STRUCTURES FOR PREPAREDNESS AND RESPONSE TO CROSS-BORDER HEALTH THREATS

5 September 2011

I. European Commission

	1. Structure in place	2. DG in the lead	3. Objective of the structure	4. Actors involved	5. Risk Assessment	6. Risk management	7. Public Health threat assessment carried out	8. Link to / input by Public Health Structures	9. link to international frameworks	10. Comments / Link to HSI
A. Health and Consumer Protection										
Communicable diseases										
Alert System and Management	**Early warning and response system for communicable diseases (EWRS)**	SANCO C3	**EWRS** promotes cooperation and coordination between the Member States, with the assistance of the European Commission, to improving the prevention and control, in the Community, of communicable diseases. EP and Council Decision 2119/98/EC;	Member States, ECDC, Commission	To send alerts about communicable disease events with a potential impact on the EU, share information, and coordinate their response. (MedISys - Medical Information System - a real-time news alert system for medical and health-related topics is a tool used for collecting relevant information)	EWRS Network brings into permanent communication with one another the Commission, ECDC and the competent public health authorities in the Member States responsible for determining the measures which may be required to protect public health (HEDIS - an internet based Health Emergency an Diseases Information System - is used as a tool for sharing of information between Commission services and public health authorities in Member States during disease outbreaks and health emergencies).	YES. ECDC carries out the RA.	yes	Inter-link with WHO alerting system; IHR reporting. The Global Outbreak Alert and Response Network (GOARN) is a technical collaboration of existing institutions and networks which pool human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance.	core instruments for Communicable diseases
Food and Feed										
Alert System	**Rapid Alert System for Food and Feed (RASFF)**	SANCO E2	**RASFF** provides food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. This exchange of information helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. Regulation EC/178/2002, art. 50-52	Member States, EFSA and Commission	Existence of a serious direct or indirect risk to human health deriving from food or feed.	The Member States, the Commission and EFSA have designated contact points, which form a network. The Commission is responsible for managing the network.	YES. EFSA carries out the RA.	Inter-exchange between Commission services operating RASFF and EWRS	The International Food Safety Authorities Network (INFOSAN) is a joint initiative between WHO and the Food and Agriculture Organization of the United Nations. Each Member State has a designated INFOSAN emergency contact point for communication between national food safety authorities and the INFOSAN secretariat regarding urgent events.	good cooperation in practice/ EWRS to be linked technically to RASFF

Animal Diseases										
Alert System	**Animal Disease Notification System (ADNS) and Animal Health Emergency System (AHES)**	SANCO G2	**ADNS** application ensures rapid exchange of information between the competent national authorities responsible for animal health and the Commission on outbreaks of contagious animal diseases. It is based on Council Directive 82/894/EEC and Commision Decision 2005/176/EC, It allows co-ordination and monitoring of outbreaks of contagious animal diseases and enables Member States and Commission services to take immediate measures to prevent disease spread. **AHES** is not legally formalised and provides for rapid dissemination of more detailed information on disease outbreaks and measures taken at national and Commission level within the Commission, to Member States, third country trading partners and international organisations such as OIE, FAO,	**ADNS:** Member States and Commission **AHES**: Commission	The Veterinary authorities in Member States assess the risk. This permits immediate access to information about contagious animal disease outbreaks and ensures that trade in live animals and products of animal origin are not affected unnecessarily.	The risk management is coordinated between Member States and Commission services. The action of the Commission consists of the adoption of Decisions as proposed by the Standing Committee on the Food Chain and Animal Health (below).	NO	No direct link between ADNS and EWRS AHES informs SANCO C3 and ECDC in case of outbreaks of zoonotic diseases	OIE (World Organization for Animal Health) and FAO (Food Agriculture Organisation of the UN)	thorough interlink between ADNS and EWRS as regards risk assessment of public health consequences resulting from animal diseases has to be envisaged.
Management	**Standing Committee on the food chain and animal health (SCFCAH)**	several SANCO units	**SCFCAH** is a Regulatory Committee [Regulation (EC) No 178/2002] consisting of eight sections managing risks along the food chain including animal health matters, biological and toxicological safety, controls and Import conditions, genetically modified food and feed and environmental risks, Animal Health specific legal bases for adoption of safeguard measures: Council Directives 90/425/EEC, 89/622/EEC (live animal/products of animal origin within EU) and 91/496/EEC and 97/78/EEC (imports) which will be replaced by the new Animal Health Law,	European Commission, Member States	risk assessment carried out by EFSA, Member Sates and Commission depending on which SCFCAH section concerned,	Based on the favourable opinion of the Committee - or in extreme urgency as an interim measure by the Commission alone - the Commission can rapidly adopt protection measures to prohibit or restrict movements within the EU and imports from third countries of animals, food and feed and other commodities posing a threat, Its mandate covers the entire food supply chain, ranging from animal health issues on the farm to the product that arrives on the consumer's table, thus significantly enhancing its ability to target risks to health wherever they arise in food production. The Committee consists of representatives of the Member States and is chaired by a European Commission representative.		Protection measures are focused on restrictions on free circulation of animals and food products.	measures on international trade in animals and products of animal origin in line with OIE (World Organization for Animal Health) standards,	public health issues are focused on restriction on the free circulation of animals, food products including withdrawal from the market. The follow up of medical measures is not addressed.
expert group	**advisory group on the food chain and animal and plant health**		This group brings together key stakeholders including farmers, the food industry, retailers, consumer organisations and others to advise the European Commission on food safety policy [2004/613/EC]	European Commission, Member States		The Commission shall consult the group on its programme of work in food and feed safety, food and feed labelling and presentation, human nutrition, in relation to food legislation, animal health and welfare and matters relating to crop protection, plant protection products and residues thereof, and conditions for the marketing of seed and propagation material, including biodiversity, and including matters pertaining to industrial property. In addition, the Commission is able to consult the group on any measures which the Commission has to take or propose in these fields.				public health issues are focused on restriction on the free circulation of food products including withdrawal from the market. / follow up of medical measures is not addressed.
Plant health										
	European Network of Plant Health Information Systems (EUROPHYT)	SANCO F4	**EUROPHYT is a** Web-based network supporting the protection of human, animal and plant life and health. Article 21(6) of Council Directive 2000/29/EC	Member States and Commission	Notifications of interceptions of plants or plant products that do not comply with EU legislation.	Exchange of official information between plant health services of the EU Member States and the European Commission. Standing Committee on plant health for emergency report	YES. EFSA carries out the RA.	Inter-exchange between Commission services operating EUROPHYT and EWRS		public health issues are focused on restriction on the free circulation of plant products including withdrawal from the market. / follow up of medical measures is not addressed.
CBRN threats				AHES Commission						

Alert System	**RAS CHEM**	SANCO C3	**RAS CHEM** is a Rapid alert system for the exchange of health related information on incidents including chemical agents relevant to terrorism and other events leading to release of chemicals, and consultation and coordination of counter-measures.	EU MoH, EU Poison centres	RAS CHEM, which is in a test phase, aims to improve the effectiveness of the public health response to acute and potentially chronic effects following chemical incidents or emergencies. The national public health authorities notify events in Ras Chem. Risk assessment is done by them based on information they have received by national Poison Centres. The Poison Centres already cooperate via an informal platform (the EUPC Forum) to be prepared for potential chemical events.	Yes, Health Security Committee ensures public health risk and crisis management within its limited mandate. In addition, other national authorities/Ministries may be in charge.	YES	YES	events notified to WHO under IHR	RAS CHEM is under development, it will not be a formal alert system for notification, exchange of information, and risks assessments. Member states are not obliged to notify and in addition the Poison Centres do not exchange information within a formalised structure which could result in an information gap. The financial sustainability of Ras Chem notification system is not ensured today because it has not been formalised. the future status to be decided.
Alert system	**RAS-BICHAT Rapid alert system**	SANCO C3	**RAS-BICHAT** is a rapid alert and notification system on health threats due to deliberate release of chemical, biological and radio-nuclear agents (CBRN).	Health Security Committee, Member States and Commission	RAS BICHAT has been developed to provide a rapid exchange of information on intentional and terrorist release of CBRN agents. It aims to help in coordinating and supporting the public health/health security preparedness and response capacity and planning of the Member States against CBRN attacks ((MedISys - Medical Information System - a real-time news alert system for medical and health-related topics is a tool used for collecting relevant information).	Yes, Health Security Committee ensures public health risk and crisis management within its limited mandate. In addition, other national authorities/Ministries may be in charge. (HEDIS - an internet based Health Emergency an Diseases Information System is used as a tool for sharing of information between Commission services and public health authorities in Member States during disease outbreaks and health emergencies)	Yes	Inter-exchange between the Health Security Committee and Member States		In case of criminal or terrorist events informal information exchange between law enforcement authorities and the Health Security Committte.The current standard operating procedures need to be reviewed and their application improved. Formal structure to be established.
International partnership	**GHSI**	SANCO C3	**GHSI** - Global Health Security Initiative of the G7 countries, and in addition Mexico, the Commission and WHO; it is an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza	Member States, Commission, WHO and any other third country	GHSI has agreed on a process for international collaboration on risk assessment and management and a common language for risk communication. GHSI share surveillance data from national public health laboratories and information on real or threatened contamination of food and water supplies along with information on risk mitigation strategies to ensure safe food supplies	GHSI explore joint cooperation in procuring vaccines and antibiotics, further support the World Health Organization's disease surveillance network and WHO's efforts to develop a coordinated strategy for disease outbreak containment. GHSI improve linkages among laboratories, including level four laboratories, in those countries which have them	Yes	Inter-exchange between public health structures in partner countries, the Commission and WHO	exchange between partner countries and other international organisations, e.g. WHO and other UN agencies	The GHSI would continue to be interlinked with the European Commission Public Health Directorate.
Medical products safety										
	MEDDEV safety		the Medical Device Vigilance System promotes a common approach by MANUFACTURERs and Notified Bodies involved in the conformity assessment procedures and by the National Competent Authorities charged with safeguarding public health. Council Directive 90/385/EEC, Council Directive 93/42/EEC and Directive 98/79/EC.							Not of immediate concern for HSI
Alert system	**EU pharmacovigilance system**	SANCO C8	**Pharmacovigilance** is part of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. It is a key public health function. The system linked to this process is **Eudravigilance** hosted by the European Medicine Agency. Directive 2001/83/EC and Regulation (EC) 726/2004	Member States' competent authorities, the European Medicines Agency (EMA) and the European Commission	Yes. Collecting and managing data on the safety of medicines/ Looking at the data to detect 'signals' /Evaluating the data and making decisions with regard to safety issues	Acting to protect public health (including regulatory action)/ Communicating with stakeholders/ Audit, both of the outcomes of action taken and of the key processes involved.	Yes	yes	link with agencies in third countries	The Commission is informed by the EMA on the safety of pharmaceutical products on the market.
consumer products										

Alert system	**RAPEX**	SANCO B3	**RAPEX**: EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices. It allows for the rapid exchange of information between Member States via central contact points and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. Article 12 of Directive 2001/95/EC	Member States, Commission	Every week, the Commission publishes a weekly overview of the dangerous products reported by the national authorities (the RAPEX notifications) and the names of the countries that have found the notified product on their market and have taken appropriate measures (and have submitted a reaction to a RAPEX notification as a consequence). This weekly overview gives you all information on the product, the possible danger and the measures that were taken by the reporting country In order to give a better view on the overall level of enforcement, including the follow-up activities of the national market surveillance authorities.	When a product is found to be dangerous, the competent national authority takes appropriate action to eliminate the risk. It can withdraw the product from the market, recall it from consumers or issue warnings. The National Contact Point then informs the European Commission about the product, the risks it poses to consumers and the measures taken by the authority to prevent risks and accidents.	No	no systematic inter-exchange with the Health Security Committee and public health authorities in Member States	link with agencies in third countries	The system is focused on warnings on risks related to consumer products freely circulating in the market (including withdrawal of consumer products) / follow up of medical measures is not addressed.
Scientific Committees										
Committees	the Scientific Committee on Consumer Products (**SCCP**), the Scientific Committee on Health and Environmental Risks (**SCHER**), the Scientific Committee on Emerging and Newly Identified Health Risks (**SCENIHR**).		**The Scientific Committees** are an advisory framework to give scientific advices to the Commission relating to consumer safety, public health and the environment. It ensures an easier access to highly qualified scientific expertise in a wide range of fields. [COM Decision 2008/721/EC]	European Commission, Scientific advisors	An advisory structure on scientific risk assessment in the areas of consumer safety, public health and the environment is hereby established. The Commission may also request the Scientific Committees to provide rapid advice on the state of scientific knowledge concerning specific risks in case of urgent needs.			the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).		More extended use of the committees for ad hoc risk assessment of immediate health threat to be envisaged.
B. Structures in place in other sectors relevant for tackling cross border health threats										
chemical threats										
Information System	**Major Accident Reporting System (MARS)**	ENV / JRC (Major Accident Hazards Bureau (MAHB))	**MARS** reports chemical accidents and near misses to the European Commission according to the criteria established in the Seveso II Directive 96/82/EC	Member States, Commission, OECD, UN-ECE	Accidental Risk Assessment Methodology for Industries in the framework of SEVESO II directive (ARAMIS): Characterisation of risk levels of industrial installations based on the determination of Reference Accident Scenarios and integrates : - Consequence severity evaluation of scenarios, - Prevention management efficiency; - Environment vulnerability estimation. MARS extracts important lessons from chemical accidents and near misses that occurred in order to and prevent similar occurrences in the future.	No / just technical assessment	no	no	Inter-link with OECD (Organisation of Economic Co-operation and Development) and UN-ECE (The 1992 Convention on the Transboundary Effects of Industrial Accidents is designed to protect people and the environment against industrial accidents. The Convention aims to prevent accidents from occurring, or reducing their frequency and severity and mitigating their effects if required.)	The MARS data would be analysed in view of more extended use for risk assessment related to the public health consequences. / not all chemicals are covered (only industrial chemicals are covered).
radiological and nuclear threats										

Alert System	**European Community Urgent Radiological Information Exchange (ECURIE)**	ENER D4 Radiation protection	**ECURIE** is a Community arrangement for the early notification and exchange of information in the event of a radiological or nuclear emergency. Euratom, Chapter 3 "Health and safety" Council Decision 87/600/Euratom	Member States, Croatia, Switzerland, FYROM, Commission	Measurement of radioactivity levels by Member States radio-nuclear authorities. A group of Member States experts provides opinion to the Commission on basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. It provides also periodically advice on any major problem affecting radiation protection.	Member states carry out health threats assessment deriving from radio nuclear exposures	Interservice collaboration between DG ENER, SANCO and JRC; information exchange between ECURIE, RAS BICHAT and HSC	Interservice collaboration between DG ENER, SANCO and JRC; information exchange between ECURIE, RAS BICHAT and HSC	Cooperation and information exchange with other international organisations, e.g. the IAEA early notification system ENATOM, WHO, and international partners.	Interchange between EURATOM radio/nuclear experts and Public Health experts (e.g. HSC) would need to be strengthened especially as regards preparedness to rapid risk assessment and management of events. The 2011 Japanese nuclear event demonstrated differences in perception of risk assessment and risk management between Public Health Authorities and Radio Nuclear authorities and agencies would be of advantage if the HSI would lead to closer inter-link be established between the EURATOM radio/nuclear experts and public health experts at EU level.
Committee	**EURATOM Art. 31 Committee**	ENER	Group of radiology and nuclear scientific experts attached to the Commission and with advisory status.	European Institutions, Member States, external bodies	Yes	Yes	Commission to consult the Group when revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation	Commission to consult the Group when revising and supplementing the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation	The Commission is cooperating with IAEA and WHO on issues of radiation protection	Public health issues are focused on providing advice to the Commission on radiological and nuclear events, rapid response to health threats needs to be reinforced. / follow up of medical measures is not addressed. / cooperation with HSC to be strengthened.
Civilian Disaster response										
Alert System and Management	**The Monitoring and Information Centre (MIC) of the EU Civil Protection Cooperation Mechanism**	ECHO	**MIC** facilitates civil protection assistance across EU Member States in case of EU and international disasters. Council Decision 2007/779/EC, Euratom	Member States, Commission, any other third country	Through MIC risks related to natural and man made disasters and and evenual health consequences resulting thereof are assessed and analysed in close cooperation with DG SANCO and ECDC as necessary. Through the EU Civil Protection Mechanism experts may be dispatched on site of disaster to carry out to carry out risk assessment to establish the exact needs for civil protection interventions and assistance and facilitate coordination and delivery of incoming assistance from the EU Member States. MIC facilitates logistics, distribution of equipment and essential goods. MIC uses several early warning tools including the European Flood Alert System (EFAS) for flood forecasting, the European Forest Fire Information System (EFFIS) for fighting forest fires. MIC receives information from SANCO and ECDC as regards communicable diseases. Medical assistance and protective gear can be part of emergency assistance provided under the civil protection mechanism in case of sudden accute health emergency or CBRN event.	Yes, health threats as a consequence of sudden natural or man made disasters are assessed as part of the EU Civil Protection Mechanism. Health threats assessment is carried out by MIC on the basis of expertise dispatched by Member States under the EU civil protection team.	Close inter-exchange between DG SANCO, ECHO and HSC.	Close inter-exchange between DG SANCO, ECHO and HSC.	Mechanism interventions in third countries, particularly in the developing world, are closely coordinated with and complementary to humanitarian activities of ED ECHO and are usually conducted in close collaboration with other actors, such as the UN Office for the Coordination of Humanitarian Affairs (OCHA), and tif appropriate WHO through DG SANCO.	Fill the gaps: - Enhance communication mechanisms between Civil Protection and Health [Early alerting]; - Preparedness: develop common projects or cooperation between existing projects [e.g. EpiSouth in the Mediterranean region] - Synergise the expertises / capacities available in both areas (SANCO and EU agencies): e.g. communicable diseases and CBRN threat assessment, advice on public health measures, - Cooperation between existing networks, - Joint training, exercises, workshops - reinforce response to public health consequences.
Internal security										
	DG Home's "analytical and crisis manage-ment" capability	HOME	To provide information and assessments, in particular threat and risk assessments, to support policy formulation and implementation, as well as to support crisis management situation awareness and communication needs. Focus on intentional threats to EU internal security	EC, EU Agencies (Frontex, Europol), EU institutions	DG Home's analytical capability focus on strategic analysis, internal security threats. Supporting policy development and implementation in the JHA area as well as to feed in JHA aspects into other policy areas.	Response to crises originated by intentional malicious acts is under the responsability of Member States.	NO	NO	NO	Links between Public Health aspects and law enforcement dimension - intentional CBRN incidents impacting on EU internal security
	Community Customs Risk Manage-ment System (CRMS)	TAXUD	The objective of CRMS is to provide for the rapid, direct and secure exchange of risk information to support targeting of consignments for customs controls, and for the Commission to be able to disseminate information concerning Community-wide threats.	EC,customs offices in MS	Risk information is communicated rapidly and directly to all customs offices to be incorporated into national and local risk profiles; customs administrations will benefit from the use of CRMS because controls can be better focused on higher risk consignments.		indirect links	indirect links	international trade aspects	Information disseminated to or by customs authorities in MS can include public health-related elements. It is thus input to the risk assessment/management process of HSI.
Global Monitoring										

	Global Monitoring for Environment and Security (GMES)	ENTR	The purpose of GMES is to deliver information on environment and security which correspond to identified user needs. GMES provides data to help deal with a range of disparate issues including managing natural resources and biodiversity, monitoring the chemical composition of our atmosphere, climate change, and emergency and security issues. An EU GMES Programme Regulation entered into force in 2011 supporting the initial operations of services (Emergency Management Service in support to crisis management, Land Monitoring service). The development and pre-operations of other services are supported by FP7 projects (Marine service and Atmosphere service dealing with Air Quality for example)	EC, EU Agencies, European Space Agency, MS	GMES federates a wide range of observational networks and data providers, exploiting the most recent observation techniques and technologies, for developing edge-cutting information products to end-users.		NO	NO	YES	GMES provides scientific data for the state of the environment which can support the risk assement process of HSI.
Inter-sector coordination										
Coordination of Preparedness, Alert and Response at Commission corporate level	**ARGUS (Commission crisis coordination system for major or multisectoral crises)**	SG	**ARGUS** is the Commission's corporate general alert system. It includes an information sharing network and a specific coordination process to be activated in case of major multi-sectoral crisis. The system is currently under review. A revised system is expected to be in place in 2012.	European Commission Other actors (European Institutions, Member States, Agencies) are given selected access to information on an ad hoc basis through a dedicated Portal	In the context of the ARGUS review, a new cororate coordination process will be established for cross-hazard threat and risk assessment. This process will build on sector-specific threat and risk assessments processes.	Health threats assessment provided by DG SANCO.	DG SANCO forms part of ARGUS and gives input from the health point of view to the information sharing and coordination process.	DG SANCO forms part of ARGUS and gives input from the health point of view to the information sharing and coordination process.	Cooperation with international frameworks for crisis response takes place through the Commission sector specific structures.	ARGUS will continue to function as the Commission cross-sector crisis response coordination system which brings together sector specific structures.

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II. EU Agencies

	1. Structure in place	2. DG in the lead /	3. Objective of the structure	4. Actors involved	5. Risk Assessment	6. Risk management	7. Health threat assessment carried	8. Link to / input by Public Health	9. link to international frameworks	10. Comments / link to HSI
Communicable Diseases										
	European Centre for Disease Prevention and Control (ECDC)	SANCO	ECDC mission is to help strengthen Europe's defence against infectious diseases. ECDC to enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease; ensure complementary and coherent action in the field of public health by bridging together the tasks and the responsibilities of the Member States, the EU Institutions and the relevant International Organisations. Regulation (EC) 851/2004	European Institutions, Member States, EEA/EFTA countries	Risk assessment, by its own initiative or by request of the Commission or a Member State, on communicable diseases and diseases of unknown origin, The ECDC works in partnership with national health protection bodies to strengthen and develop continent-wide disease surveillance and early warning systems. Through such collaboration the ECDC pools Europe's health knowledge, in order to develop authoritative scientific opinions on risks posed by new and emerging infectious diseases	Carried out by the Commission by taking into account the risk assessment by ECDC.	Yes, continuously.	ECDC is fully integrated into the relevant public health structures in the EU.	The World Health Organization (WHO) is one of ECDC's most important strategic partners. ECDC works closely together also with the EEA/EFTA countries (Norway, Iceland and Liechtenstein), candidate countries (Croatia, the former Yugoslav Republic of Macedonia, Montenegro, and Turkey) and potential candidates (Albania, Bosnia and Herzegovina, Serbia, and Kosovo.	Regulation on the establishment of the ECDC is concerned by the HSI.

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	European Agency for the Management of Operational Cooperation at the External Borders (FRONTEX)	HOME	FRONTEX strengthens border security by ensuring the coordination of Member States' actions in the implementation of Community measures relating to the management of the external borders. Council Regulation 2007/2004	Member State, EEA/EFTA countries, European Institutions	FRONTEX has an ongoing information-gathering system to monitor the day-to-day situation at the EU's external borders and to carry out risk analyses. This information is then used to optimise the allocation of resources.	FRONTEX - coordinates operational cooperation between Member States in the field of management of external borders; - assists Member States in circumstances requiring increased technical and operational assistance at external borders; and - provides Member States with the necessary support in organising joint return operations. - liaises closely with other Community and EU partners responsible for the security of the external borders and cooperation on phyto-sanitary and veterinary controls, in order to promote overall coherency.	No	FRONTEX, through its role in coordination of EU external border management, can help reinforcing public health measures at the external borders of the EU, especially in case infectious diseases outbreaks to occur across external borders;	Frontex had concluded working arrangements with the competent authorities of : Russia, Ukraine, Croatia Moldova, Georgia, the Former Yugoslav Republic of Macedonia, Serbia, Albania, Bosnia and Herzegovina, the United States, Montenegro, Belarus, Turkey, Libya, Morocco, Senegal, Mauritania, Egypt, Brazil, Nigeria, Canada and Cape Verde as well as with the CIS Border Troop Commanders Council and the MARRI Regional Centre in the Western Balkans. Fluent regular contacts and cooperation are established with EUBAM in Moldova and Ukraine, or the EUSR Border Support Team in Georgia, as well as with the BSRBCC in the Baltic, the BSCGF in the Black Sea and others.	Through HSI improve cooperation between public health sector and FRONTEX on assessment and management of cross border health threats that concern external borders of the EU.
Medical products safety										

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	European Medicines Agency (EMA)	SANCO	EMA's main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The safety of medicines is monitored constantly by the Agency through a pharmacovigilance network. All medicinal products for human and animal use derived from biotechnology and other high-technology processes must be approved via the centralised procedure. The same applies to all human medicines intended for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative diseases and for all designated orphan medicines intended for the treatment of rare diseases. Similarly, all veterinary medicines intended for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals have to go through the centralised procedure. Regulation (EC) 726/2004	Member State, EEA/EFTA countries, European Institutions	EMA is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). The Agency also has a role in promoting innovation and research in the pharmaceutical sector. The EMA gives scientific advice and protocol assistance to companies for the development of new medicinal products. It publishes guidelines on quality, safety and efficacy testing requirements.	The EMA takes appropriate actions if adverse drug reaction reports suggest changes to the benefit-risk balance of a medicinal product. For veterinary medicinal products the Agency has the responsibility to establish safe limits for medicinal residues in food of animal origin.	Yes, constantly.	The Agency brings together the scientific resources of over 40 national competent authorities in 30 EU and EEA-EFTA countries in a network of over 4,000 European experts.	It contributes to the European Union's international activities through its work with the European Pharmacopoeia, the World Health Organization, and the ICH and VICH trilateral (EU, Japan and US) conferences on harmonisation, among other international organisations and initiatives.	Reinforce inter exchange between EMA and framework for dealing with health threats at European level as regards technical and scientific advice by EMA.
Food Safety										
	The European Food Safety Authority (EFSA)	SANCO	EFSA's role is to assess and communicate on all risks associated with the food chain. EFSA provides independent scientific advice and clear communication on all matters with a direct or indirect impact on food safety — including animal health and welfare and plant protection. Regulation (EC) 178/2002	European Institutions, Member States, other non-EU countries	As the risk assessor, EFSA provides risk managers (EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety. EFSA also collect and analyse the scientific data, identify the emerging risks and gives scientific support to the Commission, particularly in case of a food crisis. EFSA's scientific opinions and advice are provided by the Scientific Committee (SC) and nine scientific panels, each competent in a specific area of risk assessment.	Carried out by the Commission, DG SANCO, by taking into account risk assessment by EFSA.	Yes, EFSA provides appropriate, consistent, accurate and timely communications on food safety issues to all stakeholders and the public at large, based on the Authority's risk assessments and scientific expertise.	EFSA works closely together with EU Institutions, specifically with risk managers in the European Commission, the European Parliament and the Member States. EFSA also works with national food safety authorities responsible for risk assessment through the Advisory Forum network.	EFSA has links with international organisations such as WHO and FAO, scientific experts, stakeholders and the media were interviewed.	EFSA's expertise in food safety will remain to be a key compo-nent of prepared-ness and response to health threats originating or related to the food chain.

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Chemical Treats										
	European Chemicals Agency (ECHA)	ENTR	ECHA's mission is to contribute to consistency in chemicals management across the EU and to provide technical and scientific advice, guidance and information on chemicals. Regulation (EC) 1907/2006	**ind**ustry,Member States, European Parliament, European Commission,	Under REACH, industry is responsible for risk assessment of every registered substance in the first place. ECHA is responsible for implementing a number of the provisions introduced by the REACH and CLP Regulations. ECHA manages the registration and evaluation processes and provides significant input into the authorisation, restriction and classification & labelling processes for chemical substances to ensure consistency across the European Union. It provides via its Committees for Risk Assessment and Socio-Economic Analysis expert opinions to the European Commission in the authorisation and restriction procedures, as well as regarding harmonised classification and labelling of particularly hazardous chemical substances. The Member State Committee in ECHA identifies substances of very high concern and makes recommendations to the Commission concerning the inclusion of such substances into Annex XIV of REACH (which makes them subject to authorisation).	Industry is responsible for identifying and applying risk management measures under REACH. ECHA can take directly certain risk management measures (e.g. identification of substances of very high concern) and provides significant input for risk management measures to be taken by the European Commission (e.g. on classification & labelling, restrictions and authorisations).	Industry has the primary role. ECHA conducts assessments of the hazards and risks posed by chemicals in particular during evaluation, restriction, authorisation and classification&labelling of chemicals.	ECHA provides expertise on the assessment of chemicals. It works closely with the Member States competent authoritities, European Commission and other stakeholders.	ECHA has the specific mandate to contribute to the role of the EU and the Member States through its cooperation with organisations having interests in the harmonisation of international regulations (e.g. OECD)	more extended use of ECHA expertise for rapid response to chemical threats. / ECHA expertise on assessment of chemicals is essential for preparedness and response to chemical threats and events.
Workplace Health										
	European Agency for Safety and Health at Work (EU-OSHA)	EMPL	The mandate of EU-OSHA is to contribute to improvements in the working environment, as regards the protection of the safety and health of workers, and to provide for this purpose the Community bodies, the Member States, the social partners and those involved in the field with the technical, scientific and economic information of use in the field of safety and health at work. Council Regulation (EC) 2062/94	European Institutions and Agencies, Member States	EU-OSHA acts as a catalyst for developing, analysing and disseminating information that improves occupational safety and health in Europe. The Agency has developed a risk assessment tools database with tools from all over Europe.	Carried out by by the Commission by taking into account risk assessment and risk analysis by EU-OSHA.	EU-OSHA pursues initiatives on health threats assessment at the workplace.	The Agency cooperates with a wide range of partners in the health community, including the European Commission, other European institutions, national authorities and agencies and the social partners.	The EU-OSHA also cooperates with international organisations and safety and health organisations worldwide.	The HSI would lead to EU-OSHA expertise and networks on occupational health be integrated more closely in prepared-ness and response to health threats of cross border nature.
Drugs treats										

	1. Structure in place	2. DG in the lead /	3. Objective of the structure	4. Actors involved	5. Risk Assessment	6. Risk management	7. Health threat assessment carried	8. Link to / input by Public Health	9. link to international frameworks	10. Comments / link to HSI
	European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	JUST	The EMCDDA's mandate is to provide the Community and its Member States with factual, objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences. Regulation (EC) 1920/2006	European Institutions and Agencies, Member States	The role of EMCDDA is to gather, analyse and disseminate 'objective, reliable and comparable information' on drugs and drug addiction and, in so doing, provide its audiences with a sound and evidence-based picture of the drug phenomenon at European level.	Although it does not propose policy, the agency has an impact on decision-making through the analyses, standards and tools it provides.	No specific health threats assessment carried out, although the Centre is responsible for an Early Warning System for the detection and risk assessment of new psychoactive substances. The Centre obtains information primarily from a group of focal points in each of the 27 EU Member States, Norway, and the candidate countries to the EU. The Annual report on the state of the drugs problem in the European Union offers a yearly overview of the latest European drug situation and trends.	The national focal points collect from different sectors – health, justice, law enforcement – in cooperation with experts and national organisations active in the field of drugs policy, all relevant information on drugs and drug addiction, as well as on policies and solutions applied. In particular, they shall provide data for the five epidemiological indicators specified by the Centre.	The EMCDDA works with partners in other world regions to exchange information and expertise.	The HSI would lead to EMCDDA information on drugs and drug addiction in Europe be used more extensively as background information on infectious disease in related to a specific group in society.
Criminal treats										
	European Police Office (EUROPOL)	HOME	EUROPOL is the European Union law enforcement agency that handles the exchange and analysis of criminal intelligence. Its mission is to improve the effectiveness and cooperation between EU law enforcement authorities in preventing and combating serious international crime and terrorism. Europol supports law enforcement activities of EU Member States in areas such as: illicit drug trafficking, terrorism, illegal immigrant smuggling, trafficking in human beings and child sexual exploitation, counterfeiting and product piracy, money-laundering, orgery of money and other means of payment. Council Decision 2009/371/JHA	Member State, other countries, European Institutions and agencies.	Europol supports Member States by: - Facilitating the exchange of information and criminal intelligence between EU law enforcement authorities and the Secure Information Exchange Network Application (SIENA), - Providing operational analysis in support of Member States' operations, - Generating strategic reports (e.g. threat assessments) and crime analysis on the basis of information and intelligence supplied by Member States, - generated by Europol or gathered from other sources, - Providing expertise and technical support for investigations and operations carried out within the EU, under the supervision and legal responsibility of the Member States concerned.	Europol helps coordinating sector specific risk management in the law enforcement field across the EU.	No	Information exchange, through RAS BICHAT, between Europol, the EU Health Security Committee and the Health Threats Unit of the European Commission on health threats for the European Population related to real or potential criminal or terrorist activities.	Operational and strategic agreements with Non-EU States (Australia, Russia, Ukraine, Croatia, the Former Yugoslav Republic of Macedonia (FYROM), Albania, Bosnia and Herzegovina, the United States, Norway, Republic of Serbia, Turkey, Colombia, Iceland, Switzerland, Canada) and International organizations.	Information by EUROPOL is valuable for the health sector to prepare and respond to health threats. / Expertise and input by networks on criminal intelligence would need to be reinforced in order to provide information on early alerting on criminal or terrorist activities with the view for the health sector to be better prepared to such threats.

	1. Structure in place	2. DG in the lead /	3. Objective of the structure	4. Actors involved	5. Risk Assessment	6. Risk management	7. Health threat assessment carried	8. Link to / input by Public Health	9. link to international frameworks	10. Comments / link to HSI
	European Defense Agency (EDA)		EDA's mission is to support the Council and the Member States in their effort to improve the European Union's defence capabilities for the Common Security and Defence Policy (CSDP). Council Joint Action 2004/551/CFSP	Member State, other countries, European Institutions and agencies.		enhance the effectiveness of European Defence Research and Technology, which includes the promotion of R&T collaboration; promote and enhance European Armaments Cooperation through establishing programmes, quicker and more effective; strengthen the Defence Technological and Industrial Base and create an internationally competitive European Defence Equipment Market.				Information by EDA is valuable for the health sector to prepare and respond to health threats. / Expertise and input by EDA networks would need to be reinforced in order to provide information useful for the health sector to be better prepared.
	European Environment Agency (EEA)		The European Environment Agency aims to help the Community and member countries make informed decisions about improving the environment, integrating environmental considerations into economic policies and moving towards sustainability and to coordinate the European environment information and observation network. Regulation (EC) No 401/2009	European Union institutions and Member countries business community, academia, non-governmental organisations and other parts of civil society	The core objective of the EEA is to produce European, pan-European and regional integrated environmental data and indicator sets, assessments and thematic analyses in order to provide a sound decision basis for environmental policies in the EU and Member countries and for cooperation with candidate and potential candidate countries and those covered by the European Neighbourhood Policy.					strengthen inter exchange with EEA on health threats related to environmental risks.