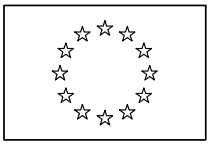

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COMMISSION STAFF WORKING DOCUMENT

Health Security in the European Union and Internationally

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1. PURPOSE AND OBJECTIVES

This Commission Staff Working Document is the first response to the call for action in the Health Council Conclusions adopted in December 2008 on health security[1] and the Conclusions on influenza A (H1N1) adopted on 30 April 2009[2]. It is also a contribution to global collaboration on health security, as advocated by the World Health Organisation in its 2007 annual report[3].

The key objective of the Commission Staff Working Document is to describe the strategic framework that is in place for health security, and the work of the EU Health Security Committee. The Commission Staff Working Document also presents the work of the Global Health Security Initiative (GHSI), of which the Commission is a member. Both of these mechanisms deal with related areas of work, so links and orientations for future work at international level are suggested at the end of the document.

A separate document on the activities of the Health Security Committee for the period of September 2007 – October 2009, as requested in the Council Conclusions prolonging and extending the mandate of the Committee[4], is annexed to this Commission Staff Working Document.

2. LEGAL FRAMEWORK

At EU level, the legal basis for addressing health threats is EC Treaty Article 152[5], which states that Community action shall complement national policies directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Accordingly, EU action has focused on coordinating information and measures on communicable diseases and substances related to chemical, biological and radio-nuclear (CBRN) agents. The EU has established a system for epidemiological surveillance and reporting of communicable diseases[6] and it is one of the key mechanisms for Europe-wide coordination on diseases between the Member States, the WHO and relevant public health agencies.

Under EU legislation on communicable diseases[7], the European Commission has a role in coordinating the Member States' efforts to address health security threats in an effective and

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

2 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/107492.pdf

3 The World Health Report 2007: A safer future: global public health security in the 21st century. WHO 2007

4 Council Conclusions of 22 February 2007 on the Health Security Committee

5 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E152:EN:HTML

6 The Early Warning and Response System (EWRS) used by the Member States is used frequently for notification of threats, exchange of information and coordination of measures among partners and is operated by the ECDC.

7 Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

coherent way. To support European scientific and technical work on communicable diseases, the European Centre for Disease Prevention and Control[8] has been working since 2005 to provide scientific opinions, technical data and scientific risk assessment for effective control of communicable diseases in Europe.

At international level, the Commission is also actively developing and strengthening existing relationships and collaborations on health security. The Global Health Security Initiative (GHSI) is an international partnership of like-minded countries to strengthen health preparedness and the global response to threats of CBRN substances and pandemic influenza. The initiative was launched by the G7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom and the United States) plus Mexico and the European Commission in November 2001.

The World Health Organisation leads the implementation of the revised International Health Regulations (IHR), which entered into force on 15 June 2007 and requires members of the World Health Organisation to report certain disease outbreaks and public health events to the WHO. A total of 194 States Parties to the IHR have been implementing these global rules to enhance national, regional and global public health security.

3. EUROPEAN UNION STRATEGIC FRAMEWORK ON HEALTH SECURITY

The European Union health security framework addresses three main areas of work including prevention of health threats, preparedness, and responses to threats. Health threats are often cross-border problems with a possible international impact. Member States cannot act effectively alone so a coordinated European approach is needed. In the area of public health, one of the three key strategic themes of the EU health strategy[9] is the Protection of Citizens from Health Threats.

Within this strategy, and in order to coordinate the Member States' actions and policies in this area, the Commission has established a number of mechanisms and tools for Europe-wide coordination of prevention, preparedness and response to health security threats, and to develop sustainable collaboration with its world partners on global health security. An important part of the overall framework for this coordination has been set up by the Communication "Reinforcing the Union's disaster response capacity"[10], where the Commission addressed for the first time in a holistic way all phases and types of crises.

The Commission's Consumer Strategy 2007–2013 also includes mechanisms of this kind, especially for product safety.

The strategic policy framework on health security was developed after the terrorist attacks in the USA on 11 September 2001 and the subsequent anthrax scare. Other health threat incidents in Europe have also helped to shape the approach of the EU. In particular, the threat of CBRN agents, ranging from natural disease outbreaks to deliberate attacks, has demonstrated the need to be prepared for large-scale public health emergencies with

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8 Regulation (EC) 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control

9 http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf.

10 COM(2009) 130 of 5 March 2008

significant international impact. Foreign security policy makers have recognised this by creating a clear priority to put global health security higher on foreign policy agendas[11].

Increasingly new and re-emerging health threats such as Severe Acute Respiratory Syndrome (SARS), avian influenza A(H5N1) and most recently the pandemic (H1N1) 2009 as well as climate change, are causing new disease patterns requiring a new approach towards European cooperation on health security challenges. In addition, the challenges arising from economic and social globalisation call for intensified global collaboration and solidarity in facing health security threats today and in the future.

Prevention of health security threats

In order to address health security issues such as the prevention and management of pandemic flu, the deliberate release of CBRN substances and other non-specific threats to health, the Council of Health Ministers set up an informal Health Security Committee[12] (HSC) in 2001. The HSC, chaired by the Commission, is made up of officials from national governments and it has established a multi-annual work programme (2008–2010). The 2007-2013 Health Programme of the European Union has been the key financing mechanism for projects, setting up networks and initiatives to support the work of the HSC. Under the programme's work plan for 2009, several projects related to health security are being financed.

The Justice and Home Affairs Council adopted on 6 December 2007 Conclusions 'on addressing chemical, biological, radiological and nuclear risks and on bio-preparedness'[13]. On 24 June 2009 the Commission adopted a Communication on 'Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union' with an EU CBRN Action Plan, including recommendations in the areas of prevention, detection and response. A significant amount of financial resources (up to €100 million) is allocated to its implementation. The Communication is accompanied by a Commission Staff Working Document 'Bridging security and health: Towards the identification of good practices in the response to CBRN incidents and the security of CBR substances'.

In April 2009 the European Commission adopted a three-year programme (2009–2011) to fight terrorism, trafficking and proliferation of weapons of mass destruction[14]. Links between terrorism and organised crime are addressed in areas such as drugs trafficking, trafficking in small arms and light weapons, and illicit trafficking in chemical, biological, radiological and nuclear (CBRN) materials. With a budget of €225 million, the programme will address the broad range of threats outlined in the European Security Strategy and complement actions funded by other EU instruments and Member States. Other areas where international action has been developed are within international conventions, e.g. the Biological and Toxin Weapons Convention (BWC) and the UN (UN Security Council decision 1540) and the Cartagena protocol. Global coordination takes place within the EU Council's Weapons of Mass Destruction Monitoring Centre (WMD-MC).

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11 http://www.who.int/trade/events/Oslo_Ministerial_Declaration.pdf (accessed on 12 October 2009).

12 Council conclusions of 22 February 2007 on the transitional prolongation and extension of the mandate of the Health security committee

13 16589/07, of 17 December 2007

14 See also 17172/08, Council Conclusions and New Lines for Action by the European Union in Combating the Proliferation of Weapons of Mass Destruction and their Delivery Systems, 17 December 2008.

Preparedness for health security threats

Significantly reinforced in the EU Framework Programme for Research, FP7, the newly created 'Security' theme has an overall budget of €1.3 billion for 2007–2013. This theme is entirely dedicated to develop civil security research activities in support of EU policies and industry, aiming at developing the new knowledge and technologies needed to ensure security of citizens against threats such as CBRN agents, (organised) crime, natural disasters and industrial accidents, while respecting fundamental human rights. In the field of Health Security, this scheme is particularly dedicated to supporting the needs of private and public end users involved in the preparedness, prevention, detection, response and recovery in case of (health) crisis management. In the last two years significant small as well as large scale research projects related to the whole CBRN cycle have been launched and are now beginning to deliver results.

The "Health" theme of FP7 funds relevant collaborative research in health, notably on infectious diseases, genomics, health biotechnology and public health. It has a considerable international dimension, particularly regarding health issues in developing countries.

The "Emerging Epidemics" activity in the "Health" theme focuses on the threat of naturally occurring infectious diseases with pandemic potential, and will aim to support research projects emphasising the benefits of preparedness for threats to health security and stresses the connection to policy makers and public health stakeholders. The Commission intends to strengthen some areas of synergy between the "Health" and the "Security" themes of the Framework Programme in order to reap full benefits from these complementary approaches.

Considerable progress has been made in recent years in terms of preparedness for influenza pandemics and all EU Member States have put in place national preparedness plans which have now been tested in practice during the pandemic (H1N1) 2009. The Commission adopted on 15 September 2009 a Commission Communication on Pandemic (H1N1) 2009. In the Council Conclusions adopted in December 2008 on health security and the Conclusions adopted on 12 October on Pandemic (H1N1) 2009 the Health Council has called on the Commission to review the 2005 influenza preparedness and response plan in the EU to update national preparedness plans and strengthen intersectoral aspects[15].

Although the HSC has managed to develop a strategic framework for its core work areas, a number of new and re-emerging challenges require a concerted global approach on health security preparedness. Pandemics other than influenza, such as tuberculosis and HIV/AIDS and regional endemic diseases with cross-border and socioeconomic implications, are currently overwhelming the already weak health systems of developing countries.

Response to health security threats

In 2005[16], the Commission established a general rapid alert system called ARGUS. ARGUS aims at (i) providing an internal platform enabling the services of the Commission to exchange, in real time, relevant information on emerging multisectoral crises or foreseeable or imminent threat; (ii) making available an appropriate coordination process to be activated in the event of a major crisis; (iii) providing the context to communicate effectively with citizens and to offer a balanced, coherent and complete picture of the efforts deployed by the

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

16 COM(2005) 662

Commission. ARGUS complements the other sectoral Rapid Alert Systems established by the Commission and operates in the event of multisectoral crises requiring action at Community level (such as the pandemic (H1N1) 2009).

The EU has also reinforced its capacity to ensure a coordinated approach for and support to Member States in disastrous situations. This cooperation takes place through the Community Mechanism for Civil Protection. It is aimed at cooperation and assistance in civil protection in case of major emergencies. It facilitates mutual assistance between Member States if national response capacities become overwhelmed, and it may include immediate civil protection and medical assistance. Non-EU countries can also call for assistance.

The Civil Protection Financial Instrument (which runs until 31 December 2013) provides funding to support the Member States and facilitate reinforced EU-wide cooperation on preparedness for disasters including CBRN incidents. Through the Monitoring and Information Centre (MIC), the Commission actively supports the mobilisation, transport and coordination of civil protection assistance to countries affected by major emergencies. In this connection, the Commission encourages Member States to fully exploit the possibilities of the CECIS (Common Emergency Communication and Information System)[17] to help identify and address any shortages and facilitate the provision of pharmaceuticals and medical assistance on a voluntary basis by other Member States.

The Commission has set up a system of National Focal Points on Urban Transport Security in each Member State. The aim is to facilitate the exchange of best practice and to support networking amongst operators and authorities. The National Focal Points are supported by three supporting expert working groups of which one is dedicated to incident management. This network could facilitate the collection and dissemination of information on health security as urban transport operators often are closely involved with the implementation of health security policy at national level.

In past years, the HSC has not been limited to core areas of its work but has also discussed and coordinated measures during recent food crises. In 2008, PCB was detected in pork fat in Ireland, where the meat exceeded the legal limit of dioxin contamination. Also in 2008, the melamine in baby milk in China caused a world-wide alert which was discussed in urgent audio conferences of the HSC under the leadership of the Commission, with the support of scientific advice from the European Centre for Disease Prevention and Control and the European Food Safety Authority.

The shortage in supply of radioisotopes for medical use (Technetium-99m, which is the radioisotope most widely used in nuclear medicine diagnostics, e.g. for cancer) started in the EU in 2008, following a simultaneous shutdown of reactors in which radioisotopes are produced. The Council of Health Ministers asked the Commission to coordinate an exchange of information on the situation.[18] Against this background, an emergency meeting of the EU HSC was convened and the Commission services produced a report on the situation. The EU Health Ministers discussed the issue again at their meeting of 7 July, on the basis of the Commission's report, and requested that the situation will continue to be monitored closely.

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17 CECIS has been developed within the framework of the Council Decision 2007/779 EC, Euratom establishing a Community Civil Protection Mechanism.

18 Presidency conclusions of 15 September 2008.

The 2005 International Health Regulation (IHR), which applies to the 27 Member States, has created an international framework to support global cooperation to detect and respond to major health threats. It is important to note that the IHR (Article 44) calls for solidarity between countries in detecting and responding to health threats, and this should be the basis for greater equity in global health security.

The EU has been a driving force behind the international response to recent major health crises. The Commission has designed and implemented its international assistance in this field in a way that not only addresses the immediate threats (avian influenza and the pandemic (H1N1) 2009) but also reinforces capacities for preparedness and response to all sanitary hazards, with a potential high impact.

In close coordination with major international partners, including the United Nations System Influenza Coordination, the WHO, other UN agencies, the World Organisation for Animal Health and the World Bank, the Commission is promoting the 'One Health' approach to health hazards. This approach focuses on risks and potential crises originating at the interface between humans, animals and ecosystems. The emphasis that 'One Health' puts on the cross-sectoral aspects of preparedness and crisis response resonates perfectly with the EU approach to health security.

It is against this background that the Commission has actively been pursuing global collaboration to share the benefits of the European work and initiatives on health security whilst learning from others. In November 2008, concurrent meetings of GHSI and the HSC provided an early opportunity for talks between members, and reflection on common priorities and challenges. The Commission has also hosted and chaired two Ministerial meetings of the GHSI on 5 December 2008 and 11 September 2009 on Pandemic (H1N1) 2009[19].

4. GLOBAL HEALTH SECURITY INITIATIVE

The GHSI was established in 2001, giving countries fighting bioterrorism an opportunity to share information and coordinate efforts generally aimed at improving global health security. The GHSI has developed into a trusting forum of like-minded countries working together on public health preparedness and responses to health crises and terrorist-related threats. Members of the GHSI include Canada, the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. The World Health Organisation is a technical advisor[20]. In spite of its limited geographical representation, the GHSI is a unique forum for health ministers to meet on a regular basis and discuss health issues of global interest.

The GHSI structure comprises a ministerial forum which meets annually to discuss the work programme and flag up any emerging or current health security challenges. The senior officials' network steers the work which is carried out by working groups/networks mandated by ministers. The GHSI is an informal forum through which the members share information on broader issues with linkages to health security and where there is a need for exchange and dialogue. For example, in 2008, the GHSI served as a forum for information exchange on supply challenges for medical radioisotopes.

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

20 http://www.ghsi.ca/english/index.asp.

The work programme of the GHSI is based on similar health security challenges as those that the HSC is working with. CBRN threats, preparedness for and response to pandemic influenza and generic preparedness form the backbone of GHSI's work. The GHSI working groups and networks are on risk management and communications, pandemic influenza, chemical events and laboratory networking.

In the area of CBRN threats, the GHSI has worked on vaccine and antibiotic availability for the acquisition, sharing and distribution of medical countermeasures for a number of health security threats, including key biological agents, pandemic influenza (pre-pandemic and pandemic vaccines and antiviral drugs) as well as for chemical and radio-nuclear events. The stockpiling of smallpox vaccines has been a key area where the GHSI has contributed to enhancing global health security. The Commission cooperates with the GHSI, in consultation with the HSC, how to best address a lack of knowledge on prevention and countermeasures.

Progress has also been made in developing criteria for prioritising chemical substances, establishing tools for assessing the threat posed by specific chemicals, and identifying gaps in public health capacity to address chemical and radio-nuclear threats. Laboratory networking and sharing on CBRN threats is a key area of work where the GHSI members have benefited from sharing capacities and exchanging expertise. Moreover, the GHSI has developed a chemical expert contact list for each country/organisation for use in the event of a chemical incident, and has carried out joint training on emergency response procedures in relation to a radio-nuclear event.

As regards risk communication, the GHSI members have agreed to share information effectively on public health security threats and on measures planned or taken by the members. A common language for risk communication is an essential tool to ensure that messages across the GHSI members do not conflict.

In the area of pandemic preparedness, the GHSI members have worked with the WHO to develop approaches for improving pandemic vaccine production capacity and access to vaccines. In support of the work of the WHO in these areas, the GHSI has been engaged in efforts to develop a framework agreement for the sharing of influenza virus samples under the auspices of the WHO for risk assessment purposes. During the current pandemic, the Commission ensured during meetings of the HSC that the EU Member States were fully informed of the GHSI's work on the pandemic and issues such as vaccine development and vaccination strategies.

Joint training and planning has also taken place since 2001 among the GHSI members. The Commission will also organise a joint GHSI - HSC exercise in 2010 to share good practices and learn from each other, and to develop contacts. Under the GHSI, an Emergency Contacts Network supported by the Risk Management and Communications Working Group can bring together senior officials at short notice.

The GHSI provides a good model for sharing information and experience during global emergencies, as demonstrated during the pandemic (H1N1) 2009. The GHSI network has proved to be an effective platform for rapid communication and discussing approaches on vaccine production and vaccination strategies between all members as well as bilaterally.

5. CONCLUSIONS

Concerted action on health security and responses to health threats requires a strategic framework allowing both long-term policy planning and short-term emergency responses. This Commission Staff Working Document describes the strategic frameworks where the Commission has been pursuing this double objective, both under the HSC and GHSI.

However, as new and re-emerging health security threats arise and are increasingly linked to sectors other than health alone, it is necessary to review how EU-level cooperation could best be aligned with the global work in this area. Therefore it would be useful to consider a genuinely global approach to tackling health security threats comprehensively and through concerted international action.

Furthermore, the Commission is considering an improved policy framework on global health which will address wider areas on global equity, coherence, governance, knowledge. To this end Commission services have organised a public consultation exercise to gather orientations and views from relevant stakeholders regarding the rationale, scope and strategic objectives relating to an EU role in Global Health.[21]

In particular, the work of the GHSI has been valuable to its members in the development of national pandemic plans, emergency response procedures, and the identification of national priorities and areas for action on health security.

As requested by the Council in its Conclusions adopted on 12 October 2009 on Pandemic (H1N1) 2009, the Commission will review the intersectoral dimensions of pandemic preparedness to improve coordination and interoperability between Member States, the EU and relevant global players for this specific health security threat. It is essential that not only governments and health authorities play a part in developing health security approaches for inter- and multisectoral preparedness and response in Europe and globally. Stakeholders such as citizens, relevant professional groups and industrial associations must also be able to contribute to improving global health security, for example by way of public consultations on policy proposals.

The strengthening of health systems in developing countries, including surveillance systems and contingency plans for emergencies, is a cornerstone for the effective implementation of the IHR and contributes to global health security. Strengthening early warning systems and surveillance is important, to ensure that diseases are detected as early as possible. The Commission supports Member States and developing countries in generic preparedness planning and provide funding targeted towards comprehensive health systems via EU development aid, including support for the implementation of the IHR. The International Health Partnership offers an additional useful framework to advance health system strengthening, which links to the commitments on aid effectiveness.

In the area of research for health security it would be useful to have closer collaboration both at European level amongst Member States' research programmes as well as worldwide. In particular new diseases emerging as a result of climate and demographic changes will need to be considered. Furthermore, support will continue under the FP7 health and security programmes where the greatest European added value can be identified, aiming to fill gaps in

[21] http://ec.europa.eu/development/how/consultation/index.cfm?action=viewcons&id=4765

health security policy research for both long-term strategic planning and emergency work. The existing framework on health security has contributed towards a coordinated and a coherent approach at the EU and international level in areas such as vaccine research and development against viruses with pandemic potential.

The European Union strategic framework on health security connects with many policies all contributing to the prevention of, preparedness for, and response to health security threats. Strengthened intersectoral cooperation and pooling of efforts would be essential in developing this framework further.

International collaboration in different fora such as under the GHSI should continue to be strengthened and joint work and approaches on health security further developed with international partners. The Commission has a key role in the sharing of experiences and information with the GHSI and the HSC.

In order to explore ways to jointly meet the future challenges of global health security, the Commission plans to organise an international conference on global health security and pandemic preparedness in 2010 under the Belgian presidency to bring together international players in the field of health security, the European Union Member States, the Commission and its relevant agencies.

ANNEX

Activities of the Health Security Committee for the period of September 2007-October 2009

1. INTRODUCTION

This Commission Staff Working Document reports on the activities of the Health Security Committee (HSC) during the period September 2007–October 2009 thus responding to request by the Council in Conclusions prolonging and extending the mandate of the Committee[22].

Following the Council Conclusions of 22 February 2007 on a transitional prolongation and extension of the mandate of the Health Security Committee, the HSC has worked on the implementation of the strategic Work Plan for 2008-2010. Following the extension of its mandate, the HSC working structure has been re-organised into three closely coordinated sections for implementation of the work plan: the Generic Preparedness Planning section (GPP), the Chemical, Biological and Radio-Nuclear threat section (CBRN) and the Influenza Preparedness and Response section (IPR).

Besides the overall work programme, the HSC has also developed its internal cooperation capacities and has expanded its work on international cooperation with key health security mechanisms such as the Global Health Security Initiative. As demonstrated during the current pandemic (H1N1) 2009 the HSC has become an important player in international and EU health security preparedness.

The HSC plenary meetings took place in 2008 on 12 June and 5-6 November. In 2009 the HSC met on 18 June and 12-13 November. The individual sections met as follows: GPP section met in 2008 in March, May, December, and in 2009 in April and October. The CBRN section met in 2008 in March, June and October, and in 2009 in April and September. The IPR section met in 2008 in April and September, and in 2009 in April, May and September.

This report is structured around the seven priorities of the strategic Work Plan for 2008-2010. It also provides information on rapid mobilisation and response of the HSC in reaction to unforeseen health emergencies.

2. DETECTION, INFORMATION MANAGEMENT AND COMMUNICATION

Ensuring timely detection, alerting and distribution of information to relevant stakeholders is a key element of preparedness and response to health security threats.

To improve rapid alert systems the HSC has enhanced the Early Warning and Reporting System on communicable diseases and has set up a Rapid Alert System for Biological Threats - Rapid Alert System on Biological and Chemical Attack (RAS-BICHAT). In addition, a Rapid Alert System on chemical threats (RAS CHEM), which includes accidental events as well, has been was developed and is technically complete and ready to be used by the Member States The Health Security Committee will review the RAS-CHEM as regards the

[22] Council Conclusions of 22 February 2007 on the Health Security Committee.

standard operating procedures and which national authorities should act as contact points in the system. The HSC proposes that national poison centres should be designated as contacts for efficient communication and coordination under the RAS-CHEM.

The HSC has also further improved alerting efficiency by enhancing cooperation between Canadian Global Public Health Intelligence Network (GPHIN), the US Programme for Monitoring Emerging Diseases (PROMED) and the Medical Information System (MediSys) These electronic reporting systems have indispensable roles in the information diffusion and risk management for the Member States and other relevant institutions working on the outbreaks of emerging infectious diseases and toxins.

Regular meetings have taken place between all system holders in order to enhance the cooperation and sharing of outputs between these information systems. The cooperation has been completed with the launch, in the context of GHSI (Global Health Security Initiative) and its Action Group (GHSAG), of an Early Alerting and Reporting project (EAR) which brings together European and international detection tools such as those mentioned above and others developed by Japan, the USA and Finland. These tools provide added value for those countries who want to use them in public health information in order to in information and communication about a crisis. A specific project called ESANREP was also started to create a single entry point to access all the alerting systems run by the Commission and ECDC[23]. Its completion and testing phases are scheduled for the end of 2009.

The HSC is currently coordinating a project where Member States identify "national reference laboratories" for biological, chemical and radioactive threats in order for these laboratories to share capabilities and capacities. To support this, the European Centre for Disease Prevention and Control (ECDC) has carried out a study on laboratory structures in Member States concerning biological agents. Another study is being elaborated to establish national contacts regarding chemical and radio-nuclear laboratories.

3. THREAT AND RISK ASSESSMENT

Following the improvement of capacities for rapid alerting and information communication, threat assessment by Member States is another key priority of the work plans that have been developed by the HSC. The HSC has enabled cooperation between Member States in sharing threat and risk assessment either by using the expertise of the ECDC or other relevant EU agencies such as the European Medicines Agency (EMEA) or the European Food Safety Authority (EFSA). The regular meetings of the HSC have provided the structure to identify in a coordinated manner the priorities for the Member States.

The HSC also addressed secure IT communication and secure access to premises. Audio and video-conference systems are regularly tested and used. A proposal for an operating procedure for audio tools is drafted (video will follow). In particular, a lot of experience in the use of audio-facilities has been gained.

Secure audio-conferences of the HSC have not been developed yet. However, for the plenary meetings, the Grand Duchy of Luxembourg provides secure installations in Senningen Castle.

[23] European Centre for Disease Prevention and Control

4. ADVICE

The need for immediate and effective reactions to public health events implies comprehensive work for HSC as it integrates scientific advice in the assessment and management of health threats. Through the mobilisation of expert groups and committees on risk assessment, the HSC has carried out the assessment of toxic industrial chemicals and radioactive threats.

Concerning chemical health threats, the Alerting System for Chemical Health threats project (ASHT) was given particular attention and presented to the HSC. It aims at developing scientifically validated public health measures for non- biological health threats based on a threat assessment.

With regard to radioactive threats, a proposal for public health aspects of risk assessment and management of radio- nuclear events and threats has been prepared. The proposal entails the setting up of a network of experts who assess and advise on public health related aspects of RN events and threats. It also includes a plan for the creation of a rapid alert and response system at EU level to communicate on RN events and threats. This could be linked with the other existing rapid alert systems already running or planned under the HSC.

Based on threat assessment, the HSC is now able to develop scientifically validated public health measures for non-biological health threats. Eventually, the HSC created momentum in the development of national capacity to use modelling in public health decision making. Extensive work has been undertaken in order to establish a European Network on modelling control strategies for infectious diseases and other health threats (NEMO network) which is expected to include all Member States. Member States have been requested to nominate experts to the network. Further work on risk and threat assessment in chemical and climate change issues is currently carried out in cooperation with the Joint Research Centre.

5. MANAGING A CRISIS (LIAISE AND CONTROL)

With the view to ensuring good relationships between command and control centres in the Member States, the Commission, the Community agencies and international organisations and third countries, the HSC has invested efforts into setting up guidelines and protocols for communication sharing.

The HSC has decided to revise the technical guidance document on generic preparedness focusing particular attention on a checklist on good preparedness practice. Also, an *ad hoc* working group was set up in 2008 for this purpose. Member States have contributed to its development as it provide for a useful tool to help them to review how well prepared they are and to identify ways of improving preparedness for public health emergencies. The document is being finalised and will be presented to the HSC in its plenary on 12-13 November 2009.

In order to streamline communication and ensure coherent a communication strategy during outbreaks, the HSC created the HSC Communicators network. Following its creation at the beginning of 2009, the HSC Communicators network has met twice in face-to-face meetings and has been deeply involved in the management of the pandemic (H1N1) 2009. The first annual meeting in March 2009 was followed by a two-day training session and a one-day exercise. A second meeting took place in Brussels beginning of September 2009 to discuss the initial lessons learned from the first months of pandemic (H1N1) 2009 and to consider further joint actions and approaches to the challenges relating to vaccines and communication.

During the pandemic, the Communicators network has exchanged regularly information through audio-conference meetings, by sharing information daily on the HEDIS (Health Emergency and Disease Information System) platform, and via regular e-mail exchanges in case of important notices. Meetings proved to be useful for getting an understanding of the developing situation, for reviewing the concerns of the media, and for discussing the various approaches in Member States towards the public.

The work of the network also includes setting up its own rules and procedures and a draft "Red Book[24]" which provides information on national communication structures. The first three areas of communication addressed by the network include issues such as risk assessment, consequences of risk as well as public, professional and media communication and scientific advice. On the basis of the Council Conclusions adopted on 12 October on pandemic (H1N1) 2009 – a strategic approach the Commission will continue facilitating cooperation on common approached for communication through the HSC communicators network.

6. PREPAREDNESS

Preparedness is another area where coordination between Member States and the Commission is crucial to ensure coherent responses. In this area, the HSC has focused on coordination for capacity building to respond to health threats and cross-sectoral approaches.

Technical guidance on risk assessment and management on chemical and radio-nuclear threats is particularly needed. Two ad hoc working groups were created to fill the gap of knowledge on C and RN preparedness. Technical guidelines have been drafted and are ready to be presented to the HSC Plenary in November 2009. Regional exercises to test these specific guidelines for radio-nuclear threats have been also organised.

Concurrent responses to threats and preventive measures have also revealed a gap in cooperation between security and health law enforcement. In order to bridge this gap, three regional workshops with Member States were held in 2008. Good practices resulting from the workshops were gathered in a single document and it was presented as a Commission Staff Working Paper, accompanying the Communication on "Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union" with an EU CBRN Action Plan adopted on 24th June 2009.

The HSC has also addressed the issue of passenger name records for public health reasons. The HSC aim has been to produce a procedure for contact tracing of passengers. To address the data collection issue, the Commission distributed a questionnaire which will enable to identify if Member States already have the possibility of obtaining such data from airlines on the basis of national law and if they encounter difficulties in collecting the data from airlines operating outside the EU. In June 2009, less than 1/3 Member States replied and the HSC decided to stop their work on passenger name records and move on with the mitigation of pandemic (H1N1) 2009.

Climate change was included in the HSC work plan during the HSC Plenary in November 2008. The focus was on rapidly evolving and major events linked to climate change. A Commission Staff Working Document relating to health and climate change has been

[24] a Reference document including a directory, national structures, procedures and mandate of the network

published to accompany the White Paper on Climate Change. HSC contributed to the Staff Working Document.

7. INTER-SECTORAL AND INTERNATIONAL CO-OPERATION

Within the Commission, intersectoral coordination is ensured via (i) the ARGUS system, (ii) a task force on Crises, Disasters and Emergencies that is chaired by the President's Cabinet and (iii) the inter-service group "Community Capacity in Crisis Management" which brings together all Commission services and Community agencies involved in crisis management.

As health security entails a global dimension, the HSC is also contributing towards improving international cooperation. High level cooperation is ensured by permanent contact between the Global Health Security Initiative (GHSI) and the HSC in order to share good practices and information effectively. The Commission is a member of the GHSI and reports regularly to the HSC on the work of the GHSI. In addition, there is coordination on risk management and communication on early warning for CBRN threats. Commissioner Vassiliou chaired ministerial meetings of the GHSI on 5 December 2008 and on 11 September 2009 in Brussels.

Particular attention is also given to the implications and benefits of the World Health Organisation's International Health Regulations (IHR) for multisectoral efforts. The Early Warning and Reporting System (EWRS) on communicable diseases is now linked with IHR notification system to assure that all relevant events which are notified in EWRS are accessible to WHO. In addition, Member States are carrying out a review of their implementation of the IHR in order to ensure compatibility of IHR with EU legislation. Under IHR requirement to achieve assessment of core capacities, a report should be finalised by 15 June 2009.

8. EVALUATION AND TESTING OF PLANS

The HSC members have shared results of analyses of national preparedness plans and will review interoperability with particular attention to influenza, using results from available reports and surveys in order to identify core elements for improving influenza preparedness.

Assisted by an HSC drafting group, the WHO and ECDC have produced an elaborate set of Joint European National Pandemic Preparedness Self-Assessment Indicators addressing core elements of influenza preparedness. As the pandemic H1N1 2009 happened, it was decided to stop working on these indicators of national preparedness in order to concentrate on the pandemic. Indicators will be reviewed in light of lessons learnt from the pandemic (H1N1) 2009.

Other actions to improve interoperability and preparedness are under review of the ECDC work plan on influenza for 2009 include coordination on border measures, a survey on policies in pandemic influenza planning, WHO global surveillance guidelines, the 2006 WHO global survey on influenza vaccines and review of the current Community preparedness plans. A template for reporting on stockpiling of vaccines, antivirals, pharmaceuticals and medical devices was also circulated. The extension of life of stockpiled antivirals was discussed, as was modelling during a pandemic, hospital capacity during a pandemic, guidance on therapeutics.

The HSC has tested specific scenarios and reviewed communication capabilities. Among numerous training sessions and exercises, the HSC organised an exercise repository, an exercise were all tools of communication were tested and a cross sectoral exercise with other services in 3-6 Member States (AEOLUS).

The MASH survey[25] on "Generic preparedness" in health systems was carried out in order to get relevant background information on chemicals and radio-nuclear preparedness.

The Euroflu seminar on 3 September 2008 in Angers, France, addressed policy inconsistencies in the area of influenza preparedness. The seminar examined interoperability of plans and cross-border issues. Final conclusions have served as an important guidance on priorities for further work on influenza preparedness. It has also led to the current review of the 2005 Community preparedness plan with a focus on intersectoral dimension. The Swedish presidency also organised a workshop in Jönköping on 2-3 July 2009 on influenza preparedness and lessons learnt from the pandemic (H1N1) 2009 situation.

9. HSC AUDIO-CONFERENCES

In parallel with the work and activities of the sections and plenary meetings, the HSC also meets in audio-conferences in preparation for future plenary meetings and to discuss and adopt decisions. At the start of the pandemic outbreak the HSC met every day during April, May and June in audio-conferences to review the epidemiological situation and to coordinate public health measures in the EU. Regular audio-conferences (on average once a week) took place in August, September, October and December in 2008 and in January and March before the pandemic started in 2009. The HSC adopted a formal operating procedure for audio and video conferences.

Other urgent audio-conferences have also been organised in case of health emergencies in order to ensure timely surveillance and coordination between Member States. For example, urgent discussions were organised on shortage of radioisotopes (in September 2008) and on dioxin contaminated meat (in December 2008).

10. PANDEMIC (H1N1) 2009

The sudden pandemic (H1N1) 2009 outbreak necessitated extraordinary efforts and mobilisation of the HSC structure. Urgent joint audio-meetings between EWRS representatives and the HSC were organised every day during the peak of the pandemic. Between late April and 18 September up to 30 joint meetings were arranged. The HSC has discussed a number of public health measures based on the existing legal and public health mechanisms:

– Agreement on advice to persons planning to travel to or returning from affected areas on 18 May 2009;

– - Extension of the surveillance system to identify new cases in the EU on 18 May 2009;

[25] Mass Casualities and Health care following the release of toxic chemicals and radioactive material

– Guidelines on case management and treatments and advice on medical countermeasures for health professionals on 18 May 2009;

– Advice for the general public on personal protective measures agreed and made available to Member States in all the official EU languages on 4 May 2009;

– Statements by the Health Security Committee and the Early Warning and Response System (EWRS) contact points on school closures and travel advice on 13 August 2009;

– Statement on 'Vaccination strategies: target and priority groups' agreed by the Health Security Committee and the EWRS contact points on 25 August 2009.