

EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health Health threats

Report of the Stakeholder Consultation on

Health Security in the European Union

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EXECUTIVE SUMMARY OF THE CONSULTATION

The key outcome of the stakeholder consultation on health security in the European Union (EU) is that an overwhelming majority of respondents strongly argue for having all serious cross-border health threats included in the EU health security policy. The following main areas of strengthening EU public health response on health security threats have been identified in this consultation.

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

Secondly, **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 be added values.

Thirdly, **risk management (including communication)** should be improved for all serious cross-border health threats. A better coordination at EU level of national public health measures, including information and communication, among Member States in the event of a serious cross-border health threat is needed. A coherent risk management mechanism for serious cross-border health threats at EU level would be added value.

In addition, the **Health Security Committee** (HSC) is seen as a useful platform for public health risk management and risk communication for coordinating at EU level the response to public health consequences of serious cross-border health threats. The legal formalisation of the status of the HSC is strongly supported.

[Note: After the public consultation, it has been agreed that events of radiological and nuclear origin will be excluded from the initiative as a sufficient preparedness and response capacity is already provided by the provisions of the Treaty establishing the European Atomic Energy Community concerning all public health aspects of such events.]

KEY RESULTS OF THE CONSULTATION

General questions

The mechanism in place to handle infectious diseases at EU level, considering preparedness, risk assessment and management, is good. This mechanism should be extended to other serious cross-border threats (chemicals, biological, radio/nuclear and environmental events).

Serious cross-border threats to health should be treated equally at European Union (EU) level and public health consequences of these threats should be coordinated and handled at EU level in a similar or in a more stringent way as infectious diseases. Members of the Health Security Committee (HSC) and the Early Warning and Response System (EWRS) Network Committee support this approach but specified that existing structures and systems should be used as far as possible to serve public health purposes.

Coordination between Member States and communication are essential for efficient management of public health crisis. According to HSC and EWRS members, there is a need to create synergy with the International Health Regulations (IHR) 2005.

Preparedness planning

The present discrepancies in level of preparedness planning between Member States lead to non complementary responses at EU level and the less prepared Member States will weaken the EU response capacity to cross-border public health threats. Therefore, the EU should encourage a better national preparedness planning and support coherent and interoperable preparedness plans based on lessons learnt from the pandemic Influenza H1N1 in order to develop a common approach between Member States. In addition, the International Health Regulations (2005) require EU Member States individually to build core capacities for surveillance and response to all public health emergencies of international concern.

At national level, the EU should encourage and coordinate national preparedness planning, focusing on an all-hazard approach.

At EU level, this all-hazard approach is also foreseen for EU preparedness plans; serious cross-border threats other than an influenza pandemic should be considered and minimum core capacity standards should be set up on preparedness planning.

Member States' health systems are not sufficiently connected at EU level to allow an efficient coordination for chemical, radio/nuclear agents and environmental events.

The other sectors at EU level (e.g. transport, telecommunications, energy) do not take sufficiently into account public health consequences resulting from serious cross-border health threats of a chemical, biological, radio/nuclear or environmental nature.

Risk assessment

A better evaluation of public health issues resulting from all serious cross-border threats is needed. Risk assessment for infectious diseases is sufficient at EU level through the European Centre for Disease Prevention and Control (ECDC). As regards other serious cross-border threats of CBRN origin, capacities for public health risk assessment are not sufficient to support a coordinated risk management at EU level - no dedicated agency is addressing the public health aspects of these risks - and it would bring an added value to have EU capacity to conduct risk assessment from the public health perspective for these threats. Limited scientific

evidence-based and risk assessment methodologies can increase risks of inappropriate decision making and public health response.

According to the members of the HSC and the EWRS, there is a need for risk assessment of health related aspects of chemical and radio/nuclear events and threats from a public health perspective.

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). The current IHR (2005) decision instrument for notifying public health emergencies of international concern to the WHO (IHR 2005 Annex 2) is sufficient for notifying at EU level serious cross-border threats.

Risk management

At EU level, for infectious diseases, a formal channel for coordination of public health measures exists: the EWRS Network Committee. For all other serious cross-border health threats, the coordination of risk management from a public health perspective is not sufficiently addressed at EU level. So far, these other threats have been dealt informally under the context of the HSC, established by the Council and with the help of the Commission.

A coherent risk management mechanism for serious cross-border public health threats at EU level would bring added value.

Health Security Committee

The HSC as a platform for coordinating at EU level the response to public health consequences of serious cross-border health threats brings added value. But a legal formalisation of the status of the HSC would be better.

Communication

Information and communication between Member States should be better coordinated at EU level and coherent communication messages (key messages) should be addressed to the public.

When several sectors are involved, the Ministry of Health takes the lead for communication with the public on public health consequences regarding infectious diseases and diseases caused by biological agents (e.g. toxins). But, when considering public health consequences from chemical agents, radio/nuclear agents or environmental events, communication should be in the lead of another ministry in collaboration with the Ministry of Health, coordinated at EU level.

1. BACKGROUND

On 16 December 2008, the Council of the European Union (EU) adopted its conclusions on health security, inviting 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 (2005)¹".

The Council of the EU also invited the Commission 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 European Centre for Disease Prevention and Control (ECDC) and the need to consider providing the Health Security Committee (HSC) with a legal basis".

On 13 September 2010, the Council of the EU, in its conclusions on Lessons learned from the A/H1N1 pandemic - Health security in the European Union, available under <u>http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/fr/lsa/116479.pdf</u>, invited Member States and the Commission to examine options for the legal basis of the HSC to support the Council in achieving a coherent approach to preparedness for and response to health threats and especially public health emergencies of international concern as defined in IHR (2005); to base their approaches on solid independent scientific risk assessment.

2. HEALTH SECURITY INITIATIVE

The European Commission is currently developing an initiative on health security in the EU to protect more effectively citizens' health against serious cross-border threats. The aim of the initiative is to ensure that, from a public health perspective, any health threats are addressed in a way similar to communicable diseases.

This could include events of biological (including communicable diseases), chemical or environmental origin 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.

Such threats arise from public health events affecting more than one Member State. In most cases, cross-border events occur within the EU but they can also originate outside the EU and affect one or more Member States.

The principles for this initiative were set out in the Commission Staff Working Document of 18 November 2010 on lessons learnt from the H1N1 influenza pandemic and on health security in the EU, available under: http://ec.europa.eu/health/preparedness_response/docs/commission_staff_lessonsh1n1_en.pdf

¹ <u>http://www.who.int/ihr/en/</u>

This initiative is due to cover preparedness planning in Member States, public health risk assessment, risk management and risk communication. The Commission coordinates health security measures in the EU through its HSC. This is an informal cooperation and coordination body concentrating on health-related threats from terrorism or any deliberate release of biological or other agents, as well as raising levels of preparedness for cross-border threats, in particular an influenza pandemic. The initiative will also put on a more formal footing the work done within the HSC (http://ec.europa.eu/health/preparedness_response/hsc/index_en.htm).

3. CURRENT SITUATION

The Treaty on the Functioning of the European Union gives the EU the competence to carry out action to support, coordinate or supplement the action of Member States in the area of protection and improvement of human health. The EU has been empowered to engage in "monitoring, early warning of and combating serious cross-border threats to health". In particular article 168 sets out the specific legal basis for EU level actions on serious cross-border health threats.

Prevention and control of **threats from communicable diseases** at EU level are already addressed under the legislation adopted in 1998 (Decision $2119/98/EC^2$) which provides a basis for epidemiological surveillance and coordination of the response. This system has proved its worth for more than a decade now (e.g. in response to the outbreaks of Severe Acute Respiratory Syndrome - SARS and the H1N1 influenza pandemic).

However, no such legislation exists on health threats from chemical agents, biological agents other than communicable diseases, radio/nuclear agents, and environmental events. The aim of this initiative is, therefore, to ensure that *other* types of public health threats are addressed in a way similar to infectious diseases.

New developments also need to be taken into account, such as adoption of the International Health Regulations (2005), establishment of the ECDC^3 and the new provisions of the Treaty on the Functioning of the EU.

The ECDC Founding Regulation states that the mission of the Centre shall be to identify, assess and communicate current and emerging threats to human health from communicable diseases. In the case of an outbreak which clearly is not caused by a communicable disease, the Centre shall act only in cooperation with the competent authority upon request from that authority (article 9 in relation with article 3 states that ECDC can offer assessment only upon request). Subsequent to this request, ECDC will be informed by capacities within other authorities and institutes.

² 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)

³ Regulation 851/2004/EC: <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0851:EN:NOT</u>

4. CONSULTATION PROCESS

4.1. Open stakeholders consultation

The European Commission launched an open stakeholder consultation on Health Security in the European Union on 8 March 2011. The initial closing date was 29 April 2011 which was extended to 31 May 2011. This open consultation process met the Commission's minimum standards on stakeholder consultation.

The purpose of the consultation was to gather the views of stakeholders on what actions the European Commission should take to protect EU citizens more effectively against serious cross-border health threats arising from deliberate or accidental biological, chemical, radio/nuclear and environmental events. The consultation questions on preparedness planning, risk assessment, management of health threats and on how to better communicate with citizens and professional groups.

The consultation documents and the online questionnaire were published on the "Your Voice in Europe" website. The consultation title, policy area and closing date were made available in 23 languages on the Your Voice website. The consultation paper and the online questionnaire were in English.

The consultation was also published on the DG SANCO public website and on the Global Health Europe website. The public health portal of the European Union is available to everybody on the Internet. A PDF version of the consultation paper and the online questionnaire was available on the SANCO website and the Your Voice in Europe website.

In addition, information on the consultation was sent to more than 10'000 subscribers to the SANCO public health eNews and to other 9'000 recipients of the SANCO newsletter.

The Commission issued also an information email on the consultation to the following key stakeholder groups:

- Member States through the Health Security Committee;
- Flu Section of the HSC;
- CBRN Section of the HSC;
- General preparedness section of HSC;
- Communicators Network of the HSC;
- Members of the EWRS;
- DG HOME;
- European Academies Science Advisory Council (EASAC)
- ECDC
- EMA
- European Food Safety Agency
- Health Policy Forum
- GHSAG / GHSI;
- WHO and WHO Europe
- Business Europe

Additional stakeholders' opinion has been taken into consideration. These stakeholders are:

- the Health Security Committee (HSC);
- the Early Warning and Response System (EWRS) Network Committee;
- the Health Policy Forum;
- some Member States.

4.2. HSC members

The Health Security Committee (HSC) where representatives of Health Ministries discuss and coordinate health measures was consulted on the Health Security Initiative. The comments and remarks of this important stakeholder are included in Chapter 5. Consultation – results.

4.3. EWRS members

The Early Warning and Response System (EWRS) Network Committee where representatives of Health Ministries discuss and coordinate health measures on communicable diseases was consulted on the Health Security Initiative. The comments and remarks of this important stakeholder are included in Chapter 5. Consultation – results.

4.4. Bilateral meetings with some Member States

Several bilateral meetings between representatives of the European Commission and representatives of ministries or institutions from Member States took place during the consultation period. These meetings were organised in an informal way at the request of the Member States to discuss the health security initiative with the Commission. The Commission presented the background and rationale for the new initiative on health security. The Member States expressed their views on the initiative and were invited to give their opinion through the online questionnaire.

4.5. EU Health Policy Forum

The EU Health Policy Forum brings together 52 umbrella organisations representing European stakeholders in the fields of public health and healthcare. The forum meets regularly in Brussels, helping to ensure the EU's health strategy is open, transparent and responds to public concerns. At the last meeting of the Health Policy Forum on 19 May 2011, the Health security initiative was presented and members of the Forum were invited to give their opinion through the online questionnaire.

4.6. Public consultation on European Pandemic Influenza Preparedness

On 27th May 2010, the European Commission launched a Public Consultation on European Pandemic Influenza Preparedness. The aim of the consultation was to seek the views of key

stakeholders on what action the European Commission should take to strengthen European Union Pandemic Influenza Preparedness. The key elements of this public consultation are taken into consideration and included in Chapter 5 of the present report. The whole report of the consultation on Pandemic Influenza Preparedness is presented in Annex 2 of the present report.

5. **RESULTS OF THE ONLINE QUESTIONNAIRE**

The results from the online questionnaire are presented below. The responses from all applicants are presented also with the help of graphs. For open questions, the opinion of every stakeholder was taken into consideration and presented generally through a synthesis of the different comments and remarks. When appropriate, only the response on behalf of public authorities (who have the responsibility for pandemic influenza planning and response at Member States level) was presented. The opinion of the HSC and EWRS members is important and their comments and remarks are included in the text.

The results are divided into five main areas which correspond to the structure of the online questionnaire:

- 5.1. General questions
- 5.2. Preparedness
 - International Health Regulations (IHR) 2005
 - Laboratory capacity
 - Personal data with a view to contact tracing
- 5.3. Scientific evaluation and assessment of risks from serious cross-border health threats
- 5.4. Management of public health consequences of serious cross-border health threats
 - Health Security Committee (HSC)
- 5.5. Communication

Contributions have been very diverse with many different types of stakeholders represented. A total of **75** responses to the online questionnaire were received, from which 21 were on behalf of national, regional or local authorities, 31 on behalf of organisation and 23 from individual citizens (Figure 0).

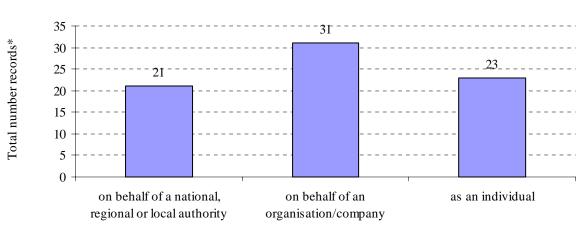


Figure 0: Stakeholders' responses to the online questionnaire on "Health Security in the European Union" were received:

At national level, the following 14 Member States national health authorities contributed to the consultation:

- Austria, Federal Ministry of Health
- Belgium, Federal Public Service Public Health, Food safety and Environment

^{*} Total number records is 75

^{**} Total number of national, regional or local authorities is 21

- Cyprus, Ministry of Health
- Czech Republic, Ministry of Health
- Estonia, Health Board
- Finland, Ministry of Social Affairs and Health/ Preparedness unit
- France, Direction générale de la santé, Secrétariat d'Etat à la santé
- Ireland, Department of Health and Children
- Italy, National Institute of Health, National Centre for Epidemiology
- Lithuania, Ministry of Health, Health Emergency Situation
- Portugal, Instituto Nacional de Saúde Doutor Ricardo Jorge
- Slovakia, Public Health Authority, Department of Epidemiology
- Spain, Ministry of Health, Social Policy and Equality
- United Kingdom, Department of Health, London and Health Protection Agency

Contributions have also come from non-EU countries:

- Norway, Ministry of Health and Care Services

5.1. General questions

5.1.1. Infectious diseases

According to Commission services, prevention and control of threats from infectious diseases are already addressed at EU level. Mechanisms and structures for monitoring, early warning of and combating public health consequences of these serious cross-border threats are in place to protect the health of EU citizens.

In view of recent events (SARS, H1N1 influenza pandemic) 63% of all respondents found that the handling of infectious diseases at EU level, either taken globally (Figure 2) or considering the different processes separately (Figure 3) was appropriate. The mechanism in place to handle infectious diseases at EU level, considering preparedness, risk assessment and management, is good.

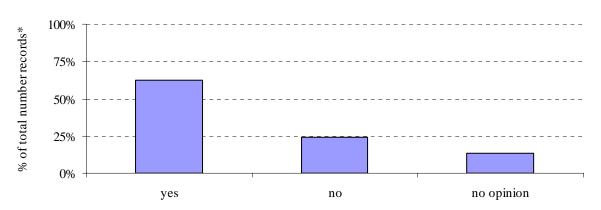


Figure 2: Do you consider that the handling of infectious diseases at EU level has been appropriate in view of recent events and developments in this area (e.g. SARS, H1N1 influenza pandemic, implementation of the IHR 2005)?

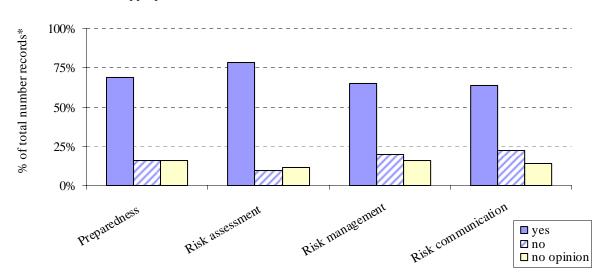


Figure 3: For those who considered the handling of infectious diseases appropriate, in which areas do you consider that the handling of infectious diseases at EU level has been appropriate?

The explanations given by the stakeholders not satisfied with the handling of infectious diseases include:

- Health security in the EU can be strengthened by establishing: an objective process to identify and assess health threats, independent of international health authorities; a robust policy for handling advisors' conflicts of interest in relation to decisions about medicines or other therapies intended for use in health emergencies.
- As pointed out in the Council conclusions on Lessons learned from the A/H1N1 pandemic

 Health security in the European Union, epidemiological surveillance needs to be
 improved in terms of enhanced coordination amongst different organizations;
 harmonization of data collection; communication and most of all capacity building and
 preparedness planning for emergency situations.
- Communication: there is a need to improve the coordination between Member States to harmonize key messages, to use all possible channels to disseminate a clear, correct, coherent, balanced and uniform communication to the public and healthcare professionals in all Member States. Healthcare professionals' organizations should be used for spreading the information. Taking the example of the pandemic Influenza H1N1, speculations were developed by the press due to lack of correct information. Risk communication and risk management can be negatively affected by economic, political and media coverage concerns. Regarding the H1N1 influenza, there was lack of standardization and communication that caused delays with the implementation of some public health measures.
- The response has often been disharmonious across the borders of EU Countries, and communication to the public has more often than not spread the feeling that industrial stake-holders and other lobbyists where driving the response.
- HSC communicators should be linked directly to the HSC representatives.

- Preparedness: the EU should be more involved in the preparedness and risk assessment. More preparedness should have been in place in advance. Response should be flexible, proportionate and adapted to the severity of the threat. There is a need to update and exercise regularly the available response plans and to undertake joint cross-border exercises for health emergency preparedness for all the parties involved to react in health-related emergencies. For example improve the knowledge of Border officers on controlling free movement of persons within the EU and to the EU based on public health concern (Schengen Border Code).
- Management and coordination: coordination between Member States should be improved

 as shown during the pandemic H1N1 when divergent actions were taken by different countries (vaccination). Various levels of protection were offered to citizens throughout the EU. Due to different national approaches (proactive vs. reactive) and organizations (central vs. regional/local) each country dealt with the pandemics differently.
- Risk management and risk communication are Member State issues.

5.1.2. Serious cross-border threats other than infectious diseases

The majority of the stakeholders (95%) considered that all serious cross-border threats to health should be treated equally at EU level. For this purpose, they support an all-hazard approach as well as the coordination and handling role of the EU. They considered that the EU should include threats other than infectious diseases in its health security policy (Figure 1) and that public health consequences of these threats should be coordinated and handled at EU level in a similar way to infectious diseases or even more stringently (Figure 7).

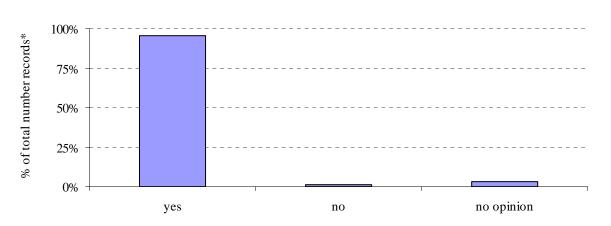


Figure 1: Do you consider that the EU should take action to include threats other than infectious diseases in its health security policy?

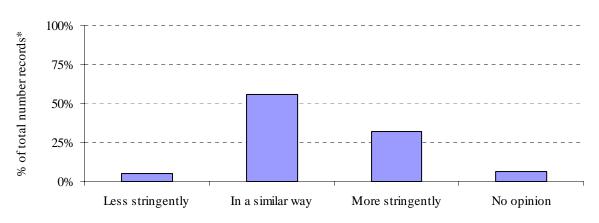
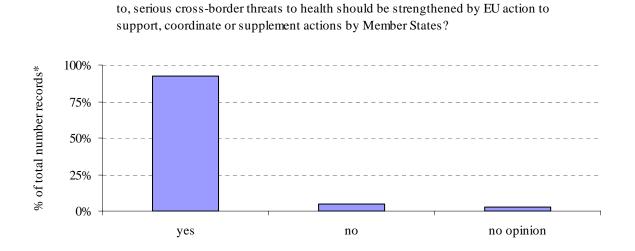


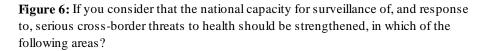
Figure 7: How should the coordination of public health consequences of serious cross-border health threats be handled at EU level in comparison with infectious diseases?

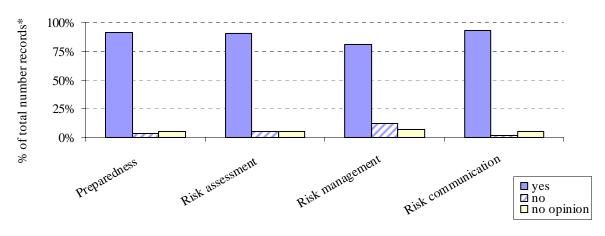
Members of the HSC and the EWRS also support this all-hazard approach but specified that existing structures and systems should be used as far as possible and developed to serve public health purposes. Establishing new groups, committees or networks should be avoided as much as possible. There is also a need to improve coordination of the structures in place. The mechanism in place for infectious diseases should be transferred to other serious cross-border threats (chemicals, biological, radio/nuclear and environmental events).

92% of all respondents considered that the EU should strengthen national capacities for surveillance and response, by actions supporting, coordinating or supplementing actions by Member States (Figure 5), this in all different areas (preparedness, risk assessment, risk management, risk communication) (Figure 6).

Figure 5: Do you consider that the national capacity for surveillance of, and response







Additional comments or suggestions from the stakeholders are (Question 8):

- In accordance with the "all-hazard" approach enshrined in the International Health Regulations, cross-border non-infectious threats should be coordinated in a similar way in comparison with infectious diseases.
- When public health implications of chemical, biological and radio/nuclear threats are approached, special attention should be focused on promoting collaboration among all the different stakeholders (Institutions, Networks, Ministries, etc.).
- Coordination of preparedness, assessment procedures, and foreseeable measures should be supported by EU in respect of the principles of subsidiarity and proportionality. Better coordination between different Directorate General of the Commission and EU agencies is needed to fulfil public health needs. Coordination of the Member States policies is needed.
- Cooperation and support from a centralised authority are needed when Member States face dangerous and unusual pathogens. The European Commission should help the Member States coordinate the creation and management of regional stockpiles of response resources such as medical countermeasures against biological pathogens. Such stockpiles in each member state would not be economically viable, and Commission assistance in the coordination of a network of regional stockpiles would ensure comparable protection to citizens throughout the union while avoiding over-investment.
- Member States are responsible for chemical, biological, radio/nuclear policy, but a close cooperation and coordination at EU level is nevertheless a necessity in case of serious cross-border threats. A better coordination and strong support are required. Proper coordination and preparedness need to be established well in advance, as do the necessary stockpiles of countermeasures. Serious cross-border health threats will strike without any lead time, systems need to be in place in advance.
- Chemical threats: there is a high degree of variability between EU Member States in tools, methodology and practises related to the assessment of health risks of chemical incidents. This can result in variability in response and risk communication, which may be a problem especially in cross-border incidents. Therefore, standardized guidelines and procedures for

the assessment of public health risks of chemicals should be developed. EU-wide collaboration in the field of preparedness and risk management should be strengthened.

- Radio/nuclear threats: formalized and well functioning structures for surveillance, alert and crisis management regarding radio/nuclear events exist both at national and international levels (through international agreements and conventions in the EU, e.g. ECURIE, in the UN/ IAEA, CTBTO, WHO/IHR, WHO/REMPAN and other forums like CBSS, OSPAR, OECD/NEA etc). Unnecessary double structures should be avoided.
- There are currently no standards and/or regulatory frameworks placing constraints on the production, radioactivity, concentration, handling, use and transportation of Naturally Occurring Radioactive Materials (NORMs), as waste of industrial (mining) oil activities. Therefore, non-state actors with malevolent purposes and misuse intentions can raise the radioactivity concentration of NORMs, without incurring in any legal constraint, to manufacture radiological dispersion devices (dirty bombs).
- The existing EU crisis management should be evaluated. Similarly, the roles of the Commission and its agencies should be reviewed.
- More emphasis should be put on helping less prepared Member States manage the public health consequences of serious cross-border health threats. In addition, a greater capacity in Member State laboratory areas should be developed, ensuring that all Member States have the capacity and competence to manage proper risk assessments
- The EU needs a solid response system to protect its citizens and its vital economic and social infrastructure.
- Health threats regardless of their origin are frequently tackled using medicinal products. Medicines not only play a central role in treating illness, but they can also be crucial to preventing the onset and spread of disease. Therefore, any strategy to promote health security in the EU needs to consider how medicines can be used rationally to achieve the best health outcomes and widest social benefits. A conflict of interest can jeopardize the credibility of decision making bodies and the public trust afforded to their decisions. The rigorous application of a policy for handling conflicts of interest can safeguard EU decision-making from undue influence, ultimately supporting public security and patient safety.
- Sustainable solutions must include proper education of risk factors and integrate regulatory mechanism for preventative measures required to project future outcomes as a function of multi local space interference.

5.2. Preparedness planning

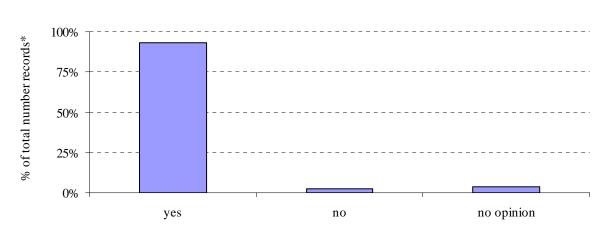
Preparedness planning is about developing and strengthening capacities to respond rapidly to any kind of emergency affecting or likely to affect public health.

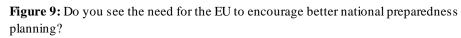
First of all, 93% of all the respondents stressed that the EU should play a central role in <u>encouraging</u> national preparedness planning (Figure 9). The same opinion was clearly expressed through the 2010 consultation on pandemic preparedness, where 98% of all respondents thought that improved cooperation at EU level would enhance preparedness. 94% of all respondents thought also that it was important that countries' plans worked well with other countries in the EU. 90% of all respondents and 88% of those responding on behalf of a

^{*} Total number records is 75

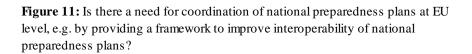
^{**} Total number of national, regional or local authorities is 21

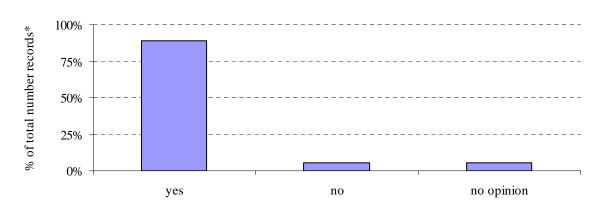
public authority felt that the interoperability of Member States plans should be facilitated at EU level.





Secondly, according to 90% of the stakeholders, the EU should <u>coordinate</u> national preparedness plans, for example in providing a framework to improve interoperability of national preparedness plans (Figure 11).

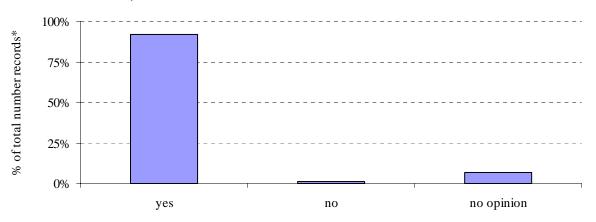




In the 2010 consultation on pandemic preparedness, 92% of all respondents and 91% of those responding on behalf of a public authority felt there was a need for the European Commission to take a coordinating role when there was a cross-border aspect involved.

Thirdly, the <u>all-hazard approach</u> is supported by 92% of all the respondents; any kind of emergency affecting public health (i.e. including chemical, biological, radio/nuclear threats) should be taken in account (Figure 10).

Figure 10: Should this preparedness planning address any kind of emergency affecting public health (i.e. including chemical, biological, radiological and nuclear threats)?



At EU level, the European Centre for Disease Prevention and Control (ECDC) provides scientific and technical expertise in the development, regular review and updating of preparedness plans for infectious diseases, mainly for influenza pandemic.

According to 96% of all respondents, EU preparedness plans should also deal with serious cross-border threats other than an influenza pandemic (Figure 12). In the 2010 consultation on pandemic preparedness, 91% of all respondents (87% of those responding on behalf of a public authority) felt it was important that a plan is in place at EU level. 90% of all respondents and the same percentage of those responding on behalf of a public authority felt the EU plan should be updated in the light of experience with H1N1.

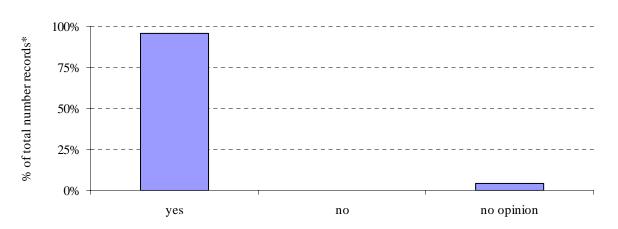
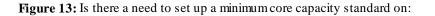
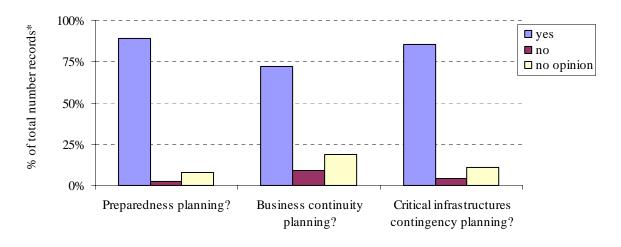


Figure 12: Is there a need for EU preparedness plans to deal with serious cross-border threats other than an influenza pandemic?

For chemical, biological, radio/nuclear and environmental threats, arrangements are in place to monitor, assess and coordinate the management of these events, but public health aspects are not sufficiently covered. In this context, minimum core capacity standards should be set up on preparedness planning (Figure 13).

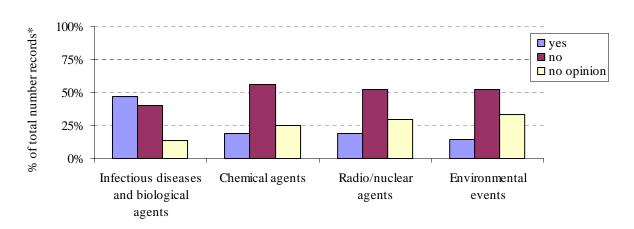




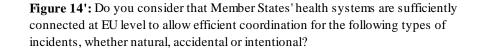
Considering the health sector, a majority of all respondents consider that the Member States' health systems are not sufficiently connected at EU level to allow an efficient coordination for chemical, radio/nuclear agents and environmental events (Figure 14).

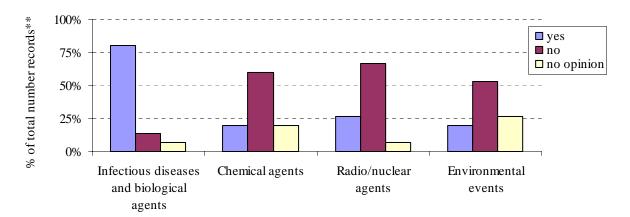
Figure 14: Do you consider that Member States' health systems are sufficiently connected at EU level to allow efficient coordination for the following types of

incidents, whether natural, accidental or intentional?



For infectious diseases and biological agents, a <u>large</u> majority of <u>public</u> authorities considers that the Member States' health systems are sufficiently connected at EU level to allow an efficient coordination (Figure 14').





Considering the other sectors at EU level (e.g. transport, telecommunications, energy) 53% of the stakeholders think that public health consequences resulting from serious cross-border health threats of a chemical, biological, radio/nuclear, or environmental nature are not sufficiently taken into account, whereas 19% think it is sufficient. Of all stakeholders who replied "no", about 20% represent public authorities, whereas 40% are individuals and 40% are organizations. Of all stakeholders who replied "no opinion", about 36% represent public authorities and 45% organizations. This means that awareness of the situation among professionals could be improved (Figure 15).

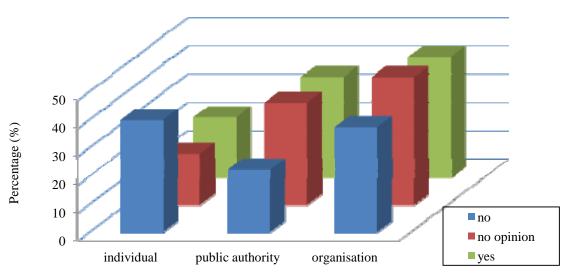


Figure 15: Do you consider that public health consequences resulting from serious cross-border health threats are sufficiently taken into account in other sectors at EU level (e.g. transport, telecommunication, energy)?

Public health consequences of serious cross-border health threats are considered in the business continuity plan or critical infrastructure contingency plan of their organisation, according to 44% of the stakeholders whereas 30% think it is not sufficient (Figure 16). In the 2010 consultation on pandemic preparedness, 92% of all respondents felt it was important that sectors other than health have business continuity plans in place.

** Total number of national, regional or local authorities is 21

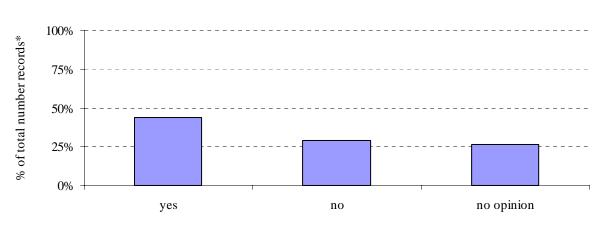


Figure 16: Does the business continuity plan/critical infrastructure contingency plan of your company/organisation consider the public health consequences of serious cross-border health threats?

5.2.1. International Health Regulations - IHR (2005)

The <u>International Health Regulations (2005)</u> are a legal instrument which provides for the coordination of the management of events that may constitute a public health emergency of international concern. The IHR introduce core capacity requirements on all countries to detect, assess, notify and respond to public health threats. They provide for bilateral collaboration between the WHO and countries concerned by such events. Under the IHR setting, the WHO is empowered to declare public health emergencies of international concern and pandemics, and to issue recommendations including health measures to be implemented at national level.

The –IHR also require that national legislation complies with their provisions covering measures also in sectors other than public health (e.g. environment, transport, customs, food safety, agriculture, animal health, radiation safety, chemical safety, security, protection of personal data, trade - including dangerous goods).

IHR entered into force on 15 June 2007 and requires gradual implementation by 15 June 2016 at the latest. It is legally binding to all WHO States Parties, including EU Member States.

Questions 17 to 19 on the IHR (2005) were only addressed to national, regional and local authorities. Some national, regional and local authorities described how and when they intend to transpose or have transposed the IHR (2005) into their national law.

- The IHR (2005) have already been published in several Member States Official Journals. To make it fully operational the specific legislation need to be adapted and work is still ongoing.
- The IHR (2005) have already been fully or partly adopted and ratified by some Member States or been transposed into some national legislations. For example the IHR (2005) may have been transposed for infectious diseases and biological agents (e.g. toxins), but not yet for chemical agents and radio/nuclear agents.
- The IHR (2005) implementation is currently under preparation by means of an action plan.

^{*} Total number records is 75

^{**} Total number of national, regional or local authorities is 21

In some Member States the transposition of IHR (2005) will cover sectors other than public health (Figure 18), such as Transport and mobility (people/goods), Environment, Agriculture, Economy, Communication, Finance, Social Affairs, Home affairs and Foreign affairs.

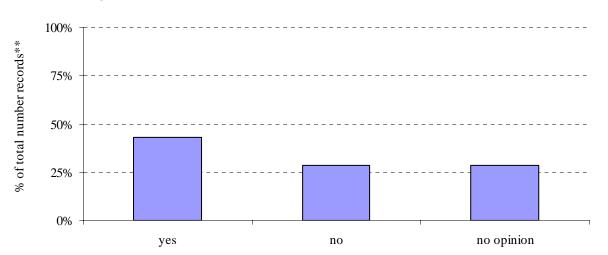


Figure 18: Will the transposition of IHR (2005) cover sectors other than public health?

The Treaty gives power to the EU to coordinate the response to health threats of cross-border relevance, in a manner very close to what is provided for by the IHR (2005). 85% of all the public authorities who answered the questionnaire, agreed with the fact that the EU initiative should reflect the same provision as the IHR (2005) (Figure 19). According to HSC and EWRS members, there is a need to create synergies with the IHR (2005). The IHR (2005) should remain the basis for the HSC and, the definition of emergency level is needed. As for the criteria for notification of health threats at EU level, it should probably not be the same as for the WHO.

Some public authorities stress that the EU should comply with IHR (2005) and avoid duplications. Crisis management (response) remains a national competence. The WHO may issue recommendations which will apply to all Member States. There is no need but risk in developing initiatives which will create confusion. A better coordination between EU Member States should be preferably strengthened.

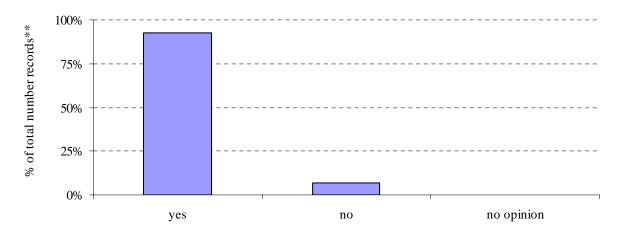


Figure 19: Do you agree that the EU initiative should reflect the same provisions as the IHR (2005)?

** Total number of national, regional or local authorities is 21

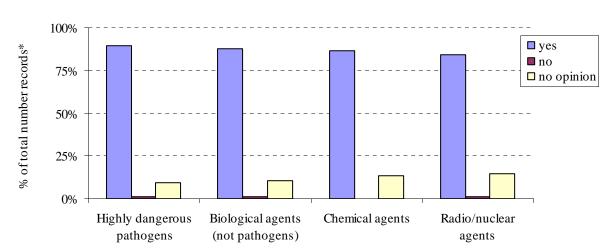
5.2.2. Laboratory capacity

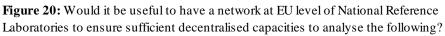
Laboratory networks at EU level ensure the availability of competent national laboratory services to analyse specific agents or pathogens in order to provide rapid and coordinated laboratory response to public health threats.

Such technical support built on laboratory capacity to deliver accurate and timely results is an integral part of the surveillance and detection systems set up through preparedness planning.

Although the infrastructure for these laboratories is in place, existing laboratory capacities and capabilities are not always sufficient. The question is how laboratory structures could be organised to serve best the needs at EU level.

It would be useful, according to more than 85% of the stakeholders, to have a network at EU level of National Reference Laboratories to ensure sufficient decentralised capacities to analyse highly dangerous pathogens, other biological agents, chemical agents, radio/nuclear agents (Figure 20).





The EU should provide support to these networks according to 92% of the stakeholders (Figure 21), by providing establishing a coordination structure (funding), quality assurance of the laboratory, organising transport of samples to ensure sample sharing or regular meetings with specific reference laboratories in the Member States (Figure 22).

Other supporting measures suggested by the stakeholders are:

- Agree on criteria to define a reference laboratory.
- Develop networks of existing competent laboratories covering all the European Union: use existing laboratories (WHO laboratorial network), no duplication is necessary nor to have a reference laboratory in each Member State. Small countries may have support from other countries.
- Regarding chemical threats, the most important action would be the creation of a network of laboratories and a database on the expertise of different laboratories in order to facilitate collaboration and EU wide availability of laboratory services. It would also be important to

identify the possible gaps in laboratory capacities and capabilities especially for the analyses of rare chemicals.

- Define common standards, laboratory practices and security warning thresholds. Improve standard procedures and documents for transport of samples recognized and accepted by all Member Sates. Develop coordination structures. Strengthen collaboration.
- Develop central data base on available expertise including details of agencies and profiles of experts.
- Develop training and general education.

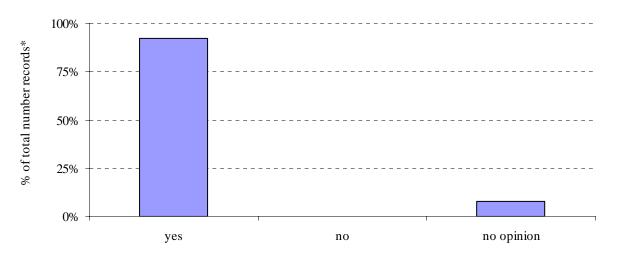
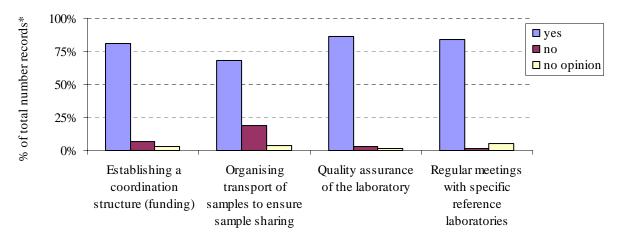
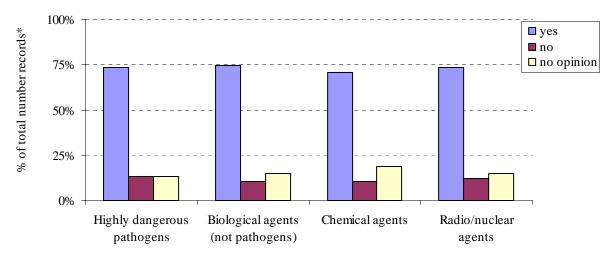


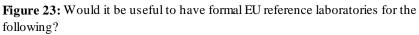
Figure 21: Do you consider that the EU should provide support to these networks?

Figure 22: If you answered yes to question 21, which of the following support measures should be provided?



The stakeholders consider it as useful to have formal EU reference laboratories for highly dangerous pathogens and other biological agents, for chemical agents and for radio/nuclear agents (Figure 23).





5.2.3. Collection, storage and disclosure of personal data with a view to contact tracing

In epidemiology, **contact tracing** is the identification and diagnosis of persons who may have come into contact with an infected person. Specific personal data are often needed to trace a contaminated person for the purposes of preventive medicine, medical diagnosis and the provision of care or treatment. However, such data are not systematically collected or stored for a sufficient time. The lack of collection and storage of these personal data for contact tracing purposes could endanger the public health response to threats, particularly where nonnational carriers are concerned.

Accordingly, the majority of the stakeholders (65%) are in favour of the collection and the temporarily storage of their personal data, and their share with public health authorities in order to be contacted in case of being infected or contaminated (Figure 24).

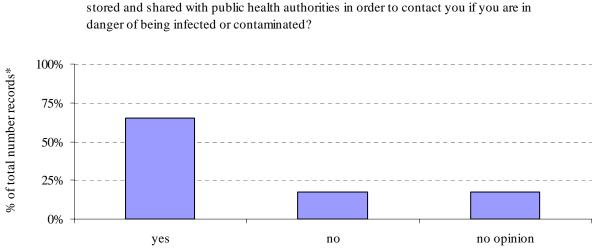


Figure 24: Would you be in favour of your personal data being collected, temporarily stored and shared with public health authorities in order to contact you if you are in

5.3. Risk assessment of serious cross-border health threats

Decision makers rely on independent expertise with sound scientific advice on emerging risks to public health when preparing their policy and activities related to public health. This process includes detecting and monitoring threats, alerting on emerging threats, evaluating potential risks to public health coming from those threats, and notifying such risks to concerned entities.

As regards infectious diseases, the creation of the ECDC and its co-existence with the EU network for the surveillance and control of Communicable diseases created by Decision 2119/98/EC has led to some overlaps in risk assessment in particular the epidemiological surveillance structures in place (e.g. dedicated surveillance networks). This duplication creates an administrative burden and is contrary to the basic principles of lawmaking (clarity, simplicity, etc.).

The ECDC Founding Regulation⁴ states that ECDC should provide risk assessment for communicable diseases and unknown threats. In the case of a crisis with another origin than communicable diseases, Article 3 of that regulation states that ECDC can provide risk assessment on other threats than communicable diseases only upon request from a national or EU authority taking fully account of the responsibilities of Member States, the Commission, other EU Agencies and the WHO.

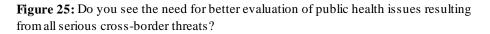
According to the members of the HSC and the EWRS, there is a need for risk assessment of health related aspects of chemical and radio/nuclear events and threats, to do risk assessment of events other than communicable diseases, from a public health perspective. For this, existing structures should be used.

The majority of the stakeholders (90%) are in favour first of all of a better evaluation of public health issues resulting from all serious cross-border threats (Figure 25) and secondly, that sectors other than the health sector should take public health aspects of risk assessment more into consideration, and this for biological agents other than infectious diseases, chemical agents, radio/nuclear agents, and environmental events (Figures 26 and 26').

⁴ Regulation 851/2004/EC: <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0851:EN:NOT</u>

^{*} Total number records is 75

^{**} Total number of national, regional or local authorities is 21



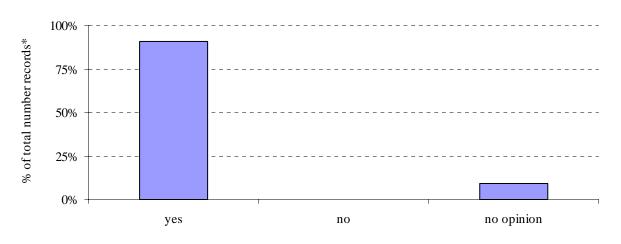
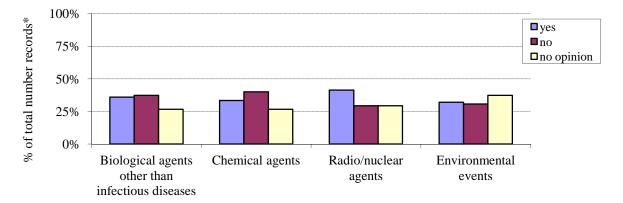


Figure 26: Do you think that sectors other than the health sector take public health aspects of risk assessment sufficiently into consideration as regards the following serious cross-border health threats?



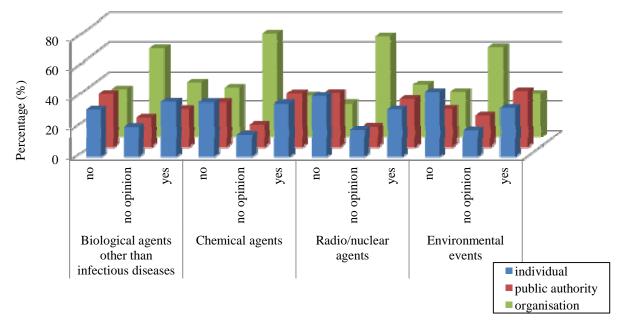


Figure 26': Do you think that sectors other than the health sector take public health aspects of risk assessment sufficiently into consideration as regards the following serious cross-border health threats?

Other sectors than the health sector do not take sufficiently public health aspects into consideration for the risk assessment. The following measures could help to improve the situation:

- Involve more generally public health authorities in all sectors in order to provide assessment of health effects. Some sectors other than health have cross-border risk assessment protocols, but health effects are not sufficiently taken into account. Develop criteria for health relevance of non infectious threats.
- Ensure close collaboration between sectors involved in risk assessment of public health threats at national and EU level. Develop a multi-sectoral approach with the public health stakeholders present or their role precisely defined in each policy, legislation or plan. Improve work at the interface of public health with other sectors involved in the management of health threats.
- Improve communication between members of different sectors. Develop mechanisms for sharing relevant alerts in order to allow the health sector to make its assessment and to participate in management of health aspects. Better and easier exchange of information.
- Strengthen coordination, avoid duplication of structures.
- Develop preparedness and response planning in certain sectors (public transport). Stockpile protective equipment; strengthen awareness of emergency workers and first responders.
- Develop education, awareness, auditing and safety checks.

Stakeholders, in particular public authorities consider that existing structures for risk assessment of infectious diseases threats are sufficient at EU level (Figures 27 and 27'). But

^{*} Total number records is 75

^{**} Total number of national, regional or local authorities is 21

for biological agents other than infectious diseases (e.g. toxins), for chemical agents, for radio/nuclear agents, and for environmental events, structures for risk assessment should be developed and stakeholders consider that it would bring an added value to have EU capacity to conduct risk assessment from the public health perspective for these threats (Figure 28).

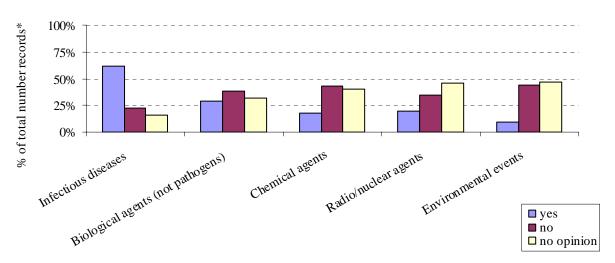
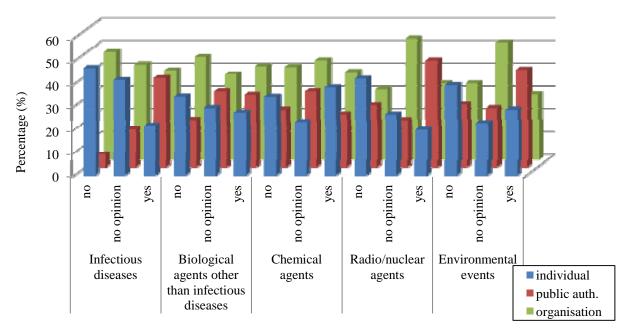
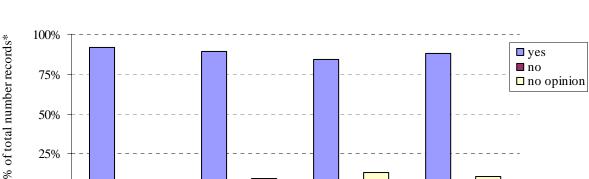


Figure 27: Do you think that existing structures for risk assessment of threats of the following types are sufficient at EU level?

Figure 27': Do you think that existing structures for risk assessment of threats of the following types are sufficient at EU level?





Radio/nuclear

agents

Environmantal

events

Figure 28: Would it bring added value to have EU capacity to conduct risk assessment from the public health perspective for threats of the following types?

As regards other serious cross-border threats, risk assessment is addressed by different structures at EU level, e.g. in the area of civil protection, law enforcement and environmental protection. However, capacities for public health risk assessment of CBRN cross-border threats are not sufficient to support a coordinated risk management at EU level - no dedicated agency is addressing the public health aspects of these risks. Limited scientific evidence-based and risk assessment methodologies can increase risks of inappropriate decision making and public health response.

Chemical agents

Around 90% of all respondents considered that these EU capacities to conduct risk assessment from the public health perspective could be created by different ways such as linking up national assessment bodies at EU level, setting up EU networks of national experts or linking existing EU assessment bodies; 58% consider that extending the current mandate of existing EU agencies is also a possibility (Figure 29).

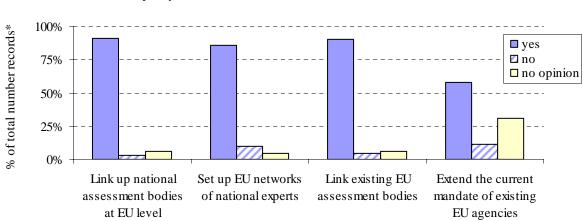


Figure 29: If you consider that it would bring added value to have EU capacity to conduct risk assessment from the public health perspective for threats, how should such EU capacity be created?

Regarding alerting tool for all health threats at EU level, stakeholders are in line with the members of the HSC and EWRS and 65% consider that a single tool would be more efficient.

0%

Biological agents

(not pathogens)

^{**} Total number of national, regional or local authorities is 21

More public authorities replied "no" than "yes" and a major part of the organizations who replied does not have an opinion on that issue (Figure 30).

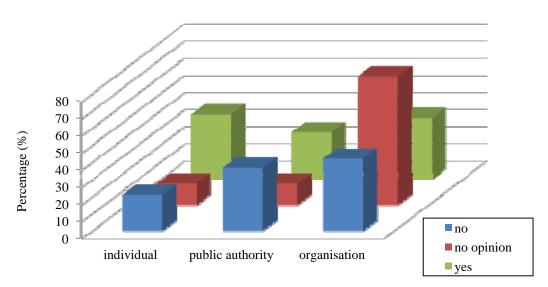


Figure 30: Do you think that a single alert tool for all health threats at EU level would be more efficient?

According to the members of the HSC and EWRS, it is important to look for the interoperability of the alert/notification systems, to avoid many and differing responsibilities to make announcements. EWRS could be considered. 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) (Figure 31).

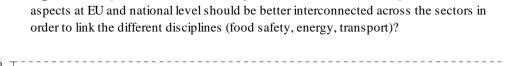
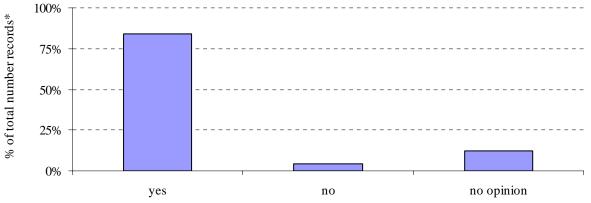
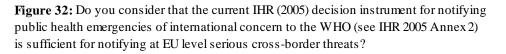


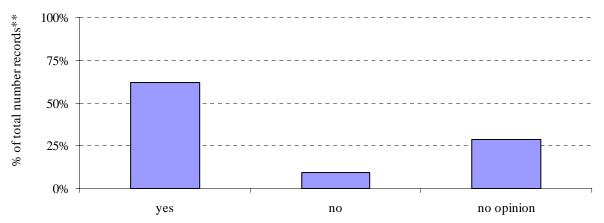
Figure 31: Do you think that the existing detection and notification systems for health



Question 32 was only addressed to national, regional and local authorities. 62% of them consider the current International Health Regulations (2005) decision instrument for notifying public health emergencies of international concern to the WHO (IHR 2005 Annex 2) as sufficient for notifying at EU level serious cross-border threats. As this instrument is still new, a quarter of the public authorities still do not have an opinion on it (Figure 32).

^{**} Total number of national, regional or local authorities is 21





5.4. Management of public health consequences of serious cross-border health threats

The response to a health-related crisis includes a set of decisions and measures taken by the authorities concerned during and after the event, including immediate relief, rehabilitation and reconstruction. In principle, this range of measures to manage public health risks is provided in a comprehensive and coordinated way and deals with the whole spectrum of emergency needs including prevention, response and recovery.

For infectious diseases, a formal channel for coordination of public health measures exists: the Early Warning and Response System (EWRS) Network Committee. The relationship of this structure with the Health Security Committee (HSC) an informal body created through Council conclusions, which does not have any decision-making powers, needs to be clarified. For example, during the H1N1 influenza pandemic, it was necessary to combine the HSC with the EWRS Network Committee to ensure that all aspects of managing the pandemic could be discussed in a coherent way.

For all other serious cross-border health threats, the coordination of risk management from a public health perspective is not sufficiently addressed at EU level. So far, these other threats have been dealt with in the context of the HSC.

This not sufficiently clarified and unbalanced situation is clearly highlighted by 92% of all the respondents who considered that a better coordination and management of all serious crossborder health threats was needed (Figure 33). An important number of respondents considered that real events in the past, with public health consequences, were efficiently managed at regional and national levels but not at EU level (Figure 34).

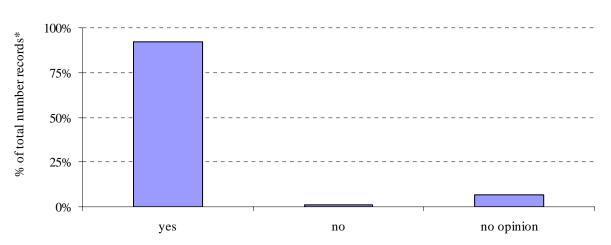


Figure 33: Do you see the need for better coordination and management of all serious cross-border health threats?

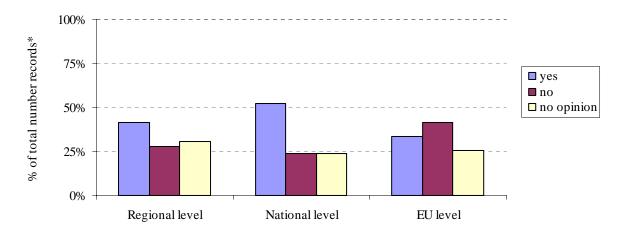
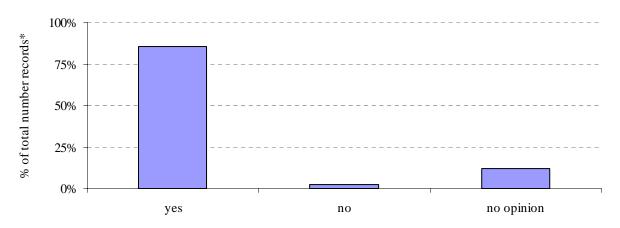


Figure 34: Do you consider that real events in the past with public health consequences were efficiently managed at:

For 85% of all the respondents, to improve coordination of national public health measures (prevention, diagnosis, treatment, control) among Member States in the event of a cross-border health threat is a need (Figure 35).

Figure 35: Do you see the need for improved coordination of national public health measures (prevention, diagnosis, treatment, control) among Member States in the event of a cross-border health threat?



79% of all respondents thought that a coherent risk management mechanism for serious crossborder public health threats at EU level would bring added value (Figure 36)

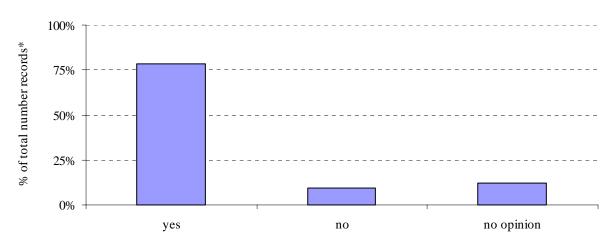


Figure 36: Do you think that a coherent risk management mechanism for serious crossborder public health threats at EU level would bring added value?

Respondents were in favour of making public health measures compulsory in order to prevent the propagation of serious cross-border health threats. This is particularly the case for quarantine, isolation, travel restrictions, medical examination (at point of entry) and compulsory vaccination status (Figure 37). Concerning closing borders, the opinion is less determined.

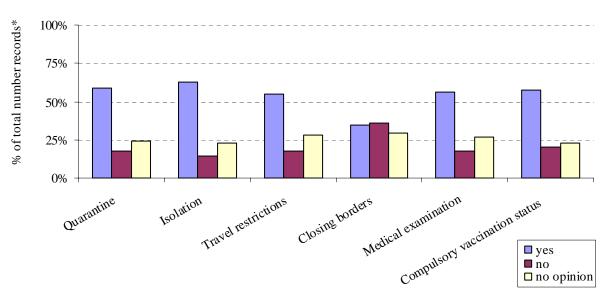


Figure 37: Would you be in favour of making the following public health measures compulsory in order to prevent the propagation of serious cross-border health threats?

Questions 38 to 39 were only addressed to national, regional and local authorities. Concerning the types of coordination provided so far at EU level for serious cross-border threats other than infectious diseases, more than 85% of the public authorities find Public health risk assessment provided by the ECDC and EU agencies useful. More than 70% find Public health risk management and risk communication under the auspices of the HSC useful (Figure 38).

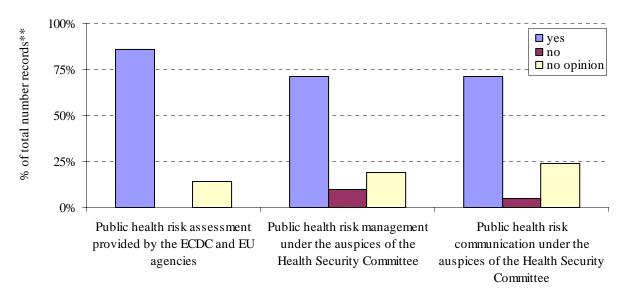
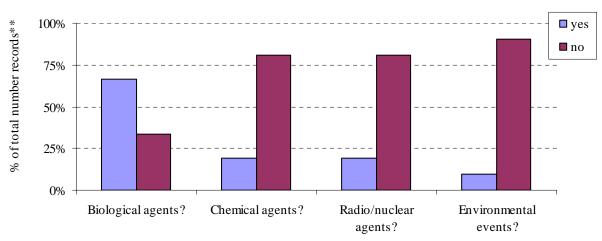
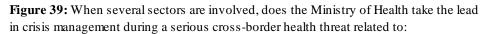


Figure 38: Do you find useful the following types of coordination provided so far at EU level for serious cross-border threats other than infectious diseases?

When several sectors are involved, according to the respondents the Ministry of Health should only take the lead in crisis management for serious cross-border health threats related to biological agents, but not for serious cross-border health threats related to chemical, radio/nuclear agents or environmental events (Figure 39).





Other leading ministries could be defined depending on the Member State national legislation in place, the nature of the event (chemical, radio/nuclear, environmental) or on a case-to-case basis evaluation. It could be one or several of the following ministries (Health, Home Affairs, Environment, Energy, Agriculture, Defence, Labour), the civil protection under the direct supervision of the Prime Minister's office, or another leading body such a cross departmental coordination mechanism at Government level; in case of a crisis needing a multi-sectoral approach, a coordination of ministries could take over, for example through a Governmental Council which members are the Secretary of the Government and the Secretary Generals from the different ministries involved.

5.4.1. Health Security Committee

The EU Health Security Committee (HSC), chaired by the European Commission, brings together all EU Member States to address health security issues.

Questions 40 to 42 on the HSC were addressed only to national, regional and local authorities. 76% of national, regional and local authorities who replied considered that the HSC as a platform for coordinating at EU level the response to public health consequences of serious cross-border health threats brings added value (Figure 40). They also considered that a legal formalisation of the status of the HSC would be better (Figure 41). When looking a little bit more in details the answers of respondents from a national authority (who are participating at the meetings of the HSC), 88% considered that HSC brings added value and 75% are in favour of a legal formalisation of its status

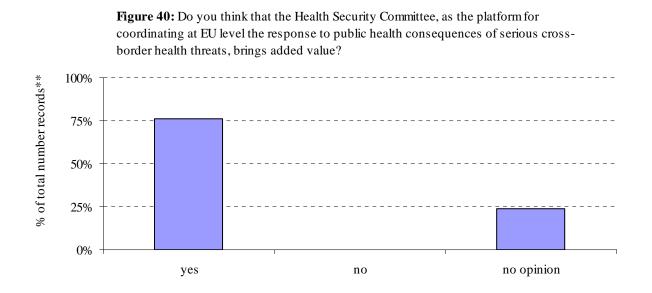
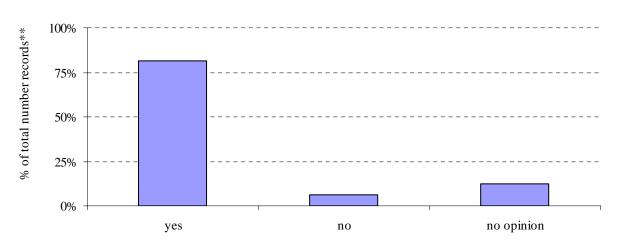


Figure 41: If you consider the HSC brings added value as a platform for coordinating at EU level, do you think it would be better to legally formalise the status of the HSC?



No other coordinating entity at EU level has been suggested by the stakeholders (Question 42).

^{**} Total number of national, regional or local authorities is 21

5.5. Communication

Effective public communication is a crucial component of emergency/crisis response. Timely, accurate information can help people at risk take appropriate protective measures, prevent illness and injury, reduce unnecessary care seeking, and facilitate relief and recovery efforts.

An informal channel for risk and crisis communication is in place under the HSC; however, a more robust setting for strengthening the coordination of such communication channels among Member States is needed to share communication strategies, key messages and guidelines.

On infectious diseases and diseases caused by biological agents (e.g. toxins) a majority of the stakeholders (63%) considered themselves as well informed. On the other hand, for chemical agents, radio/nuclear agents and on environmental events a majority of the stakeholders (45-49%) considered themselves as not very well informed (Figure 43).

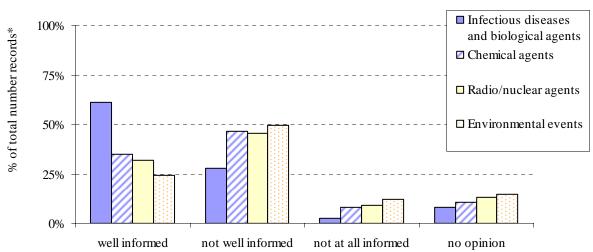


Figure 43: How well are you informed about the public health consequences of the following serious cross-border health threats?

To improve the level of awareness on public health consequences of serious cross-border health threats, as well as the public confidence in the information provided, stakeholders proposed the following measures (Questions 43 and 46):

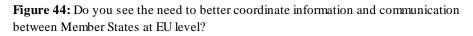
- Communication should be developed at national level to take into consideration national circumstances and traditions. However, coordination at EU level is essential to avoid contradicting messages leading to confusion and loss of public confidence. A coordinated approach is important. Key messages should be agreed and harmonized among EU Member States. Information provided by different authorities as well as in the whole EU should be coherent. Coordination of public communication could be improved through the HSC Communicators network.
- Communication should be transparent, clear, correct and quick, which means in a timely manner and supported by evidence-based research. Citizens must be informed promptly and completely.
- Transparency at every level of decision making should be ensured. In particular, the rationale behind the declaration of a health emergency and the authorisation of large-scale medical interventions is crucial to the public understanding of how and why these

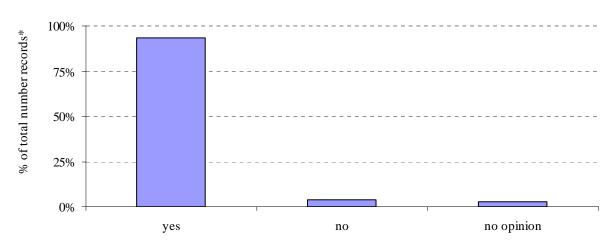
decisions are made within the EU. Make sure that the information provided for patients on medicinal products is not driven by the interests of the producing industry.

- Use of all available media for communication (national TV, radio, social media). Modern electronic communications, which allow easy and rapid spread of information from a broad range of sources, regardless of scientific accuracy or balance (as highlighted by the experience with H1N1 pandemic). EU should force inclusion of education/information in school programs and in public radio/TV shows.
- Publication of regular EU News bulletins targeted at key Sectors and Sector Leaders.
- Improving information requires the cooperation of all stakeholders, to ensure both healthcare workers and the general public trust the information provided and are motivated to act on experts' recommendations. More direct communication to healthcare professionals' organisations could help. Poison centres could play a key role in disseminating information.
- Health professional's knowledge on the situation should be improved in order to transmit more accurate messages to the rest of the population.
- Culturally competent education and information to the public, reaching out to vulnerable populations and groups within ethnic minorities, migrants should be ensured.
- Mandates and roles of the different EU institutions and bodies should be clarified and explained to the professionals and to the public.
- Better scientific advice and evidence-based guidance in public health crises for a better preparedness planning and communication.
- Involve civil society organisations, public members/patient groups in the development appropriate format and dissemination channels for communicating risk information. By including the target audience in these preparatory steps, EU authorities can enhance the readability and accessibility of their messages and ultimately, raise public awareness of the health threat in question through a variety of dissemination techniques so that they are accessible to the widest possible European audience. Use a random panel of peer-reviewers to control the adequacy of the messages. Have an EU-level independent institution. Develop research related to risk perception and risk communication.
- More awareness on public health consequences of serious cross-border health threats should be raised at EU, national and regional level towards the public but also towards the authorities. The latter are sometimes not aware that there is a working infrastructure in place. A better multisectoral cooperation and collaboration of networks of experts should be encouraged.

A majority of stakeholders (93%) see the need to better coordinate information and communication between Member States at EU level (Figure 44).

^{**} Total number of national, regional or local authorities is 21





A large majority (more than 80%) suggests that this could be done by (Figure 45):

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

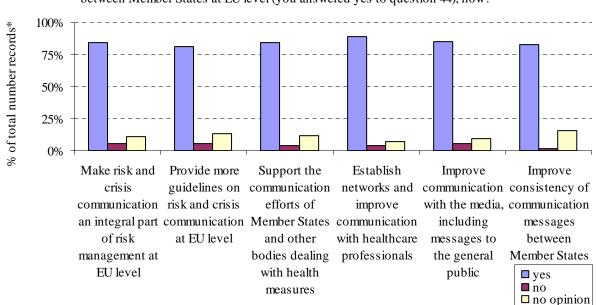


Figure 45: If you see the need to better coordinate information and communication between Member States at EU level (you answered yes to question 44), how?

Question 47 was only addressed to national, regional and local authorities. When several sectors are involved, the Ministry of Health takes the lead for communication with the public on public health consequences regarding infectious diseases and diseases caused by biological agents (e.g. toxins). For public health consequences resulting from chemical agents, radio/nuclear agents, or environmental events, the leading role of the Ministry of Health is not shared among public authorities (Figure 47).

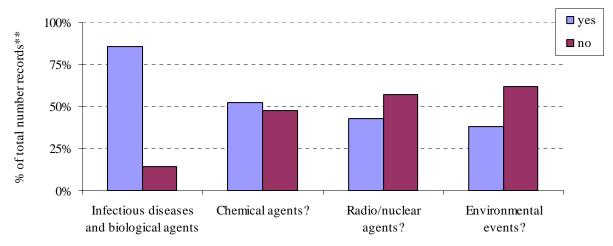


Figure 47: When several sectors are involved, does the Ministry of Health take the lead for communication with the public on public health consequences regarding:

Some public authorities think the lead for communication should be defined according to the national legislation in place, the nature of the event (chemical, radio/nuclear, environmental) or on a case-to-case basis by all involved Ministries. The leading ministry could be Health helped by Home Affairs, Environment, Energy, Labour, Agriculture or Defence.

Whereas stakeholders do not clearly define the leading ministry for communication when several sectors are involved in a cross-border health threat, they (75-85%) clearly see the coordination at EU level for communication with the public and healthcare professionals on public health consequences as an added value (Figure 48).

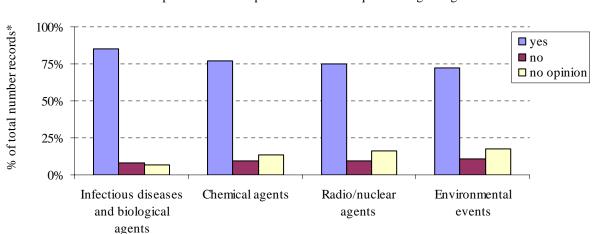


Figure 48: When several sectors are involved in a cross-border health threat, would it bring added value to have coordination at EU level for communication with the public and healthcare professionals on public health consequences regarding:

5.6. Summary of the main figures of the stakeholder consultation

The key outcomes of the stakeholder consultation are:

- 95% of all the respondents considered that threats other than infectious diseases should be included in the EU health security policy.
- 92% of all the respondents considered that preparedness planning should address any kind of emergency affecting public health (i.e. including chemical, biological and radio/nuclear threats).
- 93% of all the respondents considered that the EU should play a central role in encouraging national preparedness planning.
- 90% of all the respondents considered that the EU should coordinate national preparedness plans, for example in providing a framework to improve interoperability of national plans.
- 90% of all the respondents considered that minimum core capacity standards should be set up on preparedness planning.
- 90% of all the respondents considered that a better evaluation of public health issues resulting from all serious cross-border threats was needed.
- 90% of all the respondents considered that an EU capacity to conduct risk assessment from the public health perspective for CBRN threats would be added value.
- 92% of all the respondents considered that a better coordination and management of all serious cross-border health threats was needed.
- 85% of all the respondents considered that a better coordination of national public health measures among Member States in the event of a serious cross-border health threat was needed.
- 79% of all the respondents considered that a coherent risk management mechanism for serious cross-border health threats at EU level would be added value.
- 93% of all the respondents considered that a better coordination of information and communication between Member States was needed at EU level.
- 70% of all the respondents (on behalf of public authorities) considered that public health risk management and risk communication under the auspices of the HSC was useful.
- 80% of all the respondents (on behalf of public authorities) considered that the Ministry of Health should not take the lead in crisis management when several sectors were involved during serious cross-border health threats related to chemical agents, radio/nuclear agents or environmental events.
- 88% of all the respondents (on behalf of a national authority) considered that the HSC as a platform for coordinating at EU level the response to public health consequences of serious cross-border health threats was bringing added value.
- 75% of all the respondents (on behalf of a national authority) considered that the status of the HSC should be legally formalised.

ANNEX 1 – ONLINE QUESTIONNAIRE



ANNEX 2 – CONSULTATION ON PANDEMIC INFLUENZA PREPAREDNESS



ANNEX 3 – LIST OF RESPONDENTS TO THE ONLINE QUESTIONNAIRE

The respondents to the online questionnaire on health security in the European Union are listed in Table 1 according to their capacity of replying and in alphabetical order.

Respondent	Organisation			
* Due to miss	ing information, not all the respondents are listed here below.			
on behalf of a national, regional or local authority				
1	Austria, Federal Ministry of Health			
2	Austria, Land Vorarlberg			
3	Belgium, Federal Public Service Public health, Food safety and Environment			
4	Cyprus, Ministry of Health			
5	Czech Republic, Ministry of Health			
6	Estonia, Health Board			
7	Finland, Ministry of Social Affairs an Health/Preparedness unit			
8	France, Direction générale de la santé, Secrétariat d'Etat à la santé, Ministère du Travail, de l'Emploi et de la Santé			
9	Germany, Bavarian State Ministry of the Environment and Public Health			
10	Ireland, Department of Health and Children			
11	Italy, National Institute of Health, National Centre for Epidemiology, Surveillance and Health Promotion - Communicable Disease Epidemiology Unit			
12	Lithuania, Health Emergency Situation Centre of the Ministry of Health			
13	Norway, Ministry of Health and Care Services			
14	Portugal, Instituto Nacional de Saúde Doutor Ricardo Jorge			
15	Slovakia, Public Health Authority of the SR, Department of Epidemiology			
16	Spain, Dirección General de Salud Pública/Servicio de Epidemiología y Prevención			
17	Spain, General Directorate for Public Health and International Health. Ministry of Health, Social Policy and Equality			
18	Sweden, Centre for Prehospital and disaster medicine			
19	Sweden, Skåne Regional Council			
20	UK, Health Protection Agency			
21	UK, Department of Health, London			
on behalf of a	n organisation/company			
1	a.v.e.c. Association of Poultry Processors and Poultry Trade in the EU countries			
2	ACS			
3	BIO Deutschland e.V.			
4	Emergent BioSolutions			
5	European Association of Pharmaceutical Full-line Wholesalers			
6	EUROPEAN MEDICINES AGENCY (EMA)			
7	European Region of the World Confederation for Physical Therapy (ER-WCPT)			
8	European Vaccine Manufacturers			
9	Finnish Institute of Occupational Health, Finland			
10	German Medical Association (Bundesärztekammer)			
11	German GIZ-Nord Poisons Centre, University Medical Center Goettingen			
12	Health Action International (HAI) Europe			
13	Health Promotion and Disease prevention Directorate within he Public Health Department in the Ministry of Health, Elderly and the Community, Malta			

Table 1: List of respondents to the online questionnaire on health security in the EU Respondent

14	Institut de Veille Sanitaire - Institute for Public Health Surveillance, France				
15	International Federation of Anthroposophic Medical Associations IVAA				
16	International Ogranization of Migration				
17	Istituto Superiore di Sanità, Italy				
18	National Institute for Health and Welfare/Division of Health Protection				
19	National Institute for Infectious Diseases "Prof.Dr.Matei Bals", Romania				
20	National Poison Control Centre, University Medical centre Ljubljana, Slovenia				
21	Oracle				
22	Osakidetza Servicio Vasco de Salud, Basque Country, Spain				
23	Partnership, Italy				
24	Pharmaceutical society of Ireland - The Regulator of Pharmacists, Pharmacies and Pharmaceutical Assistants in the ROI				
25	Royal College of Nursing, UK				
26	Sindicato de Enfermería SATSE				
27	Spanish Poison Control Centre				
28	Standing Committee of European Doctors (CPME)				
29	State Emergency Medical service				
30	UNF, Ungdomens Nykterhets Förbund, Sweden				
as an individual					
1	CARIM - Maastricht University, The Netherlands				
2	Cruz Roja Espanol, Spain				
3	Department of Social Medicine and Health Care Management				
4	European Centre for Disease Prevention and Control (ECDC)				
5	European Parliament				
6	Hellenic Centre for Disease Control and Prevention, Greece				
7	Hospital Infanta Cristina, Spain				
8	Institute for Medical Research and Occupational Health, Hungary				
9	Instituto de Investigaciones en Enfermedades Raras, Instituto de Salud Carlos III, Spain				
10	Mater Dei Hospital, Malta				
11	NHS UK				
12	Norwegian Institute of Public Health, Norway				
13	Spanish Poison Control Centre				
14	Stockholm prehospital centre, Sweden				
15	ZNA Stuivenberg Hospital - Emergency Department - Belgium / Belgian Scientific Society for Emergency and Disaster Medicine				