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IMPACT ASSESSMENT

Accompanying the document

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

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This Impact Assessment report commits only the Commission's services involved in its preparation and the text is prepared as a basis for comment and does not prejudge the final form of any decision to be taken by the Commission.

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1. PURPOSE AND SCOPE¹

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 communicable², 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) will be covered by environmental threats throughout this initiative.

Climate change and its adverse effects show already impacts on human health as they can act as an amplifier of existing health problems but also contribute to new and emerging health threats. Climate-change-related threats of importance to human health are likely to increase immediate health effects from extreme weather events (heat waves, cold spells) and the distribution of food-borne or the burden of water-borne diseases, to affect the distribution and the frequency of vector-borne diseases and cause changes in the distribution and frequency of respiratory diseases over the coming decades.

Serious cross border health may range from mass contamination caused by chemical incidents to epidemics or pandemics such as those resulting from the influenza pandemic H1N1 in 2009, or SARS (Severe Acute Respiratory Syndrome) in 2003. These threats affect more than one Member State in such a way that the morbidity or mortality in humans is acute and/or rapidly rising in numbers, i.e. more people will fall ill or even die, and/or is unusual for the given place and/or time.³

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.

Not all serious cross-border threats to health are handled in a consistent manner at EU level. Threats to health of radiological or nuclear origin causing exposure to ionising radiation are dealt with by the provisions of the EURATOM treaty which constitutes the '*lex specialis*⁴' in relation to Article 168 of the Treaty of the Functioning of the EU and are therefore not covered by this initiative.

¹ This initiative implements the actions set out in the Commission staff working document on lessons from the H1N1 pandemic and on health security in the European Union, SEC(2010) 1440 final of 18.11.2010.

² 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.

³ Chronic diseases, injuries due to transport accidents, spread of blood borne infectious diseases through injecting drug use, the emergence of new psychoactive substances on the EU market, nanotechnology, GMOs, and electromagnetic fields are also not covered under this initiative. Existing instruments available at national and EU level that relate to the monitoring, early warning of and combating serious cross-border threats to health are not affected by this initiative.

⁴ EURATOM TREATY, Articles 2b) and 30-39

Threats emerging from biological (other than communicable diseases), chemical and environmental origin (such as e.g. heat waves or cold spells), are not addressed sufficiently at the EU level to protect European citizens' health appropriately. Although they occur not as often as communicable diseases their impact on public health and society might be huge. There is an established EU framework to address communicable diseases at EU level. This is done through an EU legislation which allows for rapid detection of diseases, notification at EU level, scientific assessments for every single disease and sustainable structures and mechanisms for the Member States to cooperate effectively in managing outbreaks.

This discrepancy in the way that serious cross border threats to health are addressed at EU level has led to a situation where Europe is better equipped to face an infectious disease outbreak of moderate risk than to address the public health consequences of a major incident from chemicals or biological agents e.g. caused by a criminal or terrorist act or as a result of a non-deliberate act or accident.

Therefore, 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.

In a more general strategic framework, the health security initiative will help implement the European Health Strategy⁵ and also contribute to the objectives of Europe 2020⁶ 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.⁷

The Health Security Initiative will appropriately take into account the EU external cooperation activities for health crises prevention and responses with third countries and explore synergies with the numerous bilateral EU assistance and cooperation programmes with a significant health component⁸.

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.⁹ 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:

1. 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.

⁵ 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

⁶ EU 2020- EU Strategy for smart, sustainable and inclusive growth; http://ec.europa.eu/europe2020/index_en.htm

⁷ See details in annex 7

⁸ See details in annex 7

⁹ See annex 1 for article 168 of the Lisbon Treaty

2. 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;
3. 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.¹⁰ In this context, the impact assessment will also elaborate on the status of the Health Security Committee¹¹ (HSC) and will look into ways to ensure effective communication.

2. PROCEDURAL ISSUES AND CONSULTATION OF THIRD PARTIES

Organisation and timing

An Impact Assessment Steering Group has been set up for inter-service coordination with the involvement of the Secretariat General, DG AGRI, BUDG, CLIMA, EAC, ECHO, EEAS, EMPL, ENER, ENTR, ENV, HOME, INFSO, JRC, JUST, MOVE, RTD, and TRADE. The steering group has met five times in 2011: on 25 January, 8 March, 18 May, 20 June and 1 September 2011.

2.1. Consultation and expertise¹²

Stakeholders were consulted on the health security initiative in various ways, via an open online consultation and in face to face meetings and audio-conferences.

The open stakeholder consultation on Health Security in the European Union took place between 4 March and 31 May 2011. 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.

In addition, separate meetings were held with the two main stakeholder groups in which representatives from Health Ministries discuss and coordinate health measures under the current regime: the Early Warning and Response System (EWRS) network points discussed the health security initiative in their meeting in February 2011 and the Health Security Committee (HSC)¹³ was consulted six times on the initiative; the European office of the World Health Organisation (WHO) is represented on both committees as an observer. In addition, bilateral meetings with six Member States were organised at their request and the initiative was also presented to the EU Health Policy Forum on 19 May 2011.

¹⁰ 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.

¹¹ The name of this body might be changed in the legal proposal.

¹² Further information related to the views of stakeholders as regards the actions described in the options is included in Chapter 7, policy options. The detailed analysis of the consultation is attached as Appendix 2 to this report.

¹³ See annex 2

The key outcome of these stakeholder consultations on health security in the EU is that a majority of stakeholders argue strongly in favour of having all serious cross-border health threats included in the EU health security policy. The public consultation results show broad support for strengthening EU public health response in the following three areas:

First, preparedness planning should address all serious cross-border health threats (i.e. communicable diseases as well as chemical, biological and environmental threats). The EU should play a central role in encouraging national preparedness planning and in coordinating national preparedness plans, for example in providing a framework to improve interoperability of national plans. Minimum core capacity standards should be set up on preparedness planning.

Second, risk assessment should take into consideration public health issues resulting from all serious cross-border threats; a better evaluation and an EU capacity to conduct risk assessment would provide added value to support decision makers with reliable, consistent and timely scientific expertise when preparing their policies and recommendations.

Third, risk management (including communication) should be improved for all serious cross-border health threats, including also cross-sectoral aspects of the health threat in order to improve implementation of measures and reduce delays in the response.

In this context, the Health Security Committee (HSC) is seen by national authorities as a valuable platform for public health risk management and communication of the risk of serious cross-border health threats. The strengthening of its status on a legal basis is also supported. In addition, and outside the scope of the stakeholder consultation, the European Parliament and the Council have expressed their views to review the current status of the Health Security Committee.¹⁴

Furthermore, the outcome of the open consultation process on "strengthening European Union Preparedness on Pandemic Influenza" conducted in 2010 was also considered with regard to the preparedness aspects in this impact assessment. In that consultation, more than 70% of all respondents agreed that, as regards procurement of pandemic vaccines, the joint procurement of such vaccines at EU level would be desirable, as it would help to ensure that all Member States have timely access to vaccines in a pandemic.¹⁵

In addition, and in relation to the procurement of medical countermeasures, especially the procurement of pandemic influenza vaccines and antivirals, the Commission – in response to an invitation by the Council¹⁶ – consulted experts nominated by the Health Security Committee to explore and elaborate a number of possible (joint) procurement procedures and analyse their advantages and disadvantages.

2.2. The Impact Assessment Board

On 5 October 2011 the Impact Assessment Board met to discuss the initiative on health security. In their overall opinion the board advised that the impact assessment should be strengthened in several respects.

¹⁴ European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI)); details in annex 3; e.g. in September 2010 Member States requested to "examine...options for the legal basis of the HSC" ...; in the Council Conclusions on 'Lessons learned from the A/H1N1 pandemic'- Health Security, http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/116489.pdf

¹⁵ See annex 2 of appendix 1

¹⁶ Council Conclusions on 'Lessons learned from the A/H1N1 pandemic'- Health Security: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/116489.pdf.

First, the report should provide a better description of the general context for this initiative, clearly describing the existing legal framework and the links with related EU mechanisms for disaster prevention and control. Second, the form of the proposed measures, legal or otherwise, that the Impact Assessment is intended to support should be much clearer. Third, the extent of the problem, particularly in terms of Member States' preparedness should be clarified and supported by more concrete evidence and examples. Fourth, the content and workings of the options should be better explained, particularly in relation to vaccine procurement. Fifth, the costs and benefits of the proposed measures should be elaborated, particularly in relation to potential price advantages, efficiency gains, and avoidance of duplication and administrative costs. A more concrete plan for monitoring and evaluation should be included.

Effort has been made to amend the report taking on board the comments from the board before, during and after the meeting of the board on 5 October 2011.

Further details have been provided on the policy by elaborating how the health security initiative will build on the existing EU mechanisms and strategies for disaster prevention and control and how existing gaps in public health risk management will be bridged. The content of options has been specified and the form of the proposed measures, legal or otherwise, has been clarified. Additional evidence has been provided to explain the extent of the problem, in particular as regards preparedness planning and business continuity. A graph has been added to the report as annex 18 that describes how joint vaccine procurement would work in practice. Particular attention has been paid to better explaining the financial implications and the administrative burden for the Commission and the Member States as the main stakeholders under this initiative. Efforts have been made to include a more concrete plan for monitoring and evaluation and to shorten the core document for the impact assessment.

3. POLICY CONTEXT IN THE AREA OF HEALTH SECURITY

3.1. The Health security initiative in the context of the European security and safety framework at European level

The EU has a series of policies, mechanism, instruments to cater for prevention and control of serious cross border threats in and develop capacities to manage crises¹⁷. 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 few¹⁸.

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. Last but not least, 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.

The health security initiative is part of the overall EU crisis and management framework referred to above. EU strategies and policies in the area of law enforcement and civil

¹⁷ See detailed information in annex 7

¹⁸ For further details, please see the "Inventory of Crisis Management Capacities in Commission and Agencies"

protection will be enhanced by the Health Security Initiative: the EU Internal Security Strategy makes specific reference to the health security initiative; chemical and biological security in the EU as set out in the CBRN action plan will also be strengthened and cooperation with the Monitoring Information Centre mechanism (MIG) in preparedness and response to civil disasters will also be intensified.

The Health Security Initiative is a key element of the Internal Security Strategy¹⁹ as it will contribute to reinforcing the coordination of EU risk management through strengthening the existing structures and mechanisms to tackle health threats. Thus, the Health Security Initiative will become part of a shared agenda for Member States, the European Parliament, the Council, the Commission, and European agencies to reinforce effective fight and prevention of serious and organised crime and terrorism and to strengthen resilience to natural and man-made disasters. It will be an important element in establishing a coherent risk management policy linking threat and risk assessments to decision making as envisaged by the EU Internal Security Strategy.

The Health Security Initiative is also linked to the overall European Programme for Critical Infrastructure Protection (EPCIP) framework on the identification and designation of European Critical Infrastructure and the assessment of the need to improve their protection²⁰.

To support the EU security framework and to protect citizens from serious cross border threats a series of alert, information and management systems, scientific committees and Agencies is already operating to ensure food and feed safety, plant health, medical products safety, consumer protection. Systems have been put in place to control chemical accidents, radiological events, border security and protection against crime and terrorisms.

In order to avoid overlaps with these existing disaster prevention and control structures in other sectors a gap analysis has been carried out.²¹ This analysis revealed that these mechanisms do not address cross border health threats preparedness and response in a sufficient manner. They can take action to take e.g. products from the market and to define the toxicity of chemicals; however, apart from the instruments in radiological protection they do not provide a satisfactory basis for decisions on public health measures for the population to be implemented in case of contamination or poisoning. The health security initiative will build on these existing instruments, intensify cooperation and strengthen cooperation by establishing standard operating procedures

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 programme²². It

¹⁹ See COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL: "The EU Internal Security Strategy in Action: Five steps towards a more secure Europe" Brussels, 22.11.2010 - COM(2010) 673 final

²⁰ COUNCIL DIRECTIVE 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection; <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:345:0075:0082:EN:PDF>, see chapter 4.2.1.1. for details;

²¹ See Gap analysis in appendix 3 on "Structures for preparedness and response to cross-border health threats

²² See annex 9 for details on projects funded under the health programmes

is planned that for important elements of the initiative, specific actions will be supported by the future Health programme²³.

3.2. The current public health security framework at European and International level

The EU has a well established policy and legal framework on communicable diseases and the main purpose of this Health Security Initiative is to extend the protection provided to European citizens also to serious cross border threats to health caused by biological, chemical and environmental threats.²⁴

In the area of communicable diseases, new diseases and threats such as SARS, avian influenza H5N1, pandemic influenza H1N1 and *E. coli* STEC O104 have emerged which are having a marked impact not only in the health sector but also in other sectors of society.

As regards other serious cross-border health threats, in the aftermath of the terrorist attacks in 2001, and in particular the deliberate release of Anthrax toxins in the US, the EU health ministers decided to set up the EU Health Security Committee (HSC)²⁵ as an informal structure for better coordination of public health risk assessment and management of other serious cross-border health threats in the EU. Initially the HSC mandate was limited to tackling bioterrorism; it has subsequently been extended to cover all types of public health-related crisis²⁶ and further prolonged²⁷.

²³ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020; COM(2011) 709 final, 2011/0339 (COD); http://ec.europa.eu/health/programme/policy/proposal2014_en.htm

²⁴ See description of the alerting, assessment and management aspects in annex 4; Reports on the operation of the EWRS are prepared annually, listing the events communicated through the system and coordination of measures undertaken http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm; Most recent examples of the use of the mechanism are the pandemic H1N1 event in 2009; http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2; and the *E. coli* STEC O104 outbreak in 2011; http://ec.europa.eu/food/food/coli_outbreak_germany_en.htm; As regards the events treated under the EU Health Security Committee, annual reports are also prepared, describing the main activities, including coordination of management of events; http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf Examples of recent activity of the Committee include management of pandemic H1N1 in 2009 and a multi state incident of anthrax contaminated heroin http://ec.europa.eu/health/preparedness_response/hsc/index_en.htm

²⁵ Presidency Conclusions of 15 November 2001 on bioterrorism: (<http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/01/415&format=HTML&aged=0&lg=es&guiLanguage=en>)

²⁶ Council Conclusions of 22 February 2007 on health security committee: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/92911.pdf

²⁷ Council conclusions of 13 September 2010 on lessons learned from A/H1N1 pandemic – health security in the European Union <http://register.consilium.europa.eu/pdf/en/10/st12/st12665.en10.pdf>; see further details in annex 2 and latest activity report: Commission staff working paper on the activities of the Health Security Committee during the period from November 2009 to December 2010, SEC(2011) 984 final; 22.7.2011

Other recent cross-border events with potential health implications for the EU have included volcanic ash clouds originating in Iceland, the 'red sludge' event in Hungary caused by a release of dangerous chemicals into the Danube and climate change more generally (e.g. heat waves and cold waves)²⁸ have been addressed by the HSC.²⁹

The legal basis for addressing communicable diseases and other serious cross-border health threats has been reinforced with the entry into force of the Lisbon Treaty³⁰ in December 2009. The new provisions state that the EU has been empowered in particular to perform the action of "monitoring, early warning of and combating serious cross-border threats to health". The EU can now, in addition, take measures. Under the previous article in the Treaty establishing the European Community (Article 152,4) it was only possible to provide for incentive measures³¹ or adoption of Council Recommendations³² to coordinate Member States' approaches.

In addition, at international level, the International Health Regulations (IHR), a legally-binding new framework for the coordination of the management of events that may constitute a public health emergency of international concern, cover all hazards including communicable diseases and other health threats.³³ They impose an obligation on each Member State to individually build core capacities for surveillance and response to all Public Health Emergencies of International Concern, as well as mechanisms for bilateral reporting and collaboration in information sharing between the WHO and the Member States concerned. Under the IHR, the WHO may issue recommendations on public health measures to be taken in certain conditions by Member States which can be inconsistent with public health measures undertaken under the EU legislation. For example during pandemic H1N1 the change in the pandemic phase was declared by the WHO without consultation with the EU despite the fact that EU pharmaceutical legislation requires such a signal to launch its fast track procedure for marketing authorisation of vaccines. Similarly, a possible recommendation regarding quarantine under the IHR could interfere with free movement within the EU if done without consultation at EU level.

Moreover, in several Council meetings, Health Ministers have repeatedly called for a review of the health security framework, including options for a legal basis of the Health Security Committee, the need for reviewed pandemic preparedness planning and a proposal for a mechanism for joint procurement of vaccines and antiviral medication³⁴. The European Parliament has also recently supported a proposal for strengthened health security at European level³⁵.

²⁸ The Commission has adopted in 2009 a White Paper on "Adapting to climate change: Towards a European framework for action" and a Commission Staff Working Paper on Human, Animal and Plant Health impacts of Climate change accompanying the White Paper on Adaptation <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0147:FIN:EN:PDF>; http://ec.europa.eu/health/ph_threats/climate/docs/com_2009-147_en.pdf

²⁹ See overview in annex 6

³⁰ See annex 1 and also http://europa.eu/lisbon_treaty/full_text/index_en.htm

³¹ such as support for projects under the health programmes

³² For example council recommendations on seasonal influenza vaccinations, antimicrobial resistance and nosocomial infections

³³ See annex 5; IHR entered into force on 15 June 2007 and require gradual implementation by 2016; <http://who.int/ihr/en/>

³⁴ See annex 3 for details on Council requests.

³⁵ European Parliament resolution of 8 march 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI));

It is against the background of these new developments and legal possibilities that the current EU policy framework on public health security can be reviewed.

3.3. Effects of serious cross-border health threats on society

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.

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

The Commission has also proposed an additional budget of EUR 15 million with the purpose of helping promotional programmes of professional organizations for fresh fruit and vegetables in the single market and in third countries.

These examples³⁶ also show that impacts on society, for example as regards free movement or economic losses and financial consequences, can be significant, in addition to their impact on the health of citizens.

This underlines the need for a multi-sectoral approach to public health emergencies and also shows that all types of serious cross-border threats to health need to be included in a comprehensive health security framework at EU level.

A further characteristic of today's crises is the strong involvement of the media, the growing influence of social media, and the fact that information is transmitted rapidly and is publicly accessible. Therefore communication has become an essential aspect of crisis management as national and EU level health authorities have to communicate effectively, rapidly, and in a transparent manner.

4. THE PROBLEMS AND THEIR CAUSES

4.1. Gaps in the existing health security framework at European level

In any health crisis situation the level of preparedness, the quality of risk assessment and the appropriate response are decisive in terms of coping with the situation³⁷. Member States are in charge of preparedness planning, crisis management and of the organisation of response and recovery at national level. However, cross-border events need to be addressed in a coordinated manner at EU level in order to contain and mitigate the health danger for citizens and ensure that public health consequences are properly managed.

The different types of serious cross-border threats to health are not treated in a consistent manner at EU level. Threats emerging from biological, chemical and environmental events are not addressed in the same way as those from communicable diseases.

For serious cross-border health threats arising from communicable diseases,³⁸ the Member States, the Commission and the scientific EU agencies can build on formal structures and mechanisms at EU level that have proved their effectiveness for more than a decade³⁹.

Communicable diseases are notified on a daily basis via the EWRS system, from June 2007 to July 2011 785 cases of communicable diseases with a cross border implications were notified. Given the EU tailor made application of the system more notification are alerted than under the International Health Regulations⁴⁰

³⁶ Further examples are provided in annex 6

³⁷ See Glossary in Appendix 1 for further explanation

³⁸ See annex 4 for description of existing legal framework for communicable diseases, Decision 2119/98 and ECDC founding regulation.

³⁹ See details on the functioning of the system and examples in the information box under 3.1.

⁴⁰ See information in annex 11

However, there is currently no structure, operational tool or procedure that enables joint actions between Member States in order to ensure equitable access to medical counter-measures.

There are also other serious cross-border threats to health emerging from biological, chemical and environmental events, which cannot be addressed due to the lack of an EU legal framework.

Cross border threats to health caused by chemical, biological and environmental events are not reported as often as communicable diseases⁴¹. Based on IHR notifications we can expect on average 5-6 such events per year⁴². Under EU tailor made criteria for these incidents the threats notified - based on experience with alerts for communicable diseases - could amount to 20 -25 per year. The frequency of such events is likely to increase due to increases in global travel and trade, climate change and latent risk of criminal and terrorist attacks.

There is no possibility for a coordinated response with dedicated public health follow up measures or agreements on prophylaxis and treatment in order to protect the health of the EU citizens affected by those events. At EU level these types of crises are dealt with – as far as public health is concerned - on a case by case and ad-hoc basis⁴³.

There are structures in place at national, EU and international level which cover some aspects of preparedness, risk monitoring, risk assessment and risk management for serious cross-border threats which may also have public health consequences, e.g. in the field of food and feed safety, animal health, border security and chemical accidents. An internal analysis⁴⁴ carried out by Commission's services to support this impact assessment indicates that these structures do not systematically address comprehensive health protection of the population; nor do they cover specific public health measures that might be necessary in order to respond to risks and/or to the follow-up of events.

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

The current situation therefore does not make fully use of the new competences given to the EU under the Lisbon treaty i.e. to allow the European Parliament and the Council to adopt measures designed to protect and improve human health.

4.2. The problems in addressing serious cross-border health threats at EU level⁴⁵

The following chapters will describe in more detail the problems related to preparedness, risk assessment and risk management at European level, in particular:

- insufficient and inconsistent preparedness and response planning between EU Member States for all types of serious cross-border health threats;

⁴¹ This lesser frequency may, at least partially, be due to different monitoring and lack of detection tools.

⁴² See information in annex 11

⁴³ e.g. the event of anthrax contaminated heroine in 2010 necessitated support from Europol and EMCDDA

⁴⁴ See details in appendix 3: structures for preparedness and response to cross-border health threats "

⁴⁵ Problems and public health consequences are illustrated in annex 12.

- gaps and inconsistencies in mechanisms for public health risk monitoring and risk assessment of chemical, biological (other than communicable diseases) and environmental threats;
- insufficient and weak public health risk management measures and mechanisms to address biological (other than communicable diseases), chemical, and environmental threats and weak risk communication procedures;

4.2.1. Insufficient and inconsistent preparedness and response planning between EU Member States for all types of serious cross-border health threats

4.2.1.1. State of play

The level of preparedness, the types of threats covered the approaches on inter-sectoral preparedness and the minimum standards applied across Member States differ because this planning is currently conducted on a voluntary basis at EU level. There is an obligation for Member States to develop and implement core capacity requirements under the International Health Regulations (IHR), but there is no common EU approach to these requirements and no EU specific criteria given that the EU is not a contracting party to the IHR. Therefore, Member States are under no obligation to implement the IHR standards in a manner that is compatible at EU level or to inform the Commission and other Member States of their state of preparedness.

Public health depends strongly on a number of critical sectors such as energy, transport, tele-communication, water and finance.

Hospitals for example cannot function properly if electricity fails or if doctors are unable to proceed to work due to the break down of public transport. On the other hand, essential public services such as water or energy supply may not work because a large number of staff falls sick.

The World Health Organization (WHO) has addressed the need for improved coordination of such critical sectors under the "whole society approach"⁴⁶.

Health is also an element of the overall European Programme for Critical Infrastructure Protection (EPCIP) framework. On 8 December 2008 the Council adopted Directive 2008/114/EC⁴⁷ on the identification and designation of European Critical Infrastructure and the assessment of the need to improve their protection.

In the area of communicable diseases, preparedness planning exists in particular for pandemic influenza⁴⁸. However, it is not known to what extent sectors other than health

⁴⁶ WHO, Whole-of-society pandemic readiness - WHO guidelines for pandemic preparedness and response in the non health Sector, Geneva, July 2009, 18 available on line:http://www.who.int/influenza/preparedness/pandemic/2009-0808_wos_pandemic_readiness_final.pdf; Detailed information is provided in annex 8.

⁴⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:345:0075:0082:EN:PDF>

⁴⁸ At international level WHO has developed a pandemic influenza preparedness plan. The Commission has developed in 2005 a set of communications establishing the EU Pandemic Influenza Preparedness and Response Plan and Member States also have arrangements in place. However workshops undertaken by ECDC and WHO-Europe with the Commission in September 2011 revealed that most countries had found their pandemic plans wanting in the 2009 pandemic and they were now updating and strengthening their plans and preparedness accordingly. WHO is

have integrated pandemic preparedness in their business continuity plans. There are also variations at national level in terms of implementation of the preparedness plans. Examples of studies at EU and international level on the state of the art of pandemic preparedness planning, in particular on business continuity planning, are summarised in annex 8⁴⁹.

As regards generic preparedness, the Commission has published the "Strategy for Generic Preparedness Planning, Technical guidance on generic preparedness planning for public health emergencies"⁵⁰ for all types of health threats. However, there is no mechanism in place to ensure its implementation in all Member States.

4.2.1.2. The problems, drivers and consequences

Discrepancies in the level of preparedness planning across the EU lead to incoherent strategies, divergent standards, inconsistent procedures and methodologies. Member States are differently equipped to respond to threats as regards, for example, laboratory infrastructure needed for the diagnosis of cases, or availability of staff. In addition, not all critical sectors in society are sufficiently prepared for an emergency which might have an impact on public health or vice versa⁵¹. Lower levels of preparation in the Member States affected and in critical sectors will weaken and delay the EU response capacity and negatively impact the situation in other Member States.

These different levels of preparedness in the Member States may lead to unequal treatment and access to medical care for citizens, endanger activities intended to ensure the containment and mitigation of a public health incident and, importantly, potentially lead to an increase in mortality and morbidity rates at EU level if a major incident of a cross-border nature were to hit the EU.

Without coordination at EU level, public health measures will not be supported by established procedures and mechanisms, but managed on an ad hoc basis by individual Member States, at best following advice provided by the Health Security Committee. Member States may e.g. adopt different mutually counterproductive measures, e.g. related to border closure, impose quarantine, or issue divergent travel advice. The result will be crisis management at EU level that is ineffective and inefficient; public trust in national authorities and in those EU institutions with public health responsibilities will be undermined and, lastly, there may be important repercussions on other EU policies (free movement of persons and products, energy, transport).

not planning to update its plans in the immediate future and therefore it is important that collective EU action is taken to prevent EU Member State plans diverging.

⁴⁹ The European Centre for Disease Prevention and Control (ECDC) has facilitated systematic self assessments of pandemic preparedness in the Member States. In order to facilitate sharing of sensitive information, Member States have agreed to the terms of reference for these studies on the basis of the understanding that only aggregated data would be published and that Member States would not be identified.

⁵⁰ Commission Communication on strengthening coordination on generic preparedness planning for public health emergencies at EU level of 28 November 2005 (COM(2005) 605 final): http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0605en01.pdf; http://ec.europa.eu/health/preparedness_response/docs/gpp_technical_guidance_document_april2011.pdf

⁵¹ See annex 8 for further details

Public health measures taken during a pandemic have the potential to cause unintended adverse effects on other parts of society and the economy. This may result from restrictions on daily activity, for example as a result of a social distancing policy such that schools, business and government offices close for a period of time in an effort to reduce transmission, and the cancellation of mass gatherings.

Therefore increased multi-sectoral preparedness, i.e. preparedness not only of the health sector but also of other critical sectors in society such as energy, transport, ICT, just to name a few, is needed both to support the public health response and to mitigate the overall effect of the pandemic on society.

As regards procurement of medical countermeasures – in particular when demand outstrips supply – individual procurement increases the competition between Member States. Contractual confidentiality clauses imposed by suppliers prevent the pooling of expertise and exchange of best practices, thereby considerably weakening the purchasing power of the Member States and creating unfavourable contractual conditions. Together with restrictions in health budgets, such conditions may cause some Member States to procure an insufficient amount of medical countermeasures. This considerably weakens the EU's preparedness against serious cross-border threats to health, as Europe's preparedness is only as strong as its weakest link.

4.2.1.3. Examples illustrating the problems – lessons learnt from pandemic (H1N1)2009

The management of Pandemic Influenza H1N1 was thoroughly evaluated⁵².

Lessons learnt at EU level and key messages endorsed by the Health Security Committee include the following⁵³: Member States, the Commission and EU Agencies continue to 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.

Non-equitable access to pandemic influenza vaccines during the H1N1(2009) pandemic was due to weak purchasing power of Member States⁵⁴.

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

⁵² http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/pandemic_2009_evaluations/Pages/pandemic_2009_evaluations.aspx provides an overview of all evaluations on H1N1

⁵³ 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;

⁵⁴ Assessment report on EU wide pandemic vaccine strategies of 25.8.2010
http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf

different dates across the EU countries. 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.

The procurement of pandemic influenza vaccines is challenging for a number of reasons that characterise this specific market: Pandemic influenza vaccines cannot be manufactured / stockpiled in advance of a pandemic, because the specific virus is needed for the production of the antigen in the vaccine. Pandemic influenza vaccines are usually manufactured using the same facilities as for seasonal influenza vaccines. The production capacity of these facilities is much lower than the global demand for pandemic influenza vaccines during a pandemic. The pandemic influenza market is characterised by scarce competition, as only few vaccine manufacturers (usually with long-standing expertise in the manufacture of seasonal influenza vaccines) have the capacity and expertise to offer a pandemic influenza vaccine with a valid marketing authorisation when a pandemic emerges

As a result, 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 evaluation⁵⁵ 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 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.

Finally, the report of the European Parliament on evaluation of the management of H1N1 influenza 2009-2010⁵⁶ highlights major differences between the preparedness of EU Member States, and the lack of genuine cooperation weakened the EU's overall preparedness. The lack of a solidarity and brokerage mechanism between Member States and the absence of prior purchase agreements in several Member States were the main factors undermining the EU's better preparedness.

4.2.2. Gaps and inconsistencies in mechanisms for public health risk monitoring and risk assessment of biological (other than communicable diseases), chemical, and environmental threats

4.2.2.1. State of play

Risk monitoring and assessment for communicable diseases is well established at European level. Decision 2119/98/EC established the epidemiological surveillance system, and the European Centre for Disease Prevention and Control (ECDC) provides robust, reliable and scientific assessment for communicable diseases.

⁵⁵ http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf

⁵⁶ Report of the European Parliament on evaluation of management of H1N1 influenza 2009-2010 <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2011-0035+0+DOC+PDF+V0//EN&language=EN>

As regards other serious cross-border threats at EU level, there are a number of agencies, networks and structures which address monitoring and identification of serious cross-border health threats, including reporting and risk assessment⁵⁷.

To inform this impact assessment, an analysis has been performed to review which of the structures touch on public health and could provide for public health risk assessment.⁵⁸ However, the outcome of this analysis and the feedback from other Commission services participating in the inter service steering group indicate that these structures address primarily safety or quality aspects (e.g. related to chemical or environmental risks, or consumer safety). They do not address public health protection in a systematic and comprehensive manner. Moreover, they also do not provide options for specific public health measures that might be necessary to manage risks and to ensure an effective follow-up of events. In addition, many of the structures are operated without informing or linking with authorities and agencies responsible for public health in the Member States or at EU level.

At international level, the threat notification and risk assessment is conducted through the International Health Regulations on a bilateral basis between WHO and individual Member States. Risk assessment is not exhaustive from the public health perspective (additional information is missing, such as means of treatment for humans, clinical and laboratory detection criteria, etc.). Obviously the lack of coordination at EU level may endanger a quick and appropriate response to the threat. Risk assessment tools have been established by the Commission to address these gaps and to monitor the public health consequences of threats other than communicable diseases (e.g. RAS-CHEM). However, there are no sustainable resources in Member States to operate these systems and the activities are voluntary in nature.

4.2.2.2. The problems, drivers and consequences

Although there are a variety of notification and alert systems in place for different threats at EU level, these are not systematically linked to EU public health authorities. Notifications by Member States under the International Health Regulations cover all serious cross-border threats to health, but the criteria for such notifications are not necessarily appropriate for the EU level, given the existence of a common external border, freedom of movement and common policies. There are no criteria and no similar notification obligations at EU level, and this leads to a lack of awareness about potential threats to public health.

National risk assessments exist, but they may not be consistent when considered from the EU perspective, and there is currently no well established mechanism for a coordinated approach at EU level. The lack of public health risk assessment at EU level leads to discrepancies in the evaluation of the danger level of a given threat, duplication of assessments between Member States and inconsistent interventions at EU level. In addition, such a situation can also lead to inefficient use of the limited resources currently available and may delay appropriate public health measures, which could put at risk the overall response at EU level. Ultimately, the negative impact of this situation might result in higher levels of morbidity and mortality, i.e. more people fall sick or will die. It may also endanger common EU policies owing to the impact of health effects on

⁵⁷ For detailed information see annex 7

⁵⁸ See appendix 3: structures for preparedness and response to cross-border health threats

other critical sectors of the economy and society (e.g. breakdown of the transport or energy sectors).

Importantly, any evaluation of risks which is not comprehensive or is inappropriate may lead to unclear communication and may undermine public confidence in the measures proposed or taken by public health authorities.

4.2.2.3. Examples illustrating the problems

Insufficient notification of threats at EU level

Potential events involving biological agents are not addressed robustly at EU level. Toxins, such as Ricin⁵⁹, are not covered by any notification system.⁶⁰

Unavailability of rapid risk assessment

*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 2008.⁶¹ 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 symptoms⁶².*

⁵⁹ <http://www.bmj.com/content/326/7381/126.1.full>

⁶⁰ http://www.health.state.ny.us/environmental/emergency/chemical_terrorism/ricin.htm
<http://bioterrereurope.wikispaces.com/file/view/Biological+Weapons+and+Bioterrorism+Preparedness%3A+Importance+of+Public+Heath+Awareness+and+International+Cooperation;>
<http://www.ndma.gov.pk/Docs/BioTerrorismGuideINTERPOL.pdf>; <http://catalogue.sipri.org/cgi-bin/koha/opac-detail.pl?biblionumber=75917>

⁶¹ 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.

⁶² http://ec.europa.eu/health/preparedness_response/docs/iridium_1_2011_frep_en.pdf

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.

4.2.3. Insufficient and weak public health risk management measures and mechanisms to address biological, chemical, and environmental threats and weak risk communication procedures

4.2.3.1. State of play

The Health Security Committee (HSC) is currently the structure at EU level which manages serious cross-border health threats. In terms of preparedness, the HSC's mandate provides a platform for the informal sharing of information and experience on preparedness and crisis management strategies, advising Health Ministers and the European Commission on preparedness and response planning and also coordinating emergency planning at the EU level. In a public health crisis, the HSC can be used to coordinate crisis responses by Member States and the Commission. Under the HSC a network of communicators from the Member States and the Commission share information about their messages to the general public. The HSC also facilitates and supports coordination and cooperation efforts generally on health security, as well as initiatives at EU and international level, and it helps contribute to the implementation of these initiatives at national level. The public health authorities in the Member States are represented in this Committee at the level of middle management. The Commission provides the secretariat of the Health Security Committee and chairs the meetings. The Commission can prepare and table recommendations and advice, but does not propose any measures.

Given the informal status of the Health Security Committee, the involvement and commitment of Member States is voluntary. Agreed positions are difficult to achieve and, even if they are issued, Member States are not obliged to take them into consideration in their public health response in a crisis situation. As the HSC does not have a formal footing, there are no mechanisms in place to ensure that all Member States comply with the HSC's advice. This relative weakness has also led in recent years to a development whereby the level of attendance by some Member States has been at a technical rather than a strategic level. Furthermore, the HSC has neither the authority nor the mandate to effectively coordinate risk management at EU level and with all Member States.

At international level the International Health Regulation (IHR) covers the risk management of public health emergencies of international concern independently of the nature and origin of the threat. The IHR does not take into account the "acquis communautaire". If the threat is serious enough, its action may include restrictions on the free movement of goods and persons, border controls, travel restrictions, and limiting of personal freedom (quarantine).

Finally, the information sharing process related to the event is dealt with by Member States and WHO bilaterally, thereby excluding other Member States and the Commission from the process.

4.2.3.2. The problems, drivers and consequences

Serious cross-border health threats are unavoidable and can have a major consequence both on health and on other sectors of society and the economy (see annex 6). It is the competence of Member States to manage their health services and address health crises at national level. However, the mechanisms for risk management at EU level are inadequate and there is an absence of clear mandates, responsibilities and defined scope for decision making on the public health response.

This leads to insufficient coordination of the public health response and no cross-sectoral interlinking for decision making processes in public health. Even agreements on minimum common denominators are difficult to reach, with the risk of delays in the response to the health emergency and in implementing measures.⁶³

Although a network of communicators has been established under the HSC, the lack of a formal mechanism for agreeing consistent messages to the public and target populations does not allow an efficient information process at EU level and undermines the trust and credibility in the public health response to chemical, biological (other than communicable diseases) and environmental threats.

4.2.3.3. Examples illustrating the problems

Lack of coordination of public health measures

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 coverage⁶⁴, on travel advice⁶⁵ and on school closures⁶⁶ 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.⁶⁷

*There was also 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.*

Insufficient linkage of public health risk and crisis management across sectors - examples

*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).*

⁶³ E.g. in 2009 it took several weeks in 2009 to get agreement in the Health Security Committee on common statements relating to vaccination, travel advice and school closures:
http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2

⁶⁴ 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

⁶⁵ 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

⁶⁶ HSC/EWRS statement on School closures, 13 August 2009:

http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_school_en.pdf

⁶⁷ http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf

*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).*

Weak communication strategies

*There were difficulties in communicating with health professionals and the public on the need for pandemic vaccination in the 2009 **H1N1 pandemic**.⁶⁸*

*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.*

4.3. Baseline scenario

The situation as described in chapter 4.2. would continue and no substantial improvements to the way in which serious cross-border threats to health are addressed across the EU can be expected. The provisions of Article 168 TFEU would not be implemented in respect of monitoring, early warning of and combating serious cross-border threats to health, and no additional measures at EU level would be taken. Nonetheless, the baseline scenario is considered as an option and the detailed impacts of this scenario will therefore be thoroughly analysed under option 1.

4.3.1. Preparedness and response planning

As there is currently no commitment in place for Member States to implement coherent preparedness planning, the situation across the EU would remain as varied and multi-layered as it is now. This means that it would be impossible to ensure a coherent and efficient public health response to serious cross-border health threats at EU level.

There would be no guarantee that in a serious cross-border public health event Member States would have an equitable supply of medical countermeasures at affordable prices and under equitable contract conditions. This would lead to putting particularly vulnerable groups, such as children and persons with underlying chronic conditions, at risk of infection.

In the absence of an improved coordination of EU preparedness, there would be no proper linkage between the International Health Regulations (IHR) and the way in which serious cross-border threats to health are addressed in the EU. This would represent a risk to public health management at EU level given the differing and inconsistent implementation by Member States of minimum core capacities for surveillance of and response to public health emergencies of international concern.

4.3.2. Risk monitoring and assessment

The present gaps in risk assessment for serious cross-border health threats of chemical, biological (other than communicable disease), or environmental origin would persist. Coordination of risk assessments between different sectors, and with Member States, would not take place. In this situation, no comprehensive and coherent evaluation of

⁶⁸ http://ec.europa.eu/health/communicable_diseases/docs/assessment_response_en.pdf (chapter 12)

public health risks could be assured, and serious detrimental effects on morbidity and mortality would be likely to result.

4.3.3. Risk management and crisis communication

At EU level, cooperation in the Health Security Committee on the follow up of public health consequences of serious cross-border health threats would continue to be based on informal and ad hoc grounds. The consequence of this would be an ongoing likelihood that minimum consensus on risk management would not be reached and that the responses of Member States would be inconsistent or incoherent at EU level. The system would remain voluntary in nature with no legal obligations for coordination of public health risk management. Hence, existing shortcomings would not be addressed.

Collective agreement between Member States on shared communication activities would remain very difficult to reach. Conflicting messages may lead to a lack of trust in public health measures, undermine the acceptance of such measures by the public, jeopardize confidence in the competence of public health authorities, and endanger the efficient management of an event.

5. THE RIGHT OF THE UNION TO ACT – SUBSIDIARITY TEST

5.1. Justification of public intervention

With the entry into force of the Lisbon Treaty, the EU has been empowered to support, coordinate or supplement the action of Member States in the area of protection and improvement of human health (Article 6a TFEU). The Treaty states that EU action shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health, and in particular "monitoring, early warning of and combating serious cross-border threats to health" (Article 168 TFEU).

There is a discrepancy between the fundamental goal of the EU to ensure a high level of human health protection and the existing situation, which does not guarantee such a high level in the event of serious cross-border threats to health.

In addition, there is a need to avoid market failures, in particular to ensure that appropriate linkages are established between preparedness for the health sector and for other sectors which may be affected in an event and vice versa, and to ensure that operation of the internal market and common EU policies such as the maintenance of essential services, and circulation and availability of essential goods, are assured. Furthermore, imperfect information flows regarding health crises may endanger the decision making process and therefore endanger public health, while at the same time undermining the continuity of the internal market.

5.2. Compliance with the principles of conferral and subsidiarity

5.2.1. Principle of conferral

In the area of protection and improvement of human health, the EU acts within the limits of its competences laid down in the Treaties by supporting, coordinating or

supplementing the actions of Member States, without superseding their competences in the area of public health (Articles 2.5 and 6a TFEU)⁶⁹.

EU action shall encourage cooperation between the Member States and, if necessary, lend support to their action, while fully respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care (Article 168 TFEU).

Finally, as regards the cross-sectoral dimension of public health matters, the EU should take into account requirements linked to the promotion of a high level of protection of human health while defining and implementing its policies and activities (Article 9 TFEU and Article 35 of the Charter of Fundamental Rights of the European Union).

5.2.2. Principle of subsidiarity

Subsidiarity is respected because the action of "monitoring, early warning of, and combating serious cross-border threats to health" cannot be undertaken by individual Member States alone and therefore needs to be addressed at EU level. The subsidiary principle has two aspects: the necessity test and the EU added value test; both are described below.

5.2.2.1. Necessity test

'Serious cross-border threats to health' and 'public health emergencies of international concern', by their nature, have trans-national implications (such as the need for coherent preparedness planning, or adequate risk assessment and risk management procedures) which Member States cannot satisfactorily achieve individually. 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 comparable and coordinated to contain further spread and minimise the consequences. Less prepared Member States and critical sectors will weaken and delay the EU response capacity and negatively impact the situation in other Member States. In addition, the lack of co-ordination could result in disproportionate measures that could disrupt the internal market considerably.

Dealing with the potential public health consequences across Member States, therefore, necessitates coordinated action at EU level to ensure that all citizens independent from their origin or residence can benefit from a high level of health protection. The system in place at European level for public health crisis management is not sufficient as explained under the baseline scenario; it is poorly coordinated by the existing systems in place and based on weak and voluntary grounds. In addition, there is no appropriate link to associate cross border crisis management with international requests and obligations under the International Health Regulations.

This weakness related to coordinated EU action for monitoring, early warning and combating of serious cross-border threats to health is in conflict with the fundamental goals of the Treaty to ensure a high level of human health protection.

⁶⁹ With the exception of the common safety concerns in the public health matters for the aspects defined in Article 168(4) TFEU, which follow under shared competence between the EU and the Member States (see Article 4(2) (k) TFEU).

In addition, actions undertaken by one Member State alone may significantly damage the interests of other Member States (e.g. distortion or disruption of the internal market, limitations on equal access to medical countermeasures, restrictions on freedom of persons, interruption of trade and critical services such as transport, information technologies, health care, energy, banking). Consultation at EU level before adoption of public health measures at national level would avoid negative impacts on health sectors and other crucial sectors in the different Member States.

5.2.2.2. Test of EU added value

In addition to the cross-border aspects of such threats, they often affect crucial sectors of the economy and society. Many of these sectors are of exclusive or shared EU competence and therefore require the involvement of different stakeholders, namely the Commission, EU Agencies and national competent authorities. For instance, under the exclusive competence of the EU a health emergency may affect the sustainability of customs activities at the external frontier, impact competition policy by excluding economic operators and disrupt the operation of commercial policy.⁷⁰ Under shared competence a number of events⁷¹ provide clear examples that health emergencies can impact on the transport sector, agriculture, environment, energy, internal market and freedom and security and common safety concerns in public health matters (food safety, pharmaceuticals, etc.).

The EU already has sound experience of coordination in the field of communicable diseases, which are governed by comprehensive EU legislation and which has proved essential in handling serious outbreaks in Europe⁷². This health security initiative will build on these positive experiences, existing systems and lessons learnt to ensure that the citizens have equal protection from all health hazards.

The present initiative will improve coordination at all levels for addressing serious cross-border health threats, thus providing added value across the EU.

The preparedness of the Member States will be strengthened by establishing common procedures and shared standards, sharing of resources, and improving the exchange of expertise and information.

Capacities for rapid and efficient response will be reinforced and effective containment and mitigation of serious cross-border health threat incidents will be ensured.

Access to and availability of medical countermeasures will be better balanced between Member States.

Overall strengthened co-ordination at EU level will lead to a coherent and comprehensive approach on risk assessment and management, thus contributing to a decrease in the public health burden.

⁷⁰ In the aftermath of the 9/11 terrorist attack in the USA, the Anthrax scare undermined the availability of the antibiotic ciprofloxacin. During the SARS event, tourist and transportation industries have been heavily impacted by the restriction of movements on a global level.

⁷¹ See examples: *E. coli* STEC O104, Volcano ash, red sludge, SARS

⁷² See further details on EWRS in annex 4

Since not all Member States have the same level of preparedness, risk assessment and crisis management facilities⁷³ there is benefit from the exchange of expertise thereby strengthening the solidarity within the EU. Solidarity between countries can also be enhanced by sharing scarce medical resources in a crisis situation such as a pandemic.

As health security is a global issue, this initiative will provide EU Member States with a coordination opportunity as regards the implementation of the IHR, where relations are established only between individual states and the World Health Organization.

5.2.3. Principle of proportionality and choice of instrument

The scope of action is limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can provide added value.

The financial or administrative costs for the Union, national governments, regional or local authorities, economic operators or citizens will depend on the chosen option.

EU action leaves as much scope as possible for national decision making, while achieving satisfactorily the objectives set out for this initiative. EU action is without prejudice to the decision-making process in place at national level and is related to the monitoring, early warning and combating of serious cross-border threats to health. The aim of EU action is to better coordinate such measures. It fully respects the responsibilities of the Member States to define their health policy and for the organisation and delivery of health services and medical care.

As such, the stakeholder consultation reflected strong support for EU intervention at this level. In addition, an assessment has recently been carried out to ensure that the measures proposed in this initiative will serve to complement existing EU measures already in place.⁷⁴

The choice of the appropriate EU instrument is guided by the need to satisfactorily fulfil the Treaty obligation of protecting citizens against health threats and thus achieve the objectives of the initiative. In addition, the EU action excludes any harmonisation of the laws and regulations of Member States.

The reason for choosing a legislative instrument according to the ordinary legislative procedure is to achieve a consistent, coherent and comprehensive long term solution for improving health security related to all cross border health threats and to reproduce the positive experience gained using Decision 2119/98 for communicable diseases. Only a legal solution would also guarantee the commitment of all Member States to prepare for and respond to health threats in an equal manner. In addition, a legislative instrument is needed in order to provide EU level coordination for setting up a joint procurement of medical countermeasures.

⁷³ http://ecdc.europa.eu/en/publications/Publications/0701_TER_Pandemic_Influenza_Preparedness.pdf

⁷⁴ See appendix 3: structures for preparedness and response to cross-border health threats

6. POLICY OBJECTIVES

6.1. General objectives

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

6.2. Specific objectives

The specific objective of this initiative is to reinforce the response to *all* serious cross-border threats to health⁷⁵ based on a comprehensive and coherent approach to preparedness and response planning, risks monitoring and assessment, and risk management including risk communication.

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 among Member States. This includes improving equitable access to medical countermeasures (e.g. pandemic influenza vaccines).

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

In the area of risk management the specific objective is to create the necessary conditions to strengthen and enhance coordination among Member States, international bodies and the Commission in order to ensure a coherent and consistent policy approach to effectively manage responses to serious cross-border health threats across the EU.

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.

6.3. Operational objectives⁷⁶

In the area of preparedness and response planning the operational objectives are:

- to develop and update comparable and coherent generic preparedness and response planning and planning for *all* threats at EU level, in particular for pandemic influenza. This should ensure that critical sectors of society are also

⁷⁵ other than those associated with radio nuclear events

⁷⁶ Objectives should be specific, measurable, achievable, realistic and timed (SMART); the operational objectives listed are specific and measurable in numbers of preparedness plans, agreements etc. They are also realistic to achieve – this has been demonstrated by the framework on communicable diseases where events arise more frequently than in the area of health threats caused by chemical, biological or environmental events. Related to the timeframe for implementation the objectives should be achieved three years after adoption of the proposal.

prepared to cope with such health risks and that structures and mechanisms are in place to enhance the interoperability and coherence of policies at EU and national level;

- to develop and agree shared standards and tailor-made EU criteria for notifying threats in order to ensure stronger, continued and resilient operation of the health sector for the European Union, based on the requirements laid down by the International Health Regulations⁷⁷.
- to create an instrument to strengthen the Member States' purchasing power and to improve equitable access to medical countermeasures, e.g. via a joint procurement mechanism in which Member States can participate on a voluntary basis.

In the area of risk monitoring and risk assessment the operational objectives are:

- to strengthen, better interlink and ensure the sustainability of existing monitoring and notification mechanisms and structures;
- to strengthen and create capacities for robust, reliable, and rapidly available public health risk assessment;
- to provide mechanisms for reinforced coordination among existing structures for threats arising in policy areas other than for communicable diseases which have serious cross-border consequences for health;

In the area of risk management and crisis communication the operational objectives are:

- to strengthen the capacities and processes for and establish a sustainable structure for coordinating the public health response at EU level for any cross-border public health crisis;
- to clearly define the scope of the activities of this structure/body and give it a strong mandate for EU risk management, plus a strong commitment from Member States;
- to strengthen measures related to communication on health threats, and provide for rapid exchange and agreement on communication messages and strategies;

7. POLICY OPTIONS⁷⁸

In order to cover all aspects of crisis management in a coherent framework, each of the options presented includes solutions for preparedness and response planning, risk monitoring, assessment and management.

The actions identified in each option vary according to the level of implementation of preparedness planning and core capacity requirements and the level of obligation for implementation by the Member States, the informal or formal nature of the expertise

⁷⁷ See information as regards the International Health Regulations (IHR) in annex 5.

⁷⁸ An overview of the actions proposed under the three options can be found in annex 13.

provided for risk assessment, and the power conferred on the EU with regard to risk management:

- Option 1 (the status quo) envisages no additional action and corresponds to the baseline scenario.
- Option 2 comprises additional action based on soft instruments, in particular. Council recommendations to ensure the involvement of the Member States and closer cooperation between existing structures and systems. There are no legally binding measures under this option.
- Option 3 proposes a legal framework that lays down binding measures for Member States as regards preparedness planning, provides a legal basis for voluntary measures and implements a robust structure for crisis management. This option seeks to amend the existing Council and European Parliament Decision on communicable diseases and extend it to serious cross border health threats caused by biological (other than communicable diseases), chemical or environmental events. The provisions for risk assessment under this option are not included in the legal framework as they also build on closer cooperation between existing structures and systems and are intended to cover existing gaps in these areas.

7.1. Option 1: Status quo / baseline scenario: Maintain the current level of activities

Preparedness and response planning

On preparedness the Commission would continue the technical level work with the Member States described where appropriate in staff working documents or communications: updating and facilitating the implementation of existing guidance as regards generic and pandemic preparedness. Surveys and development of indicators would be supported. Organising of exercises and training⁷⁹ where public health crises are simulated, and exchange of best practice would continue.

To improve equitable access to medical countermeasures, the Commission would continue to support Member States' cooperation, e.g. in helping Member States prepare their national tender specifications for vaccine procurement.

The Commission would also continue to promote improved production capacity, for instance through improved vaccination coverage for seasonal influenza, which could influence capacity building for the production of pandemic influenza vaccine.

Risk monitoring and assessment

The EU would continue to work with the existing voluntary based notification and monitoring mechanisms and structures without strengthening coordination among the policy areas concerned. Communicable diseases would remain under the existing legal framework. Risk assessment related to serious cross-border health threats arising from threats caused by biological (other than communicable diseases as these are covered

⁷⁹ Using as presently funds from the EU Health Programme

already by a legal framework), chemical,) and environmental events would be delivered on the basis of ad hoc support networks as the ECDC has no mandate for risk assessment for threats other than communicable diseases.

Risk management and crises communication

The mandate of the Health Security Committee under the Council conclusions of 22 February 2007⁸⁰, as prolonged by the Council conclusions of 13 September 2010, would be maintained and the Council would be the EU institution which would prolong its mandate, as in the current situation. The HSC would remain an informal body and the commitment of Member States would be maintained at the current level.

The informal HSC communicator's network would continue to facilitate the exchange of information during a crisis and continue to share information on an ad-hoc and voluntary basis.

7.2. 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 – no legally binding measures

The essential change in comparison to option 1 consists in **a.** improved and better coordinated preparedness and response planning based on common criteria between the Member States and in relation to IHR; **b.** improved, more sustainable and structured cooperation between existing systems for health emergencies caused by biological, chemical, or environmental events; **c.** clarification of the roles of existing management bodies, in particular the EWRS network⁸¹ and the HSC⁸². Action under this option would mainly be built on soft instruments such as guidance, Commission Communications and Council Recommendations; it would rely on improved cooperation between existing systems and additional commitment of Member States by strongly using the instrument of Council Recommendations to address necessary changes; however, the actions under this option would still require cooperation of Member States on a voluntary basis even with the formal support of the Council; they would not be legally binding for Member States.

Preparedness and response planning

The Commission would propose to the Member States a shared approach on generic and specific preparedness planning, including for pandemic influenza. This approach would be non-binding and voluntary for the Member States.

This would include identification of EU core capacity standards related to surveillance, notification, verification, response and collaboration activities building on and strengthening requirements under IHR.

The Commission would provide guidance on improved cross-sectoral preparedness and interoperability and continue to encourage exchange of best practice through seminars and workshops and provide incentive measures via the Health programme.

⁸⁰ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/92911.pdf

⁸¹ See details in annex 4

⁸² See details in annex 2

In order to improve equitable access to medical countermeasures the Commission could continue, as described in option 1, to take incentive measures relating to capacity building for vaccine production and to play a supporting role in Member States cooperation, e.g. in the preparation of their national tender specifications. However, it should be noted that this option would not improve the conditions for procurement of medical countermeasures, other than the Commission supporting Member States in preparing their national tenders.

In addition, as part of option 2, the following incentives could be envisaged:

1. stimulate via the Innovative Medicines Initiative⁸³ the development of new production techniques to improve the industry's production capacity for medical countermeasures;
2. establish, complementary to national stockpiles, a real⁸⁴ or virtual⁸⁵ EU stockpile of medical countermeasures to cover urgent / unforeseen needs that exceed the capacity of national stockpiles. Examples of how such a complementary EU stockpile could look like and what it would cost are given in annex 17.
3. strengthen national procurement procedures by improving the exchange of information on contractual conditions and best practices via the confidential platform CIRCA BC.

Risk monitoring and, assessment⁸⁶

As regards notification of threats caused by chemical, biological or environmental events a Council Recommendation to Member States would be issued to mutually notify each other and the Commission of threats by means of tailor-made criteria as required by the integrated nature of the EU. However, there would be no obligations for Member States to do so.

Risk monitoring and risk assessment for other serious cross-border threats to health would rely on improved coordination by putting in place informal arrangements among existing EU structures, such as the EU agencies or informal networks currently in place as the ECDC has no mandate to carry out risk assessment for other threats than communicable diseases. This cooperation would be carried out using existing financial and administrative resources.

Risk management and crisis communication

⁸³ <http://www.imi.europa.eu/>

⁸⁴ For medical countermeasures that are available before a threat arises, e.g. ciprofloxacin against anthrax.

⁸⁵ For medical countermeasures that are not available before a threat arises, e.g. vaccines against pandemic influenza. A virtual stockpile is a guaranteed number of doses of the pharmaceutical which will be delivered when it becomes available.

⁸⁶ The required simplification and updating the framework for communicable diseases regarding epidemiological surveillance in order to take account of the establishment of the ECDC is not part of the impact assessment as changes can be considered as purely technical

The Health Security Committee⁸⁷ would be abolished in its current form and formalised as a Commission-led expert group. Its mandate would be reviewed and limited to coordination of preparedness, notification of measures implemented at national level and coordination of response for serious cross-border threats to health caused by biological (other than communicable diseases⁸⁸), chemical or environmental events or those of unknown origin. No binding requirements would be laid down for Member States under this option.

As regards communication aspects, Member States, in liaison with the Commission, would start developing shared communication approaches and guidelines, e.g. sharing best practice in dealings with the media.

7.3. Option 3: Establish a common EU legal framework covering *all* serious cross-border threats to health by extending existing legislation - improved cooperation and legally binding measures

EU competences on communicable diseases as laid down in Decision 2119/98/EC⁸⁹ would be extended to cover all other serious cross-border threats to health⁹⁰. Legal provisions would take account of specific aspects of these other threats and the measures related to preparedness, notification and risk management would be legally binding on Member States. A legal base for joint procurement of medical countermeasures would be established and new measures provided for in the Lisbon Treaty to combat serious cross border threats to health would be implemented.

The proposals for risk assessment at EU level for other threats are not part of the legal text as they can be implemented by building on improved and sustainable cooperation. Additional financial implications are proposed to ensure sustainability of existing networks in the risk assessment process, however no new agency is proposed.

This option builds on the Commission agenda Europe 2020, the EU Health strategy and the EU security framework. It also sets binding standards for cooperation between the International Health Regulations and the EU.⁹¹

Preparedness and response planning

Under this option the Member States would have the obligation to put in place an agreed approach on generic and specific preparedness planning, including for pandemic influenza and would report regularly on its implementation. As regards preparedness for multidisciplinary implications of a crisis, Member States would consent to cooperate in the cross-sectoral preparedness and response planning through the establishment of guidelines and indicators, the organisation of exchange of best practices and preparation of periodic monitoring and evaluation. Building on ongoing work to ensure business continuity in critical sectors in Europe, inter-sectoral coordination would be enhanced to ensure that other critical sectors (e.g. transport, energy, ICT) apart from public health

⁸⁷ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/92911.pdf

⁸⁸ The issue of preparedness and coordination measures regarding pandemic influenza would fall under the structures established by Decision n° 2119/98/EC.

⁸⁹ Currently limited to communicable diseases

⁹⁰ Apart from threats caused by radiological events

⁹¹ A detailed description of the tasks and obligations of the Member States and the Commission under this option is provided in annex 15.

have detailed and comprehensive preparedness plans in place. The focus would be for Member States to ensure business continuity in these sectors to improve the sustainable functioning of these sectors in the event of a crisis. Member States would also agree to implement in a complementary way requirements on shared common minimum core capacity standards for preparedness and response (e.g. adequate human resources, designation of responsible entity). Furthermore, Member States would agree to use tailor-made criteria for notification at EU level of serious cross-border threats to health, including events which may constitute public health emergencies of international concern under IHR.

This option provides a legal basis for a joint action for the purchasing of medical countermeasures, such as pandemic influenza vaccines. This would create an opportunity to set up and manage an EU mechanism for joint procurement of medical countermeasures in which Contracting Parties⁹² could participate, on a voluntary basis. The procedural and organisational arrangements of the joint procurement mechanism would not be part of the legal act but would be laid down in a 'Joint Procurement Agreement' signed by all participating Contracting Parties. The joint procurement mechanism will give full flexibility to the Contracting Parties to procure what and how much they want. The purchasing power of the participating Contracting Parties will be strengthened by pooling similar procurement requirements. Whereas the Commission will coordinate the joint procurement mechanism, the Contracting Parties will be responsible for awarding and signing framework contracts⁹³ and for the payment of any medical countermeasures they order. An illustration of how the joint procurement mechanism would work is given in annex 18.

Risk monitoring and assessment

Mechanisms and structures currently in place for risk monitoring and assessment of threats caused by chemical, biological or environmental events will be formalised and strengthened.

A coordination system will be put in place and the Member States affected by a crisis consent to notify at EU level cases of cross-border threats to health caused by chemical, biological and environmental events – as they have already done in the past – notify threats arising from communicable diseases.

In parallel, Member States would be obliged to notify the EU level in all cases where notifications are made to WHO under the International Health Regulations.

Based on experience with data protection in the area of communicable diseases provision will be taken that the existing alert systems will enable secure information sharing in respect of data protection rules, for example to trace persons exposed to a chemical contaminant.

Where the ECDC or another EU Agency, Member States or the Commission identifies serious cross-border threats to health, on the basis of either notification systems or risk

⁹² 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).

⁹³ A framework contract guarantees a certain number of doses of a medical countermeasure that will be made available when the signatory Contracting Parties wish to order. However, a framework contract does not put any obligation on Contracting Parties to order the medical countermeasures.

monitoring, a risk assessment may be performed using existing structures at EU or national levels in conjunction with the Commission. The Commission would be tasked to provide for a coherent and comprehensive public health risk assessment at EU level.

Potential gaps in risk assessments for specific threats would be covered by putting in place additional capacities for scientific expertise. Based on financial means of EUR 500,000 per year⁹⁴ provided by the Health programme, a framework contract would be established to guarantee that additional expertise can be requested when needed. This contract would help to establish permanent networks of national correspondents between health authorities and agencies competent in assessing specific health threats, for example related to toxic chemicals, maritime or air transport. Through these networks, assessment of the cross border dimension of specific health threats would be provided to the EU level where these assessments would be fed into the early warning and crisis prevention and management structures. In addition, these investments contribute to capacity building in terms of improved training and methodology.

Relevant international agencies (e.g. WHO) would be associated to these networks.

Risk management and crisis communication

As regards risk management, EU action would consist in ensuring that the public health response by Member States to a serious cross-border health threat is presented on a coherent and coordinated basis.

This involves defining the characteristics of threats to be addressed by the new regime (communicable diseases, other biological threats, chemical and environmental threats and threats of unknown origin).

On this basis, the relevant criteria for binding notification of such threats would be specified and the conditions and rules would be laid down in such a way that a coordinated and coherent public health response can be undertaken. This option would specify, as is currently the case for communicable diseases, the other types of threats to be covered, criteria for notification of events and areas where measures could be coordinated at the EU level. It would provide for EU action through advisory activities, non legislative acts and instruments for mutual agreements or joint actions between Member States.

EU action as described above will – as is the case for communicable diseases - cover the following measures as a priority:

- (a) Advisory activities on preparedness and response planning, public health response coordination such as on school closure, travel advice, communication strategies and coordinated messages, and common strategies on vaccination. On this basis the Commission may, with the support of expert groups, adopt recommendations to Member States and clarify the scope of these recommendations in a legal text.
- (b) Non legislative acts (i.e. delegated and implementing acts) would cover for example guidelines on protective measures to be taken, particularly in an

⁹⁴ Costs estimated based on the costs incurred for a framework contract in the past for setting up a pilot project on assessment of health threats other than communicable diseases.

emergency situation; guidelines on information and guides to good practice for the public (e.g. hygiene measures).

- (c) Voluntary mutual agreements between concerned Member States based on measures recommended by the Commission which might be implemented at national level.

In addition, a new and voluntary instrument mechanism for joint procurement of medical countermeasures, particularly pandemic vaccines, would be established.

Communication would be greatly improved by the development of common communication strategies and by better integrating the Communicators into the crisis management process and by closer linking decision makers and risk managers.

Coordination of a crisis would be organised with the help of a Health Security Committee composed of representatives of Member States and chaired by the Commission which provides also the secretariat to this committee. Thus, the current work consisting of coordination of public health response done by the EWRS Network and the Health Security Committee, including work on communication, would be merged in order to cover all serious cross-border threats to health within a single structure.

8. ANALYSIS OF THE IMPACTS

As described under chapter 3, health emergencies can have huge impacts on the health of citizens and society, and can also have significant financial consequences, in addition to their impact on the health of citizens.⁹⁵

A summary of impacts is provided below. The health impacts are described in more detail in annex 16 where the actions proposed under each option are thoroughly analysed as regards their effects and consequences in relation to the objectives.

In addition, annex 19 describes further impacts: in particular social and economic impacts, financial implications and administrative burden, EU added value and the impact of each option at international level.

None of the identified options will have impacts on the environment or employment that can be predicted with any accuracy.

8.1. Option 1: Status quo/baseline scenario - maintain the current level of activities

Public health impact: As the status quo is maintained under this option, there will be no impact on conditions for the protection of EU citizens from serious cross-border health threats and on the effectiveness, efficiency and coherence related to the public health security structures and systems to respond to such threats. As described under the baseline scenario and under the problems, this situation would keep in place a status quo that could potentially endanger the capacities to ensure the containment and mitigation of a cross-border health threat and lead to an increase in mortality and morbidity rates at EU level.

⁹⁵ See tables 1 and 2 in annex 6

Social impact: This option is not expected to improve communication to the EU citizens and solidarity between the Member States in the case of serious cross-border health threats, as it does not address the shortfalls identified in these areas.

Economic impact: In a status quo situation, critical sectors will not be sufficiently prepared for the consequences of a serious cross border health event⁹⁶. This could result in diverse and inconsistent responses in the event of a public health crisis and a greater risk of economic repercussions such as productivity losses and absenteeism⁹⁷). As a consequence, internal market and external trade functions could be disrupted, leading to substantial economic losses as illustrated during the recent STEC O104 outbreak⁹⁸.

Financial impact: The financial implications under this option will not change. While no additional costs would arise for Member States and stakeholders, resources to support work on combating serious cross-border health threats will mainly be allocated by the administrative budget of the EU (for example for meetings etc) and the financial resources of the Health Programme

Administrative burden: Under this option, the necessary administrative resources for both the Commission and the Member States will remain unchanged. However, the management of these resources will remain sub-optimal, as there will continue to be overlaps between the EWRS network and the Health Security Committee in the field of communicable diseases.

EU added value: The impact and EU added value in coordinating the response to cross-border health threats will remain unchanged, and collaboration at international level will not be improved either.

8.2. 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

Public health impact: The impact on public health could be improved as the overall situation in terms of preparedness for and response to a crisis will be strengthened along with the effectiveness, efficiency and coherence of public health security structures and systems. This would be achieved through EU-wide recommendations supported by Member States. However, these positive impacts would only be potential and would rely on the commitment of the Member States to agree on these recommendations and implement them. Against this background, this option could more specifically result in an increased coherence of overall preparedness, improved coordination of existing notification tools and strengthened risk assessment capacities, thus stepping up the level of capacity to react more rapidly and comprehensively to a cross-border health threat. In addition, the risk management structures supporting a coordinated response at EU level would be sustainable if they had clearer mandates, thereby improving the effectiveness of health crisis management. Crisis communication would be enhanced and benefit from a more coherent approach and capacities when managing a crisis. However the quality and

⁹⁶ See annex 8 for further details

⁹⁷ <http://www.who.int/countries/eth/areas/cds/en/index.html>

⁹⁸ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/938&format=HTML&aged=0&language=EN&guiLanguage=en> and http://pl2011.eu/sites/default/files/dokumenty/user43/sn03124_en11_comments.pdf

coordination of the response to a threat would only be as strong as the weakest link of the whole structure and depend on the preparedness of Member States to implement.

The impact of this option on access to medical countermeasures is expected to be an improvement over Option 1. Indeed, incentive measures via the Innovative Medicines Initiative could support research into the development of new production techniques to improve production capacity for medical countermeasures such as has been achieved in the United States by the Biomedical Advanced Research and Development Authority (BARDA) initiative⁹⁹. An improved production capacity means that a larger proportion of the population can be protected or treated within a short time frame when a threat emerges.

In addition, this option foresees the setting up of a complementary EU stockpile which could alleviate urgent/unforeseen needs exceeding the capacity of national stockpiles.

Social impact: Provided that the Member States implement the agreed guidance and recommendations, improved risk management and, in particular, better coordination of risk communication is likely to have a beneficial effect on citizens, as messages issued to the public would be more consistent within the EU and better avoid contradictions. Thus, the confidence in the ability of public health authorities to manage a health crisis would increase. In addition, inter-sectoral cooperation to improve public health protection will be strengthened. As regards equitable access to medical countermeasures, this option would enable expertise to be pooled among the Member States solidarity and cooperation to be improved in terms of preparation of the procurement procedures, as smaller Member States would benefit from the skills and lessons learnt from other countries. A complementary EU stockpile of medical countermeasures that can be deployed to help Member States with urgent/unforeseen needs is expected to improve solidarity, and – to a limited degree – improve equitable access to medical countermeasures.

Economic impact: Under option 2 a more rapid risk assessment and management of a given threat would reduce the economic consequences related to a health event. For example, the disruption of the internal market and external trade functions might be minimised and economic losses reduced. However, these potential impacts would rely essentially on the Member States' commitment to agree on and implement developed EU "soft law" guidance such as recommendations. In the field of medical countermeasures, option 2 could positively impact on innovation and R&D efforts related to new production techniques to improve the industry's production capacity for medical countermeasures, as further support actions could be envisaged in particular under existing instruments (e.g. Innovative Medicines Initiative¹⁰⁰).

Financial implications: The main stakeholders under this option are the Member States and the Commission. No additional costs either for Member States or for the Commission are expected under this option.

Regarding research and development of medical countermeasures, existing financial mechanisms will be used as much as possible (Innovative Medicines Initiative).

⁹⁹ <http://www.phe.gov/preparedness/pages/default.aspx>

¹⁰⁰ <http://www.imi.europa.eu/>

As regards access to medical countermeasures, option 2 remains at the level of cooperation between individual procurements with no additional significant costs for the Member States. However, there would be no financial gain either as the purchasing power and ability to obtain better financial and contractual conditions will remain much weaker compared to the option of a full joint procurement, as proposed under option 3.

Costs related to the potential setting up of complementary EU stockpiles of medical countermeasures are illustrated in annex 17. Because a complementary EU stockpile would mean that Member States still needed to procure medical countermeasures for their national stockpiles individually, the weak purchasing power identified as a major weakness during the influenza H1N1 (2009) pandemic would not be addressed. In 2006, the Commission already proposed the setting up of a complementary EU stockpile of antivirals for use in the event of an influenza pandemic. However, this initiative was withdrawn as the Health Council did not reach a consensus on the funding source for such a stockpile¹⁰¹. Alternatives such as the Swiss legislation obliging the producers to create a stockpile of essential goods (incl. antivirals)¹⁰² at marginal cost to the Government could be regarded as a way to minimise costs. However, this does not seem feasible in the EU since Article 168 of the Treaty does not provide a legal basis to legally oblige manufacturers to hold or supply medical countermeasures or raw materials for the manufacture of countermeasures.

Administrative burden: Under this option, the administrative burden for the Member States and the Commission would be reduced, as the mandates of the two relevant committees (EWRS Network Committee and the newly created expert committee based on the former Health Security Committee) would be clearly defined, thereby minimising the risks of overlap. However, these gains would be limited as there would still be two separate entities.

As regards access to medical countermeasures, the administrative burden could also be reduced for Member States as cooperation between individual national procurement procedures would allow the pooling of national expertise¹⁰³. However, this positive impact would be limited to the preparation of the technical specifications, as the rest of the procurement processes would still be implemented individually at national level.

If stockpiles at European level would be created additional administrative capacities would be needed in particular during the setting up phase and devising and testing mechanisms for delivery and distribution in a crisis.

EU added value: The EU added value would be increased as the coordination of preparedness and response to cross-border health threats could be enhanced at EU level.

Impact at international level: Under this option, the impact related to international level would be stronger, as attempts would be made to link International Health Regulations more effectively to reporting of threats at EU level.

¹⁰¹ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/732&format=PDF&aged=1&language=EN&guiLanguage=fr>

¹⁰² <http://www.bwl.admin.ch/themen/01009/01025/index.html?lang=en>

¹⁰³ In the case of Austria, savings involved in a joint procurement amounted to 60% of administrative costs: http://ec.europa.eu/environment/gpp/pdf/toolkit/module1_factsheet_joint_procurement.pdf

8.3. Option 3: Establish a common EU legal framework covering *all* serious cross-border threats to health by extending existing legislation - improved cooperation and legally binding measures

Public health impact: Under this option, the protection of EU citizens against serious cross-border health threats and the effectiveness of public health security structures and systems at EU level would be considerably improved. It would indeed allow coherent preparedness planning based on shared and common mandatory standards and a better coordinated and balanced response to all types of cross-border health threats. This would be supported by establishing a single structure addressing the management of such events and empowering the Commission to coordinate with the Member States the advisory activities, non legislative acts, recommendations, and mutual agreements to be implemented at national level.

In addition, the notification of threats would be ensured due to enhanced cooperation with the existing alert and systems and structures, as well as EU tailor-made criteria for notification of health threats. Along with enhanced and sustainable cooperation for risk assessment with existing networks of national experts, relevant Commission services, EU agencies and international organisations, this option would result in a more coherent and comprehensive approach to identification, notification and assessment of serious cross-border health threats.

Finally, by setting up a legal basis allowing voluntary joint procurement, this option would considerably improve equitable access by Member States to medical countermeasures, thereby ensuring a higher level of protection of the EU citizens across the Union. The positive public health impacts related to the development of such a mechanism were further demonstrated by previous similar initiatives developed in other countries and regions¹⁰⁴.

Furthermore, inter-sectoral cooperation would be improved in the event of cross-border health threats, also contributing to better public health protection. Critical sectors would be identified and prepared, and procedures for improved inter-sectoral coordination would be established based on the 'whole of society' approach of the WHO, in particular for pandemic preparedness.

Social impact: Along with the impacts related to improve coordination of communication already identified for option 2, increased cooperation would facilitate a better understanding of citizens' needs and worries, better targeted messages, and a coordinated approach on access to medical countermeasures would result in a more favourable public opinion and would raise confidence in the measures undertaken by public health authorities. In the context of an influenza pandemic, a joint procurement mechanism for medical countermeasures would result in a higher level of protection for vulnerable groups due to better synchronised and more effective vaccination campaigns. In addition, such a mechanism would promote solidarity between the Member States by ensuring that participating countries have a minimum level of access to medical countermeasures.

¹⁰⁴ One Year assessment of joint procurement of pharmaceuticals in the public health sector in Jordan, <http://www.sciencedirect.com/science/article/pii/S0149291809001672>

Economic impact: Under option 3 the positive impacts already described under option 2 would be expected. However, they might be stronger, given that the measures would be based on binding agreements.

In addition, in the field of innovation, development and research the setting up of a joint procurement mechanism on medical countermeasures would strengthen the supply of medical products and encourage existing and potential new suppliers to develop new products based on long term contracts agreed with the public health sector.¹⁰⁵

Financial impact: The main stakeholders under this option are the Member States, the Commission and private companies in the health sector and in other sectors.

A. Costs for preparedness, assessment and management of the Health Security Initiative

For the Member States notification costs are not expected to increase significantly as Member States are already obliged to report either at the EU level on communicable diseases or to the WHO under the International Health Regulations on "all hazards". Reviewing processes and procedures would need to be envisaged, but the costs for this can be considered marginal.

The new activity of obliging the Member States to set up generic preparedness planning would be based on the previous work and existing mechanisms. Administrative costs would not significantly increase.

The costs for coordination meetings may be at the same level or even less given the comprehensive mandate of the health group for all serious cross border threats to health.

As regards the newly established reporting and monitoring procedures to implement the improved health security framework the following costs per Member State can be envisaged: 0.3 – 0.5 Full Time Equivalent for a national expert over a period of 2-3 months to address reporting.

For the Commission: as regards preparedness additional costs could be expected, in particular in relation to human resources and the provision of technical equipment; however, it is planned to cover these staff capacities/overhead costs by reorganising the human resources available and by building on existing platforms. Hence, the additional costs are considered marginal.

If a more sustainable solution on risk assessment would be set up on a formal basis building on existing systems and better linking them this would require additional financial resources from the EU health programme in the region of EUR 500,000 per year to set up framework contracts in order cover existing gaps by making expertise available where needed. The calculation is based on experience with a similar pilot project for assessment of health threats other than communicable diseases in the past. The intended framework contract is planned to allow for such gaps to be filled by establishing permanent networks of national correspondents between health authorities and agencies competent in assessing specific health threats, for example related to toxic chemicals (94 poison centres in the EU).

¹⁰⁵ EC Green Public Procurement Training Toolkit – Joint Procurement Fact Sheet, p.3
http://ec.europa.eu/environment/gpp/pdf/toolkit/module1_factsheet_joint_procurement.pdf

Cross border threats caused by chemical, biological and environmental events do not occur as often as communicable diseases. Based on IHR notifications we can expect on average 5-6 such events per year¹⁰⁶. Under EU tailor made criteria for these incidents the threats notified - based on experience with alerts for communicable diseases - could amount to 20 -25 per year. The frequency of such events is likely to increase due to increases in global travel and trade, climate change and latent risk of criminal and terrorist attacks.

Therefore, the financial burden of the measures needed in order to prepare for serious cross-border threats to health is justified and proportionate compared to the damage and impact on society which can be significant in scale and can by far exceed the financial input. The additional costs would also be justified as scientific expertise would not only be provided for a given threat assessment, a sustainable network would also allow for capacity building and training in the area of chemical, biological and environmental threats.

It is not expected that costs for coordination of improved risk management would rise as a similar meetings cycle for the new health committee as in the present for the existing EWRS and Health Security Committee will be maintained. Administrative budget for these meetings is available.

As regards the new reporting requirements 0.3 Full Time Equivalent for an Administrator/Policy Officer for the reporting process will be needed. EUR 5,000-20,000 for external expertise to support the development of a questionnaire and the analysis of the replies by the Member States will be needed to implement the yearly reporting schemes. EUR 300,000-700,000 every five years for external and independent evaluation would be needed. The amount depends of the scope and details of the tender specifications for the evaluation.

B. Access to medical countermeasures

With regard to access to medical countermeasures, option 3 would aim to better coordinate the procurement of medical countermeasures already currently being conducted nationally. Thus there would be no new financial commitments for the Member States. On the contrary, evidence from other initiatives indicates that such a mechanism would lead to stronger purchasing power, economies of scale, more attractive offers from suppliers and improved contract conditions for the Member States¹⁰⁷ (for further details see annex 17). In addition, a joint procurement mechanism would result in lower administrative costs¹⁰⁸. Although financial implications can be expected during the setting up of the proposed mechanism and the occurrence of cross-border health threats (additional staff and administrative costs) for the entity in charge of operating the contract, these costs would be reduced during the running of the contract prior to a cross-border health threat.

Other Stakeholders/private companies

¹⁰⁶ See information in annex 11

¹⁰⁷ http://www.rho.org/files/IAVI_vaccine_procurement_pricing.pdf; Local Authority Procurement: a research report, UK Office of the Deputy Prime Minister, <http://www.communities.gov.uk/archived/publications/localgovernment/localauthorityprocurement>; One Year assessment of joint procurement of pharmaceuticals in the public health sector in Jordan, : <http://www.sciencedirect.com/science/article/pii/S0149291809001672>

¹⁰⁸ As shown by Austria, where a similar joint procurement initiative - the Eco-procurement Service of Vorarlberg - has for instance achieved savings up to 60% in administrative costs

It is not expected that private companies would have any obligations for alert reporting as such. As regards improved preparedness and business continuity in private sector companies it is worth noting that in particular large companies have already engaged in putting in place business continuity planning at their own initiative based on the rationale that investing in business continuity is highly cost effective albeit by nature never cost neutral or possible without any administrative input. There is no intention to impose measures with financial implications. The intention is to encourage the exchange of best practice illustrating the overall benefit of improved business continuity planning thereby encouraging companies to invest in business continuity planning.

Administrative burden: As regards preparedness and response planning there would be a certain administrative burden for Member States to develop and implement core capacity standards in line with the International Health Regulations; however, the additional work needed to define in addition specific EU criteria can be considered as marginal.

As regards notification and risk assessment, Member States are already obliged under EU legislation to notify health threats including communicable diseases and other incidents threats at EU level, and as well to the WHO under the International Health Regulations. There will be a certain amount on administrative burden to establish links between these systems and review existing reporting mechanisms; however, this burden will decrease once the connections and links are made. Thus established efficiency will be gained and coherence and cooperation between reporting tools will have positive effects on administrative procedures, they will be streamlined and double work will be avoided.

Costs induced for reporting are supposed to add administrative burden, however will be counterbalanced by improved reporting and information and hence better preparedness for future crises.

Under this option governance in public health risk management would be significantly improved as only one expert committee would need to be operated.

As regards the newly established reporting and monitoring procedures to implement the improved health security framework Member State would need to provide 0.3 – 0.5 Full Time Equivalent for a national expert over a period of 2-3 months to address reporting. As Member States have also reporting duties under the International Health Regulations synergies in the reporting can be expected. In addition, Member States would need to dedicate staff capacities every five years to contribute to an external evaluation.

With a more systematic and structured approach synergies in the work invested by Commission staff can be expected and no additional administrative burden.

Additional efforts would need to be undertaken by improving coordination with existing crisis notification tools and alert mechanisms; however, as contacts to these instruments are already in place, the additional investment for which human resources are needed can be considered marginal. This additional work can be done by available staff and assignment to national experts.

Increase in administration would have to be expected during the setting up phase of the proposed mechanism for joint procurement of medical countermeasures in form of additional staff and administrative burden for the entity in charge of operating the contract (see details under financial implications) but for those Member States that envisage adequate provision and preventive measures for a future pandemic the

administrative procedures have to be implemented any way. This task might be assigned to the Commission, there are however options that external support is requested for this task, e.g. by assigning this task to an Agency or Body in charge of procurement or contract management.

These administrative effects would decrease during the running of the contract prior to a cross-border health threat. In the case of an outbreak or a public health event which would require the activation of the contract, the administrative needs would rise steeply: However, for the participating countries the proposed mechanism will result in a significant reduction of administrative burden as it would enable the pooling of different skills and expertise between national authorities¹⁰⁹.

EU added value: Under option 3, 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 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 add value to strengthening the preparedness and response capacity to deal with cross-border health threats across the EU.

Impact at international level: Better coordination in the EU of the International Health Regulations implementation by the Member States and closer collaboration between the EU and WHO on preparedness for and response to public health emergencies of international concern would contribute to enhance global health security. It would contribute to better control the spread of diseases internationally from and to the EU e.g. through exchange of information and good practice with global partners and 3rd countries. In this context improved public health risk assessment and management could be undertaken more effectively at international level when the EU has defined a common approach on serious cross-border threats to health and pre-established procedures on international cooperation.

9. COMPARING THE IMPACTS OF THE OPTIONS

Based on the impact analysis, the criteria for comparing the impact of the three options are: improved impacts in the public health area, social and economic impacts, financial implications, administrative burden, EU added value and impact at international level. The options are rated according to their impact against these key criteria. Policy option 1, the status quo/baseline scenario, is set at zero (neutral) and the impacts of the policy options two and three are expressed as net changes compared to the status quo.¹¹⁰

As option 1 is about status quo and refers to the baseline scenario, these conclusions focus on options 2 and 3, where new impacts can be expected.

¹⁰⁹ EC Green Public Procurement Training Toolkit – Joint Procurement Fact Sheet, http://ec.europa.eu/environment/gpp/pdf/toolkit/module1_factsheet_joint_procurement.pdf

¹¹⁰ Annex 20 provides an overview of the ratings for the different options based on the detailed analysis set out in annex 19.

Following the analysis of impacts as summarised in annex 20, there are a number of differences between options 2 and 3, which demonstrate the added value of choosing option 3.

As regards the public health impact, both options improve the overall situation for preparedness and response to a crisis. However, as option 2 depends on a voluntary approach the positive impacts would not be guaranteed as they would rely only on the commitment of the Member States. In comparison, option 3 which sets out a new coherent framework on preparedness planning at the EU level, also establishes common mandatory standards that would lead to considerably improved coordination at EU level.

As regards risk notification and assessment, both options 2 and 3 strengthen cooperation in this area. However, option 3 would provide for a more coherent and comprehensive approach as a coordination system would be put in place and the Member States affected by a crisis would consent to notify all serious cross-border health threats at the EU level. In addition, the risk assessment capacities would be improved by filling gaps in current risk assessment capacities under option 3.

In the area of risk and crisis management, option 2 would improve the overall situation as the two committees' mandates would be clarified. However, option 3 would merge the two committees, providing a sound basis for crisis management of all serious cross-border health threats.

Risk and crisis communication would be also be improved under both options, but under option 3 the linking of communicators and crisis managers would ensure that communication strategies could be developed within the overall approach of response to public health events.

Concerning the financial and administrative implications these would result in negative impacts due to additional administrative requirements and financial input - though modest - for both options. Nevertheless, in particular as regards option 3, it can be considered that the qualitative improvements and the EU added value under this option outweigh the costs and administrative burden in the long run. Option 3 will also set up the legal basis for the joint procurement mechanism which would require increased administrative resources during the setting up period, but once operational, the overall administrative burden is expected to be less as compared to procurement at national level. In addition, joint procurement would lead to stronger purchasing powers for the Member States and economies of scale.

As regards the social impacts, option 2 could contribute to improved communication as Member States would be committed to implement common guidelines for communication. However, option 3 would provide for a much stronger basis for improved communication as there would be an EU level communication strategy which would ensure consistency of messages to the public. Moreover, option 3 would significantly increase access to medical countermeasures to citizens across the EU.

Concerning the economic impacts, option 3 is favoured over option 2, as, due to increased cross-sectoral collaboration and legally binding measures, under option 3 other sectors of the society would be better prepared for the negative repercussions of a public health event.

Finally, when considering the international impact, option 3 would also contribute to a closer collaboration between the EU and the World Health Organisation as well as other relevant global partners in the area of health security.

10. CONCLUSIONS AND PROPOSAL FOR IMPLEMENTATION

On the basis of the comparison of impacts of the three options as presented in annex 13 and the detailed impact assessment for each option separately provided in annexes 16 and 19, it can be stated that the actions proposed under option 3 address most effectively the objectives set out under the Health Security initiative and have positive social and economic impacts.

Option 3 has the strongest health impacts as it provides an improved protection of citizens against serious cross-border health threats. The key reason for this is that it proposes a comprehensive framework for health security structures and systems including obligations on Member States in terms of preparedness and response planning. It makes notifications at EU level mandatory and establishes a clear mechanism with a clear mandate to address all types of public health events by merging two existing committees into one.

Option 3 also offers the best possible EU added value and best fulfils the fundamental goals of the Lisbon Treaty of ensuring a high level of human health protection against all serious cross-border health threats.

Under this option Member States would need to be strongly committed to cooperate and to review their arrangements in the context of activities in other areas. The overall administrative burden and additional financial implications are expected to be not substantial as Member States have already to comply with requirements existing in other areas.

In this regard Member States will be faced with the following implications

Ensure that the transposition of international standards on health security is done in a coherent and coordinated manner at EU level. The Member States are already obliged to implement the International Health Regulations (IHR). In this initiative the implementation would be done in a coordinated way across all EU Member States. This would be done through binding principles and procedures for meeting core capacity standards for preparedness and response planning as set out in the IHR.

- Provide relevant information on serious cross-border threats to health collected through monitoring systems by using agreed case definitions.
- Notify measures and events of serious cross-border threats to health. These will include events which are also reported under the International Health Regulations.
- Coordinate public health measures at the EU level on serious cross-border threats to health. This coordination would involve agreeing to binding procedures concerning information exchange, consultations and coordination.

- Voluntarily participate in joint actions in particular related to joint procurement for pandemic influenza vaccines and in mutual agreements such as common vaccination campaigns.

Option 3 will ensure that European citizens are equally protected against threats caused by chemical, biological or environmental events as they are currently for communicable diseases. Under the improved conditions for preparedness in particular for joint procurement mechanisms on medical countermeasure additional protection is also ensured for communicable disease, especially pandemic influenza.

It will strengthen the capacity of the EU and Member States to manage public health crises better than today not only at European level but also in a global context as provisions at European level will be aligned to International Health Regulations.

Overall this option would not only strengthen the preparedness provisions for serious cross border threats to health caused by chemical, biological and environmental events, it would also make existing guidelines for communicable diseases more enforceable.

The legal form under this option would be a legislative act of the European Union adopted by ordinary legislative procedure that would repeal but take over the provisions of the current EP and Council Decision of 1998 on communicable diseases.

The legislative proposal would have articles on the subject matter, scope, definitions, preparedness and response planning, joint procurement of medical countermeasures, epidemiological surveillance and monitoring, early warning and response system, public health risk assessment, coordination of response, health security committee, exercise of the delegation, urgency procedure, designation of national authorities and representatives, collaboration with third countries and international organisations, protection of personal data, and reports. An annex would provide a list of communicable diseases and special health issues subject to epidemiological surveillance.

The proposal would simplify the existing legislation. It would improve transparency due to less implementing measures (all decisions implementing decision 2119/98 will be replaced by one annex); current overlaps with ECDC mandate will be cleared and only one committee with a clear mandate would be established to manage all types of health crises.

11. MONITORING AND EVALUATION

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)¹¹¹ 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 in annex 21.

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.

¹¹¹ 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

12. ANNEXES AND APPENDICES

ANNEXES

1: Treaty of the Functioning of the EU (Lisbon Treaty), Article 168

2: The Health Security Committee

3: Requests of Member States to review the health security framework and pandemic preparedness planning

4: Existing legal framework for communicable diseases, Decision 2119/98 and European Centre for Disease Prevention and Control (ECDC) and implementation of the framework

5: The International Health Regulations (IHR)

6. Examples of effects

7: EU mechanisms and strategies for disaster prevention and control – the security framework within the European Commission

8: Business continuity and preparedness panning at EU and international level

9: The Health Programmes at European level

10: Overview of Objectives of the Health Security Initiative

11: Notification of serious cross border health threats to the WHO under IHR

12: Problems and public health consequences

13: Overview of measures proposed under the three options

14: Opinions of stakeholders on the three options

15: Detailed tasks and obligations for Member States and the Commission under option 3 – legal proposal

16: Description of actions proposed under the options and their implications for the health sector

17: Examples of potential complementary EU stockpiles

18: Illustration of the joint procurement mechanism for medical countermeasures

19: Analysis of the impacts of the three options

20: Comparison of the policy options

21: Monitoring the implementation of suggested actions

22: Glossary

23: Reference Documents and Links

APPENDICES

- 1. Report on the outcome of the "Stakeholder consultation on Health Security in the European Union"**
- 2. Structures for preparedness and response to cross-border health threats**

Annex 1: Treaty on the functioning of the European Union (Lisbon Treaty), Article 168

TITLE XIV, PUBLIC HEALTH, *Article 168*(ex Article 152 TEC)

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and

improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall 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. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Annex 2: The Health Security Committee

1. History

In the aftermath of the terrorist attacks in 2001, and in particular the deliberate release of Anthrax toxins in the US, the EU health ministers decided to set up the EU Health Security Committee (HSC)¹¹² as an informal structure for better coordination of public health risk assessment and management on other serious cross-border health threats in the EU. At the beginning the HSC mandate was limited to tackling bioterrorism; subsequently it has been extended to cover all types of public health-related crisis¹¹³ and further prolonged¹¹⁴.

The Health Security Committee is not a Comitology committee. Representatives of the Health authorities of the Member States meet on a regular basis, 1 -2 times per year in face-to-face meetings. The Committee is operating on the basis of a work programme according to their mandate that is dedicated to preparedness and response planning in the field of generic preparedness, influenza preparedness, CBRN threats and communication.

The Secretariat of the Committee is ensured by the Commission and regular reports about the activities of the Committee are provided. The latest report "Staff Working Paper on the activities of the Health Security Committee during the period from November 2009 to December 2010" was published on 22 July 2011.¹¹⁵

2. Mandate

According to the Council Conclusions on HSC of 22 February 2007 the current Terms of Reference are the following:

- exchange information on health-related threats from acts of terrorism or any deliberate release of biological or other agents with intent to harm health;
- share information and experience on preparedness and response plans and crisis management strategies;
- be able to communicate rapidly in case of health-related crises;
- advise Health Ministers and the European Commission services on preparedness and response as well as on coordination of emergency planning at EU level;
- share and coordinate health-related crisis responses by Member States and the Commission;

¹¹² Presidency Conclusions of 15 November 2001 on bioterrorism:
(<http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/01/415&format=HTML&aged=0&lg=es&guiLanguage=en>)

¹¹³ Council Conclusions of 22 February 2007 on health security committee:

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/92911.pdf

¹¹⁴ Council conclusions of 13 September 2010 on lessons learned from A/H1N1 pandemic – health security in the European Union <http://register.consilium.europa.eu/pdf/en/10/st12/st12665.en10.pdf>; see further details in annex 2 and latest activity report: Commission staff working paper on the activities of the Health Security Committee during the period from November 2009 to December 2010, SEC(2011) 984 final; 22.7.2011

¹¹⁵ http://ec.europa.eu/health/preparedness_response/docs/hsc_activities_2009-2010_en.pdf

- facilitate and support coordination and cooperation efforts and initiatives undertaken at EU and international level and help contribute to their implementation at national level.

3. Development and health issues addressed

Over the years the committee has established a solid basis for preparedness activities and monitors the activities in the health areas. It exchanges information of mutual interests and evaluates health events. It is a discussion forum and such the only existing platform at European level where the health authorities responsible for public health in humans meet and exchange regularly. These certainly have an effect in bringing Member States closer together and consult on a variety of options in public health.

The Committee can also be consulted in cases of emergencies and crises or to discuss urgent matters via audio or video conferences. In this case coordination can be arranged and views exchanged.

Examples of health issues addressed by the Health Security Committee are the following:

In January 2010 discussion about the investigation of the Council of Europe into vaccination issues in the context of pandemic H1N1, and on the anthrax outbreak in Scotland and Germany, which led to the death of several drug users;

In February 2010 discussion to inform on the evaluation of the management of pandemic H1N1, to update information about IDU anthrax cases;

In April 2010 discussion on the evaluation of pandemic H1N1 and the preparations for the Belgian presidency Conference on Lessons learnt from pandemic H1N1;

In April 2010: urgent audio conference in order to discuss the public health risk after the volcano eruption in Iceland.

However, given its informal character there are no examples that the Committee has proposed strong, agreed and shared action which is then implemented by the member States and leads to a coherent response. There is no obligation for the Committee to propose recommendations, to find a common view, there is not voting according to the usual principles of comitology and hence the Committee operates entirely on voluntary and non-binding arrangements for Member States.

The handling of the pandemic influenza can be considered a good example where the lack of proper recommendations and implementation led to different approaches of Member States to address the crises depending on their own assessment of the risk and capacity to cope with. As proven by evaluations at the level of Member States, WHO, the Commission and the European Parliament this situation has led to immense costs for buying vaccines. The incoherent and contradictory communication of the different stakeholders has had devastating effects related to the trust of citizens in health authorities.

A stronger mandate of the Committee and the use of "mutual agreements" would have been more effective and less costly for Europe.

Annex 3: Requests of Member States to review the health security framework and pandemic preparedness planning

During past Council meetings the Member States have several times called for a review of the health security framework and the need for reviewed pandemic preparedness planning.

In its conclusions of 22 February 2007¹¹⁶, the Council called the Commission "to come forward as appropriate with a proposal for a long-term solution for the Community framework for health security taking into account the structures in all relevant sectors to ensure that work is taken forward in the most appropriate forum, avoiding duplication and supporting effective cross-sectoral collaboration".

In its conclusions of 16 December 2008¹¹⁷, the Council of the European Union adopted conclusions on health security inviting the Member States and the Commission 'to strengthen their coordination in facing public health emergencies of international concern within the EU, as defined in the International Health Regulations (IHR) 2005.

The Council also invited the Commission to "take into account the inter-sectoral dimension of preparing for pandemic influenza..., to develop the system of monitoring, preparation, early warning and response at European level to adapt it to the challenges of public health emergencies involving more than one Member State, taking account inter alia of the entry into force of the IHR 2005, the evaluation of the ECDC and the need to consider providing the HSC with a legal basis"... and 'to present, in 2010, a communication proposing a long-term solution for the Community framework for health security taking into account the existing structures in all relevant sectors and the need to avoid duplication accompanied, where appropriate, by a legislative proposal and adapt the status of the HSC to the health challenges of the future, taking account of the mandate of the ECDC".

In its conclusions of 13 September 2010¹¹⁸, the Council invited the Commission to:

- revise the Pandemic Preparedness Plan of the EU, taking into account lessons learned from the A(H1N1) pandemic, the national and European evaluations concerned and in coherence with the WHO review of the IHR(2005) and the international framework, giving particular attention to the need for inter-sectoral preparedness for a pandemic and to reducing the impact of a pandemic on society, to ensure that the response is flexible proportionate and adapted to the severity of the threat;
- report on and develop, as soon as possible and no later than December 2010, a mechanism for joint procurement of vaccines and antiviral medication which allows Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality;

¹¹⁶ Council conclusions of 22 February 2007 on Health Security Committee, http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/92911.pdf

¹¹⁷ Council conclusions of 16 December 2008 on health security, add links http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lisa/104770.pdf

¹¹⁸ Council conclusions of 13 September 2010 on lessons learned from the A/H1N1 pandemic – health security in the European Union, available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/116489.pdf; <http://register.consilium.europa.eu/pdf/en/10/st12/st12665.en10.pdf>

- improve the fast registration procedure for vaccines, as regards, inter alia, making it suitable for different influenza strains, varying levels of severity and differences in target population groups, the format and content of the application for marketing authorization, the requirements on packaging and leaflets, the availability of data from clinical trials, the scientific pre- and post marketing evaluation and transparency of communication on the procedure whilst safeguarding the quality, safety and efficacy of the vaccines;
- present, in 2011, a proposal for a long-term solution for health security taking into account the outcome of the examination of the options for the legal basis of the HSC referred to above and the existing structures in all relevant sectors and the need to avoid duplication of work, and in the interim, to ensure that the Council is regularly updated on the work of the HSC.

Annex 4: Existing legal framework for communicable diseases, Decision 2119/98 and European Centre for disease prevention and control (ECDC) and implementation of the framework

Since 1998 legal provisions on communicable diseases have been adopted. The EU network for surveillance and control of communicable diseases allows their implementation¹¹⁹ and specific mechanisms to monitor, alert and coordinate the EU response to communicable diseases have been put in place¹²⁰. These mechanisms have been further reinforced in 2004 by the establishment of the European Centre for Disease Prevention and Control¹²¹ (ECDC).

Under these provisions EU Member States must monitor a number of communicable diseases (46) and special health issues (2: Antimicrobial resistance and health care associated infections). They also have to notify all the acute events due to communicable diseases which have a real or potential impact at EU level, including any information related to the public health measures undertaken to respond to such events. The notification of the acute events takes place through the Early Warning and Response System (EWRS), the EU Rapid Alert System for communicable diseases. Such notification helps in coordinating the response to events, which, because of their EU impact, need to be put into practice in the same way and possibly at the same time by all the concerned Member States. In practice it would be useless, and even counterproductive, to apply different measures to fight the same outbreak spreading among different Member States. In addition, the alert system for communicable diseases is linked to the International Health Regulations and therefore the notification by Member States is issued simultaneously to the EU Early Warning and Response System (EWRS) and the World Health Organisation.

When an event is notified the Commission helps the Member States in coordinating an EU response with the help of the appropriate EU Agencies, in the case of communicable diseases mainly the European Centre for Disease Prevention and Control (ECDC). The ECDC provides all the necessary input for a robust and scientific based assessment of the situation. This assessment, called "Risk Assessment" is shared through the EWRS and it is the basis to develop and choose, with the coordination of the Commission, the best options to respond at EU level to the event.

¹¹⁹ See annex 4 and also Decision 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)

¹²⁰ Reports on the operation of the EWRS are prepared regularly, listing the events communicated through the system and coordination of measures undertaken
http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm; Most recent examples of the use of the mechanism are the pandemic H1N1 event in 2009;
http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment2; and the E. coli STEC O104 outbreak in 2011;
http://ec.europa.eu/food/food/coli_outbreak_germany_en.htm; As regards the events treated under the EU Health Security Committee, annual reports are also prepared, describing the main activities, including coordination of management of events;
http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf
Examples of recent activity of the Committee include management of pandemic H1N1 in 2009 and a multi state incident of anthrax contaminated heroin
http://ec.europa.eu/health/preparedness_response/hsc/index_en.htm

¹²¹ Regulation (EC) 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p.1)

A number of events illustrate the benefits of the mechanism currently in place.

EU case definitions of specific conditions are agreed upon so that all the Member States apply the same criteria in reporting an outbreak. This has been proved of crucial importance not only during the recent E. coli outbreak (2011), but also during the SARS epidemic (2003), the H5N1 avian influenza scare (2004), a high impact event of rabies in France (2003) and during events caused by laboratory incidents when it was of pivotal importance to quickly identify all people exposed in order to treat them.

During the H1N1 influenza pandemic the adoption of technical guidance documents on risk group to be vaccinated, school closure and travel advice was crucial in sharing common decision principles to avoid an inconsistent response across the EU. Also during SARS the adoption of EU guidance documents helped Member States to have a shared approach to fight quickly new and not well know threats.

Information sharing of personal data in full compliance with the EU legislation on data protection and through a secured informatics tool like the EWRS has helped Member States to implement contact tracing activities of persons who have been contaminated or exposed to infectious agents in order to have them treated with a matter of urgency. This happened with SARS, H5N1 avian influenza, meningitis, rabies, legionellosis, and a number of dangerous hemorrhagic diseases like Ebola, Marburg, and Lassa fever.

The consistency in the approach to address communicable diseases across Member States ensures that measures to tackle communicable diseases are being handled effectively and efficiently at EU level; and, in parallel, that WHO is also informed and, if need be, can be involved directly.

Community network for the prevention and control of communicable diseases under Decision 2119/98/EC

The Community network two parts: (1) epidemiological surveillance and (2) the early warning and response system.

(1) The epidemiological surveillance part of the Community network is composed of structures and/or authorities competent at national level for collecting information relating to epidemiological surveillance of communicable diseases¹²². It has been progressively taken over by the European Centre for Disease Prevention and Control (ECDC) since the EU Agency became operational on 20 May 2005. Now, national competent bodies for surveillance have the obligation to provide all necessary information for surveillance purposes to the ECDC under the founding regulation¹²³.

(2) The Early Warning and Response System (EWRS) is a network formed by the Commission and competent public health authorities in each MS responsible for measures which may be required to protect public health. It is responsible for notifications at EU level

¹²² See Article 1 of Decision 2119/98/EC.

¹²³ See Article 2 of Regulation (EC) 851/2004

of events of communicable diseases of Community relevance and of related public health measures as well as for coordination of responses at EU level¹²⁴.

In addition to the Community network for the prevention and control of communicable diseases, Decision 2119/98 has empowered the Commission to take binding measures via the comitology procedure, e.g. new case definitions for communicable diseases (pandemic H1N1) according to the regulatory procedure with scrutiny (RPS) and the examination procedure¹²⁵.

For detailed information see the annual EWRS reports:

- Report from the Commission to the Council and the European Parliament On the operation of the Early Warning and Response System (EWRS) of the Community Network for the epidemiological surveillance and control of communicable diseases during 2006 and 2007 (Decision 2000/57/EC) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0228:FIN:EN:PDF>
- Report from the Commission to the Council and the European Parliament On the operation of the Early Warning and Response Systems (EWRS) of the Community Network for the epidemiological surveillance and control of communicable diseases during years 2004 and 2005 (Decision 2000/57/EC) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0121:FIN:EN:PDF>
- Report from the Commission to the Council and the European Parliament on the operation of the Early Warning and Response System of the community network for the epidemiological surveillance and control of communicable diseases (decision 2000/57/EC) during 2002 and 2003 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0104:FIN:EN:PDF>

N.B. Legislation on communicable diseases is outdated and does not yet take into consideration the establishment of the European Centre for disease control and prevention (ECDC) and the International Health Regulation (IHR); there is also an issue related to the parallel existence of the EWRS network and the Health Security Committee. Action requested in these two areas is purely technical and hence not subject to this impact assessment.

¹²⁴ In the area of communicable diseases the EWRS performs the same activities as the EU Health Security Committee with the exception of preparedness matters (see the terms of reference of the EU Health Security Committee).

¹²⁵ These provisions will need to be reviewed in accordance with the rules on non-legislative acts (see inter alia Articles 290 and 291 of TFEU).

Annex 5: The International Health Regulations (IHR)¹²⁶

Since 15 June 2007 the International Health Regulations (2005) have entered into force. This legally-binding agreement provides a new framework for the coordination of the management of events that may constitute a public health emergency of international concern (PHEIC) and is expected to improve the capacity of all State Parties who have signed it (194 worldwide) to detect, assess, notify and respond to public health threats. The "old" IHR were focused only on a handful of specific communicable diseases while the current ones are addressing all kinds of public health threats (e.g. chemical, radiological, environmental etc.) as well as all communicable diseases causing public health emergencies.

Countries that are States Parties to the Regulations have two years to assess their core capacities and develop national action plans followed by three years to meet the requirements of the Regulations regarding their national surveillance and response systems as well as the requirements at designated airports, ports and certain ground crossings. IHR should be implemented by 2016.

"Core capacity" comprises the minimum requirements that a State Party should have in order to detect, assess, notify and respond to public health threats. Currently countries, including all EU Member States have to report on progress to the WHO annually on their core capacities

It would enhance the preparedness of the EU to respond to future crises if compatible systems would be established and agreement on the implementation of these capacities would be reached at EU level. In addition EU criteria for notification should be established as the IHR criteria for notification are very basic so that developing countries can cope with the requirements. Health threats in the past considered as threats at European level were not notified under the IHR. For example this was the case for Melamine contaminated milk from China.

However there are weaknesses in the IHR for example they do not require MS to transfer biological material for analysis in the sophisticated laboratories needed to determine the causes of unknown threats and to develop diagnostic tests and countermeasures such as vaccines. They are also global in their nature and sometimes have difficulty in raising and lowering alert levels at a regional level. For example under the IHR it proved impossible to lower the pandemic level in the 2009 in Europe in 2010 until August that year despite it being quite clear that transmission had ceased in the EU after January that year.

¹²⁶

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

Annex 6: Examples of effects

Table 1: Examples of effects from communicable disease outbreaks

Type of threat	Year of event	Affected persons	Health impacts	Economic and other impacts
Mad cow disease and links to Creutzfeldt-Jakob disease	1993-1998	1994 - 2008 at EU level: 209 cases ¹²⁷	Limited number of cases of variant Creutzfeldt-Jakob disease; surveillance costs; diagnostic procedures; long lasting disease in patients; no treatment available.	Suspension of free circulation of meat products; destruction of huge numbers of animals; import and export bans; reduced demands in beef products due to severe concern in public about effects of consuming beef products.
H5N1, avian influenza in humans	2003-2011	By August 2011, 556 cases worldwide, including 325 deaths. ¹²⁸	Inter species infection from animal to human of H5N1 highly pathogenic influenza strain, affecting several continents. Fatality rate of 60% ¹²⁹	Huge number of animals culled; the epidemic caused major economic problems to affected countries, e.g. collapse of trade with birds, collapse of tourism; mostly in South-East Asia where the losses were estimated at US\$ 10 billion in GDP terms during December 2003 to February 2006. ^{130 131}
SARS: Severe acute respiratory syndrome	2002/2003	8000 cases and 800 deaths worldwide ¹³²	Severe disease rapidly spreading between continents; successful containment at the beginning avoided further spread. New infective agent. High lethality. No treatment. Health care workers highly impacted.	The estimated income loss ranges from US\$12.3-28.4 billion for East and Southeast Asia as a whole ¹³³ Quarantine measures; travel restrictions
Pandemic Influenza	2009/2010	A minimum of 2900 deaths in	Heavy burden on health services including	Economic and societal disruption, particularly in

¹²⁷ http://ec.europa.eu/food/animal/diseases/strategy/docs/Public_health_E_CJD_Surveillance_en.pdf

¹²⁸ http://www.who.int/csr/disease/avian_influenza/country/cases_table_2011_08_02/en/index.html

¹²⁹ http://www.who.int/csr/disease/avian_influenza/country/cases_table_2011_08_02/en/index.html

¹³⁰ UNESCAP - United Nations Economic and Social Commission for Asia and the Pacific. Economic Impact of Avian Flu: Global Programme for Avian Influenza and Human Pandemic: Health, Nutrition and Population in East Asia and the Pacific (<http://www.worldbank.org/>).

¹³¹ <http://ideas.repec.org/h/izm/prcdng/200610.html>

¹³² http://www.who.int/csr/sars/country/table2004_04_21/en/index.html

¹³³ http://www.adb.org/Documents/EDRC/Policy_Briefs/PB015.pdf

H1N1 (2009) ¹³⁴		the EU with 18000 deaths worldwide ¹³⁵ ¹³⁶	intensive care; Initial contact tracing during assessment phase; Huge investment at national level in vaccines and antivirals; competition between MS in procuring vaccines (e.g. vaccination campaign in France cost 662M€ ¹³⁷ ; problems in maintaining public confidence in health measures.	Mexico ¹³⁸ ; school closures; disruption for tourism and travel.
<i>E. coli</i> STEC O104	2011	3.910 human cases and 46 deaths within 2 months ¹³⁹	Overflowing intensive care units in Germany; shortages of medical equipment; pressure on laboratory capacity needed to examine a sufficient number of samples in a short time; special reporting and surveillance system (medium and long term) Lack of effectiveness of WHO provisions under IHR. Problems in maintaining public confidence in health measures. ¹⁴⁰	Huge impacts on vegetable/agriculture sector in the EU; 227 Mio EUR compensation scheme established by Commission to date ¹⁴¹ ; import bans by third countries, in particular ban on EU export of fresh vegetables to Russia for 2 months with extrapolated costs of EUR 100 million ¹⁴²

¹³⁴ All evaluations related to pandemic influenza H1N1 are published at:
http://www.ecdc.europa.eu/en/healthtopics/pandemic_preparedness/pandemic_2009_evaluations/Pages/pandemic_2009_evaluations.aspx

¹³⁵ http://www.who.int/csr/don/2010_07_02/en/index.html

¹³⁶ http://www.ecdc.europa.eu/en/activities/sciadvicelists/ECDC%20Reviews/ECDC_DispForm.aspx?List=512ff74f%2D77d4%2D4ad8%2Db6d6%2Dbf0f23083f30&ID=789

¹³⁷ http://www.ccomptes.fr/fr/CC/documents/RPA/5_lutte_contre_la_grippe_A_H1N1.pdf

¹³⁸ <http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,contentMDK:20663668~pagePK:34370~piPK:42770~theSitePK:4607,00.html>

¹³⁹ Last ECDC update of 27 July 2011 after the declaration of the Robert Koch Institute in Germany on 26 July that the outbreak was officially over:

http://ecdc.europa.eu/en/activities/sciadvicelists/ECDC%20Reviews/ECDC_DispForm.aspx?List=512ff74f%2D77d4%2D4ad8%2Db6d6%2Dbf0f23083f30&ID=1166&RootFolder=%2Fen%2Factivities%2Fsciadvicelists%2FECDC%20Reviews

¹⁴⁰ <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19889>

¹⁴¹ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/938&format=HTML&aged=0&language=EN&guiLanguage=en>

¹⁴² The total value of EU exports of fresh vegetables to Russia is around 600m euros a year; the ban lasted 2 months (2 June - 8 August), hence extrapolated costs in the EU 100 million EUR

Table 2: Examples of effects of threats caused by chemical, biological and environmental events

	Year of event	Affected persons	Health impacts	Economic and other impacts
Volcanic ash clouds	2010		Risk of exposure affecting persons with respiratory diseases; delays in delivery of organs for transplants because of interruption of transport ¹⁴³	100,000 flights cancelled, 10M passengers unable to travel; disruption of business estimated up to 2.5 Billion € ¹⁴⁴
Red Aluminium sludge spill in Hungary and in Danube	2010	8 persons died and 130 individuals some in critical condition were treated in hospitals for burn injuries. ¹⁴⁵	Exposure of population in several Member States to risk of poisoning	Damages to the environment; loss in production capacity as employees were unable to work due to intoxication.
Heat wave	2003	70,000 excess deaths reported from 12 European Countries. ¹⁴⁶	Large numbers of elderly persons and persons with chronic disease requiring intensive care or suffering premature death.	Estimation by United Nations Environmental Programme for the European Region was 13 Billion € ¹⁴⁷
Fire at the Buncefield Fuel Storage Depot, England	December 2005	244 patients attended accident and emergency services in hospital. Minor injuries.	Concerns included the risk to health from smoke, contamination of the general environment (including soil, and exposure to debris), and other fallout from the smoke plume, as well as living or working under the smoke plume. ¹⁴⁸	Explosion heard in France. Smoke cloud crossed Channel. Potential for international impact (France, Belgium, Netherlands as well as UK).

¹⁴³ <http://www.sergas.es/gal/DocumentacionTecnica/docs/SaudePublica/incidencias/ECDC%20Threat%20Assessment%20-%20Volcano%20in%20Iceland.pdf>;

¹⁴⁴ <http://www.efsa.europa.eu/en/efsajournal/doc/1593.pdf>

¹⁴⁵ http://europa.eu/news/transport/2010/04/20100421_en.htm

¹⁴⁶ <http://register.consilium.europa.eu/pdf/en/10/st14/st14910.en10.pdf>

¹⁴⁷ <http://www.euro.who.int/en/what-we-do/health-topics/environment-and-health/Climate-change/facts-and-figures>

¹⁴⁸ http://www.grid.unep.ch/product/publication/download/ew_heat_wave.fr.pdf

¹⁴⁸ http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947375551

Annex 7: EU mechanisms and strategies for disaster prevention and control – the security framework within the European Commission

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 crises¹⁴⁹. 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 few¹⁵⁰.

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 adopted on 23 December 2005 a Communication establishing “ARGUS”¹⁵¹ as the Commission's general rapid alert system for major crises affecting multiple sectors. ARGUS is composed of a specific coordination process and an information network involving Directorates General and services in the Commission. Following five years of operations, ARGUS is currently under review among others at improving the Commission's preparedness capacity.

The Commission ensures broader internal coordination by means of an interservice 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. 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 a number of structures are in place at EU level:

- 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);

¹⁴⁹ See detailed information in annex 7

¹⁵⁰ For further details, please see the "Inventory of Crisis Management Capacities in Commission and Agencies"

¹⁵¹ COM(2005) 662 final

- 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 threat¹⁵².

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, civil protection and external relations:

A. The initiative will help put in place the EU Internal Security Strategy, which makes specific reference to the health security initiative.

This Internal Security Strategy was adopted in November 2010 by a Commission Communication. It establishes a four year strategy to help increase Europe's resilience to crises and disasters, including hostile or accidental releases of disease agents and pathogens. The Health Security Initiative is explicitly mentioned as an element of the strategy as it will contribute to reinforcing the coordination of EU risk management through strengthening the existing structures and mechanisms to tackle health threats. Thus, the Health Security Initiative will become part of a shared agenda for Member States, the European Parliament, the Commission, the Council and European agencies to reinforce effective fight and prevention of serious and organised crime and terrorism and to strengthen resilience to natural and man-made disasters. It will be an important element in establishing a coherent risk management policy linking threat and risk assessments to decision making as envisaged by the EU Internal Security Strategy.

Action 2 of objective 5 is in particular relevant for the Health Security Initiative:

OBJECTIVE 5: Increase Europe's resilience to crises and disasters

The EU is exposed to an array of potential crises and disasters, such as those associated with climate change and those caused by terrorist and cyber attacks on critical infrastructure, hostile or accidental releases of disease agents and pathogens, sudden flu outbreaks and failures in infrastructure. These cross-sectoral threats call for improvements to long-standing

¹⁵² http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

crisis and disaster management practices in terms of efficiency and coherence. They require both solidarity in response, and responsibility in prevention and preparedness with an emphasis on better risk assessment and risk management at EU level of all potential hazards.

Action 2: An all-hazards approach to threat and risk assessment

By the end of 2010 the Commission will develop, together with Member States, EU risk assessment and mapping guidelines for disaster management, based on a multi-hazard and multi-risk approach, covering in principle all natural and man-made disasters. By the end of 2011, Member States should develop national approaches to risk management, including risk analyses. On this basis, the Commission will prepare, by the end of 2012, a cross-sectoral overview of the major natural and man-made risks that the EU may face in the future. Furthermore the Commission initiative on health security planned for 2011 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 initiative will be instrumental to strengthen chemical and biological security in the EU as set out in the **CBRN action plan**.

In the area of security, the Commission adopted on 24 June 2009 a Communication on "Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan" accompanied by the Commission Staff Working Document on "Bridging security and health: towards identification of good practices and recommendations on response to CBRN incidents and security of CBRN substances"¹⁵³.

This plan is built on an all hazard approach to combat threats for society and includes health threats preparedness and response as one of its main columns. Risk prevention and control structures developed in the health field, especially on enhanced health security in the EU, are key components of the CBRN action plan.

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 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.

B. In the field of **civil protection** the number of requests for intervention coordination in civil disaster response through the EU Civil Protection Cooperation Mechanism is growing. The initiative will strengthen capacity in responding to health threats in a civil disaster situation.

In the area of civil protection, the Commission adopted on 5 March 2008 a Communication on reinforcing the Union's disaster response capacity.¹⁵⁴ 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"¹⁵⁵. EU co-operation in the field of civil protection aims to better protect people, their environment, property and cultural

¹⁵³ COM(2009) 273 final

¹⁵⁴ COM(2008) 130 final

¹⁵⁵ COM(2010) 600 final

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.

Examples are

- transport of pharmaceuticals and medical equipment in the course of the pandemic (2009) H1N1;
- refugees arriving on EU territory following turmoil in Northern African states;
- toxic spill of red aluminium sludge in Hungary;
- avian influenza infections;
- Cholera outbreak in Haiti, Dominican Republic, and danger to visitors.

C. There are also possible synergies between the Health Security Initiative and EU activities in the **field of external relations** under the umbrella of the European External Action Service (EEAS).

The Health Security Initiative will appropriately take into account these EU external cooperation activities for health crises prevention and responses with third countries and explore synergies with the numerous bilateral EU assistance and cooperation programmes with a significant health component.

The UN Millenium Development Goals, in particular Goals 4 (reduce child mortality rates) and especially 6 (combat HIV/AIDS, malaria, tuberculosis and other diseases), are the basis for these activities; they are complemented by cooperation with third countries to mitigate the risk of CBRN materials or agents.

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 Centres of Excellence.

Annex 8: Business continuity and preparedness planning at EU and international level

Whole-of-Society approach of the WHO and the Towards a Safer World Initiative

The World Health Organization (WHO) has addressed the need for improved coordination of such critical sectors under the "whole society approach"¹⁵⁶. This need has been emphasised by the [United Nations 'Towards a Safer World' initiative](#)¹⁵⁷.

In their paper the WHO notes that healthcare institutions depend on goods and services that are delivered by the following sectors:

- transportation for the movement of supplies, personnel, and patients;
- telecommunications to support patient care, provide tele-triage, and maintain business processing;
- energy to power facility, clinical, and security systems;
- water for healthcare facilities, pharmaceutical operations, and sanitation services;
- pharmaceuticals, including consumables, for treatment of patients; and
- finance to ensure the supply chain.

The study under the UN 'Towards a Safer World' initiative on practical approaches to advance disaster preparedness published in September 2011 confirmed that multi-sector action plans often do not effectively reach community levels and cannot be implemented at local levels. In many countries, civil society organizations are not sufficiently consulted and engaged in national planning. In many countries, the non-health sectors have lagged in developing business continuity plans and are not prepared for the disruption of supplies and services. Procurement of medical countermeasures is an essential part of preparedness planning. The current situation seriously hampers proper preparedness across the EU when Member States procure medical countermeasures individually, i.e. in competition with each other, or do not even manage to procure them at all.

Further studies on business continuity planning

A study undertaken by the International Monetary Fund (IMF) in 2006¹⁵⁸ found that in many countries, business continuity planning has not yet addressed the specific risks arising from a pandemic, particularly from possible high absenteeism and that the level of preparedness among national authorities and financial institutions varies greatly. Several large global financial institutions have advanced preparations, as do providers of payment services, mainly by establishing alternative sites, and recovery task forces. Other authorities have progressed in identifying the critical issues in handling an avian flu pandemic, but have not yet finalized their response plans, or undertaken all the necessary steps to increase resilience. In most of these cases, decisions over significant investments (e.g. in IT or telecommunications infrastructure) or cross-training of staff in different functions have yet to be made, and coordination with other private and public institutions is just beginning.

¹⁵⁶ WHO, Whole-of-society pandemic readiness - WHO guidelines for pandemic preparedness and response in the non health Sector, Geneva, July 2009, 18 available on line:http://www.who.int/influenza/preparedness/pandemic/2009-0808_wos_pandemic_readiness_final.pdf.

¹⁵⁷ Towards a safer world: Beyond Pandemics: A Whole-of-Society Approach to Disaster Preparedness: http://www.towardsasafeworld.org/sites/default/files/tasw_book_web_9.23.pdf

¹⁵⁸ <http://www.imf.org/external/pubs/ft/afp/2006/eng/022806.pdf>

A seminar on pandemic preparedness planning organised under the French presidency in September 2008¹⁵⁹ concluded that compared to the health sector other critical sectors are not as well prepared to address a pandemic and underlined the need to improve inter-sectoral preparedness.

A study carried out in 2008¹⁶⁰ found huge gaps and differences across Europe in the level of advice given to businesses to prepare for a possible influenza pandemic. The report reviewed the advice offered by 13 independent advisory organisations and that of the governments of the 27 EU countries, as well as Turkey, Norway and Switzerland. The report concluded that the advice on preparedness given to businesses in the non-health sector by European governments and independent organisations, such as consultancy firms, academic bodies and trade unions, is insufficient to ensure that the private sector is equipped to deal with a pandemic. Over a third of all governments surveyed offered no advice at all and only 8 provided significant levels of advice.

A work shop on inter-sectoral preparedness organised under the Spanish presidency in May 2010 concluded that there is a lack of data on the level of preparedness planning in critical sectors involved in the response to a pandemic.

The European Centre for Disease Prevention and Control (ECDC) has facilitated systematic self assessments of pandemic preparedness in the Member States¹⁶¹. The results show that:

- most EU Member States and countries of the European Economic Area (EEA) have health sector plans.
- many countries do not have business continuity plans to maintain essential public services during the sustained stress of a pandemic (e.g. transport, utilities, police, etc).
- only 40% have national contingency plans for maintenance of non-health essential services, such as power supply, food distribution, etc, publicly available.
- 79% have cross-sectoral national planning structures for pandemic preparedness rather than just in the health sector.
- only 61% have in place cross-sectoral mechanisms for coordinating and assessing preparedness below national level.

Critical infrastructure

On 8 December 2008 the Council adopted Directive 2008/114/EC¹⁶² on the identification and designation of European Critical Infrastructure and the assessment of the need to improve their protection.

¹⁵⁹ http://www.pandemie-grippale.gouv.fr/IMG/pdf/PROPOSALS_OF_THE_EUROGRIPPE_SEMINAR.pdf

¹⁶⁰ <http://www.lshtm.ac.uk/news/2008/pandemicfluprep.html>

¹⁶¹ Technical Report Pandemic Influenza Preparedness in the E U/EEA:
http://ecdc.europa.eu/en/publications/Publications/0712_TER_Pandemic_Influenza_Preparedness_in_E_U_EEA.pdf

¹⁶² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:345:0075:0082:EN:PDF>

The Directive establishes a common procedure for the identification and designation of European Critical Infrastructure – ECI –in two identified sectors: transport and energy. A critical infrastructure is defined as an asset, system or part thereof located in Member States which is essential for the maintenance of vital societal functions, health, safety, security, economic or social well-being of people, and the disruption or destruction of which would have a significant impact in a Member State as a result of the failure to maintain those functions.

Among the obligations put forward by the Directive, the following could be relevant from the aspect of pandemic preparedness planning for critical sectors:

- Each Member State takes forward and participates in the identification and designation of relevant ECI;
- Designated ECI must implement an Operator Security Plan (OSP);
- Each Member State performs threat assessments concerning specific sub-sectors in which ECI have been identified on their territory;
- Each Member State reports to the Commission on the types of threats, vulnerabilities and risks identified in each sub-sector in which ECI have been identified on their territory;

Member States have provided reports on the state of play to the Commission. Based on the information gathered through the ECI process, the Commission performs an assessment of whether further measures are needed concerning the protection of ECI. A review of the directive is foreseen for 2013.

Annex 9: The Health Programmes at European level

The existing policy in the field of communicable diseases has been financed through the first Public Health Programme (2003-2008) and the second Health Programme (2008-2013).

With the health programmes DG SANCO has supported Member States in their efforts to enhance generic public health preparedness planning and has ensured that cross border aspects of public health emergencies have been taken into consideration. EU priorities in this area have been the prevention and control of existing or emerging contagious diseases; preparedness for health emergencies and response capacity against chemical, biological, radio-nuclear (CBRN) threats/attacks.

It is planned that for important elements of the initiative, specific actions will be supported by the future Health programme "Health for growth". There is a dedicated "objective 4" which will develop common approaches and demonstrate their value for better preparedness coordination in health emergencies. In addition, there is a transversal objective on implementation of EU legislation. 2-4 Million € per year are envisaged internally for these purposes.

Below some examples of successful preparedness projects which have been funded in the past:

- Laboratory network (EURONET P4): Biosafety Level-4 (P4) facilities, which allow the containment and the study of very dangerous biological agents (e.g. smallpox, ebola) are very expensive to build and maintain and require a lot of expertise from very skilled staff, and very secure people. A cost effective and lower risk alternative to building new laboratories is to foster long-term sustainable collaborative networks between those laboratories that already exist. Unique in the EU, this project facilitates cooperation between all the highest biosecurity laboratories in Europe.
- SIDARTHA project: As a health threat emerges, there can be significant delays between the onset of an epidemic and the launch of an appropriate response by services and authorities – costly in terms of money spent, time wasted and lives lost. Being able to know early that a health emergency situation has begun is crucial to be able to respond appropriately. Syndromic surveillance is one of the solutions. It seeks to use existing health data in real time to provide immediate analysis and feedback to those charged with the investigation and follow-up of potential outbreaks.
- The CARRA-NET (Chemical and Radiation Risk Assessment NETwork) project is intended to help to develop a coordinated and robust preparedness and response capacity within the EU Member States (MS) in order to effectively respond to chemical and radio nuclear incidents, especially those of cross-border significance. The project addresses issues such as the timely detection, alerting and distribution of information to relevant stakeholders, the need to develop risk assessment and management strategies, the integration of scientific advice in the management of emergencies, and the need to have good liaisons systems in place between the Member States, the European Commission, the EU agencies as well as international organisations and third countries, to ensure mutual information on measures envisaged and coordination of such measures.

- SHIPSAN: SHIPSAN TRAINET aims to both facilitate the implementation of International Health Regulations to enhance the common EU policy, but also to create a common European framework for ship sanitation inspection, surveillance and the control of outbreaks. Their work is expansive, covering guidelines for inspections, food safety and hygiene, surveillance of communicable diseases, medical facilities, outbreak plans, pest and waste.
- EpiSouth-Plus: EpiSouth-Plus is unique among projects funded by the EU and other international initiatives in the field of health preparedness in its focus on the Mediterranean region as a whole, including non-UE countries as well as all three WHO Regional Offices that cover the Mediterranean. In addition to facilitating epidemiological communication and practical training, this regional approach strengthens solidarity and cohesion within the European Community and between EU and non-EU countries, especially for information sharing regarding cross-border public health threats and for the implementation of the IHR, which have among their challenges that of interacting with national procedures and legislations and that of facilitating a common international action in case of need. Moreover, it is expected to reduce the disparities in the different approaches to early warning and preparedness by bringing together EU and non-EU countries in all the planned activities. EpiSouth-Plus will fill the gaps and needs that were identified in the previous years. In particular, the laboratories in the Mediterranean region will be better connected and coordinated to ensure the development of cross-border laboratory services, enhance complementarity among vertical and fragmented laboratory networks and help to overcome of national logistic and legislation constraints. Common procedures in interoperable Generic Preparedness and Risk Management Plans will be promoted to reduce inter-country variability, enhance capacity building and cross-border concerted actions and facilitate the elaboration of national plans and communication strategies.
- ASHT: Large contamination events of hazardous chemicals require a rapid alert system in order to trigger a rapid and appropriate response, to protect the health of potential victims of the deliberate as well as accidental release of poisons, which unlike viral or bacterial agents, can harm and kill very quickly. ASHT projects have now developed the concept of the Rapid Alert System for Chemical Health Threats (RAS-CHEM), which now includes a risk assessment tier for poison control centres to share information, and a risk management tier for national authorities and health ministries to escalate information to the EU. RAS-CHEM is an early warning system for DG SANCO. Member States now have a common platform to share information and act together regarding chemical incidents that could cross borders and affect citizens throughout the European Union.
- ORCHIDS: In the event of a release of a hazardous substance, large numbers of people will need to be decontaminated quickly – and effectively – so as to halt the spread of contamination and prevent further harm, as well as to prevent the contamination of emergency responders and hospital facilities. Infrastructures, protocols and guidelines exist worldwide for the response to such incidents – such as the deliberate release of chemical agents on public transport systems, or the emergency response to an industrial accident – but very little empirical evaluation of these has been completed to date. For the first time, an EC-funded scheme, the **Optimisation through Research of Chemical Incident Decontamination Systems (ORCHIDS)** project, is exploring ways to optimise mass casualty decontamination

Annex 10: Overview of Objectives of the Health Security Initiative

general objectives		
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		
specific objectives		
to reinforce the response to <i>all</i> serious cross-border threats to health based on a comprehensive and coherent approach to preparedness and response planning, risk monitoring and assessment as well as risk management including risk communication		
<i>preparedness and response planning</i>	<i>risk monitoring and assessment</i>	<i>risk management and crisis communication</i>
to develop a common approach to preparedness planning at EU level for <i>all</i> serious cross-border threats to health ensuring coherence and interoperability among sectors at EU level and between Member States including improving equitable access to medical countermeasures	to create conditions to ensure a coherent and comprehensive identification and notification of health threats and evaluation of their risks to health, especially in case of health-related crises with a multidisciplinary dimension	<ul style="list-style-type: none"> - to create conditions to strengthen and enhance coordination between Member States, international level and the Commission in order to ensure a coherent and consistent policy approach to effectively manage responses to serious cross-border threats to health across the EU - to create and facilitate shared and coordinated communication strategies in order to avoid conflicting or inaccurate messages being released to the public
operational objectives		
<i>preparedness and response planning</i>	<i>risk monitoring and risk assessment</i>	<i>risk management and crisis communication</i>
<ul style="list-style-type: none"> - to develop and update comparable and coherent generic preparedness and response planning and planning for specific threats at EU level, in particular for pandemic influenza - to develop and agree shared standards and tailor-made EU criteria for notification of threats in order to ensure stronger, continued and resilient operation of the public health sector in the European Union based on the requirements set out by the International Health Regulations - to create an instrument to improve equitable access to medical countermeasures, e.g. through a joint procurement mechanism 	<ul style="list-style-type: none"> - to strengthen, better interlink and ensure sustainability of existing monitoring and notification mechanisms and structures - to strengthen and create capacities for robust, reliable, and rapid public health risk assessment - to provide mechanisms for reinforced coordination among existing structures for serious cross-border health threats other than communicable diseases - 	<ul style="list-style-type: none"> - to strengthen the capacities and processes and provide for a sustainable structure for coordination of the public health response at EU level for any cross-border public health crisis - to clearly define the scope of activities of this structure/body and equip it with a strong mandate for EU risk management, with a strong commitment of Member States - to strengthen actions related to risk and crisis communication on health threats, and allow for rapid exchange and agreement on communication messages and strategies

Annex 11: Notification of serious cross border health threats to the WHO under IHR

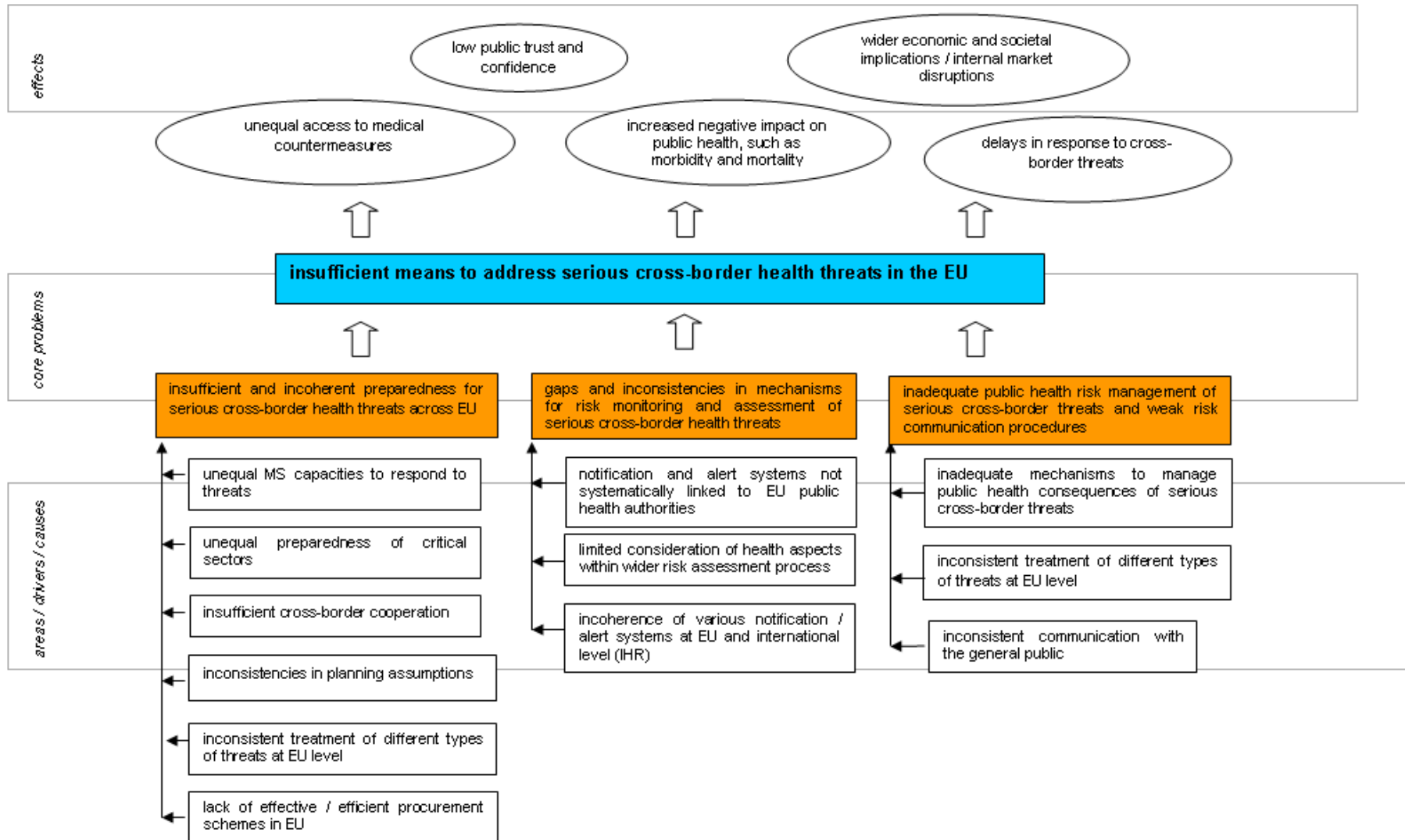
Number of IHR events/ notifications by type of event and year during 15 June 2007 - 30 July 2011

Type of event	June- Dec 2007	2008	2009	2010	Jan-July 2011	Grand Total
Animal		1	3			4
Chemical				1		1
Food Safety	4	1	3	3	1	12
Infectious	7	12	90	43	25	177
Product	2	2	1			5
Undetermined					1	1
Grand Total	13	16	97	47	27	200

Communicable diseases notified under IHR are 177, Communicable diseases notified under 2119/98/EC through EWRS are 785; so $785: 177 = 4,5$.

That finally means that the events reported through EWRS under the EWRS criteria are 4,5 times more than the events reported under the IHR under the IHR reporting criteria. This is obvious because the criteria are different. This finally confirms that the EU criteria for reporting of communicable diseases are matching more event than the IHR.

Annex 12: Problems and public health consequences



Annex 13: Overview of measures proposed under the three options

	Option 1: Status quo:	Option 2: Soft instruments	Option 3: Establish common EU legal framework covering <i>all</i> serious cross-border threats to health
Preparedness and response planning	Follow up of implementation of guidance on preparedness; organise exercises and training; exchange best practice;	Shared approach on preparedness planning, identify core capacity standards related to IHR requirements; guidance on improved cross-sectoral preparedness and interoperability,	Common EU framework for MS to: <ul style="list-style-type: none"> - put in place common elements of preparedness planning; - report regularly on implementation of preparedness plans; - cooperate in cross-sectoral preparedness and response planning - implement requirements on common minimum core capacity standards; - agree and implement EU tailor-made criteria for notification of serious cross-border health threats at EU level;.
Procurement of medical countermeasures	Support for Member States, e.g. in preparing tender specifications; promote production capacity for pandemic influenza vaccines;	Ditto option 1, plus: increase support for Innovative Medicines Initiative and/or EU stockpile of medical countermeasures, better exchange of information on contractual conditions ;	Establish legal basis for EU coordination of joint action for purchasing medical countermeasures;
Risk monitoring and assessment	No strengthening of existing notification and monitoring mechanisms and structures; risk assessment on the basis of ad hoc support networks	Recommendation to MS to notify threats with tailor-made EU criteria; improve coordination for risk monitoring and assessment by informal arrangements; develop Memoranda of Agreement with entities dealing with alert systems;	Put in place coordination mechanism to notify at EU level cases of serious cross-border threats to health; require MS to notify the EU level in all cases relevant to IHR; close gaps in public health risk assessment capacities; Commission to support this by mapping existing risk assessments in order to improve coherence at EU level (linked to SG initiative on overall threat assessment);
Risk management	Maintain current informal mandate of the Health Security Committee (HSC)	Replace HSC by expert group;	Improve coherence and coordination of risk management; EU action to cover advisory activities on preparedness and response planning and public health response coordination, non legislative acts and mutual agreements between MS; establish new instrument for joint actions, in particular joint procurement of medical countermeasures;
Risk and crisis communication	Informal HSC communicators' network to continue to facilitate exchange of information	Develop EU coordination related to shared communication approaches and guidelines ;	Develop common communication strategies, integrate communicators into crisis management process and link communicators directly to risk managers / decision makers;

Annex 14: Opinions of stakeholders on the three options

The views of the stakeholders, as gathered through the consultation, support the following actions as described in option 1: the view that the EU should play a central role in encouraging national preparedness planning is supported by 93% of all the respondents. The same opinion was clearly expressed through the 2010 consultation on pandemic preparedness, where 98% of all respondents took the view that improved cooperation at EU level would enhance preparedness. 94% of all respondents also thought that it was important for countries' preparedness planning to work well with other countries in the EU. 90% of all respondents felt that the interoperability of Member States plans should be facilitated at EU level.

In addition to the points mentioned under option 1, the views of the stakeholders, support the following actions, as described in option 2: minimum core capacity standards should be set up on preparedness planning to cover more public health aspects resulting from chemical, and environmental threats.

According to 90% of the stakeholders the EU should coordinate national preparedness plans, for example by providing a framework to improve the interoperability of national preparedness plans. In the 2010 consultation on pandemic preparedness, 92% of all respondents and 91% of those responding on behalf of a public authority felt there was a need for the European Commission to take a coordinating role when a cross-border aspect was involved.

The majority of the stakeholders (90%) are in favour of a better evaluation of public health issues resulting from all serious cross-border threats.

The stakeholders, as well as the members of the HSC and the EWRS network committee, considered that a legal formalisation of the status of the HSC would be better.

A large majority of the stakeholders (over 93%) suggested that a better coordination of information and communication between Member States could be made possible at EU level by:

- a. making risk and crisis communication an integral part of risk management at EU level;
- b. providing more guidelines on risk and crisis communication at EU level;
- c. supporting the communication efforts of Member States and other bodies dealing with health measures;
- d. establishing networks and improving communication with healthcare professionals;
- e. improving communication with the media;
- f. improving the consistency of communications between Member States.

In addition to the points mentioned under options 1 and 2, the views of the stakeholders, as gathered through the consultation, support the following actions, as described in option 3: it is important, according to the members of the HSC and EWRS network committee, to ensure interoperability of the alert/notification systems, in order to avoid a wide range of differing

responsibilities to make announcements. The EWRS could be considered for this purpose. In the same way, 84% of the stakeholders consider that the existing detection and notification systems for health aspects at EU and national level should be better interconnected across the sectors in order to link the different disciplines (food safety, energy, transport).

92% of all the respondents believe that, better coordination and management of all serious cross-border health threats is needed. 85% of all the respondents believe that improved coordination of national public health measures (prevention, diagnosis, treatment, control) among Member States is also needed in the event of a cross-border health threat. 79% of all respondents think that a coherent risk management mechanism for serious cross-border public health threats at EU level would create added value.

Annex 15: Detailed tasks and obligations for Member States and the Commission under option 3 – legal proposal

The following aspects related to preparedness would be covered by the legal proposal:

Member States

- inform and consult each other, in liaison with the Commission, in order to coordinate their efforts for the purpose of ensuring an adequate coherence of national preparedness and response planning at EU level in respect of monitoring, early warning of and combating serious cross-border threats to health.
- coordinate among themselves actions to encourage the consistency, interoperability and multi-sectoral aspects of preparedness and response planning at national level for the perspective of protection and improvement of human health, in particular in critical sectors of society.
- for core capacity requirements for preparedness and response planning at national level, take into account international standards on health security, in particular developed in the framework of the World Health Organisation

The Commission

- provides for the coordination of these actions at EU level in collaboration with the Member States.
- adopts recommendations directed to the Member States on minimum core capacity requirements for preparedness and response planning, including technical guidelines for setting up generic and specific plans in critical sectors of the society.
- by means of implementing acts, adopt procedures for information, consultation and coordination in relation to preparedness and response plans, in order to ensure consistency, interoperability and multi-sectoral aspects of national plans at EU level, including adequate coherence between specific national plans developed for the critical sectors of the society.

In the area of risk assessment, the Commission:

- will make available to the competent authorities of the Member States an assessment of the risks to public health carried out by an Agency of the European Union ;
- will provide an assessment of the risks to public health, in collaboration with the competent authorities of the Member States, if a assessment is not available or not comprehensive or not consistent with another assessment carried out by an Agency of the European Union. The assessments will be based on objective expertise and robust scientific evidence, and review key research to identify any potential health impacts that the given threat may cause, determine the amount, duration, and pattern of exposure to the threat, assess the ability of the agent to cause illness or death and identify the vulnerable groups, estimate dose-related health effects that may lead to illness or death, develop models for the likely progression of spread and disease outcome and define options for public health measures and assess the potential impacts of those options on the critical sectors of society.

Risk management

Member States consult each other in liaison with the Commission in order to coordinate national responses to serious cross-border threats to health, they consult Member States and the Commission on the nature, purpose and scope of intended measures and adopt them.

The Commission will provide for the coordination of response to serious cross-border threats to health in collaboration with the Member States.

Member States may, in conjunction with the Commission, conclude a joint action, relating to a serious cross-border threat to health; e.g. declaration of public health emergency at EU level, coordination of prevention and control campaigns, including vaccination; coordinated information and communication initiative, including awareness campaigns as appropriate; coordinated communication messages, joint procurement on medical countermeasures.

When concluding a joint action, the Member States will ensure that these measures are proportional and limited to the risks to public health caused by the serious cross-border threats to health, and respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care.

In duly justify cases, the Commission may, by means of implementing acts, adopts:

- (a) guidelines on protective and control measures to be taken on serious cross-border threats to health, in particular in public health emergency of international concern;
- (b) guidelines on communication with the public and on good practice for the public.

The Health Security Committee would:

- (a) advise the Member States and the Commission, at the Member States' or the Commission's request, on policy, strategy and technical issues relating to health security as well as on Commission proposals in that field;
- (b) coordinate preparedness and response planning
- (c) coordinate public health response

The committee may invite experts and observers to attend meetings and would meet at regular intervals and whenever the situation requires.

Annex 16: Description of actions proposed under the options and their implications for the health sector

Option 1: Status quo: Maintaining the current level of activities

Actions proposed under status quo	Justification/Motivation of the rating and impact
<p>The Commission would continue the technical level work with the Member States: updating and ensuring implementation of existing guidance as regards generic and pandemic preparedness. Surveys and development of indicators would be supported.</p> <p>Organising exercises where public health crises are simulated, and exchange of best practice would continue.</p> <p>Shared standards and EU tailor-made criteria for notification in order to ensure implementation of the requirements as set out in the IHR would not be addressed.</p>	<p>Experience leads to the assumption that EU planning has only a limited impact on Member States (MS). Given the voluntary nature of the approach, MS are not obliged to take on board EU guidance. There is no overview and knowledge on how Member States use information, guidelines, case studies and results of exercises to improve their national planning in relation to each other. In addition, under this option, there would be no sustainable and comprehensive implementation of the findings and recommendations of the currently funded projects under the Health Programme.</p> <p>This option will not coordinate in a coherent way the implementation and sharing of core capacity requirements under the International Health Regulations in MS. Preparedness planning will remain as diversified as it is now and parallel and uncoordinated implementation of IHR requirements by Member States will not lead to any common baseline for EU preparedness. In a crisis situation, bilateral arrangements with WHO would prevail over EU coordination.</p> <p>Related to specific preparedness planning in the field of communicable diseases, where the ECDC is mandated to provide guidance and advice to Member States and to the Commission, the differences and incompatibilities between MS could prevail in the absence of a robust solution. In addition, the most recent overview on how the existing EU pandemic preparedness plan (set out in a Commission Communication from 2005) has been used, indicates substantial areas for further work to ensure national readiness in case of a pandemic [see ECDC reports on the basis of country visits pre2009 for evidence¹⁶³]. In this context, in its resolution of 8 March 2011, the European Parliament calls for the prevention plans established in the EU and its Member States for future influenza pandemics to be revised in order to gain in effectiveness and coherence and to make them sufficiently autonomous and flexible to be adopted as swiftly as possible and on case-by-case basis to the actual risk.¹⁶⁴The EU state of preparedness will not improve under this option given that all the levers remain at national level with no EU power to implement an overall coherent and consistent approach. For example, the evidence of a lack of a joint approach was demonstrated in the evaluation report on H1N1 (2009) in paragraph. 7.2¹⁶⁵, where only seventeen MS report that consultation occurred between them and neighbouring European countries in the development of plans during the preparedness phase.</p>

¹⁶³ http://ecdc.europa.eu/en/publications/Publications/0701_TER_Pandemic_Influenza_Preparedness.pdf

¹⁶⁴ European Parliament resolution of 8 march 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

¹⁶⁵ http://ec.europa.eu/health/communicable_diseases/docs/assessment_response_en.pdf

	<p>The situation in other critical sectors will not improve; the risk therefore remains that in a health crisis, critical sectors will not be enough prepared for health consequences of a serious event. This may lead to serious consequences as regards capacities of the health system to respond effectively. (See conclusions of French presidency conference Eurogrippe 2008: "However, the results of this preparedness work show heterogeneity among Member States. It is incomplete in the public health sector, but even more so in other sectors (some countries need to take further into account an inter-sectoral dimension in their preparedness plans). Several priorities were identified as leading to critical distances, among which several are Inter-sectoral" .)¹⁶⁶</p> <p>The impact of option 1 would be low as the current systems would be maintained but not strengthened.</p>
<p>To improve equitable access to medical countermeasures, the Commission would continue to support Member States' cooperation, e.g. in the preparation of their national tender specifications for vaccine procurement.</p> <p>The Commission would also continue to promote improved production capacity, through e.g. improved vaccination coverage for seasonal flu which could influence capacity building for pandemic influenza vaccine production.</p>	<p>Maintaining the status quo would mean that the access to medical countermeasures will be left in the responsibility of the Member States with no EU component to improve the purchasing power of the Member States and the contractual conditions under which the contracts are made. It will also not ensure that risk groups are covered by a common approach for vaccination. The Commission would continue to play an assisting role to help Member States drafting technical specifications for national tenders, sharing best practices and expertise on tendering procedures, which could assist smaller Member States and those with less public procurement experience to improve the efficiency of the process at national level.</p> <p>However, in 2009 a similar effort by the Commission to provide such assistance during the H1N1 pandemic only met with limited success with a maximum of 5 Member States participating in the exercise. Nevertheless this effort confirmed the value of such EU intervention for the smaller Member States. Building on this experience, the Council subsequently called on the Commission in October 2009¹⁶⁷ to continue to support procurement processes for the vaccine for those Member States, candidate countries, potential candidates and neighbouring countries who do not have a current agreement with manufacturers. The Council called on the same occasion to explore further the Commission initiative in 2009 to create a virtual stockpile of pandemic influenza vaccines and antivirals (enabling sharing of surplus supply)¹⁶⁸.</p> <p>The Commission would propose actions based on Council Recommendation of 22 December 2009 on seasonal influenza vaccination (2009/1019/EU)¹⁶⁹ calling upon the Member States to increase seasonal vaccination coverage of the risk groups up of 75% (currently only 11 Member States have a vaccination coverage for these groups higher than 50%¹⁷⁰). This process is intended to put in place of higher level of production capacity for vaccines in Europe in case of a</p>

¹⁶⁶ http://www.pandemie-grippale.gouv.fr/IMG/pdf/PROPOSALS_OF_THE_EUROGRIPPE_SEMINAR.pdf

¹⁶⁷ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/110500.pdf

¹⁶⁸ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/111599.pdf

¹⁶⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>

¹⁷⁰ http://www.eurosurveillance.org/images/dynamic/EE/V13N43/Venice_Survey_Figure2.jpg

	<p>Pandemic in order to improve their availability for citizens. However the implementation depends entirely on MS and it is the MS responsibility to review their vaccination strategies for seasonal flu.</p> <p>In addition, the Commission would continue to support through the EU Research and Development Framework Programme which encourages the development of pharmaceutical products¹⁷¹.</p> <p>As a consequence, under this option, the Commission would continue to offer limited value support to the Member States but they have shown during the Pandemic H1N1 2009 (a mild pandemic) very modest impact. Therefore, this option would not create an instrument to support access to medical countermeasures by the Member States.</p>
<p>The EU would continue to work with the existing notification and monitoring mechanisms and structures without strengthening coordination among concerned policy areas.</p> <p>Communicable diseases would remain under the existing legal framework.</p> <p>Risk assessment related to serious cross-border health threats arising from threats caused by biological (other than communicable diseases), chemical, and environmental related events would be delivered on the basis of ad hoc support networks as it is the case now.</p>	<p>Under option 1, coordination among networks and mechanisms in place would not be strengthened and no additional arrangements will be put in place to improve coordination. Alerts from rapid alert systems for other policies will not be notified systematically to the public health authorities for the purpose of risk monitoring and assessment and gaps in the notification of serious cross-border threats to health of chemical, biological or environmental origin would persist. The Commission would also not be notified of such threats through the IHR. The impact would be lack of specific requests to carry out a risk assessment from the public health perspective. This weakens the capacity of the EU to respond in the case of such health threats. For example, in a Member State exercise carried out in 2011, it was concluded that there was no linkage between major cross-border chemical events and the EU public health authorities leading to an absence of adequate information as a basis for a coherent response¹⁷². In addition, real life situations such as the forest fires in Russia and the volcanic eruption in Iceland demonstrated that there was no tool to share information at EU level on public health impact. Although there were strong concerns of public health impacts, happily these turned out not to be the case.</p> <p>The use of incentive measures to link public health authorities in respect of risk monitoring for chemical, biological or environmental related threats would continue under the Health Programme. However the value of such initiatives is modest as they are not linked to other policy areas, as the funding is not sustainable and since the experience has shown that the Member States are reluctant to use these unsustainable notification systems for regular reporting; disparities and incompleteness of reporting would be the consequences which might lead to delayed and incoherent response in the event of a crisis. In addition these informal public health systems may duplicate other reporting systems in the same fields based on legal requirements in those policy fields¹⁷³.</p>

¹⁷¹ http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/fp7projects_en.html

¹⁷² Exercise Iridium; http://ec.europa.eu/health/preparedness_response/docs/iridium_1_2011_frep_en.pdf

¹⁷³ eMars - <http://emars.jrc.ec.europa.eu/>; MIC - http://ec.europa.eu/echo/civil_protection/civil/prote/mic.htm; CleanSeanet <http://www.emsa.europa.eu/operations/marine-pollution/cleanseanet.html>; SEIS <http://www.eea.europa.eu/about-us/what/shared-environmental-information-system>

	<p>As regards risk assessment, this option would continue to rely on networks whose expertise can be gathered on an ad hoc basis. This would not lead to strengthening capacities either in the short-term or long term and gaps would remain and may lead to inefficient and ineffective response.</p> <p>Option 1 may as it is now lead to inappropriate risk assessment and response.</p>
<p>The mandate of the Health Security Committee under Council conclusions of 22 February 2007 as prolonged by the Council Conclusions of 13 September 2010, would be maintained and the Council would be the EU institution to prolong its mandate, as is the situation currently. The committee would remain an informal body and commitment of Member States would be maintained on the same level as currently.</p>	<p>Under this option, risk management will continue to be ensured by two existing structures, one legally based (and responsible for communicable diseases¹⁷⁴) and another informal entity (the Health Security Committee) which is intended to coordinate public health response <i>mainly</i> for other health related threats, but with functions relating to pandemic preparedness.</p> <p>In a crisis situation, the Health Security Committee can discuss public health measures to be implemented in the MS. However, these measures are at times difficult to agree and are not legally binding. An example was during the H1N1 pandemic, when obtaining agreement in the Committee for joint statements on school closure, vaccination policy and travel advice¹⁷⁵ was not easy to agree and the final statements were not uniformly implemented at member state level. However, since the committee was set up by the Council and is composed of high level representatives of ministers of health, it has a political and strategic credibility and responsibility which goes beyond a technical level committee. It also has the advantage of allowing a cross sector approach acting as a focal point, which might be difficult to replicate in a more formal committee structure.</p> <p>As neither the mandate of the Health Security Committee nor the scope of measures which it could agree on would be changed under this option, there would be no impact on strengthening its role. Furthermore, the current overlap of formal and informal structures, in particular in the area of pandemic preparedness, would persist. This was dealt with in 2009 by holding joint audio conferences of both groups, but this did not resolve the issue of the mixed competences, different conferral of powers (one could vote on legal measures, the other not) nor the fact that both groups have different memberships.</p> <p>In its resolution of 8 March 2011, the European Parliament requests clarification, and if necessary review, of the roles, duties, remits, limits, relationships and responsibilities of the key actors and structures at EU level for the management</p>

¹⁷⁴ Early warning and response network, Decision 2119/98 (OJ L 268 3 10 1998, p.1)

¹⁷⁵ 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/statement_travel_en.pdf
http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_school_en.pdf

	<p>of medical threats. It welcomes the fact that the Commission has committed itself to studying the possibility of a revision and a long-term reinforcement of the legal basis of the Health Security Committee.¹⁷⁶</p> <p>This option would also not address the current absence of a legal basis under which public health measures could be coordinated in the Health Security Committee as regards serious cross-border health threats other than communicable disease. Therefore, for example, in case of a serious cross-border deliberate release of a biological agent (such as Ricin), the EU coordination through the Health Security Committee would remain as it is at present, on an informal and voluntary basis. There would continue to be an unbalanced approach between the communicable disease threat framework and that for other threats, one being legal the other not. This is illogical and unfortunate since the public health consequences of these other types of threats (such as a weapon containing pathogens or chemicals (dirty bomb)¹⁷⁷) might be significantly more serious than traditional threats caused by communicable diseases (such as Mumps¹⁷⁸). Examples of the potential dangers of such events arose during the mustard gas stockpile event in 2011 in Libya during the current civil disturbance¹⁷⁹, or the dispersal of Sarin gas in the metro in Japan in 1995¹⁸⁰.</p>
<p>The informal HSC communicator's network would continue to facilitate exchange of information in the event of a crisis and continue to provide guidelines on communication</p>	<p>As basic parameters remain unchanged, no improvement in impact can be expected. Structures are not strengthened and conditions for communication will not be further improved. This would result in non implementation of "lessons learnt" from the evaluation report of H1N1 in 2009 which stressed the importance of improving public communication coordination at EU level for cross-border health threats.</p>

176 European Parliament resolution of 8 march 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))
177 http://ec.europa.eu/home-affairs/summary/docs/com_2009_0273_en.pdf
178 <http://www.ecdc.europa.eu/en/healthtopics/mumps/Pages/index.aspx>
179 http://www.iss.europa.eu/uploads/media/The_return_of_the_Gaddafi_and_his_chemical_weapons_spec_tre_01.pdf
180 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(95\)92170-2/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(95)92170-2/abstract)

Option 2: Separate and different handling of serious cross-border threats to health – enhanced EU cooperation by use of soft instruments based on a voluntary approach

Actions proposed as regards different handling of serious cross-border to health to strengthen the current system	Justification/Motivation of the rating and impact
<p>The Commission would propose to the Member States a shared approach on generic and specific preparedness planning, including for pandemic influenza. This approach would be non-binding and voluntary for the Member States.</p> <p>This would include identification of core capacity standards related to surveillance, notification, verification, response and collaboration activities building on and strengthening requirements under IHR.</p> <p>Finally, the Commission would provide guidance on improved cross-sectoral preparedness and interoperability and continue to encourage exchange of best practice through seminars and workshops and provide incentive measures via the Health programme</p>	<p>Under option 2, the Commission would develop guidance on generic and preparedness planning in cooperation with MS (for instance, Council recommendations under Article 168.6 TFEU), and would propose shared requirements on core capacity in line with the International Health Regulations. The approach would also include guidance for other crucial sectors of the economy and society, in particular for preparedness for pandemic influenza in line with the "whole society approach" of the World Health Organisation and the Treaty provisions on "health in all policies" in Article 9 TFEU. This approach would bring more consistency and compatibility in preparedness at EU level and across sectors because it would move from the current voluntary and informal approach under the baseline and option 1 scenario, towards a more formalised approach with reporting requirements. In addition, criteria for notification as set out in the IHR¹⁸¹ would be adapted for EU requirements in order to ensure that all serious cross-border health threats would be notified (please refer to the part for Risk monitoring and assessment for additional information).</p> <p>Member States would be encouraged to implement Council recommendations following the outcomes of regular evaluation of their implementation, which would increase impact at national level, even if it is not binding. There are many examples where such recommendations have had a measurable impact on Member States policy making (eg. dealing with health care associated infection, seasonal flu vaccination and anti microbial resistance).¹⁸²</p> <p>In addition, the Commission would continue to encourage exchange of best practice and provide incentive measures, using the EU health programme as is currently the case. This would lead to better dissemination of data and probably even trigger innovative aspects but sustainability cannot be expected given that these activities are carried out using project grants of limited duration.</p> <p>Under this option, the objective can be <i>partially addressed</i>. If Member States contribute to guidance and implement accordingly on the basis of a soft instrument such as a Council Recommendation, there is an improvement of the preparedness situation as common indicators and arrangements can be put in place, and as progress can be monitored and reported on by the Commission. Smaller Member States will probably benefit more than bigger countries which have</p>

¹⁸¹ http://www.who.int/ihr/annex_2_guidance/en/index.html

¹⁸² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>; http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:034:0013:0016:EN:PDF>

	more resources for preparedness planning and more developed cross-sector crisis management structures.
<p>In order to improve equitable access to medical countermeasures, the Commission could continue, as described in option 1,</p> <ul style="list-style-type: none"> - to take incentive measures relating to capacity building for vaccine production, and - to play a supporting role to Member States cooperation, e.g. in the preparation of their national tender specifications. <p>In addition, as part of Option 2,</p> <p>incentives related to the Innovative Medicines Initiatives or/and EU stockpile of medical countermeasures</p> <p>The Commission could strengthen the purchasing power of the MS by improving the exchange of information on contractual conditions through the confidential platform CIRCA BC.</p>	<p>Under this option, the initiatives proposed in Option 1 above would be implemented as a baseline.</p> <p>In addition to the financial measures improving capacity building that are envisaged under option 1, the Commission may envisage under option 2 to use the Innovative Medicines Initiative¹⁸³, Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. However, these incentives will only cover activities related to research and development and not directly contribute to improve the availability of medical countermeasures on the short term and therefore only partially address the objectives.</p> <p>Furthermore, the setting up of stockpile of medical countermeasures could also be envisaged under this option to increase equitable access to medical countermeasures; however the Commission has already proposed such initiative and was withdrawn following political opposition from the Council in 2006 on grounds of subsidiarity and costs¹⁸⁴. In other regions and countries similar initiatives have however been implemented. 2 regional stockpiles of medical countermeasures for South East Asia were funded through the Japanese Government over a 5 year period for a budget of 48M\$¹⁸⁵. Alternatively, the Swiss Government has a legislation obliging the producers to create a stockpile of essential goods (incl. antivirals) with marginal costs to the Government¹⁸⁶.</p> <p>Regarding equitable access to medical countermeasures, the Commission could play a supporting role to Member States by facilitating cooperation in the preparation of the tender specifications and, following a bundle of individual calls for tender launched simultaneously, cooperate in the evaluation of tenders and the award of national contracts.</p> <p>This impact of this option is expected to be an improvement over individual national procurement mechanisms and compared to the limited assistance provided during the influenza H1N1 (2009) pandemic which was restricted to working on the drafting of national tender specifications. It allows pooling the expertise of the Member States and improves transparency. The value of previous efforts at the European level in the field of procurement of medical countermeasures was recognised in Council Conclusions in 2009¹⁸⁷ and 2010¹⁸⁸ which extended requests to the</p>

183 <http://www.imi.europa.eu/>

184 <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/732&format=PDF&aged=1&language=EN&guiLanguage=fr>

185 http://www.flu.mn/mgl/images/stories/Sudalgaa_shinjilgee/WPRO2011_pdm/10%20ASEAN%20ASEF%20Stockpile%20Project_JICS_Beijing_Mar2011.pdf

186 <http://www.bwl.admin.ch/themen/01009/01025/index.html?lang=en>

187 "To ensure timely availability of vaccines for all Member States, the possibility of a mechanism or a bundle of tender notices should be considered by those Member States with no current or with partial agreements with manufacturers as the most efficient way to proceed." "Invites the Commission to continue to support procurement processes for the vaccine for those Member States, candidate countries, potential candidates and neighbouring countries who do not have a current agreement with manufacturers;" http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/110500.pdf

	<p>Commission to develop it further. In addition, in its resolution of 8 March 2011, the European Parliament expresses its approval for the introduction of a procedure enabling Member States to make purchases of vaccines and medical products on a voluntary basis, in order to obtain, for a given product, inter alia, equitable access, advantageous rates and flexibility for the order.¹⁸⁹ However, the current option remains at the level of cooperation between individual procurements and the purchasing power and ability to obtain better contractual conditions will remain much weaker compared to the option of a full joint procurement, as proposed under Option 3.</p> <p>It would not guarantee implementation of the Council's own political commitment in the same conclusions to "ensure timely availability of vaccines for all Member States".</p> <p>Also, it would not ensure a joint procurement mechanism as requested by the Council in Conclusions in 2010 "Inviting the Commission to report on and develop [...] a mechanism for joint procurement of vaccines and antiviral medication which allows Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality"¹⁹⁰.</p>
<p>As regards notification of threats other than those caused by communicable diseases a proposal/recommendation to Member States would be issued to mutually notify each other and the Commission of health threats with tailor-made criteria required because of the integrated nature of the EU.</p> <p>Risk monitoring and risk assessment for other serious cross-border threats to health would rely on improved coordination by providing informal arrangements among existing EU structures, such as EU agencies or informal</p>	<p>Under this option, notification will be strengthened and knowledge from other rapid alert systems will be improved and agreements for mutual alerting will be established at EU level. At present this exchange of information between the different alert systems is informal, not systematic and depends on the individual awareness of the potential cross-sectoral aspects of an event by the responsible officers¹⁹¹. For example, communicable diseases (West Nile virus, Chikungunya, Q fever, etc.) with impact on blood, organs and tissues' safety, have triggered such internal informal communication. This mutual notification from one system to another allows risk assessment in full knowledge of all aspects of the alert and a coordinated response among sectors. The impact of a more robust system will be that public health authorities will be informed earlier when alerts are notified through other EU alert systems and vice versa and define at an earlier stage whether the notified events would constitute a serious cross-border threat to health.</p> <p>This option would also address the current problem that threats other than communicable diseases are notified to WHO through the IHR without informing the EU. Under this option, notification would be linked to IHR and tailor-made EU criteria will be developed at EU level. For instance at the moment, there is a ratio of almost 5 to 1¹⁹² between the alerts notified to the EU for communicable diseases (in 27 Member States) and those notified to the IHR for the same diseases</p>

¹⁸⁸ http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf

¹⁸⁹ European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

¹⁹⁰ http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf

¹⁹¹ Currently messages from the ECURIE system dealing with radiological events are transmitted by fax and therefore may not be transmitted to the right responsible authorities of DG SANCO.

¹⁹² <http://www.who.int/csr/don/archive/year/en/index.html>

<p>networks currently in place.</p>	<p>groups (in 194 WHO States Parties). The EU needs to have tailor-made criteria for notification for threats since IHR criteria apply worldwide and are not adapted to the fundamental freedoms of the EU such as the principle of free movement¹⁹³. For example the contamination of milk from China with melamine which had not been notified through the IHR despite the fact that the contaminated product was circulating worldwide and was affecting the health of children¹⁹⁴. An other example was in 2009 when there was some delay by WHO declaring a pandemic for H1N1. As a result, because of the linkage with the EU pharmaceutical legislation, production of pandemic vaccines could not begin¹⁹⁵. Overall under this option notification of threats would be improved; however, be based only on recommendations.</p> <p>In order to have a rapid, coherent and comprehensive public health risk assessment, pre-established internal agreements between the Commission services, EU Agencies and existing networks of Member States experts providing scientific expertise to cooperate in a crisis would be of advantage, and standard operating procedures on information exchange would be established. The inventory of existing networks relevant to deliver expertise would be regularly updated which includes information on structures, networks and contact details both in Member States and at EU level so that in case of a crisis expertise could be collected within a relatively short time period. For instance a model for such an approach would be the network established in the chemical sector already set up by the Commission under the Health Programme and which links public health authorities with responsibilities in the chemical sectors (80 poisons centres in the EU) in order to share expertise and risk assessment through a rapid alert system (RAS Chem¹⁹⁶)¹⁹⁷. In addition a package of exercises (Iridium 1, 2 and 3) are being undertaken to test the operational level of the network for chemicals.</p> <p>This option would, even if build on recommendations, significantly strengthen risk assessment capacities in short and long term and create a strong basis to respond to serious cross-border threat to health.</p>
<p>The Health Security Committee¹⁹⁸ would be abolished in its current form and would be formalised as a Commission expert group. Its mandate would be reviewed and limited to coordination of preparedness, notification of measures implemented at national level and coordination of response for serious cross-</p>	<p>Under option 2, the Health Security Committee would be replaced by a new expert group under the Commission remit. Its mandate would focus on other serious cross-border health threats. The impact of this option would be to have two distinct expert groups. The Early Warning and Response System Network would continue to coordinate response in case of a serious cross-border threat due to communicable diseases. The new expert group would ensure this coordination for other threats. The advantage would be that responsibilities and scope would be clarified, mandates clearly distinguished and duplication, as described in option 1 in respect of pandemic preparedness and coordination of response to communicable diseases, avoided. Secondly, clarification of roles would mean that risk management would be carried out</p>

¹⁹³ http://ec.europa.eu/consumers/safety/rapex/index_en.htm + http://ec.europa.eu/food/food/rapidalert/index_en.htm

¹⁹⁴ <http://www.eurosurveillance.org/images/dynamic/EE/V13N40/art18998.pdf>

¹⁹⁵ http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html

¹⁹⁶ http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1247728923224

¹⁹⁷ CARRA NET Draft final report, Framework Service Contract No 2009 61 05 Lot 2

¹⁹⁸ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/92911.pdf

<p>border threats to health caused by biological (other than communicable diseases¹⁹⁹), chemical, environmental or events of unknown origin. No binding requirements would be foreseen for Member States under this option.</p>	<p>by the appropriate experts in the appropriate setting.</p> <p>As a result of this option, the Commission would be able to recommend measures for risk management to Member States based on the expertise of the new expert group. Although this will increase the sustainability of risk management for other threats coordination we will still have a weaker approach for threats other than communicable diseases, as measures will remain non binding for the first and binding for the second. As the former Health Security Committee will be become a Commission advisory group instead of a Council establish group, it will not have the same strategic status and role as at present.</p>
<p>As regards risk and crisis communication aspects, Member States, in liaison with the Commission, would develop shared communication approaches and guidelines e.g. sharing best practice in approaching the media.</p>	<p>Under this option, as the former Health Security Committee Communicators' Network will be part of a new expert group, the Commission could recommend messages to Member States and, shared communication approaches.</p> <p>Under the lessons learned on the 2009 pandemic, the Commission evaluation report²⁰⁰ as well as the European Parliament report²⁰¹ placed particular stress on coordination and streamlining of communication as a vital component of risk management. This was most recently demonstrated during the <i>E. coli</i> STEC O104 outbreak in Germany, where the importance of communication on a public health threat was confirmed^{202, 203}. This option would provide the Member States a more robust base to commit themselves to provide a common shared message to the media. As, based on experience in the past, Member States²⁰⁴ are keen to agree on common procedure and content that are more formalised²⁰⁵. This option would have a more significant impact that the actions foreseen under option 1.</p>

¹⁹⁹ The issue of preparedness and coordination measures regarding pandemic influenza would fall under the structures established by Decision n° 2119/98/EC.

²⁰⁰ http://ec.europa.eu/health/communicable_diseases/docs/assessment_vaccine_en.pdf (TOR 2) chapter 6 p.81 and

http://ec.europa.eu/health/communicable_diseases/docs/assessment_response_en.pdf (TOR 1) chapter 12 p.51

²⁰¹ <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0077&language=EN&ring=A7-2011-0035>

²⁰² http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressData/fr/agricult/123823.pdf En ce qui concerne le système d'alerte rapide, certains États membres ont relevé que la communication et la coordination devraient être améliorées afin d'éviter de telles répercussions catastrophiques sur le marché. La plupart des États membres ont demandé qu'une campagne de promotion soit rapidement engagée au niveau de l'UE afin de rétablir la confiance à l'égard du secteur des fruits et légumes.

²⁰³ <http://www.europarl.europa.eu/en/pressroom/content/20110601IPR20702/html/E.-coli-outbreak-lessons-to-be-learnt-for-the-future>

²⁰⁴ see para 17; Council conclusions on Lessons learned from the A/H1N1 pandemic – Health security in the European Union

(<http://www.consilium.europa.eu/uedocs/NewsWord/en/lsa/116478.doc>)

²⁰⁵ See paragraph 8 of the CSWP on the activities of the Health Security Committee during the period from November 2009 to December 20

(http://ec.europa.eu/health/preparedness_response/docs/hsc_activities_2009-2010_en.pdf)

Option 3: Establish common EU legal framework covering *all* serious cross-border threats to health- improved cooperation and legally binding measures

Actions proposed under integrated approach; extended EU competence option	Justification/Motivation of the rating and impact
<p>Under this option the Member States would be obliged to put in place an agreed approach on generic and specific preparedness planning, including for pandemic influenza and would report regularly on its implementation.</p> <p>Member States would consent to cooperate in cross-sectoral preparedness and response planning through establishment of guidelines and indicators, the organisation of exchange of best practices, preparation of periodic monitoring and evaluation.</p> <p>Member States would also agree to implement in a complementary way and in particular on shared common minimum core capacity standards for preparedness and response (e.g. adequate human resources, designation of responsible entity, etc.). Furthermore, Member States would agree to use tailor-made criteria for notification at EU level of serious cross-border threats to health, including events which may constitute public health emergencies of international concern.</p>	<p>Member States are already obliged to have in place minimum core capacity standards for surveillance and response (Articles 5 and 13 of the International Health Regulations) by 2016 at the latest. Under this option it is proposed that this implementation is done in a coordinated manner at EU level. This would be achieved by the creation of EU generic and specific preparedness plans which would have an obligatory nature. General criteria for core capacity for surveillance and response based on those set out in Annex 1 of the IHR²⁰⁶ would be incorporated in the EU legislation and further implementation ensured by non legislative acts.</p> <p>This would provide in particular for cross sectoral cooperation to reach a coherent level of preparedness against the consequences of a serious cross-border health threat among essential services and across Member States. For example, it would be possible under this option by use of the IHR core standards to ensure overtime that key sectors of the economy and the society would be ready for health effects arising from a serious cross-border threat. This has already been demonstrated to exist in several Member States, for example UK²⁰⁷, France²⁰⁸ and Poland²⁰⁹. However, at present, the EU dimension (internal market / common policies aspects) is not addressed.</p> <p>Continuous monitoring of implementation of core capacity standards would be put in place at EU level, based on the regular reporting by Member States according to agreed indicators.</p> <p>The situation related to preparedness would be significantly improved over time and become much more coherent than under the current situation, based on shared and common standards. Secondly, this option would result in more complete reporting on serious cross-border threats than is the case at present.</p> <p>This option would best address the objectives for preparedness planning.</p> <p>In principal no additional burden or charges are foreseen as IHR core capacities need to be implemented anyway.</p>

²⁰⁶ http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf

²⁰⁷ <http://www.cabinetoffice.gov.uk/content/pandemic-flu>

²⁰⁸ See para 2.6. Continuité de la vie sociale et économique (http://www.pandemie-grippale.gouv.fr/IMG/pdf/PLAN_PG_2009.pdf)

²⁰⁹ See p.29-32 for pandemic (http://rcb.gov.pl/wp-content/uploads/2011/02/zagr_okres1.pdf)

	<p>However some non-substantial organisational expenses might be expected in order to achieve greater interoperability of sectors and greater coherence among MS.</p>
<p>This option would also create a legal basis for the setting up and management of mechanisms for the joint procurement of medical countermeasures within the TFEU legal framework.</p>	<p>In line with the lessons learnt from the Pandemic and the conclusions of national, EU and independent investigations on the management of the Pandemic H1N1 (2009)²¹⁰, this option provides for a legal basis for a joint action for purchasing of medical countermeasures, notably pandemic influenza vaccines. This would create an opportunity to set up and manage an EU mechanism for the joint procurement enabling Member States to participate on a voluntary basis.</p> <p>Joint procurement means combining the procurement of two or more contracting authorities. Studies and concrete examples have highlighted the very clear benefits for contracting authorities in engaging in a joint action²¹¹.</p> <p>The potential positive public health impacts of the development of such mechanism were further demonstrated by previous similar initiatives developed in other countries and regions²¹².</p> <p>Based on the above mentioned illustrations, an EU mechanism for the joint procurement of medical countermeasures will notably yield the following impacts:</p> <ul style="list-style-type: none"> • promotes solidarity by ensuring that participating countries have a minimum level of equitable access to medical countermeasures. • better pandemic preparedness by putting in place advance purchase agreements through framework contracts with suppliers. <p>In the field of pandemic influenza vaccines, joint procurement will result in a more synchronised start of the vaccination campaigns in the participating countries.</p> <p>The advantages of a joint procurement will result in a more favourable public opinion reaction, and more confidence by the public.</p>

²¹⁰ Cour des Comptes, Sénat, Rivasi, TOR II, BE Presidency

²¹¹ EC Green Public Procurement Training Toolkit – Joint Procurement Fact Sheet

²¹² An assessment of the development of a joint procurement of pharmaceuticals in the public health sector in Jordan has demonstrated that purchasing through the joint procurement process achieved an estimated savings of 2.4% (increased to 8.9% when not considering one particular product which raw material price increased significantly during the period concerned). Based on these initial findings, applying a joint procurement system for pharmaceuticals in the public health sector in Jordan confirmed its potential to reduce expenditures for the purchase of medicines and provide treatment continuously throughout the year.

	<p>In addition, along with the potential actions identified in option 1 and 2 regarding increasing the availability of medical countermeasures, a joint procurement would encourage existing and potential new suppliers to develop new products through a long-term guaranteed contract²¹³.</p> <p>This option will therefore be the only one to achieve the objective to improve availability and access to medical countermeasures by the Member States in case of a cross-border health threat.</p>
<p>Mechanisms and structures currently in place for risk monitoring and assessment of communicable diseases will be maintained as they stand.</p> <p>A coordination system would be put in place and involved Member States consent to notify to the EU level, cases of cross-border threats to health caused by chemical, biological and environmental events and - as already in the past - communicable diseases.</p> <p>In parallel, Member States would be obliged to notify the EU level in all cases where notifications are made to WHO under the International Health Regulations.</p> <p>In case the ECDC or another EU Agency, Member States or the Commission identify serious cross-border threats to health either on the basis of notification system or risk monitoring, a risk assessment may be performed through existing structures at EU or national levels in liaison with the Commission, depending on the EU and Member States respective competences in the given field. The Commission would seek to provide for a coherent and comprehensive public health risk assessment at EU level.</p>	<p>The monitoring of serious cross-border threats to health would remain as it stands and would continue to be dealt separately among different policies as the surveillance is in principle already in place at EU level for various types of threats.</p> <p>In this option, the Member States will notify to an EU system cases of serious cross-border health threats arising from sources other than communicable disease. These notifications will be based on EU tailor-made criteria due to the integrated nature of the EU, the internal market and the many common policies, which depend on a common response to common threats.</p> <p>This option will not affect or replace the multitude of existing EU alert systems but simply provide a mechanism for identifying those alerts with public health significance. This could e.g. be done through existing electronic tools, such as RAS CHEM, which links a network of member states public health actors in the field of chemicals. It would require continuing support by the EU level for the operation and development of this tool and network, through financial instruments such as the EU health Programme and continued support by member states. It could be examined on the basis of need whether to provide specific tools for other threats (biological other than communicable diseases, environmental and events of unknown origin), although the frequency and severity of such threats and the cost of new systems would guide this choice. This flexible and informal approach is the most appropriate because these events arising from causes other than communicable diseases are not regular and are less frequent than communicable disease events²¹⁴, and therefore require a lower proportionate response at the EU level.</p> <p>In addition to the elements proposed under option 2, an obligation for Member States to report all threats notified under the International Health Regulations to the WHO, whether these arise from communicable diseases or from other causes, at EU level would be established. Reporting would be done by using existing EU tools. This is because the Regulations are legally binding, and it is appropriate that alerts passed on an obligatory basis to the WHO are also passed on the</p>

²¹³ EC Green Public Procurement Training Toolkit – Joint Procurement Fact Sheet

²¹⁴ See annex 11

<p>Current gaps in risk assessment would be covered by additional capacities for scientific expertise. This work would be underpinned by associating relevant international agencies (e.g. WHO).</p>	<p>same obligatory basis to the EU level. This has already been achieved through legally binding provisions for communicable diseases.²¹⁵</p> <p>For risk monitoring and assessment, this option would entail support for networks of Member States experts, working together with relevant Commission services, EU agencies, and international organisations. This is done currently through projects supported under the EU health programme, for example a network for risk assessment on chemical events (RAS CHEM)²¹⁶, and would require continued investment to enable sustainability. A possible improvement could entail a framework contract allowing risk assessment support on an ad hoc basis when required, particularly to ensure quality control. This would ensure a capacity when needed for a robust, reliable and rapid public health risk assessment.</p> <p>This option building on existing tools is sufficient to address the needs for notification, monitoring and assessment. Establishing new instruments is not considered proportionate, nor required by the frequency of such events. The option would however, as has been noted, require continued investment at the EU level and at national level. It would in conclusion address the objectives set out for risk monitoring and assessment under the present initiative to a satisfactory if not ideal level.</p>
<p>As regards risk management, EU action would consist in ensuring that public health response by Member States to a serious cross-border health threat is done on a coherent and coordinated basis.</p> <p>This involves defining the notion of "serious cross-border threats to health" covered by the new regime (communicable diseases, biological threats other than communicable diseases, chemical and environmental related threats and threats of unknown origin).</p> <p>On this basis, the relevant criteria for notification of such threats would be specified and the conditions and rules would be laid down in a way that a coordinated and coherent public health response can be provided.</p>	<p>Under this option, the Commission will be empowered to coordinate with Member States as a priority the following measures:</p> <ul style="list-style-type: none"> a. Advisory activities on preparedness and response planning, public health response coordination such as on school closure, travel advice, communication strategies and messages, common strategies on vaccination. On this basis the Commission may adopt with the support of expert groups recommendations to Member States. b. Non legislative acts (i.e. delegated and implementing acts) would cover e.g. preparedness plans, guidelines on protective measures to be taken, notably in an emergency situation; guidelines on information and guides to good practice for the public (e.g. hygiene measures). c. Voluntary mutual agreements between concerned Member States based on measures recommended by the Commission that might be implemented at national level. <p>In addition, a new and voluntary instrument for actions, in particular a mechanism for joint procurement of medical</p>

²¹⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:021:0032:0035:EN:PDF>; annex I

²¹⁶ http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1247728923224

<p>In this way, the current work consisting of coordination of public health response done by the EWRS Network and the Health Security Committee, including work on communication would be merged in order to cover all serious cross-border threats to health under a single structure.</p> <p>This option would specify, as it is currently the case for communicable diseases, the other types of threats to be covered, criteria for notification of events and areas where measures could be coordinated at the EU level. It would provide for EU action through advisory activities, non legislative acts and instruments for mutual agreements or joint actions between Member States.</p> <p>EU action as described above will – as it is the case for communicable diseases – cover as a priority the following measures:</p> <ul style="list-style-type: none"> a. Advisory activities on preparedness and response planning, public health response coordination such as on school closure, travel advice, communication strategies and messages, common strategies on vaccination. On this basis the Commission may adopt with the support of expert groups recommendations to Member States. b. Non legislative acts (i.e. delegated and implementing acts) would cover guidelines on protective measures to be taken, notably in an emergency situation; guidelines on information and guides to good practice for the public (e.g. hygiene measures). c. Voluntary mutual agreements between concerned Member States based on measures recommended by 	<p>countermeasures, particularly pandemic influenza vaccines, would be established.</p> <p>Under this option, a unique structure to manage health emergencies at European level would be created, regardless of their cause. The positive impact would be to provide a platform where crises could be managed from the public health perspective by a single group of decision makers with a clear mandate as regards scope and responsibilities.</p> <p>For this option, this will have a positive impact on coordination of health measures at European level. There would be a clear added value from a coordinated European response because Member States would respond in a coherent way, thereby also strengthening trust in public authorities.</p>
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<p>the Commission that might be implemented at national level.</p> <p>In addition, new and voluntary instrument for joint actions, in particular a mechanism for joint procurement of medical countermeasures, particularly pandemic vaccines, would be established.</p>	
<p>Common communication strategies would be developed; the communicators would be integrated in the crisis management process and would be directly linked with the risk managers.</p>	<p>As regard the communication on public health risks, as described above, this option will enable a coordinated approach on communication issues (for example development of communication strategies, exchange of information, consultation and coordination on messages to be delivered to the public, better responding to citizens' needs for information, enhanced sharing of resources for engaging social media) in the context of a cross-border health threat integrating the issue into risk management. It would build on previous initiatives taken on a voluntary basis on the Health Security Committee Communicators' Network and in addition establish common communication strategies and envisage targeted campaigns which could help to improve awareness among the population and strengthen the implementation of public health measures. Combined efforts to approach and convince health professionals such as health care workers, pharmacists, patient groups can also be undertaken.</p> <p>The Commission would be empowered to define the procedures on how this coordinated approach would be implemented in a coordinated way at EU level.</p>

Annex 17: Examples of potential complementary EU stockpiles

The number of doses held in a virtual or real EU stockpile would need to be agreed with the Member States. In any case, an EU stockpile would not replace national stockpiles but would be a complementary strategic stockpile that can be quickly deployed to control the spread of a threat ('fire blanket' approach) in Member States. This applies when there are urgent and unforeseen needs that exceed the capacity of the national stockpile. Article 168 of the Treaty does not provide a possibility for an EU stockpile replacing national stockpiles: the organisation and delivery of health services and medical care is a Member State competence and that includes the autonomy for a Member State to decide on what percentage of the population it wishes to cover with a stockpile.

The cost of a complementary EU stockpile depends on the product to be stockpiled and the threat against which the countermeasure is intended to be deployed (determining the quantity to be stockpiled). A few cost examples (not including maintenance of the stock):

- 5% population coverage 'fire blanket' stockpile of pandemic influenza vaccines: ~7 euro/dose, 1-2 doses needed, i.e. 175 – 300 million euro
- 1% population coverage 'fire blanket' stockpile of the antiviral 'oseltamivir' against pandemic influenza: extrapolated from a stockpile established in Asia through the ASEAN²¹⁷/ASEF²¹⁸ organisations (where a stockpile covering 1 million people did cost 40 million euro), a stockpile covering 5 million people would cost 200 million euro.
- 0.5% population coverage 'fire blanket' stockpile of ciprofloxacin against anthrax: ~0.75 euro/500mg, 2x 500mg x60 days needed, i.e. 225 million euro

Similar to the organisational arrangements made for the Asian stockpile set up by ASEAN/ASEF, the distribution flow could be as follows:

- When a Member State is facing an urgent and unforeseen need exceeding the capacity of the national stockpile, it would simply make a request to the authorities in charge of the oversight of the stockpile (e.g. the Commission or a board with representatives from the Commission and the Member States).
- After evaluation of the request (and of any requests by other Member States that may have been made), the manager of the stockpile (the Commission, an agency, a service provider...) can be instructed to transfer the requested amount (or a part thereof) to the MS's relevant authorities that would be responsible for its distribution to the affected citizens.

The funding source (contributions from Member States or EU budget) for a complementary EU stockpile would need to be decided at a political level. In 2006, a proposal from the

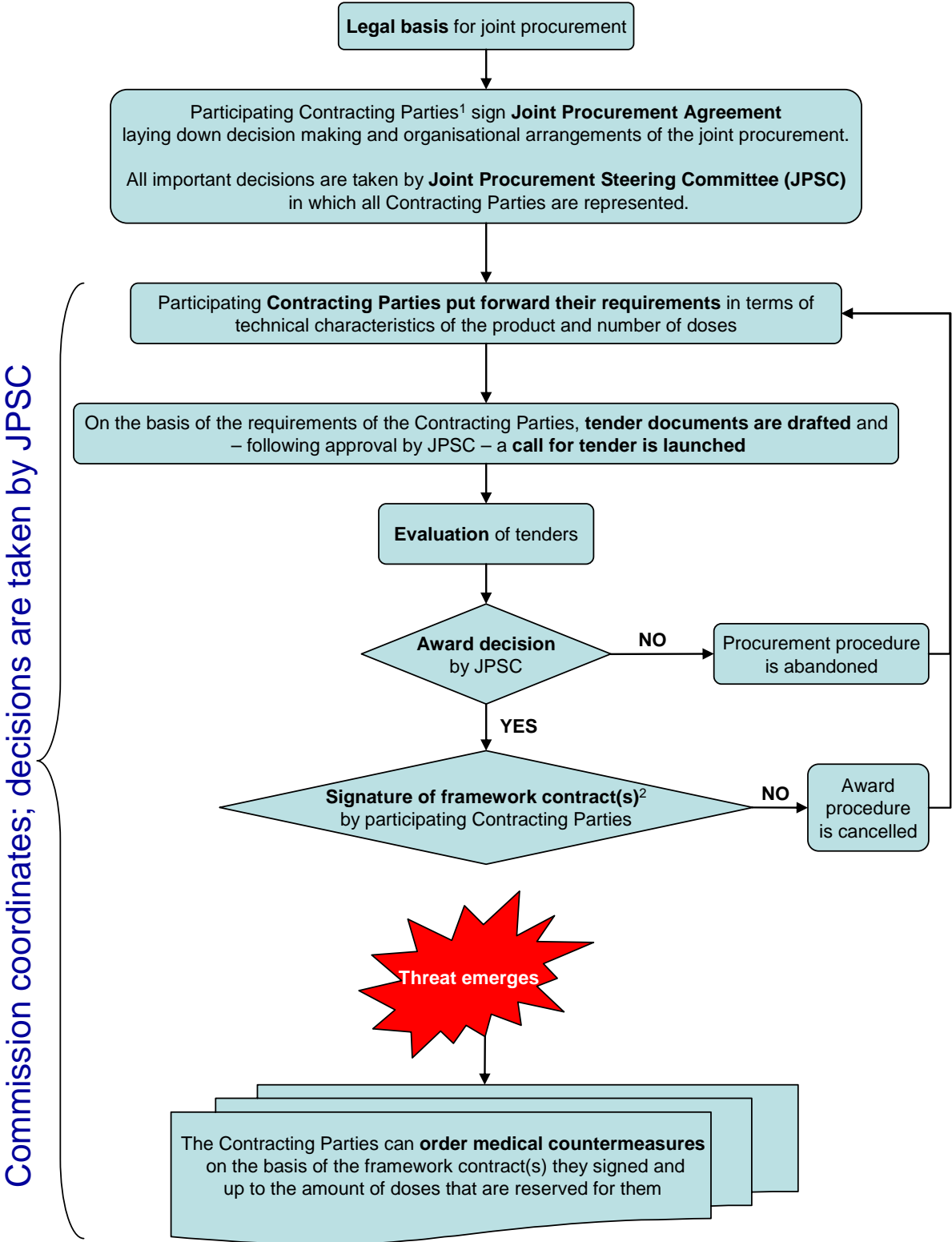
²¹⁷ Brunei, Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Viet Nam

²¹⁸ EU + ASEAN + India, Japan, Korea, Mongolia, New Zealand, Pakistan, China (Russia and Australia are in the process of joining).

Commission to set up an EU stockpile of the antiviral 'oseltamivir' was withdrawn because no consensus could be reached at the Council (June 2006 Health Council) on the funding source.

As medical countermeasures are provided free of charge to the public, no reimbursement issues are expected.

Annex 18: Illustration of the joint procurement mechanism for medical countermeasures



¹ 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)

² A framework contract guarantees a certain number of doses of a medical countermeasure that will be made available when the signatory Contracting Parties wish to order. However, a framework contract does not put any obligation on Contracting Parties to order the medical countermeasures

Annex 19: Analysis of the impacts of the three options

Rating:

0 Baseline scenario; neutral;
 + small positive impact; ++ big positive impact - small negative impact; -- big negative impact

Option 1: Status quo: Maintaining the current level of activities

Assessment Criteria	Rating	Motivation of the rating and aspects of the policy action necessary to achieve the impact
1. Improved protection of citizens of the EU from serious cross-border threats to health	0	Impact on public health will be the same as it is now; conditions for public health protection will not be improved.
2. Public health security structures and systems: Effectiveness ²¹⁹ , efficiency ²²⁰ and coherence ²²¹ as regards the objectives described in this initiative		This option will not improve effectiveness, efficiency and coherence related to structures and systems of public health security.
2.1 Coherent and comprehensive overall approach for all serious cross-border threats to health (preparedness and response planning, risk monitoring and assessment as well as risk management including	0	Incoherence and incompleteness would remain as regards the handling of serious cross-border threats to health. Disparities between the framework on communicable diseases and on other threats would be maintained leading to an unequal response to health-related crises. Preparedness and response planning, as well as risk monitoring, risk assessment and risk management of public health would be inadequately addressed for serious cross-border threats to health other than communicable diseases.

²¹⁹ Effectiveness= the extent to which options achieve the objectives of the proposal

²²⁰ Efficiency/cost effectiveness = the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)

²²¹ 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

communication)		
<p>2.2. preparedness and response planning, common approach at EU level for all 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>d. equitable access to medical countermeasures</p>	0	<p>The impact of option 1 would be low as the current system would be maintained but not strengthened; a common EU approach on serious cross-border threats caused by biological (other than communicable diseases), chemical or environmental events would not be developed. Considerations of the European Parliament²²² and the Council²²³ for providing better support for the Member States in achieving a coherent approach to preparedness for and response to health threats and especially public health emergencies of international concern as defined in the IHR would not be addressed.</p> <p>a. Under this option preparedness planning would remain as diversified as it is now. Member States may follow EU guidance related to generic and specific preparedness but are not obliged to implement it. This option will not improve the EU level of preparedness and response planning and will not provide a coherent approach.</p> <p>b. There will be no significant impact on preparedness in other critical sectors of society, therefore the interoperability will not be ensured.</p> <p>c. The questions of core capacity requirements for preparedness and response and EU tailor-made criteria for notification of health threats will not be addressed. Parallel and uncoordinated implementation of the International Health Regulations by Member States will not lead to any common baseline for EU preparedness. Differences and incompatibilities between Member States will prevail in the absence of a robust solution.</p> <p>d. Under this option, no impact is expected in terms of improving access to medical countermeasures. As the proposed action only relies on national procurement procedures and a limited support from the EU, the shortfalls (limited purchasing power, etc.) identified and experienced by the Member States during the Pandemic H1N1 2009 will not be addressed.</p>
<p>2.3. risk monitoring and assessment: coherent and comprehensive approach for</p> <p>- identification (detection) and notification of health threats, based on improved linkage between</p>	0	<p>Under option 1, impact would be low as there would not be a coherent and comprehensive approach for risk notification, risk monitoring and risk assessment.</p> <p>Coordination among networks and mechanisms in place would not be strengthened and no additional arrangements will be put in place to improve coordination. For risk monitoring information available from rapid alert systems for other policies will not be notified systematically to the public health authorities. The Commission would also not be notified of such threats through the IHR.</p>

²²² European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

²²³ Council conclusions of 13 September 2010 on Lessons learned from the A/H1N1 pandemic – Health security in the European Union (12665/10)

<p>existing monitoring and notification mechanisms and structures</p> <p>- improved capacities for robust, reliable, compatible between sectors, and rapid public health risk assessment for other serious cross-border threats to health</p>		<p>As regards risk assessment, no additional impact can be expected either, as this option would rely on networks of experts being established under the public health programme. This expertise could be called upon on an ad hoc basis. In addition, incompatible risk assessments from the public health perspective might be delivered among different policy areas (such as civil or environmental protection) implicated in the same cross-sectoral crisis. This would not lead to strengthening capacities either in the short-term or long term, and gaps and inconsistencies would remain and may lead to inefficient and ineffective response.</p> <p>Option 1 may as it is the case now lead to inappropriate risk monitoring and risk assessment with negative consequences for public health response.</p>
<p>2.4. risk management: improved coordination :</p> <p>- sustainable structure at EU level for any serious cross-border public health crisis;</p> <p>- clear mandate for this structure with stronger commitment of Member States</p>	0	<p>Under this option, impact would be low as coordination at EU level would neither be improved nor would there be a sustainable structure for addressing all serious cross-border threats with a clear mandate and a strong commitment of Member States Considerations of the European Parliament²²⁴ and the Council²²⁵ for the possibility of a long-term solution on health security, including provision of a legal basis for the Health Security Committee, are not addressed.</p> <p>Risk management would continue to be ensured by two existing structures, one legally based (and responsible for communicable diseases²²⁶) and another one, an informal entity (the Health Security Committee) which is intended to coordinate public health response <i>mainly</i> for other health related threats, including pandemic preparedness. Therefore, the current overlap of formal and informal structures, in particular in the area of pandemic preparedness, would persist. Furthermore, as neither the mandate of the Health Security Committee nor its scope would be changed under this option the current absence of a legal basis would not strengthen its role and public health measures would not be sufficiently coordinated under the status quo.</p>
<p>2.5.crisis communication: improved conditions for crisis communication</p>	0	<p>The impact under this option is low as structures are not strengthened and conditions for communication will not be further improved. This would result in non implementation of "lessons learnt" from the evaluation report of H1N1 in 2009 which stressed the importance of improving public communication coordination at EU level for cross-border health threats.</p>
<p>3. Social impacts</p>	0	<p>Under this option no changes are expected related to the employment, labour market and job quality. Under status quo no other effects on society, such as impacts on social inclusion, protection of particular groups, equality of treatment and opportunities, non-discrimination, social protection and security as well as education can be expected.</p> <p><u>Communication:</u> Under this option coordination of communication will not be improved and could lead to discrepancies on</p>

²²⁴ European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (2010/2153(INI))

²²⁵ Council conclusions of 16 December 2008 on health security (16515/08)

²²⁶ Early warning and response network, Decision 2119/98 (OJ L 268 3 10 1998, p.1)

		<p>communication and messages for the general public, which could cause uncertainty among the population. As demonstrated during recent outbreaks (for example <i>E. coli</i> STEC 0104) this could result in EU citizens being misinformed because of uncoordinated and conflicting messages and finally, lead to mistrust towards public health authorities and the measures introduced for controlling an outbreak.</p> <p><u>Social inclusion and protection of particular groups</u>, e.g. vulnerable groups: This option will not have particular impacts on vulnerable groups in terms of health protection.</p> <p><u>Solidarity and equitable access to medical countermeasures</u>: as the current situation will be maintained and the identified shortfalls would not be addressed, the proposed activities under this option will have no impact on solidarity and equitable access to medical countermeasures between the Member States. As a result, this maintains a situation where, in case of cross-border health threats, Member States will be pitched against each other by the producers for access to medical countermeasures. Cooperation with other sectors of society will continue to be done on an ad-hoc basis and therefore this option will not strengthen the cooperation in a sustainable and systematic way.</p>
4. Economic impacts	0	<p>Serious cross-border health threats can affect large number of persons and entire regions and therefore have repercussions on the economy due to absenteeism of people at work, costs for treating patients, disruption of businesses and productivity losses. For example, in a pandemic it is anticipated that there will be growing demand for hospitalisation and medical treatment.</p> <p><u>Internal market, free movement of people, capital, goods and services</u> (e.g. travel restrictions): The lack of sound coordination at the EU level could result in diverse and incoherent responses in an event of a public health crisis. As a consequence, internal market and external trade functions could be disrupted leading to substantial economic losses. Disruption in the internal market might occur and limit access to essential goods and services, and in addition might have serious consequences as regards capacities of the health system to respond effectively to the crisis.²²⁷</p> <p>An example of a public health outbreak that had a major impact on the economy is the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003 which caused anxiety around the globe due to its novelty and potential for a serious pandemic. The estimated income loss ranges from US \$ 12.3-28.4 billion for East and Southeast Asia as a whole²²⁸.</p> <p>In terms of influenza epidemics in industrialised countries total estimated direct and indirect costs may reach EUR 56.7</p>

²²⁷ See tables 1 and 2 in annex 6

²²⁸ See end note 28 related to table 1 in annex 6

	<p>million per million people²²⁹. Therefore, a coordinated approach to mitigate the spread of a disease may have a positive impact on economy and reduce costs.²³⁰</p> <p><u>Preparedness of critical sectors of society and interoperability</u>: There is currently a limited cross-sectoral coordination to ensure business continuity in critical sectors and therefore there can be an important negative economic impact in a major public health crisis such as a pandemic. Public health measures taken during a pandemic have the potential to cause unintended negative effects on other parts of society and the economy. This may result from restrictions on daily activity for example as a result of a social distancing policy such that schools, businesses and government offices close for a period of time in an effort to reduce transmission and mass gatherings are cancelled. The need for increased preparedness in sectors other than health has been identified as an area where pandemic preparedness needs to be strengthened. This increased multi-sectoral preparedness is needed both to support the public health response and mitigate the overall effect of the pandemic on society. The World Health Organization (WHO) has presented this approach under the label "whole society approach"²³¹ Actions undertaken by one Member State alone may also significantly damage the interest of other Member States (e.g. interruption of trade and critical services such as transport, IT technologies, energy). The European Parliament and the Council, respectively in its resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU and in its conclusions of 12 October 2009 on Pandemic (H1N1) 2009 – strategic approach, also focus on the importance of cooperation on multi-sectoral issues related to public health. At the start of pandemic (H1N1) 2009, Mexico implemented social distancing measures (schools, government offices and businesses) were shot down for a week. This has had a major impact on the Mexican economy²³².</p> <p><u>Innovation, development and research</u> in the field of medical countermeasures (impact on the sector of pharmaceutical industry): Under the status quo option capacity building for seasonal influenza vaccine production and manufacturing is envisaged with an indirect effect on pandemic influenza vaccine production. However, this depends on national planning on vaccination for seasonal influenza, and therefore its implementation depends entirely on MS and it is the MS responsibility to review their vaccination strategies for seasonal flu. Thus, the impact will depend on whether MS are committed to support approaches to increase production capacity generally.</p> <p>It should be noted that under option 1 research and development on pharmaceutical products is generally supported through</p>
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²²⁹ Explanatory Memorandum to the proposal for a Council recommendation on seasonal influenza vaccination; COM(2009) 353 final/2; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0353:FIN:EN:HTML>

²³⁰ <http://www.who.int/countries/eth/areas/cds/en/index.html>

²³¹ http://www.who.int/csr/disease/influenza/CP045_2009-0808_WOS_Pandemic_Readiness-FINAL.pdf

²³² Stern A; Markel H What Mexico Taught the World About Pandemic Influenza Preparedness and Community Mitigation Strategy, JAMA, September 16, 2009; 302:1221-1222

²³³ http://ec.europa.eu/research/fp7/index_en.cfm?pg=health

		the EU Framework programmes for Research and Development. However, this allows only for long term solution to increase availability of vaccines and medical countermeasures and does not have a direct impact on short term availability of these products in an outbreak or major public health event. ²³³
5. Financial implications	0	<p>The main stakeholders that are affected by the health security initiative are the Member States and the European Commission; in an indirect way private companies might be affected.</p> <p>Member States: There are no additional costs for reporting, meetings or notification of threats</p> <p>The Commission will also not have additional costs; the level of costs for staff, administration such as organisation of meetings will stay the same. As option 1 is consistent with the baseline scenario, i.e. the current situation resources to support work on combating serious cross-border health threats will mainly be allocated by the administrative budget of the EU (for example to organise meetings) and the financial means of the public health programme. Between 2008 and 2013 the total budget for the health programme is EUR 321.5 million. The activities covered and co-funded under the programme correspond well with the objectives of the health security initiative. E.g. in 2010, 13 projects were supported with an EU contribution of EUR 8.6 million and in 2011, two projects with an EU contribution of EUR 800,000 will be financed. For 2012, EUR 3.6 million are ear marked for five projects related to health security.</p> <p>Other Stakeholders/private companies will not be affected.</p> <p>No benefits or efficiencies can be expected; the inefficiencies and overlaps in the current situation will persists and certainly not lead to reduction of financial implication.</p> <p>Administrative costs will be the same as in the current situation.</p>
6. Administrative burden	0	<p>The main stakeholders that are affected by this option are the Member States and the European Commission.</p> <p>The current situation would persist; administrative resources (e.g. human resources) for both the Commission and Member States would remain the same. There would be no additional costs for notification, coordination or reporting.</p> <p>Negative impacts are related to overlaps concerning the use resources between the EWRS network and the Health Security Committee related to communicable diseases in the EU. Negative impacts also relate to the lack of sustainable capacity to address serious cross-border health threats other than communicable diseases, in particular for the Commission; Ad-hoc solutions mobilising external expertise may affect the quality of independent scientific advice as external experts in emergency situations may not be available as needed due to prior commitments and the process of ending expertise at all may be time-consuming.</p>

7. EU added value	0	The EU added value in handling a serious cross-border health threat will remain unchanged as the current system is not strengthened.
8. Impact at International level	0	<p>Option 1 has an impact at international level in case of serious cross-border health threats potentially relevant outside the EU, as for example the recent outbreak of <i>E. coli</i> STEC O104 (impact on trade of food with 3rd countries) and of cholera related with Haiti earthquake in 2010 (involvement of the EU in combating the disease on the spot), or in case of contact tracing procedures to identify potentially contaminated persons (e.g. multi-drug resistant Tuberculosis).</p> <p>Information available on outbreaks or serious threats due to communicable diseases is potentially accessible and can be provided and exchanged with those third countries concerned by these events either directly or through other mechanisms in place (WHO and the Global Health Security Initiative Network). The impact, however, can be considered as low, as the mechanism is neither formal nor sustainable.</p> <p>Overall, and in particular for other serious cross border threats to health, collaboration at international level will not be improved.</p>

Option 2: Separate and different handling of serious cross-border threats to health – enhanced cooperation by using soft instruments based on a voluntary approach

Assessment Criteria	Rating	Motivation of the rating and aspects of the policy action necessary to achieve the impact
1. Improved protection of citizens of the EU from serious cross-border threats to health	+	Impact on public health would be improved as the overall situation for preparedness and response to a crisis will be strengthened. Future policies would be based on recommendations supported by Member States; hence the commitment of Member States would be higher than today.
2. Public health security structures and systems: Effectiveness ²³⁴ , efficiency ²³⁵ and coherence ²³⁶ as regards the objectives described in this initiative		This option would improve effectiveness, efficiency and coherence related to public health security structures and systems provided that Member States are committed to agree on recommendations and implement them.
2.1.. Coherent and comprehensive overall approach for all serious cross-border threats to health (preparedness and response planning, risk monitoring and assessment as well as risk management including communication)	+	Under this option, serious cross-border health threats are still addressed separately (division between the EU legal regime on communicable diseases and the formal Commission framework on other threats). Although other threats are dealt within a formal structure (Commission expert group), the integrated approach is not achieved as communicable diseases are covered by EU legislation which is legally binding on Member States and that other threats follow under a soft instrument which is not binding for Member States. This option would strongly commit the Commission services to coordinate preparedness and public health response in different policies which would have a certain impact on respective national policies and therefore facilitate the coordination of health-related crisis among sectors in Member States.
2.2. preparedness and response planning, common approach at EU level for all serious cross-border threats to health	+	This option would bring more consistency and compatibility in preparedness at EU level and across sectors because it would move from the current voluntary and informal approach under the baseline and option 1 scenario, towards a more formalised approach with reporting requirements. Member States would be more committed to implement Council recommendations related to generic and specific

²³⁴ Effectiveness= the extent to which options achieve the objectives of the proposal

²³⁵ Efficiency/cost effectiveness = the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)

²³⁶ 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

<ul style="list-style-type: none"> - generic and specific preparedness - ensuring coherence and interoperability among critical sectors of society - common core capacities for preparedness / EU tailor-made criteria for notification (to address IHR with a common approach) - access to medical countermeasures 	<p>preparedness, which would increase impact on MS. If MS contribute to guidance and implement it accordingly on the basis of a soft instrument such as a Council Recommendation, there would be an improvement of preparedness as common indicators and arrangements can be put in place, and progress can be monitored and reported by the Commission. In addition, the Commission would continue to encourage exchange of best practices and provide incentive measures, using the EU health programme as is currently the case. This would lead to a wider dissemination of best practices on preparedness plans and probably even trigger innovative aspects, sustainability, however, cannot be achieved in that way given that these activities are carried out using project grants of limited duration. As regards interoperability between different sectors the mutual exchange of preparedness plans would increase the coherence of overall preparedness at EU level.</p> <p>In addition, notification criteria as set out in the IHR²³⁷ would be adapted for EU requirements in order to ensure that all serious cross-border health threats would be notified (please refer to the part for Risk monitoring and assessment for additional information).</p> <p>The impact of this option on access to medical countermeasures is expected to be an improvement over option 1. Indeed, incentive measures via the Innovative Medicines Initiative could support research into the development of new production techniques to improve production capacity for medical countermeasures. For example, further research into optimising cell-based production for pandemic influenza vaccines could yield a considerable increase in production capacity. An increased production capacity means that a larger proportion of the population can be protected or treated within a short time frame when a threat emerges.</p> <p>In addition, this option foresees the setting up of a complementary EU stockpile which could alleviate urgent/unforeseen needs exceeding the capacity of national stockpiles. In the area of communicable diseases, such a complementary stockpile may be able to contain the threat by stopping further spread ('fire blanket' approach).</p>
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http://www.who.int/ihr/annex_2_guidance/en/index.html

<p><u>2.3. risk monitoring and assessment:</u> coherent and comprehensive approach for</p> <p>- identification(detection) and notification of health threats, based on improved linkage between existing monitoring and notification mechanisms and structures</p> <p>- improved capacities for robust, reliable, compatible between sectors, and rapid public health risk assessment for other serious cross-border threats to health</p>	+	<p>In comparison to option 1, improved coordination of existing monitoring and alert tools would step up the level of capacity for detection and notification and therefore allow for a more rapid and comprehensive reaction to a cross-border health threat.</p> <p>Knowledge from other rapid alert systems will be improved and arrangements for mutual alerting will be established at EU level. Mutual notification from one system to another would allow for an improved risk assessment in full knowledge of all aspects of the alert and contribute therefore to a coordinated and comprehensive response among relevant sectors. The impact of a more formalised system will be that public health authorities will be informed earlier when alerts are notified through other EU alert systems and vice versa, and define at an earlier stage whether the notified events would constitute a serious cross-border threat to health.</p> <p>There is also improved impact as notification would be linked to IHR and EU tailor-made criteria for notification will be defined at EU level, taking severity into account.</p> <p>A positive impact would be that due to arrangements (to be established prior to the events) with existing networks, EU Agencies and expert groups and due to standard operation procedures on information exchange, rapid, coherent and comprehensive public health risk assessment compatible among different policy areas could be carried out.</p> <p>This option would significantly strengthen risk assessment capacities in the short and long term and create a basis for solid and independent scientific expertise to respond to serious cross-border threat to health.</p>
<p><u>2.4. risk management:</u> improved coordination - sustainable structure at EU level for any cross-border public health crisis;</p> <p>clear mandate and strong commitment of Member States</p>	+	<p>The impact of option 2 would be that two independent structures would be clearly distinguished and mandated to manage and coordinate health related crisis: the EWRS network for communicable diseases and a newly created formal Commission expert group (that would replace the informal Health Security Committee) for all other serious cross-border threats to health.</p> <p>These redefined structures would be sustainable and improve effectiveness of coordination of health crisis management in the EU.</p> <p>As a result of this option, the Commission would be able to recommend measures for risk management to Member States based on the expertise of the new expert group. Although this would increase the sustainability of risk management and coordination for serious cross-border health threats, the EU would still have a weaker approach for threats other than communicable diseases, as measures will remain non binding for the first and binding for the second. As the former Health Security Committee would become a Commission advisory group instead of a Council group, it will not have the same strategic status and role as at present.</p>
<p><u>2.5.crisis communication:</u> improved conditions for crisis communication</p>	+	<p>Under this option the Commission could recommend joint communication messages to Member States, shared communication approaches and guidelines.</p>

		This option would have a more significant impact than the measures under option 1.
3. Social impacts	+	<p>Similarly to the status quo option 2 will not have impacts on employment, labour market and job quality.</p> <p><u>Communication</u>: As described above this option would provide the Member States with the opportunity to commit themselves on a voluntary basis to provide common and shared messages to the media. This option would have a more significant impact than the actions under option 1. Coordination of communication would also have a beneficial effect on citizens as messages issued to the public would be more coherent within the EU and not contradictory. Thus, trust in public health authorities to manage a health crisis would increase.</p> <p><u>Social inclusion and protection of particular groups</u>, e.g. vulnerable groups: This option will not have significant impacts on vulnerable groups in terms of health protection.</p> <p><u>Solidarity and equitable access to medical countermeasures</u>: a complementary EU stockpile of medical countermeasures that can be deployed to help Member States with urgent/unforeseen needs is expected to improve solidarity, and – to a limited degree – improve access to medical countermeasures. This option 2 also includes increased transparency between the Member States regarding their respective procurement processes and pooling of expertise in public procurement. Although this would improve solidarity between the Member States it would not ensure equitable access to medical countermeasures.</p> <p>Cooperation with other important sectors of society would be improved under this option as notification systems would be linked better and structures for risk assessment and management in the various sectors would be better interlinked to improve public health protection. In particular a newly created expert group would provide a platform for more effective sharing of information of coordination of actions and measures between different sectors in relation to serious cross-border health threats.</p>
4. Economic impacts	+	<p>As described under option 1 serious cross-border health threats can affect large number of persons and entire regions and therefore have repercussions on the economy due to absenteeism of people at work, costs for treating patients, disruption of businesses and productivity losses.</p> <p>Impacts under this option depend to a large degree on the cooperation and commitment of Member States to implement EU guidance developed under "soft law" such as recommendations. Against this background the following positive impact could be achieved.</p> <p><u>Internal market, free movement of people, capital, goods and services</u> (e.g. travel restrictions): The improved interaction between monitoring and alert systems in different policy areas would lead to a more rapid and substantiated risk assessment and management of a given threat. Better coordination would therefore allow responding earlier in order to contain and mitigate threats better. As a consequence, internal market and external trade functions might be less disrupted and economic</p>

		<p>losses could be reduced²³⁸.</p> <p>The <i>E. coli</i> STEC O104 outbreak has shown that economic damage can be immediately huge and substantial; therefore it is important to respond rapidly and effectively to a health crisis. (see table 1 in annex 6: Effects of serious cross-border threats to health on society).</p> <p><u>Preparedness of critical sectors of society and interoperability</u>: Under this option cross sectorial cooperation would be improved; other sectors would be earlier informed, better prepared and hence equipped to respond effectively to a given threat. In return the public health sector would also benefit as exchange of information would be mutual.</p> <p><u>Innovation, development and research</u> in the field of medical countermeasures (impact on the sector of pharmaceutical industry): In terms of availability of medical countermeasures option 2 is expected to be an improvement over the current situation as support of development and research of medical countermeasures would be strengthened via the existing Innovative Medicines Initiative (IMI). For example, for medical countermeasures that have already been developed, research could focus on improved production techniques to increase the industry's production capacity. However, for the development of new medical countermeasures, IMI would only address the initial phases of research and development as it does not provide support for clinical studies.</p>
5. Financial implications	-	<p>The main stakeholders under this option are the Member States and the Commission. Except for joint procurement, no additional costs either for Member States or for the Commission are expected under this option.</p> <p>Proposals on preparedness, assessment and management will be carried out in the existing framework both at the level of Member States and in the Commission. There will be no additional costs for notification, reporting or additional meetings; however, the quality of the outcomes is expected to be higher and would commit Member States more.</p> <p>As under option 1 the available means of the health programme and the existing budget for administrative costs will be used.</p> <p>The parts of option 2 relating to enhanced cooperation would have no substantial financial impacts as existing mechanisms and systems in place would be maintained.</p> <p>Regarding research and development of medical countermeasures, existing financial mechanisms will be used as much as possible (Innovative Medicines Initiative).</p> <p>Option 2 remains at the level of cooperation between individual procurements with no additional significant costs for the Member States. However, there would be no financial gain either as the purchasing power and ability to obtain better</p>

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See tables 1 and 2 in annex 6

		<p>financial and contractual conditions will remain much weaker compared to the option of a full joint procurement, as proposed under Option 3.</p> <p>Financial implications of the potential setting up of a complementary EU stockpile of medical countermeasures are illustrated in annex 17. Because a complementary EU stockpile would mean that Member States still needed to procure medical countermeasures for their national stockpiles individually, the weak purchasing power identified as a major weakness during the influenza H1N1 (2009) pandemic would not be addressed. In 2006, the Commission already proposed to set up a complementary stockpile of antivirals at EU level but this initiative was withdrawn following political opposition from the Council in 2006 on grounds of subsidiarity and costs²³⁹.</p>
6. Administrative burden	0	<p>Under this option governance would be improved as mandates of the two relevant committees, namely the Early Warning and Response System Network (EWRS Network) and a newly created expert group (formerly Health Security Committee) would be clearly defined. Responsibilities would be divided and the new expert group would be formalised under the Commission setting. This clear division of work would save resources in Member States as well as in the Commission as there would be no overlaps in responsibilities. The operating costs for the two committees would be reduced as there is no overlap in organising meeting and addressing twice same events in different expert groups. However, as there would still be two separate entities administrative burdens would be only reduced marginally.</p> <p>No additional administrative burden would arise from reporting to other EU Institutions because already today the Commission reports annually to the Council on the activities and progress of the Health Security Committee.</p> <p>As regards access to medical countermeasures the administrative burden would also be reduced for Member States as cooperation between individual national procurement procedures would allow pooling national expertise²⁴⁰.</p> <p>If stockpiles at European level would be created additional administrative capacities would be needed in particular during the setting up phase.</p>
78. EU added value	+	<p>The EU added value would be increased as the coordination of preparedness for and response to a cross-border health threats could be enhanced at the EU level through improved and coherent preparedness, risk monitoring, assessment and management. Development of core capacities at EU level, strengthened links between notification systems of different sectors, and improved functioning of the two committees at the EU level would contribute to this objective.</p>

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<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/732&format=PDF&aged=1&language=EN&guiLanguage=fr>

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In the case of Austria, savings involved in a joint procurement amounted to 60% of administrative costs:

http://ec.europa.eu/environment/gpp/pdf/toolkit/module1_factsheet_joint_procurement.pdf

		In addition, as regards medical countermeasures and their procurement in particular, the transparency of procedures and conditions would improve exchange of best practices of purchase agreements and therefore help Member States across the Union.
80. Impact at International level	+	Under this option, the impact related to international level would be stronger than in status quo as this option would also address the reporting conditions of threats other than communicable diseases being notified to WHO through the IHR without informing the EU. Under this option, notification would be linked to IHR and EU tailor-made criteria for notification will be developed at EU level.

Option 3: Establish common EU legal framework: covering all serious cross-border threats to health – improved cooperation and legally binding measures

Assessment Criteria	Rating	Motivation of the rating and aspects of the policy action necessary to achieve the impact
1. Improved protection of citizens of the EU from serious cross-border threats to health	++	The EU citizens would be protected in the same way from communicable diseases and from other serious cross-border threats to health independently of their origin (biological, chemical, environmental).
2. Public health security structures and systems: Effectiveness ²⁴¹ , efficiency ²⁴² and coherence ²⁴³ as regards the objectives described in this initiative	++	Option 3 would be the option that improves most effectiveness, efficiency and coherence related to preparedness, risk monitoring, assessment and management for health security in the European Union. In addition, it would be the best option to achieve the objective to improve availability and access to medical countermeasures by the Member States and therefore strengthen the capacity of Member States to mitigate the public health impact of a serious cross-border health threats.
2.1 Coherent and comprehensive overall approach for all serious cross-border threats to health (preparedness and response planning, risk monitoring and assessment as well as risk management including communication)	++	Handling of all serious cross-border threats to health would be ensured in the same way under a single and robust framework. Shared common standards on preparedness related to minimum core capacities for surveillance and response would be agreed at EU level. Based on these common standards, specific procedures would be set up to coordinate a coherent and comprehensive approach at EU level. This strengthened EU collaboration would cover monitoring, early warning and combating serious cross-border threats to health and would be ensured through the following actions: a. The detection of serious cross-border threats to health would be considerably improved at EU level as the monitoring systems in place in different policy areas would collaborate closely together and exchanged information on potential serious cross-border threats to health. b. All alerts related to serious cross-border threats to health, including those notified under IHR, would be reported at EU level according to the EU tailor-made criteria for notification. c. Public health risk assessment would cover all serious cross-border threats to health. Existing entities responsible for risk

²⁴¹ Effectiveness= the extent to which options achieve the objectives of the proposal

²⁴² Efficiency/cost effectiveness = the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)

²⁴³ 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

		<p>assessment would be identified in advance depending of the type of threat to timely deliver independent scientific evaluation of risks to public health. The Commission would ensure that public health risk assessment for non-communicable disease threats is coherent and comprehensive from the point of view of various policies.</p> <p>d. The EU coordination of public health response to all serious cross-border threats to health would be ensured in a robust way and would be dealt under a common "all-hazards" approach. There would be no distinction between communicable diseases and other threats as regards the implementation at EU level of public health measures. The communication activities related to all serious cross-border threats to health would also be coordinated in a solid manner as they are strictly linked to the risk management.</p>
<p>2.2. preparedness and response planning, common approach at EU level for all serious cross-border threats to health</p> <p>a. generic and specific preparedness</p> <p>b. common core capacities for preparedness / EU tailor-made criteria for notification (to address IHR with a common approach)</p> <p>c.- ensuring coherence and interoperability among critical sectors of society</p> <p>d equitable access to medical countermeasures</p>	+++	<p>a. Under this option preparedness planning would be significantly improved and would become much more coherent than under the two first options as preparedness would be based on shared and common standards for serious cross-border threats to health and would be mandatory for Member States. This would be a major step forward in setting a common approach at EU level.</p> <p>b. General criteria for core capacity for surveillance and response based on those set out in Annex 1 of the IHR²⁴⁴ would be incorporated in the EU legislation and adapted accordingly to EU common standards. Better coordination in the EU of IHR implementation by the Member States would also have positive effects to the IHR and would support WHO. There would be less burden on MS who would only have to make one report on improving core capabilities</p> <p>c. Impacts would also be positive for cross-sectoral cooperation in reaching a coherent level of preparedness for serious cross-border health threats among critical sectors of society and across Member States as the shared standards would be applied by different sectors.</p> <p>d. This option would be the best one to achieve the objective to improve availability and access to medical countermeasures by the Member States in the event of a cross-border health threat as it provides a legal basis for setting up a mechanism for joint procurement of medical countermeasures, in particular pandemic influenza vaccines.</p>
<p>2.3. risk monitoring and assessment: coherent and comprehensive approach for</p>	++	<p>The impact of this option would be that notification of threats would be improved due to enhanced cooperation with existing alert systems and networks, EU tailor-made criteria for notification and thus, better identification of alerts with public health significance would be achieved. This impact can already be achieved by this flexible and informal approach which is the most</p>

<p>- identification(detection) and notification of health threats, based on improved linkage between existing monitoring and notification mechanisms and structures</p> <p>- improved capacities for robust, reliable, compatible between sectors and rapid public health risk assessment for other serious cross-border threats to health</p>		<p>appropriate because events arising from causes other than communicable diseases are not regular and are less frequent than communicable disease events²⁴⁵.</p> <p>Similarly, in the area of risk assessment legal arrangements are not required as positive effects can already be achieved by enhanced and sustainable cooperation with existing networks of Member State experts, relevant Commission services, EU agencies, and international organisation. In order to strengthen these already existing capacities complementary action (e.g. through a framework contract) would be undertaken to bridge existing gaps in the current structures. This would ensure a capacity when needed for a robust, reliable and rapid public health risk assessment.</p> <p>The impact of this option for risk monitoring and assessment is less than would be achieved by a legal solution. However, a stronger and more formal option is not considered proportionate, nor required by the frequency of such events. The option would, however, as has been noted, require continued investment at the EU level and at national level. It would also in conclusion address the objectives set out for risk monitoring and assessment under the present initiative to a satisfactory if not ideal level.</p>
<p>2.4. risk management: improved coordination - sustainable structure at EU level for any cross-border public health crisis;</p> <p>clear mandate and strong commitment of Member States</p>	<p>++</p>	<p>The positive impact would be to provide one unique structure where all serious cross-border health crises could be managed from the public health perspective. This structure merges the existing formal EWRS network and the informal Health Security Committee. A newly established committee/expert group would have a clear mandate as regards scope and responsibilities to overcome the current challenges in coordination of response to serious cross-border health threats. There would be a clear added value from a coordinated European response because Member States would respond in a coherent way, thereby also strengthening trust in public authorities.</p> <p>This solution would also put on a strong formal footing the management structure on health security as requested by the Council.</p> <p>Contributing to this positive impact the Commission would be empowered to coordinate with Member States as a priority the following actions: Commission advisory activities, non legislative acts, joint actions (such as joint procurement of medical countermeasures) and voluntary mutual agreements between Member States that might be implemented at national level following recommendations from the Commission.</p>
<p>2.5.crisis communication: improved conditions for crisis communication</p>	<p>++</p>	<p>The impact of option 3 would be greater than the other two options as the procedures for effective communication coordination across the EU would be implemented in a coherent way by the Member States and in addition, Member States would agree on communication strategies and key messages; this would have a more structured and far reaching impact as e.g. identified target groups could be reached throughout the EU; in addition the communication activities would be supported</p>

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See annex 11

		<p>by improved tools. Such an improved coordinated approach on communication issues, would also include e.g. development of communication strategies, enhanced of information increased media monitoring in order to better and quickly understand the needs for information and the concerns of citizens.</p> <p>In addition, risk and crisis communication would be extended to cover all serious cross-border health threats and cross sectoral cooperation on communication would be enhanced in a public health crisis.</p>
3. Social impacts	+	<p>Option 3 would not have significant impacts on employment, labour market and job quality.</p> <p><u>Communication:</u> improved coordination of communication would also have a beneficial effect on citizens as shared and coordinated messages issued to the public would be coherent within the EU and not contradictory. Thus, trust in public health authorities to manage a health crisis would significantly increase.</p> <p>Along with better communication a coordinated approach on medical countermeasures (such as a joint procurement scheme) would also result in a more favourable public opinion and more confidence in measures undertaken by public health authorities.</p> <p><u>Social inclusion and protection of particular groups,</u> e.g. vulnerable groups: In the context of a pandemic influenza a joint procurement mechanism would result in higher levels of protection for vulnerable groups due to better synchronised and more effective vaccination campaigns.</p> <p>Cooperation with other important sectors of society will be improved under this option as notification systems will be linked better and structures for risk assessment and management in the various sectors will be better interlinked to improve public health protection. There would also be only one counterpart for other sectors to address all serious cross-border health threats, thus providing improved means for inter-sectoral cooperation.</p> <p><u>Solidarity and equitable access to medical countermeasures</u> Joint procurement mechanisms for medical countermeasures promotes solidarity by ensuring that participating countries have a minimum level of equitable access to medical countermeasures.</p>
4.. Economic impacts	++	<p>As described under the previous options serious cross-border health threats can affect large number of persons and entire regions and therefore have repercussions on the economy due to absenteeism of people at work, costs for treating patients, disruption of businesses and productivity losses.</p> <p>The positive impacts described already under option 2 would be increased as measures foreseen under option 3 are mainly legally binding.</p>

		<p><u>In addition in the field of innovation, development and research</u> the setting up of a joint procurement mechanism on medical countermeasures would strengthen the supply of medical products and encourage existing and potential new supplier to develop new products because of guarantees related to public long term contracts.</p>
5. Financial implications	-	<p>The main stakeholders under this option are the Member States, the Commission and private companies in the health sector and in other sectors.</p> <p>1. Costs for preparedness, assessment and management of the Health Security Initiative</p> <p>Member States:</p> <ul style="list-style-type: none"> • Notification costs are not expected to increase significantly as Member States are already obliged to report either at the EU level on communicable diseases or to the WHO under the International Health Regulations on "all hazards". Reviewing processes and procedures would need to be envisaged, but the costs for this can be considered marginal. • The new activity of obliging the Member States to set up generic preparedness planning would be based on the previous work and existing mechanisms. Administrative costs would not significantly increase. Member States are already obliged to do this under the implementation of the International Health Regulations. • The costs for coordination meetings may be at the same level or even less given the comprehensive mandate of the health group for all serious cross border threats to health. • As regards the newly established reporting and monitoring procedures to implement the improved health security framework the following costs per Member State can be envisaged: 0.3 – 0.5 Full Time Equivalent for a national expert over a period of 2-3 months to address reporting. <p>Commission:</p> <ul style="list-style-type: none"> • As regards preparedness additional costs can be expected in particular related to fees for human resources and provision of technical equipment; however, it is planned to cover these staff capacities/overhead costs by reorganising the human resources available and by building on existing platforms. Hence, the additional costs are considered marginal. • If a more sustainable solution on risk assessment would be set up on a formal basis building on existing systems and better linking them this would require additional financial resources from the EU health programme (500.000 - 1 Mio € per year in addition) to set up framework contracts in order cover existing gaps by making expertise

		<p>available where needed.</p> <p>The calculation is based on experience with a similar pilot project for assessment of health threats other than communicable diseases in the past. The intended framework contract is planned to allow for such gaps to be filled by establishing permanent networks of national correspondents between health authorities and agencies competent in assessing specific health threats, for example related to toxic chemicals (94 poison centres in the EU).</p> <p>Cross border threats caused by chemical, biological and environmental events do not occur as often as communicable diseases. Based on IHR notifications we can expect on average 5-6 such events per year²⁴⁶. Under EU tailor made criteria for these incidents the threats notified - based on experience with alerts for communicable diseases - could amount to 20 - 25 per year. The frequency of such events is likely to increase due to increases in global travel and trade, climate change and latent risk of criminal and terrorist attacks.</p> <p>Therefore, the financial burden of the measure needed in order to prepare for serious cross-border threats to health is justified and proportionate compared to the damage and impact on society which can be significant in scale and can by far exceed the financial input. The additional costs would also be justified as scientific expertise would not only be provided for a given threat assessment, a sustainable network would also allow for capacity building and training in the area of chemical, biological and environmental threats.</p> <ul style="list-style-type: none"> • It is not expected that costs for coordination of improved risk management will rise as a similar meetings cycle for the new health group as in the present for the existing EWRS and Health security Committee will be maintained. Administrative budget for these meetings is available. • As regards the new reporting requirements 0.3 Full Time Equivalent for an Administrator/Policy Officer for the reporting process will be needed. EUR 5,000-20,000 for external expertise to support the development of a questionnaire and the analysis of the replies by the Member States will be needed to implement the yearly reporting schemes. • EUR 300,000-700,000 every five years for external and independent evaluation. The amount depends of the scope and details of the tender specifications for the evaluation. <p>Other Stakeholders/private companies:</p> <ul style="list-style-type: none"> • It is not expected that private firms would have any obligations for alert reporting as such. As regards improved preparedness and business continuity in private sector companies it is worth noting that in particular large companies have already engaged in putting in place business continuity planning at their own initiative; however,
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See information in annex 11

	<p>there is no possibility and no intention to impose measures with financial implications.</p> <p>2. Access to medical countermeasures:</p> <p>With regard to access to medical countermeasures option 3 would aim at better coordinating the procurement of medical countermeasures. As Member States would need to take provisions for such procurement anyway individually, a joint process would not lead to new financial commitments for the Member States. Increased administrative resources during the setting up period can be considered similar to what they would need to do anyway if they were to launch the procurement procedure alone individually. Once the joint procurement mechanism is operational, the overall administrative burden is expected to be less as compared to separated procurement at national level (example Austria/Vorarlberg).</p> <p>On the other hand, a joint procurement mechanism such as that already employed by the Pan American Health Organization would allow for benefits and generate savings resulting from stronger purchasing power, economies of scale, more attractive offers from suppliers and improved contract conditions for the Member States. Indeed, if the joint procurement is carried out by concluding advance purchase agreements before the actual need for the medical countermeasure arises, better contractual conditions will be obtained for the following reasons:</p> <ul style="list-style-type: none"> - in the absence of a health threat, the demand for the medical countermeasure is little. Even if the demand exceeds the current production capacity, suppliers have the time to expand production capacity to match the demand. The advance purchase agreements allow for forecasting the demand so that costly production under- or over-capacity can be avoided. - the security of having advance purchase agreements, even if at less favourable conditions for the supplier, is more attractive for a supplier than the insecurity of not knowing when or if a future need will arise ("<i>a bird in the hand is worth 2 in the bush</i>"). The security of advance purchase agreements allows the supplier to discount investments for product development and maintenance of production capacity against revenue²⁴⁷ from advance purchase agreements. - The increased size of the advance purchase agreements through joint procurement will generate economies of scale and will cause stronger competition between suppliers. <p>In contrast, if joint procurement carried out when there is an acute need for a medical countermeasure will generate limited benefits, if any, because:</p> <ul style="list-style-type: none"> - there is no time to make suppliers compete with each other
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²⁴⁷ Such revenue can take the form of (1) fees to guarantee a reserved quantity of a medical countermeasure that *can* be delivered in the event of a health threat, (2) an advance purchase commitment (with payment of an advance) to buy a certain quantity of a medical countermeasure that *will* be delivered in the event of a health threat or (3) an advance purchase of a medical countermeasure to be stockpiled by the buyer or by the supplier.

		<p>- the high and acute demand for the medical countermeasure will result in a 'seller's market' where the demand is much higher than the offer.</p> <p>In terms of administrative costs, the Eco-procurement Service of Vorarlberg (Austria) has achieved savings up to 60% through joint procurement.</p> <p>Setting up a joint procurement is unique at the EU level, therefore the financial implication for the Commission can only be estimated on the work carried out so far. Increase in administration and in financial implications is expected during the setting up of the proposed mechanism. These effects would decrease during a kind of routine running of the contract prior to the emerging pandemic. Once a pandemic is declared, it would require the activation of the contract and lead to the administrative needs to rise steeply for a short period of time. In order to set up a mechanism for joint procurement the financial implications would – based on the current experience be the following: 2 Full Time Equivalent at AD level, in addition for meetings to consult with Member States EUR 150,000 and for external expertise on the matter external expertise to draft the tender specification EUR 25,000 will be requested.</p>
6. Administrative burden	-	<p>For Member States</p> <p>Preparedness and response planning: There is a certain administrative burden for Member States to develop and implement core capacity standards in line with the International Health Regulations, the additional administrative burden to define in addition specific EU criteria can be considered as marginal.</p> <p>As regards notification and risk assessment: Member States are already obliged to notify health threats to the WHO under the International Health Regulations, to communicable diseases and to certain other threats under EU legislation. There will be a certain amount on administrative burden to establish links between these systems and review existing reporting mechanisms; however, this burden will decrease once the connections and links are made. Thus established efficiency will be gained and coherence and cooperation between reporting tools will have positive effects on administrative procedures, they will be streamlined and double work will be avoided.</p> <p>Costs induced for reporting are supposed to add administrative burden, however will be counterbalanced by improved reporting and information and hence better preparedness for future crises.</p> <p>Under this option governance would be significantly improved as only one expert group needs to be operated.</p> <p>As regards the newly established reporting and monitoring procedures to implement the improved health security framework Member State would need to provide 0.3 – 0.5 Full Time Equivalent for a national expert over a period of 2-3 months to address reporting. As Member States have also reporting duties under the International Health Regulations synergies in the</p>

	<p>reporting can be expected.</p> <p>In addition, Member States would need to dedicate staff capacities every five years to contribute to an external evaluation.</p> <p>Increase in administrative burden would have to be expected during the setting up phase of the proposed mechanism for joint procurement, but for those Member States that envisage adequate provision and preventive measures for a future pandemic the administrative procedures have to be implemented any way.</p> <p>For the Commission</p> <p>The Commission is already committed to implement preparedness and response planning; this was in particular done to enhance pandemic preparedness, but efforts on generic preparedness were undertaken as well. With a more systematic and structured approach synergies in the work invested by Commission staff can be expected and no additional administrative burden.</p> <p>Additional efforts would need to be undertaken by improving coordination with existing crisis notification tools and alert mechanisms; however, as contacts to these instruments are already in place, the additional investment for which human resources are needed can be considered marginal. This additional work can be done by available staff and assignment to national experts.</p> <p>Governance for management would be significantly improved as only one expert group needs to be operated.</p> <p>Increase in administration would have to be expected during the setting up phase of the proposed mechanism for joint procurement of medical countermeasures in form of additional staff and administrative burden for the entity in charge of operating the contract. (see details under financial implications). This task might be assigned to the Commission, there are however options that external support is requested for this task, e.g. by assigning this task to an Agency or Body in charge of procurement or contract management.</p> <p>These administrative effects would decrease during the running of the contract prior to a cross-border health threat. In the case of an outbreak or a public health event which would require the activation of the contract, the administrative needs would rise steeply: However, for the participating countries the proposed mechanism will result in a significant reduction of administrative burden as it would enable the pooling of different skills and expertise between national authorities.</p> <p>For other stakeholders/private companies:</p> <p>No additional administrative burden is expected</p>
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7. EU added value	++	<p>Under option 3 EU added value would be increased throughout all elements of preparedness and response planning, risk assessment and risk management by setting up a strategic and technical level cooperation on health security at the EU level. This would be guaranteed by the establishment of a sound legal basis for all serious cross-border health threats.</p> <p>In providing also a legal basis for operating a joint procurement mechanism for medical countermeasures it would add value to strengthening preparedness and response capacity to cross-border health threats across the EU.</p>
8.. Impact at International level	++	<p>Better coordination in the EU of IHR implementation by the Member States and closer collaboration between the EU and WHO on preparedness for and response to public health emergencies of international concern would contribute to enhance global health security. It would contribute to better control the spread of diseases internationally from and to the EU through e.g. through exchange of information and good practice with global partners and 3rd countries.</p> <p>In this context improved public health risk assessment and management could be undertaken more effectively at international level when the EU has defined a common approach on serious cross-border threats to health and pre-established procedures on international cooperation.</p> <p>The importance of the new EU expert group in the relation with other international entities (e.g. GHSI) would be significantly increased.</p> <p>In addition, improved communication strategies at EU level can also be useful and shared with third countries and other international partners and organisations.</p>

Annex 20: Comparison of the policy options

Rating:

0 Baseline scenario, neutral impact

+ positive impact; ++ significant positive impact,

- negative impact; -- significant negative impact,

Assessment Criteria	Option 1 Status quo	Option 2 improved cooperation by use of soft instruments- voluntary approach	Option 3 Improved cooperation; legally binding measures
1. Improved protection of EU citizens against serious cross-border threats to health	0	+	++
2. Improved public health security structures and systems			
2.1. Coherent and comprehensive overall approach for all serious cross-border threats to health	0	+	++
2.2. Improved preparedness and response planning, common approach at EU level for <i>all</i> serious cross-border threats to health	0	+	++
2.3. Improved risk monitoring and assessment	0	+	++
2.4. Improved coordination and risk management	0	+	++
2.5. Improved crisis communication	0	+	++
3. Social impacts	0	+	++
4. Economic impacts	0	+	++
5. Financial implications	0	-	-
6. Administrative burden	0	0	-
7. EU added value	0	+	++
8. Impact at international level	0	+	++
Total	0	9	18

Annex 21: 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 ²⁴⁸ , efficiency ²⁴⁹ and coherence ²⁵⁰ 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>

²⁴⁸ Effectiveness = the extent to which options achieve the objectives of the proposal

²⁴⁹ Efficiency/cost effectiveness = the extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness)

²⁵⁰ 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	
<p><u>2.3. risk monitoring and assessment:</u> coherent and comprehensive approach for</p> <ul style="list-style-type: none"> - identification and notification of health threats, based on improved linkage between existing monitoring and notification mechanisms and structures - improved capacities for robust, reliable, and rapid public health risk assessment for serious cross-border threats to health 	<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
<p><u>2.4. risk management:</u> improved coordination –</p> <ul style="list-style-type: none"> - sustainable structure at EU level for any serious cross-border public health crisis; - clear mandate for this structure with strong commitment of Member States 	<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
<p><u>2.5.crisis communication:</u> improved conditions for crisis communication</p>	<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

Annex 22. Glossary: Public Health Security in the European Union

Case definition	<p>For the scope of coordination of public health measures during outbreak (or epidemic, or incidents, or pandemics) Case definition is the method by which public health professionals define who is included as a <i>case</i> in an outbreak investigation, (i.e. a person considered directly affected by an outbreak) or in the surveillance of public health conditions. A case definition has the following characteristics; it defines a case in time, person and place. Time criteria may include all cases of a disease identified from, for example, January 1, 2008 to March 1, 2008. Person criteria may include age, gender, ethnicity, and clinical characteristics such as symptoms (e.g. cough and fever), clinical tests (e.g. pneumonia on chest X-ray). Place criteria will usually include a geographical entity such as a town, state, or country but may be as small as an institution, a school class, or a restaurant meal session. Case definitions may also be categorised into suspect, probable and confirmed cases.</p> <p>For example in the investigation of an outbreak of pneumococcal pneumonia in a nursing home the case definition may be specified as:</p> <p>Suspect Case: All residents of Nursing Home A with onset of cough and fever between January 1, 2008 and February 1, 2008.</p> <p>Probable Case: Meet the suspect case definition plus have pneumonia on chest X-ray.</p> <p>Confirmed Case: Meet the probable case definition plus have pneumococcal infection confirmed by blood culture or other isolation of pneumococci from normally sterile site.</p> <p>By creating a case definition, public health professionals are better equipped to study an outbreak and determine possible causes. As investigations proceed, this definition may be expanded or narrowed. This is characteristic of the dynamic nature of outbreak investigations.</p>
Core capacity requirements	<p>Core capacity requirements refer a core set of capacities, structures, mechanisms, processes and procedures which need to be in place and available for preparedness and response to address serious cross-border health threats in the EU.</p>
Crisis management	<p>Management of any critical situation that causes a disruption to the balance between the demand for and supply of medical services. Crisis management involves the plans, structures and arrangements established to bring together the normal endeavors of government, voluntary and private agencies in a comprehensive and coordinated way to deal with the whole spectrum of emergency needs including prevention, response and recovery.</p>
Crisis communication	<p>Communicating in a situation that somehow challenges the public's sense of appropriateness, traditional values, safety, health, security or</p>

	the integrity of the government.
Crisis management circle	<p>Preparedness and response planning is about developing and strengthening capacities to respond rapidly to any kind of emergencies affecting or likely to affect public health.</p> <p>Risk assessment, i.e. independent expertise with sound scientific advice on emerging risks to public health, is needed to enable decision makers to prepare their policy and activities relating to reinstalling public health. This risk assessment process includes the detection/alerting and monitoring/surveillance of emerging threats, the evaluation of potential risks to public health coming from those threats, as well as the notification of such risks to concerned entities.</p> <p>Risk management covers the sum of the decisions and actions taken by competent authorities during and after a crisis. Risk management includes the whole spectrum of emergency needs including prevention, response and recovery. These, for example cover the diagnosis of cases by specialised laboratories, providing medical care if necessary even in mobile units, vaccination, containment of people, travel advice, rules on personal protection and hygiene, or decontamination measures. Efficient communication has become an important part of risk management.</p>
Crisis preparedness and response planning	Developing and strengthening capacities to respond rapidly to any kind of emergencies affecting or likely to affect public health.
Crisis preparedness plan	<p>A written document or map for public health crisis management published by the responsible authority. The organisation, responsibilities and measures are defined - with details on how, when and whom - both before and after an event with public health consequences occurs. It aims to provide a policy for preparedness and response to both internal and external disaster situations that may affect the population and the community.</p> <p>Preparedness is the knowledge and capacities developed by government, organisations and communities to effectively anticipate, respond to, and recover from, the impacts of a likely, imminent or current crisis.</p>
Critical infrastructures	Critical infrastructures are those physical and information technology facilities, networks, services and assets which, if disrupted or destroyed, would have a serious impact on the health, safety, security or economic well-being of citizens or the effective functioning of governments in EU countries.
Cross-sectoral action	Interdisciplinary, collaborative activity that is carried on with the help and/or involvement of several sectors at the same time.

Health measure	Procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures.
Health security	Activities required, both proactive and reactive, to minimise vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries.
IHR (2005)	International Health Regulations - IHR (2005): the WHO international regime providing global rules to enhance national, regional and global public health security. This legally-binding agreement significantly contributes to global public health security by providing a new framework for coordinating the management of events that may constitute a public health emergency of international concern, and improves the capacity of all countries to detect, assess, notify and respond to public health threats (www.who.int/ihr/en/).
IHR (2005) Annex 2	The annex 2 of the IHR (2005) is a decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern. It is available under: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf .
Interoperability	Property referring to the ability of diverse sectors, disciplines or organisations to work together.
Joint procurement	Two or more contracting authorities joining their public procurement actions.
Quarantine	Restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination.
Real events in the past	Some examples: Influenza A(H1N1) pandemic in 2009, Severe Acute Respiratory Syndrome (SARS), milk contaminated with melamine, food contaminated with dioxin, stainless steel contaminated with cobalt-60.
Response	Sum of public health decisions and measures taken during and after a disaster, including immediate relief, rehabilitation and reconstruction.
Risk assessment	A scientifically based process consisting of the following steps: (i) threat detection and identification, (ii) threat characterisation, (iii) exposure assessment, and (iv) risk characterisation.
Risk communication	The exchange and dissemination of appropriate information about risks to enable decision makers, stakeholders and the public to make appropriate decisions.
Risk	A process, distinct from risk assessment, of weighing policy

management	alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for health protection of consumers, and if needed selecting appropriate prevention and control options.
Serious cross-border public health threat	An event of biological, chemical, radiological and nuclear or environmental origin or caused by climate change, with potentially severe consequences for public health which affects or could affect more than one Member State in such a way that the morbidity or mortality in humans is acute and rapidly growing in scale or is unusual for the given place and/or time.
Stockpile of medical countermeasures	A supply of medical countermeasures stored for future use against a health threat.

Annex 23: Reference Documents and Links

Health Security Committee (HSC)

Presidency conclusions of **15 November 2001** on bioterrorism - Informal cooperation and coordination body by Health Ministers and the European Commissioner for Health and Consumer Protection **2384th Council meeting**

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/DOC.68699.htm

<http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/01/415&format=HTML&aged=0&lg=nl&guiLanguage=en>

What is the Health Security Committee? - What is the Early Warning and Response System (EWRS)? **MEMO/09/363**

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/363&type=HTML>

Council conclusions of **5 February 2007** on the Communication from the Commission to the Council on the transitional prolongation and extension of the mandate of the HSC in view of a future general revision of the structures dealing with health threats at EU level - in 2007, the Council agreed that the mandate of the HSC was temporarily prolonged covering also pandemic influenza and generic preparedness and response planning and the general revision of the structures dealing with health threats at EU level (5862/07).

Council conclusions of **22 February 2007** on Health Security Committee - Transitional prolongation of the HSC mandate and extension of Terms of reference for the HSC; request for long-term solution for the EU framework on health security **2786th Council Meeting**

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/92911.pdf

Council conclusions of **16 December 2008** on health security (after informal Health Ministers meeting Angers, 8-9 September 2008) - Provide HSC with legal basis and Legislative initiative to adopt the status of HSC to the health challenges **2916th Council meeting**

http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lisa/104770.pdf

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/104835.pdf

<http://register.consilium.europa.eu/pdf/en/08/st16/st16515.en08.pdf>

Council conclusions on lessons learned from the A/H1N1 pandemic - health security in the European Union of **13 September 2010** - present in 2011 a proposal for health security and further prolong the current HSC mandate **3032nd Council meeting**

http://ec.europa.eu/health/preparedness_response/docs/council_lessonsh1n1_en.pdf

Health Security Initiative

Communication of **2 June 2003** from the Commission to the Council and the European Parliament on cooperation in the European Union on preparedness and response to biological and chemical agent attacks (Health Security) **COM(2003) 320 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0320:FIN:EN:PDF>

Communication of **28 November 2005** from the Commission to the Council, the European Parliament, ... on strengthening coordination on generic preparedness planning for public health emergencies at EU level **COM(2005) 605 final**

http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0605en01.pdf

Commission Staff Working Document of **23 November 2009** on Health Security in the European Union and Internationally. The health security concept is about our society's vulnerability to major public health threats and about mitigating such threats. To set out the current EU policy framework in the area, the Commission has analysed how to deal with major public health threats and published a Commission Staff Working Document **SEC(2009) 1622 final**

http://ec.europa.eu/health/preparedness_response/docs/commission_staff_healthsecurity_en.pdf

Commission Staff Working Document of **18 November 2010** on lessons learnt from the H1N1 pandemic and on health security in the European Union. The health security initiative was requested by the EU Council, in its conclusions adopted on 13 September 2010 on lessons learned from the A/H1N1 pandemic - health security in the European Union. The principles for the initiative were set out in the Commission Staff Working Document **SEC(2010) 1440 final**

http://ec.europa.eu/health/preparedness_response/docs/commission_staff_lessonsh1n1_en.pdf

Communicable diseases

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

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:268:0001:0006:EN:PDF>

Early Warning and Response System (EWRS)

Commission Decision No 2000/57/EC of **22 December 1999** on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC of the European Parliament and the Council

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/14517.en0.doc.html

[http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000D0057:20090714:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000D0057:20090714:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000D0057:20090714:EN:PDF)

European Centre for Disease Prevention and Control (ECDC)

Regulation (EC) No 851/2004 of the European Parliament and the Council of **21 April 2004** establishing a European centre for disease prevention and control

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:142:0001:0011:EN:PDF>

Pandemic Influenza

Communication of **28 November 2005** from the Commission to the European Parliament and the Council on Pandemic Influenza Preparedness and Response Planning in the European Community **COM(2005) 607 final**

http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0607en01.pdf

Communication of **15 September 2009** from the Commission to the European Parliament and the Council on Pandemic (H1N1) 2009 **COM(2009) 481 final**

http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf

Accompanied by SEC(2009) 1188 / 1189 / 1190 / 1191 / 1192

Commission Staff Working Document of **15 September 2009** on Joint procurement of vaccine against influenza A(H1N1) **SEC(2009) 1188 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:1188:FIN:EN:PDF>

Commission Staff Working Document of **15 September 2009** on Vaccination strategies against pandemic (H1N1) 2009 **SEC(2009) 1189 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:1189:FIN:EN:PDF>

Commission Staff Working Document of **15 September 2009** on Communicating with the public and the media on Pandemic (H1N1)2009 **SEC(2009) 1190 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:1190:FIN:EN:PDF>

Commission Staff Working Document of **15 September 2009** on Regulatory process for the authorisation of antiviral medicines and vaccines in the protection against Pandemic Influenza (H1N1) 2009 **SEC(2009) 1191 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:1191:FIN:EN:PDF>

Commission Staff Working Document of **15 September 2009** on Support to third countries to fight the Influenza A(H1N1) **SEC(2009) 1192 final**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:1192:FIN:EN:PDF>

International Health Regulations (IHR)

Communication of **26 September 2006** from the Commission to the European Parliament and the Council on the International Health Regulations **COM(2006) 552 final**
http://ec.europa.eu/health/ph_international/documents/comm_ihr_552_2006_en.pdf

International Health Regulations (2005), Second edition, **Authors:** World Health Organization (WHO), Publication date: 2008, ISBN: 9789241580410
<http://www.who.int/ihr/9789241596664/en/index.html>

Home Affairs – Action Plan CBRN

Communication of **24 June 2009** from the Commission 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**
http://ec.europa.eu/home-affairs/summary/docs/com_2009_0273_en.pdf

Accompanied by SEC(2009) 790 / 791 / 874

Commission Staff Working Document of **24 June 2009** on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union. Impact Assessment **SEC(2009) 790**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:0790:FIN:EN:PDF>

Commission Staff Working Document of **24 June 2009** on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union. Summary of the Impact Assessment **SEC(2009) 791**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2009:0791:FIN:EN:PDF>

Council conclusions on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union – an EU CBRN Action Plan

<http://register.consilium.europa.eu/pdf/en/09/st15/st15505-re01.en09.pdf>

Climate Change

The Commission has adopted in 2009 a White Paper on "Adapting to climate change: Towards a European framework for action" and a communication on climate change **COM(2009) 147**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0147:FIN:EN:PDF>

Commission Staff Working Document of **1 April 2009**, accompanying document to the WHITE PAPER "Adapting to climate change: Towards a European framework for action", on Human, Animal and Plant Health Impacts of Climate Change **SEC(2009) 416**

http://ec.europa.eu/health/ph_threats/climate/docs/com_2009-147_en.pdf

APPENDICES

1. Report on the outcome of the "Stakeholder consultation on Health Security in the European Union"



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2. Structures for preparedness and response to cross-border health threats



Appendix
3_Structures for prep