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COMMISSION STAFF WORKING PAPER

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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

{COM(2011) 866 final} {SEC(2011) 1519 final}

1. THE HEALTH SECURITY INITIATIVE

The aim of the Health Security Initiative is to streamline and strengthen health security capacities and structures in order more effectively to protect the citizens of the European Union (EU) against serious cross-border threats that can affect public health.

The EU has a well established policy and legal framework to address communicable diseases that has been in place since 1998. It sets out legal requirements for the surveillance of communicable diseases, the notification of acute events at EU level through a secure Early Warning and Response System (EWRS) and the exchange of information on public health measures taken to control such outbreaks. Member States are therefore under the obligation to notify outbreaks of communicable diseases. Information on such diseases is shared in real time with all Member States, and measures to address them are coordinated at EU level. Since 2005, the European Centre for Disease Prevention and Control (ECDC) provides scientific risk assessment on communicable diseases.

However, not all serious cross-border threats to health are handled in such a consistent manner at EU level. The Health Security Initiative therefore aims to provide a comparable level of protection against other types of serious cross-border threats to health caused by biological, chemical and environmental events. The specific nature of these threats will be taken into consideration.

The Health Security Initiative will also help implement the European Health Strategy and contribute to the objectives of Europe 2020 by promoting health as an integral part of the smart and inclusive growth objectives. In addition, it will contribute to the overall European security effort and in particular help achieve the agenda set out in the Internal Security Strategy. The initiative will also be instrumental in strengthening chemical, biological, radiological and nuclear (CBRN) security in the EU as set out in the CBRN action plan and stepping up cooperation with the Monitoring and Information Centre mechanism in preparedness for and response to civil disasters.

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 component¹.

In the context of this initiative, serious cross-border threats to health are events caused by communicable diseases, or by biological agents causing non-communicable diseases, of chemical, environmental or unknown origin, or caused by climate change, with potentially severe consequences for public health. For the purposes of the initiative, threats emerging from the effects of climate change will be covered by environmental threats. Radiological events are excluded from the initiative as they are dealt with under the provisions of the Euratom Treaty.

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E.g. 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 this initiative to create regional CBRN Centres of Excellence.

The scope of the initiative will cover the EU-level coordination of preparedness and response planning for these threats to health, including the procurement of medical countermeasures, monitoring and assessment of the risks to public health arising from these potential threats and management and communication of the identified risks and health-related crises.

The initiative was developed following an extensive consultation process including an open stakeholder consultation on health security in the European Union, several meetings with the Early Warning and Response System (EWRS) network and the Health Security Committee (HSC)², bilateral meetings with six Member States and a presentation to the EU Health Policy Forum. The outcome of the open consultation process on 'strengthening European Union preparedness on pandemic influenza' from 2010 was also taken on board. Relevant Commission departments have been involved in developing the initiative, including the Secretariat-General.

2. PROBLEM DEFINITION

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

Member States are differently equipped to respond to serious cross-border health threats with regard to laboratory infrastructure, analytical tools or staff levels, for instance. Moreover, not all the critical sectors in society are thoroughly prepared for a wide range of events that may have an impact on public health. Member States and critical sectors that are less well prepared will weaken and delay the EU response and adversely impact on the situation in other Member States.

In the event of an emergency, a wide range of public health measures may be necessary, for example the diagnosis of cases by specialised laboratories, the provision of medical care, vaccination or treatment, travel advice, rules on personal protection and hygiene, or decontamination measures. Apart from health, other critical sectors need to be prepared. Hospitals, for example, cannot function properly if electricity fails or if doctors are unable to travel to work due to the breakdown 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 fall sick.

Discrepancies in the level of preparedness planning across the EU may lead to incoherent strategies, divergent standards, and inconsistent procedures and methodologies. They may, for example, entail unequal access to treatment and medical care, endanger management of outbreaks, and even lead to an increase in the number of people falling sick or dying. Without coordination at EU level, Member States may adopt different mutually counterproductive measures e.g. as regards closing borders, imposing quarantine or issuing travel advice, and public health measures will be managed on an ad hoc basis by individual Member States. Risk management at EU level will be less effective and public trust in national authorities and in EU institutions will be undermined. Ultimately this may lead to major repercussions on other EU policies, not least the functioning of the internal market.

Individual procurement of medical countermeasures may increase competition between Member States. Confidentiality clauses in contracts may considerably weaken Member

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

States' purchasing power and, when combined with restrictions on health budgets, may lead to procuring insufficient amounts of medical countermeasures, thereby considerably weakening EU preparedness.

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

Although there are a variety of monitoring and alert systems for different threats at EU level, these are not systematically linked to EU public health institutions.

The International Health Regulations (IHR) — an international treaty for the coordination of all health emergencies — stipulate that Member States must notify the World Health Organisation (WHO) about any event that may constitute a public health emergency of international concern, independently of its origin (biological, chemical, radiological, nuclear or environmental).

There are no similar notification obligations at EU level. What is more, 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, which necessitate a more sensitive system.

National public health risk assessments exist, but may not be comprehensive and consistent when considered from the EU perspective, and there is currently no mechanism for a coordinated approach at EU level. The lack of public health risk assessment at EU level leads to discrepancies in evaluating the danger of a given threat, duplication of assessments between Member States and incoherent measures at EU level. Such a situation can also lead to inefficient use of the limited resources currently available and may delay appropriate public health measures, thereby potentially putting at risk the overall response at EU level. The adverse impact of this situation might result in higher levels of morbidity and mortality. It may also endanger shared EU policies because of the impact of health effects on other critical sectors of the economy and society. Importantly, the absence of comprehensive or proper risk evaluation may lead to unclear communication and may undermine public confidence in measures proposed or taken by public health authorities in Member States.

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

Serious cross-border health threats are unavoidable. They do not happen as frequently as communicable diseases, but they can have huge consequences both for health and for other sectors of the society and economy. The basis for coordinating the public health response at EU level is weak compared with the potential impacts. The structures and mechanisms for public health risk management at EU level are not tailored to the new international legal framework (the International Health Regulations) and are inadequate to deal with a health-related crisis.

In addition, the respective mandates, responsibilities and scope for taking decisions on the public health response are not clearly differentiated between the two existing bodies, namely the Early Warning and Response System (EWRS) network and the Health Security Committee (HSC). This informal committee was set up by the EU health ministers in 2001 in

the aftermath of the terrorist attacks, as a structure for better coordinating public health risk assessment and management of serious cross-border health threats in the EU. At the beginning, its mandate was limited to tackling bioterrorism; it was subsequently extended to cover all types of public health-related crisis and further prolonged. It is composed of representatives of health authorities of the Member States and chaired by the Commission.

Given the informal nature of the Committee and its ad hoc mandate, there is insufficient coordination of the public health response and no cross-sectoral interlinking of decision making processes in public health. Even shared statements on minimum common denominators are difficult to achieve without a robust framework, leading to the risk of delays in the response to health emergencies. Although a Communicators' network has been established under the Health Security Committee, the lack of a formal mechanism for agreeing consistent messages to the public and target populations is not conducive to an efficient information process at EU level. This undermines the confidence in and credibility of the public health response to chemical, biological (other than communicable diseases) and environmental threats.

3. THE RIGHT OF THE UNION TO ACT

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 the protection and improvement of human health (Article 6(a) TFEU). The Treaty states that EU action must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health, and in particular 'monitoring, early warning of and combating serious cross-border threats to health' (Article 168 TFEU).

'Serious cross-border threats to health' as defined in the Treaty and 'public health emergencies of international concern' as defined under the International Health Regulations have, by their nature, transnational implications which Member States cannot satisfactorily address individually. They often affect crucial sectors of the economy and society. Many of these sectors fall under exclusive or shared EU competence, and therefore require the involvement of different stakeholders.

The EU already has good experience of coordination in the field of communicable diseases, which is governed by a comprehensive body of EU legislation and has proved essential in handling serious outbreaks in Europe. The Health Security Initiative will build on this positive experience, as well as on the existing instruments and lessons learnt. Because not all Member States have the same level of preparedness, risk assessment and crisis management, the Health Security Initiative will improve the coordination of the management of serious cross-border health threats at all levels. Member States' preparedness will be strengthened by establishing common procedures and standards, sharing resources, and improving the exchange of expertise and information. Capacities for rapid and efficient response will be reinforced, and effective coordination of the management of serious cross-border health threats will be ensured. Access to and availability of medical countermeasures will be better balanced between Member States. Strengthened coordination at EU level will lead to a coherent and comprehensive approach to risk assessment and management. This initiative will also provide the EU Member States with an opportunity to coordinate their action in implementing the International Health Regulations.

4. POLICY OBJECTIVES

Given the problems identified in Section 2, the health security initiative aims to achieve the objectives set out in the table below.

Table 1: Objectives of the Health Security Initiative

General objectives					
More effectively protect the citizens of the European Union against serious cross-border threats to health and ensure a high level of human health protection in framing and implementing EU policies and activities					
Specific objectives					
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, and risk management, including risk communication					
Preparedness and response planning	Risk monitoring and assessment	Risk management and crisis communication			
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 among Member States, including improving equitable access to medical countermeasures	Create the necessary conditions to ensure the 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	- 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 - Create and facilitate shared and coordinated			
		communication strategies in order to avoid conflicting or inaccurate messages being released to the public			
	Operational objectives				
Preparedness and response planning	Risk monitoring and risk assessment	Risk management and crisis communication			
 Develop and update comparable and coherent generic preparedness and response planning, and planning for specific threats at EU level, in particular for pandemic influenza Develop and agree shared standards and tailor-made EU 	diess and response planning, and planning for specific at EU level, in particular for pandemic influenza alop and agree shared standards and tailor-made EU for notifying threats in order to ensure stronger, and resilient operation of the public health sector in operation based on the requirements laid down by the sustainability of existing monitoring and notification mechanisms and structures - Strengthen and create capacities for public health sessent that is robust, reliable, compatible between sectors, and rapidly available - Provide mechanisms for reinforced coordination				
criteria for notifying threats in order to ensure stronger, continued and resilient operation of the public health sector in the European Union based on the requirements laid down by the International Health Regulations					
- Create an instrument to improve equitable access to medical countermeasures, e.g. through a joint procurement mechanism	health threats other than communicable diseases	- Strengthen measures related to risk and crisis communication on health threats, and provide for rapid exchange and agreement on communication messages and strategies			

5. POLICY OPTIONS

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

The measures identified in each option vary according to the level of implementation of preparedness planning and core capacity requirements and the level of obligation on Member States in terms of implementation, the informal or formal nature of the expertise 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.

A summary of the measures related to the three options is attached in Table 3 in the Annex.

6. ANALYSIS OF THE IMPACTS

6.1. Option 1: Status quo/baseline scenario — maintain the current level of activities

Under this option the current situation including the problems described in Section 2 would remain unchanged.

6.2. 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

<u>Public health impact</u>. The impact on public health would be improved as the overall situation in terms of preparedness for and response to a crisis would be strengthened along with the effectiveness, efficiency and coherence of public health security structures and mechanisms. This would be achieved through EU-wide recommendations supported by Member States. However, these positive impacts would rely on the commitment of the Member States to agree on these recommendations and implement them on a non-binding basis. To a certain extent, this option could lead to increased coherence of overall preparedness, improved

coordination of existing notification tools and strengthened risk assessment capacities. The risk management structures supporting the coordinated response at EU level would be sustainable with clearer mandates, thereby improving the effectiveness of health crisis management, including communication. Regarding equitable access to medical countermeasures, the impact of this option is expected to be an improvement on individual national procurement procedures. However, the proposed activities would remain at the level of cooperation between individual authorities in charge of procurements, and purchasing power and the ability to obtain better contractual conditions would remain weak at best.

<u>Social impact</u>. Provided that the Member States implement the agreed guidance and recommendations, improved risk management and in particular better coordination of risk communication would have a beneficial effect on citizens as messages issued to the public would be more consistent within the EU, thereby boosting confidence in the ability of public health authorities to manage a health crisis. Inter-sectoral cooperation to improve public health protection would be strengthened. As regards equitable access to medical countermeasures, this option would enable expertise to be pooled among the Member States and solidarity to be improved in terms of preparation of the procurement procedures.

Economic impact. Option 2 could lead to more rapid risk assessment and management of a given threat. These improved structures and systems at EU level would result in strengthened capacities to contain and mitigate a serious cross-border health threat and its related economic consequences. As a result, 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 commitment of the Member States. Option 2 could positively impact on innovation and R&D efforts related to the development of such products. However, this would not ensure improved access to medical countermeasures.

<u>Financial implications</u>. No additional costs would arise for Member States and stakeholders, because the financial situation would be the same as described in option 1.

<u>Administrative burden</u>. Under this option, the administrative burden for the Member States and the Commission would be reduced as the mandates of the two relevant committees — the Early Warning and Response System Network and the Health Security Committee — would be clearly defined, thereby limiting the risks of overlap. As regards access to medical countermeasures, the administrative burden could also be reduced for Member States, as national expertise would be pooled.

<u>EU added value</u>. The EU added value would be increased as the coordination of preparedness for and response to cross-border health threats would be enhanced at EU level.

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

<u>Public health impact</u>. Under this option, the protection of EU citizens against serious cross-border health threats and the effectiveness of public health security structures and mechanisms at EU level would be considerably improved. This would allow coherent preparedness planning based on shared and common mandatory standards and a better coordinated and balanced response to all types of serious cross-border health threats. For example, all Member States would need to have preparedness plans in place that would cover both health measures and other critical sectors, and structures and capacities would need to be

set up in compliance with agreed check lists. This option would also result in a more coherent and comprehensive approach to the identification, notification and assessment of serious cross-border health threats. By setting up a legal basis allowing joint procurement, this option would considerably improve equitable access to medical countermeasures by Member States, thereby ensuring a higher level of protection of EU citizens across the Union. Furthermore, inter-sectoral cooperation would be improved in the event of cross-border health threats, also contributing to better public health protection.

<u>Social impact</u>. Along with the impacts related to improved coordination of communication already identified for option 2, a coordinated approach to access to medical countermeasures would raise confidence in measures undertaken by public health authorities, as they would rely on a robust legal instrument. For those Member States that had opted to participate in joint procurement, the mechanism would lead to a higher level of protection for vulnerable groups by ensuring a guaranteed supply and would promote solidarity between the Member States by providing common minimum coverage for vulnerable groups of society.

<u>Economic impact</u>. The positive impacts already described under option 2 could increase, because the planned measures under option 3 would be based on binding agreements. The setting-up of a joint procurement mechanism for medical countermeasures would boost the supply of medical products and encourage development of new products based on long-term contracts agreed with the public health sector.

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

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

<u>EU</u> 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 cooperation on health security at EU level. This would be guaranteed by the establishment of a robust legal instrument for all serious cross-border health threats. By also providing a legal basis for operating a joint procurement mechanism for medical countermeasures this option could add value to strengthening preparedness and response capacity to deal with cross-border health threats across the EU.

<u>Impact at international level</u>. 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 enhancing global health security.

7. COMPARING THE IMPACTS

Table 2: Comparison of the policy options

Rating: 0 Baseline scenario, neutral

positive impact
 negative impact
 significant positive impact
 significant negative impact

Assessment criteria	Option 1	Option 2	Option 3
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

This comparison focuses on options 2 and 3, where new impacts can be expected. There are a number of differences between options 2 and 3 which demonstrate the added value of choosing option 3.

As regards the <u>public health impact</u>, 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 also establishes common mandatory standards that would lead to considerably improved coordination at EU level. Both options also strengthen <u>risk notification and assessment</u>. However, option 3 would provide for a more coherent and comprehensive approach as a coordination system would be put in place. Risk assessment capacities would be improved by filling gaps in current risk assessment capacities under option 3. For <u>risk and crisis management</u>, option 2 would improve the overall situation as the mandates of the two committees 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.

8. CONCLUSIONS AND PROPOSAL FOR IMPLEMENTATION

Option 3 has the strongest health impacts as it provides improved protection of citizens against serious cross-border health threats. 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 to address all types of public health event by merging the two existing committees.

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

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 and extend them to health threats caused by biological, chemical and environmental events.

9. MONITORING AND EVALUATION

Systematic follow-up of the policy measures in the field of preparedness and response planning, risk assessment and risk management will be ensured by evaluating the implementation of the legislative instrument.

The Commission will submit to the European Parliament and the Council regular reports evaluating the implementation 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, WHO and EMA. The reporting system will be approved and implemented by the new committee.

A more detailed inventory of existing capacities, measures and plans in terms of preparedness, risk assessment and risk management and communication 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 refined and serve as the benchmark against which progress will be measured after approval of the legal initiative.

10. ANNEX

Table 3: Overview of measures proposed under the three options

ANNEX: Table 3: 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 implementation of guidance on generic and pandemic preparedness; organise exercises and training; exchange best practice	Shared approach to preparedness planning; identify core capacity standards related to IHR requirements; guidance on improved cross-sectoral preparedness and interoperability	Common EU framework for MS to: - put in place common features 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 the 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 Member States 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 committee	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 action, 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 the crisis management process and link communicators directly to risk managers/decision makers