid (Article 214), cohesion policy and home affairs. In addition, TFEU lays down provisions on EU's external action in relation with international cooperation on assistance in case of natural or man-made disasters (Article 21). Furthermore, EU secondary legislation establishes specific rules in the field of EU disaster prevention and control (e.g. Seveso II).

The EU has a series of policies, mechanisms and instruments to cater for prevention and control of serious cross border threats to health and develop capacities to manage crises<sup>68</sup>. A non-exhaustive list includes the civil protection mechanism, the Internal Security Strategy, the Cohesion and Solidarity Funds, pan-European alert networks such as ECURIE, to name only a few<sup>69</sup>.

All these are managed by the responsible Commission services. Furthermore, over twenty EU Agencies provide information and advice, oversee operations and support policymaking. Crisis management coordination at corporate level is done through ARGUS, the Commission's crisis management corporate system. The Commission ensures broader internal coordination by means of an inter-service group on Community Capacity in Crisis Management which brings together all relevant Directorates-General and services as well as EU Agencies. In this group DG SANCO has informed on the health security initiative and has also received input for the impact assessment.

<sup>66</sup> Health Strategy: COM(2007) 630 final - White paper - Together for Health: A Strategic Approach for the EU 2008-2011; [http://ec.europa.eu/health-eu/doc/whitepaper\\_en.pdf](http://ec.europa.eu/health-eu/doc/whitepaper_en.pdf)

<sup>67</sup> EU 2020- EU Strategy for smart, sustainable and inclusive growth; [http://ec.europa.eu/europe2020/index\\_en.htm](http://ec.europa.eu/europe2020/index_en.htm)

<sup>68</sup> See detailed information in annex 7

<sup>69</sup> For further details, please see the "Inventory of Crisis Management Capacities in Commission and Agencies"

The health security initiative is part of the overall EU mechanisms and strategies for disaster prevention and control. It will lead to intensified inter-action with all relevant sector specific disaster management structures which are in operation at EU level.

In the area of health security, there are already a number of EU structures in place, namely:

- EU Agencies, such as the European Food Safety Authority (EFSA), European Medicines Agency (EMA), European Maritime Safety Agency (EMSA), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), European Agency for Safety and Health at Work (EU-OSHA) and the European Chemicals Agency (ECHA);

- designated networks such as the Animal Disease Notification System (ADNS), Rapid Alert System for Feed and Food (RASFF), European Telecommunication Network in Pharmaceuticals (EUDRANET), Rapid Alert System for Non-Food Dangerous Products (RAPEX), Monitoring and Information Centre (MIC), and RAS-CHEM, which is a rapid alert system for chemical health risks;

- scientific committees (on consumer products, health and environment risks and newly identified health risks) are in charge of risk assessment, depending on the type of threat<sup>70</sup>;

To avoid overlaps with the existing structures, a **gap analysis** based on the mechanisms and structures in place within the Commission and various EU Agencies, such as the European Centre for Disease Prevention and Control, the European Medicines Agency, the European Food Safety Authority and Frontex was done to support this impact assessment. The review revealed that these structures do not address cross border health threats preparedness and response in a sufficient manner. Especially, they do not provide a coherent and satisfactory basis for decisions on public health measures that might be necessary to manage risks and to ensure effective follow-up of events. Also, many of the structures are operated without being sufficiently inter-linked with authorities and agencies responsible for public health in the Member States and/or at EU level.

The Health Security Initiative will contribute to other EU initiatives in the area of law enforcement and civil protection:

The initiative will help put in place the EU Internal Security Strategy<sup>71</sup>, which makes specific reference to the health security initiative.

The initiative will be instrumental to strengthen chemical and biological security in the EU as set out in the CBRN action plan<sup>72</sup>. The close cooperation that is ongoing between Member States' authorities and agencies and DG HOME and SANCO, backed up by Europol and the European Centre for Disease Prevention and Control, and which is undertaken in the

70

[http://ec.europa.eu/health/scientific\\_committees/policy/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/policy/index_en.htm)

71

[http://ec.europa.eu/commission\\_2010-2014/malmstrom/archive/internal\\_security\\_strategy\\_in\\_action\\_en.pdf](http://ec.europa.eu/commission_2010-2014/malmstrom/archive/internal_security_strategy_in_action_en.pdf)

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[http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/com/com\\_com\(2009\)0273\\_/com\\_com\(2009\)0273\\_en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/com/com_com(2009)0273_/com_com(2009)0273_en.pdf);

framework of the “bridging security and health” arrangement will be reinforced through improved cross border health threats preparedness and response as a result of the initiative.

In the area of civil protection, the Commission adopted on 5 March 2008 a Communication on reinforcing the Union's disaster response capacity.<sup>73</sup> It was followed after by a Commission Communication of 26 October 2010 on "Towards a stronger European disaster response: the role of civil protection and humanitarian assistance"<sup>74</sup>. EU co-operation in the field of civil protection aims to better protect people, their environment, property and cultural heritage in the event of major natural or manmade disasters occurring both inside and outside the EU.

Close cooperation between DG ECHO, DG SANCO, backed up by ECDC, in preparedness and response to civil disasters is ongoing and has proven to be effective in several crisis situations.

In 2010 under the “Instrument for Stability” the EU started a project that will allow third countries to collaborate in numerous regions of the world to build capacities for mitigating risks from chemical, biological, radiological and nuclear materials, irrespective of the origin of the risk (natural, criminal, industrial accident). Possible synergies will be explored under the Health Security Initiative with the activities of these regional CBRN (Chemical, Biological, Radio-Nuclear) Centres of Excellence.

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<sup>73</sup> COM(2008) 130 final: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0130:FIN:EN:PDF>

<sup>74</sup> COM(2010) 600 final:  
[http://ec.europa.eu/echo/civil\\_protection/civil/prote/pdfdocs/COM\\_2010\\_600\\_European\\_disaster\\_response\\_en.pdf](http://ec.europa.eu/echo/civil_protection/civil/prote/pdfdocs/COM_2010_600_European_disaster_response_en.pdf)

### 5.5. Duration and financial impact

Proposal/initiative of **limited duration**

–  Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

–  Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

– Full-scale operation on the day following that of its publication in the Official Journal of the European Union.

### 5.6. Management mode(s) envisaged<sup>75</sup>

**Centralised direct management** by the Commission

**Centralised indirect management** with the delegation of implementation tasks to:

–  executive agencies

–  bodies set up by the Communities<sup>76</sup>

–  national public-sector bodies/bodies with public-service mission

–  persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

**Shared management** with the Member States

**Decentralised management** with third countries

**Joint management** with international organisations (*to be specified*)

*If more than one management mode is indicated, please provide details in the "Comments" section.*

#### Comments

Where the (potential) serious cross-border threats to health is related to a communicable disease or from unknown origin, the European Centre for Disease Prevention and Control (ECDC) will be involved in the areas of preparedness and response planning, and risk monitoring and assessment.

<sup>75</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

<sup>76</sup> As referred to in Article 185 of the Financial Regulation.

## **6. MANAGEMENT MEASURES**

### **6.1. Monitoring and reporting rules**

*Specify frequency and conditions.*

The expenditure will be monitored on an annual basis in order to both assess headway towards the achievement of its specific objectives against its outcome and impact indicators and allow for any necessary adjustments of the policy and funding priorities.

Given that expenditure will mainly be covered by the Health Programme, the expenditure will be subject to the mid-term term and ex-post evaluation of the Programme. A mid-term evaluation will aim at measuring progress made in meeting the Programme objectives, determining whether its resources have been used efficiently and assessing its European added value.

The ex-post evaluation of the current Programme (2008 – 2013), which is foreseen before the end of 2015, will also provide useful elements for the implementation of the Programme 2014 – 2020.

Expenditure not covered by the Programme, ie the expenses financed by Medical services, from BL 2601, will be subject to an evaluation every 5 years, where the Commission shall examine the need to amend this Regulation and shall present a report to the European Parliament and the Council on its application accompanied, if appropriate, by a legislative proposal. In this respect,

### **6.2. Management and control system**

#### *6.2.1. Risk(s) identified*

The main risks are the following:

\* Risk of inefficient or non-economic use of funds awarded for procurement (sometimes limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers);

\* Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system, often rather small in size.

#### *6.2.2. Control method(s) envisaged*

The budget will be implemented by centralised direct management, though parts of the implementation tasks might be delegated to the ECDC. This agency set up its own internal control system, is supervised by DG SANCO, and audited by the Court of Auditors.

DG SANCO and the ECDC alike put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the financial regulation and include cost-benefit considerations. Within this framework, SANCO continues to explore possibilities to enhance the management and to increase simplification. Main features of the control framework are the following:

**Characteristics of the selection process of offers:** each call for proposal/tender is based on the annual Work Programme adopted by the Commission. In each call, the exclusion, selection and award criteria for selecting proposals/offers are published. Against these criteria, an evaluation committee, possibly assisted by external experts, evaluates each proposal/offer observing the principles of independence, transparency, proportionality, equal treatment and non-discrimination.

**External Communication strategy:** DG SANCO has a well developed communication strategy that seeks to ensure the contractors'/beneficiaries' full understanding of the contractual requirements and provisions. Following means are being used: EUROPA website, "frequently asked questions", a help desk, extensive guidance notes as well as information meetings with beneficiaries/contractors.

**\* Controls before and during the implementation of contracts:**

- DG SANCO uses the model service contracts recommended by the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF.
- All staff signs the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the contracts also sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.
- Technical implementation of a contract is checked at regular intervals at the desk on the basis of technical progress reports of the contractor; in addition contractors' meetings and on-site-visits are foreseen on a case by case basis.
- DG SANCO's financial procedures are supported by the Commission's IT tools and have a high degree of segregation of duties: all financial transactions related to contracts are verified by two independent persons before they are signed by the authorising officers responsible for the activity. Operational initiation and verification is carried out by different members of staff of the policy areas. Payments are made on the basis of a number of pre-defined supporting documents such as approved technical reports as well as verified cost claims and invoices. For a sample of transactions, the central financial cell performs second-level ex-ante desk verification; on a case by case basis, also an ex-ante on-site financial control can be carried out prior to final payment.

**\* Controls at the end of the contract:**

DG SANCO has a centralised audit team which verifies on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control



impact, the selection of contractors to be audited foresees to (a) combine a risk based selection with a random sampling, and (b) pay attention to operational aspects whenever possible during the on-site audit.

**\* Costs and benefits of controls:**

The Programme's management and control measures are designed on the basis of past experience: in the past three years, the established internal control system ensured an average residual error rate of less than 2% as well as compliance with the procurement procedures laid down in the financial regulation. These are the two main "control objectives" of both the previous and the new Health Programme.

As the main design features of the new Programme are not significantly different from the previous Programme, the risks related to Programme implementation are considered to remain relatively stable. Thus, the established management and control measures are planned to be continued; nevertheless, further simplifications that might become possible under the new financial regulation will be taken up as soon and as far as possible.

Thanks to risk based ex-ante and ex-post controls as well as desk checks and on-site audits, the "control objectives" will be achieved at a reasonable cost level. The benefits of achieving an average residual error rate of less than 2% and compliance with the provisions of the financial regulation are assessed as sufficiently important to justify the chosen management and control measures.

### **6.3. Measures to prevent fraud and irregularities**

*Specify existing or envisaged prevention and protection measures.*

In addition to the application of all regulatory control mechanisms, DG SANCO will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure inter alia that its internal anti-fraud related controls are fully aligned with the CAFS and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases will be set up in particular a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the Health Programme will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;
- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

**7. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

**7.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected**

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description..... ]	Diff./non-diff. <sup>(77)</sup>	from EFTA <sup>78</sup> countries	from candidate countries <sup>79</sup>	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3. Security and citizenship	17 03 06 Union action in the field of health	Diff.	YES	YES	NO	NO
3. Security and citizenship	17 01 04 Programme of the European Union action in the field of health – Expenditure on administrative management	non-diff.	YES	YES	NO	NO
5. Administration	17 01 02 11 External staff and other management expenditure in support of the ‘Health and consumer protection’ policy area – Other management expenditure	non-diff.	YES	YES	NO	NO
5. Administration	26 01 50 01 Administrative expenditure of the ‘Commission’s administration’ policy area – Personnel policy and management – Medical service	non-diff.	NO	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of	Budget line	Type of	Contribution
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<sup>77</sup> Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

<sup>78</sup> EFTA: European Free Trade Association.

<sup>79</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

multiannual financial framework	Number [Heading..... .....]	expenditure				
		Diff./non- diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation

## 7.2. Estimated impact on expenditure

### 7.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places) in current prices

<b>Heading of multiannual financial framework:</b>	Number 3	Security and citizenship
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DG: SANCO			Year 2013 <sup>80</sup>	Year 2014	Year 2015	Subsequent years	TOTAL <sup>81</sup>
• Operational appropriations							
17 03 06	Commitments	(1)	2.081	2.123	2.165	=(commitment year-1)*1.02	
	Payments	(2)	0.694	1.415	2.165		
Budget line	Commitments	(1a)					
	Payments	(2a)					
Appropriations of an administrative nature financed from the envelope for specific programmes <sup>82</sup>							
17 01 04		(3)	0.084	0.086	0.088	=(commitment year-1)*1.02	
<b>TOTAL appropriations for DG SANCO</b>	Commitments	=1+1a +3	2.165	2.209	2.253		
	Payments	=2+2a +3	0.778	1.501	2.253		

<sup>80</sup> Year N is the year in which implementation of the proposal/initiative starts. Depends on year of adoption of the Decision (co-decision procedure).

<sup>81</sup> For the first three years. 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 from the previous years will be forwarded to the European Parliament and the Council.

<sup>82</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)	2.081	2.123	2.165	=(commitment year-1)*1.02	
	Payments	(5)	0.694	1.415	2.165		
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.084	0.086	0.088	=(commitment year-1)*1.02	
<b>TOTAL appropriations under HEADING 3 Security and citizenship</b> of the multiannual financial framework	Commitments	=4+ 6	2.165	2.209	2.253		
	Payments	=5+ 6	0.778	1.501	2.253		

**If more than one heading is affected by the proposal / initiative:**

• TOTAL operational appropriations	Commitments	(4)					
	Payments	(5)					
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)					
<b>TOTAL appropriations under HEADINGS 1 to 4</b> of the multiannual financial framework (Reference amount)	Commitments	=4+ 6					
	Payments	=5+ 6					

<b>Heading of multiannual financial framework:</b>	<b>5</b>	" Administrative expenditure "
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EUR million (to 3 decimal places) in current prices

	Year2013	Year2014	Year2015	Subsequent years	TOTAL
DG: SANCO					

• Human resources (17 01 01 01)		0;540	0.540	0.540		<b>0.540</b>	
• Other administrative expenditure (17 01 02 11)		0.096	0.096	0.096		0.096	
<b>TOTAL DG SANCO</b>	Appropriations						

		Year 2013	Year 2014	Year 2015	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
DG: HR								
• Human resources <sup>83</sup>								
• Other administrative expenditure (26 01 50 01)		0.030						
<b>TOTAL DG HR</b>	Appropriations	0.030						

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)						
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EUR million (to 3 decimal places)

		Year N <sup>84</sup>	Year N+1	Year N+2	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments							
	Payments							

<sup>83</sup> Joint procurement of pandemic influenza vaccines coordinated by DG SANCO

<sup>84</sup> Year N is the year in which implementation of the proposal/initiative starts.

7.2.2. *Estimated impact on operational appropriations*

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Indicate objectives and outputs  ↓			Year 2013	Year 2014	Year 2015	TOTAL				
	OUTPUTS									
	Type of output <sup>85</sup>	Average cost of the output	Number of outputs <sup>86</sup>	Cost	Number of outputs <sup>87</sup>	Cost	Number of outputs	Cost	Total number of outputs <sup>88</sup>	Total cost
<b>SPECIFIC OBJECTIVE No 1<sup>89</sup></b> <b>Preparedness and response planning</b>										
output	New preparedness plans established at EU and national level		1	0.066	0	0.000	0	0.000	1	0.066
output	Further developed generic preparedness principles (possible detailed provisions for specific threats)		1	0.066	1	0.066	1	0.066	3	0.198
output	Preparedness and response planning in critical sectors of society		1	0.066	0	0.000	0	0.000	1	0.066

<sup>85</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>86</sup> Only outputs at EU level are considered

<sup>87</sup> Only outputs at EU level are considered

<sup>88</sup> Only outputs at EU level are considered

<sup>89</sup> As described in Section 1.4.2. "Specific objective(s)..."



output	Agreements on minimum core capacities and shared standards at EU level to address IHR		1	0.066	1	0.066	1	0.066	3	0.198
output	Proposal to set up a joint procurement mechanism and its implementation: countries participating, medical counter-measures purchased through this mechanism		1	0.066	0	0.000	0	0.000	1	0.066
<b>Sub-total for specific objective N°1</b>			<b>5</b>	<b>0.330</b>	<b>2</b>	<b>0.132</b>	<b>2</b>	<b>0.132</b>	<b>9</b>	<b>0.594</b>
<b>SPECIFIC OBJECTIVE No 2</b>										
<b>Risk monitoring and assessment</b>										
output	Standard operation procedures in place and memoranda of understanding agreed with relevant sectors to closer link existing notification structures		1	0.050	1	0.050	1	0.050	3	0.150
	EU tailor-made criteria implemented for notification of health threats agreed at EU level		1	0.050	0	0.000	0	0.000	1	0.050
	Links to IHR established		1	0.050	0	0.000	0	0.000	1	0.050
	Strengthened capacities in place for assessment of health threats, regardless of their cause, and networks in place		3	0.100	0	0.000	0	0.000	3	0.100
<b>Sub-total for specific objective N°2</b>			<b>6</b>	<b>0.250</b>	<b>1</b>	<b>0.050</b>	<b>1</b>	<b>0.050</b>	<b>8</b>	<b>0.350</b>
<b>SPECIFIC OBJECTIVE No 3</b>										
<b>Risk management</b>										
output	Sustainable mechanism (operational EU health group) and structure in place for EU wide crisis management		1	0.063	0	0.000	0	0.000	1	0.063

output	Standard Operation procedures for crisis management agreed with Member States		1	0.063	0	0.000	0	0.000	1	0.063
output	Internal rules of procedures established for a unique structure (level of participation of Member States)		1	0.062	0	0.000	0	0.000	1	0.062
output	Committee in charge of implementing acts put in place		1	0.062	0	0.000	0	0.000	1	0.062
<b>Sub-total for specific objective N°3</b>			<b>4</b>	<b>0.250</b>	<b>0</b>	<b>0.000</b>	<b>0</b>	<b>0.000</b>	<b>4</b>	<b>0.250</b>

**SPECIFIC OBJECTIVE  
No 4**

**Risk and crisis  
communication**

output	Agreement on reinforced operating procedures for risk and crisis communication (who, why, when, where, how, what)		1	0.050	0	0.000	0	0.000	1	0.050
output	Campaigns implemented; exercises carried out; common press statements, communication tools, brochures, guidance documents, posters etc produced;		3	1.201	5	1.941	5	1.983	13	5.125
<b>Sub-total for specific objective N°4</b>			<b>4</b>	<b>1.251</b>	<b>5</b>	<b>1.941</b>	<b>5</b>	<b>1.983</b>	<b>14</b>	<b>5.175</b>
<b>TOTAL COST</b>		<b>0.193</b>	<b>19</b>	<b>2.081</b>	<b>8</b>	<b>2.123<sub>90</sub></b>	<b>8</b>	<b>2.165<sub>91</sub></b>	<b>35</b>	<b>6.369</b>

<sup>90</sup>

=(commitment year-1)\*1.02

=(commitment year-1)\*1.02

### 7.2.3. Estimated impact on appropriations of an administrative nature

#### 7.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places) in current prices

	Year 2013 <sup>92</sup>	Year 2014	Year 2015	Subsequent years	TOTAL
--	----------------------------	--------------	--------------	------------------	-------

<b>HEADING 5 of the multiannual financial framework</b>					
Human resources	0.540	0.540	0.540		
Other administrative expenditure (17 01 02 11)	0.096	0.096	0.096	0.096	
Administrative expenditure of the 'Commission's administration' policy area – Personnel policy and management - Medical service (26 01 50 01)	0.030				
<b>Subtotal HEADING 5 of the multiannual financial framework</b>					

<b>Outside HEADING 5<sup>93</sup> of the multiannual financial framework</b>					
Human resources					
Other expenditure of an administrative nature (17 01 04)	0.084	0.086	0.088	=(commitment year-1)*1.02	
<b>Subtotal outside HEADING 5 of the multiannual</b>					

<sup>92</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>93</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

<b>financial framework</b>					
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<b>TOTAL</b>					
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### 7.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full amounts (or at most to one decimal place)*

	Year 2013	Year 2014	Year 2015	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)		
<b>• Establishment plan posts (officials and temporary agents)</b>							
17 01 01 01 (Headquarters and Commission's Representation Offices)	4	4	4	4	4	4	4
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External personnel (in Full Time Equivalent unit: FTE)<sup>94</sup></b>							
XX 01 02 01 (CA, INT, SNE from the "global envelope")	0.5	0.5	0.5	0.5	0.5	0.5	0.5
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
XX 01 04 yy <sup>95</sup>	- at Headquarters <sup>96</sup>						
	- in delegations						
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>

**XX** is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

<sup>94</sup> CA= Contract Agent; INT= agency staff ("*Intérimaire*"); JED= "*Jeune Expert en Délégation*" (Young Experts in Delegations); LA= Local Agent; SNE= Secoded National Expert;

<sup>95</sup> Under the ceiling for external personnel from operational appropriations (former "BA" lines).

<sup>96</sup> Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

Description of tasks to be carried out:

Officials and temporary agents	
External personnel	

7.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible the current multiannual financial framework and with the 2014-2020 multiannual financial framework as proposed in Commission Communication COM(2011)500.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>1</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

7.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
<i>Specify the co-financing body</i>								
TOTAL appropriations cofinanced								

<sup>1</sup> See points 19 and 24 of the Interinstitutional Agreement.

### 7.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative <sup>2</sup>						
		Year N	Year N+1	Year N+2	Year N+3	... insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
Article .....								

<sup>2</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.