

Interim document: technical guidance on generic preparedness planning for public health emergencies

Introduction

The anthrax attacks in the US in September and October 2001, forced countries all over the world to review, adapt and impose plans for large-scale health emergencies. Such plans were often geared towards managing the consequences of events linked to a particular disease or agents that threatened health. A lot of effort went subsequently into improving plans to face up to deliberate releases of CBRN agents that were thought to be likely candidates for terrorist acts. With the advent of SARS, there came the realisation of the possibility of new, previously unknown agents causing many casualties and huge economic losses. Moreover, the spectre of a pandemic from influenza is a permanent cause of concern for health authorities all over the world. The implications for the organisation of defences and for preparing for this vast array of threats are enormous. It was soon realised that the same personnel and assets would have to be mobilised and deal with the various emergencies. Hence the need to have an overall health emergency preparedness plan with as much streamlined and harmonised components as is possible, in order to cope with various kinds of emergencies both from the spread of regularly appearing agents as well as from the emergence of unknown agents.

Recognising these challenges, the Council, during its meetings of 6 May 2003 and 2 June 2003, requested the Commission to consider “developing a general preparedness plan on communicable diseases and health threats”.

The scope and objectives of generic preparedness planning

Most or all Member States have “emergency” or “contingency” or “crisis” management plans, which can be of general applicability or address specific situations or threats, such as natural disasters or industrial accidents or other man-made events. A general emergency management plan comprises a range of activities to protect communities, property and the environment, and is usually based on a ‘comprehensive’ approach, an ‘all hazards’ approach, a ‘multi-sectoral and inter-sectoral’ (or ‘all agencies’ or ‘integrated’) approach that encompasses all elements that are relevant in ensuring that Member States have a ‘prepared community’. Preparedness planning for health emergencies forms an essential and major component of such general emergency management plans.

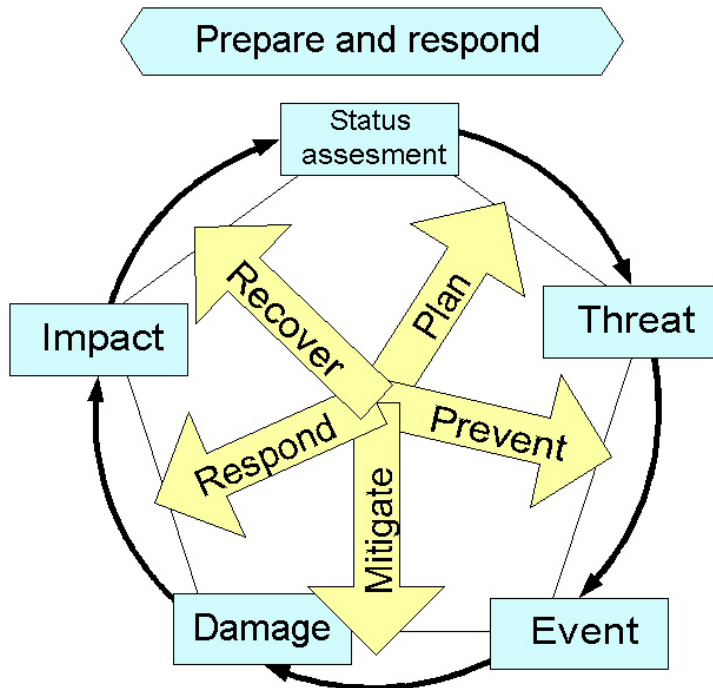
Planning may help to reduce the burden associated with the health threat in terms of mortality and morbidity, hospitalisations and demand for healthcare goods and services, maintain essential services, minimise economic and social disturbance and enable a quick return to normal conditions. Member States have, to various degrees, developed capacities towards planning and response to health threats that require a rapid response.

The proposed “generic” planning should not be confused with planning for outbreak response: the populations potentially exposed may be so large or heterogeneous, the disease may be extremely contagious and/or carrying high severe morbidity or mortality, or the potential response requires co-ordination of so many partners, that the usual outbreak response measures or existing disease-specific plans are insufficient to identify the source or to prevent further spread in order to control the outbreak or to mitigate its consequences.

General preparedness planning at EU level deals with threats and emergencies of EU concern, that is with events, incidents, situations and circumstances which are threatening or are likely to threaten public health in more than one Member State.

The overall goal of EU action in general public health preparedness planning is to assist Member States in developing their plans and factoring in them the EU dimension with its body

of laws in various sectors that impinge on emergency plans. The strategy developed in this document should provide the backbone for developing core elements addressing generically different types of health threats, whether anticipated (such as pandemic influenza) or unexpected (e.g. a SARS –type epidemic), whether they are associated with biological, chemical, physical or radionuclear agents, or linked to deliberate, accidental or natural events or acts and should lead to the establishment and improvements of the inter-operability of national plans, mainly by the creation of co-ordination mechanisms and analysis and communication tools that enhance co-operation between key Member States' and Commission players.



The focus of action under this strategy is on conducting comparisons, drawing up checklists, provide a mechanism for undertaking reviews, validations and tests and making recommendations for improvements and fine-tuning of national plans and EU procedures to reduce vulnerabilities and incompatibilities. These actions should lead to measures and recommendations and a co-ordination / communication system EU-wide with agreed procedures and mechanisms. The basis to identify shortcomings, vulnerabilities and incompatibilities is the recent experience with preparedness plans and measures dealing with smallpox, influenza and SARS. In this connection, the role of each player (EC and Member States) needs to be stated in advance.

The objectives of generic preparedness plans at EU level are:

- Highlighting the minimal Public Health attention points each Member State plan should consider.
- Identifying the attention points for the European Commission and Agencies, organisation and procedures in support to the Member States plans.
- Raising mutual awareness, comparisons and follow-up of the Member States plans.
- Providing a blueprint for developing core elements to the different types of health threats and checklists of good preparedness practice.
- Identifying the EU dimension with its body of laws in various sectors that impinge on emergency plans and making the inter-operability of national plans possible.
- Clarifying the needs and objectives of planning and co-ordinated approaches in public health: human health emergencies are primarily dominated by events related to diseases transmitted from to humans from other humans, food or other products or plants or animals or by caused by biological, chemical or physical agents directly. This

planning will have to take into account existing scientific and legal mechanisms for food, product, and plant and animals health as well as those concerning releases of agents to the environment.

The methods and tools of generic preparedness planning at EU level

Experience has shown that the ability to respond to an international threat to health is profoundly influenced by the extent to which the issues have been considered in advance and plans are in place for co-ordinated action. This document addresses the planning required in order that the European Community is prepared to detect and respond effectively to a health threat. Existence of regularly updated national preparedness plans in the Member States is a pre-requisite for responding adequately to threats at Community level.

A preparedness plan would be comprised of components that address fundamental issues in organising resources to act in a coordinated, effective and cost-efficient manner to deal with an emergency. For each key issue, there would be a series of attention points that have to be looked carefully in advance and appropriate arrangements made to deliver the intended response. To this end, the drawing up and use of a preparedness checklist outlining the essential minimum aspects of preparedness for Member States, Commission and Community Agencies concerned by the protection of health would be of significant value. Such a checklist is not intended to substitute for preparedness plans, but, rather, to serve as a guide that may be used to assist in the development, revision or assessment of comprehensiveness of preparedness plans.

For each key topic of preparedness planning, there are three concerns that have to be addressed:

- the "Outcome expected", which is what the plan should have achieved, once all elements have come into place;
- the respective roles of Member States, the European Commission and Agencies in this outcome: who should do what in which response activity;
- the degree of interdependence and added value of co-operation and EU or international binding commitments

The framework for cooperation in general preparedness planning contains three main activities: First, sharing national plans and making comparisons, evaluations and improvements on the basis of the key issues and checklists outlined above; second, identifying the contribution and role of Community legislation and arrangements so that plans take them fully into account and examining the need for further measures, and third, making appropriate arrangements and algorithms for sequence of events and actions to make interoperability and congruence of plans and responses possible.

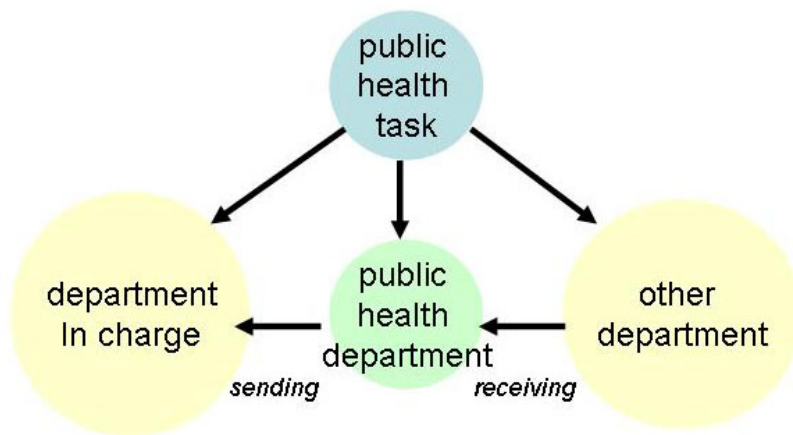
Preparedness planning is not a quick process: it would be unrealistic to consider that it is possible to have a detailed, comprehensive and reliable general health emergency plan in weeks, or even months. Two of the reasons these plans take time is that there is a need for a multi-sectoral approach, with the public health players present or their role precisely defined in each policy, legislation or plan. Finally, there is a need to involve the community at large.

Multisectoral approach means involvement of many levels of government and people with different areas of skill, including policy development, legislative review and drafting, animal health, human population health, patient care, laboratory diagnosis, laboratory test development, communication expertise and disaster management. Community involvement means that one is making optimal use of local knowledge, expertise, resources and networks. It is the only way to enlarge commitment for policy decision.

Generic preparedness planning at EU-level may assist the development of national plans by providing guidance on the key issues in emergency and response the national plans and helps identifying the EU-dimension in these plans for each player. In parallel, the EU elements in such plans and the existing EC legislation (in all relevant fields, such as coordination and

consultation provisions in health, food safety, veterinary legislation etc) determine what needs to be done at EU level in case of a major health emergency.

With the focus on the public health functions, this planning document addresses the key issues in emergency planning, namely: information management, communication, scientific advice, liaison and control structures, preparedness beyond the health area, health sector preparedness, co-ordination of actions between Services with available assets and resources and management of plans. Each of these key issues is presented as a separate chapter. In each chapter, the key public health functions are further developed, with the understanding that depending on the internal organisation in every Member State, these functions could be the responsibility of different departments..



Guidance on principles and choice on tools and processes in each area are developed in the chapters that follow.

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1 Information Management

Information management concerns the gathering, handling, use and dissemination of information related to an emergency: pre and post-event surveillance, risk analysis, clinical, laboratory and environmental analysis of samples, monitoring side-effects and archiving. All the relevant information converges into a single setting (see HEOF, 4.4).

1.1 Pre-event surveillance

Outcome expected

Early identification of potential public health events or emergencies of international concern, that may lead to major public crisis requires pre-event surveillance tools and mechanism to decide that the event deserves the full attention of all actors. This entails the principles of collection, collation, analysis, interpretation of data and dissemination to those who need the information for action.

The Commission provides an exchange platform for methods and tools and the Member States decides on implementation. Public health has the lead role in early identification of potential public health events or emergencies of international concern, that may lead to major public crisis. Furthermore it needs to be recognised that the first indications of an upcoming event might come from outside the public health sector such as media, veterinarians, law enforcement and security services and others. An extensive network for screening, verifying and sharing of information is needed.

MS, Commission and Agencies

Checklist on pre-event surveillance for incidents with public health consequences:

- Are the following minimal requirements fulfilled?
 - System for early recognition by clinicians and organisations;
 - Evaluation screening and verification of threats to public health;
 - Collation, survey, analysis, evaluation and reporting medical intelligence and disease surveillance data, which integrate the detection capability for “suspicious” events;
 - System for “rumour clearing” to assess and verify events potentially constituting public health threats
 - System for timely reporting to the proper authorities;
 - Access to high quality laboratory facilities to confirm or exclude the diagnosis;
 - Guidelines for investigation and case reporting and investigation, including criteria both on diseases recognised as potential bio terror agents and others;
 - Access to epidemiological expertise for collation and interpretation of reports, and initiation of further investigations;
 - Integration between and with the national public health structures to ensure that reports initiate appropriate and timely response action;
- Who are the competent authorities / structures?
- Are Public health issues integrated in case of an incident? Basis of integration? Flow chart?
- Is it implemented and assessed?
- Do operational links exist and are used with authorities and structures competent for epidemiological surveillance?
- Do operational links exist and are used with animal – plant – food authorities and services?
- Do operational links exist and are used with WHO – other international public health organisations?
- Are operational links required with law enforcement structures and authorities? As of when will intervention be mandatory?

Interoperability

Intra-Community exchange of information requiring:

- Operational links with EU and the Decision 2119/98 authorities and structures competent for epidemiological surveillance (as defined by article 1 of the Decision)
- Operational links with WHO – other international required organisations: implementation of IHR.
- Operational links with EU mechanisms on animal health – plant, food, civil protection, radiological issues, law enforcement - EUROPOL.

- Operational links with ECDC (risk assessment)
 - Establishment of procedures for collaboration with a wide selection of actors in the CBRN fields
 - An EU surveillance programme for health threats in ECDC requires the development of a systems that allows:
 - evaluation screening and verification of threats to public health
 - collation, survey, analysis, evaluation and reporting medical intelligence and disease surveillance data, which integrate the detection capability for “suspicious” events
 - ensuring collaboration at an EU level with support to individual Member State
- ECDC develops an activation mechanism, communication lines and logistics.

1.2 Risk analysis using Medical Intelligence and Media Reporting and other information sources

Outcome expected

A strong instrument of risk analysis exists connecting information and surveillance resources in EU and complementing them with resources at EU level. This instrument is a fundamental resource in the development of common perceptions of the threat.

Tools are available to assess and verify unconfirmed rumours of outbreaks / public health threats.

A ‘Medical Intelligence Tool’ examines several times a day a list of articles of interest, selected on the basis of keywords, in several languages, and of worldwide scope. Beside this electronic Web monitoring tool, it associates analytical features as well as an instrument for a rapid identification of diseases outbreaks, public health crisis and possible health threats.

An enhanced analysis of existing surveillance data through existing surveillance schemes (Dedicated Surveillance Networking) identifies temporal and geographical changes in epidemic level of known diseases with epidemic / pandemic potential. Thereto, the ongoing systematic collection, collation, analysis and interpretation of data, results in improved standardisation, timeliness and completeness of reported data. The system provides detailed description of clusters of cases by time, place and person.

Each event detected will be evaluated for its threat potential according to the same criteria and commonly EU pre-defined categories.

Each step of the evaluation leads to a simple scoring, which aims to be realised by each staff on duty. This evaluation process leads eventually to triggering an action mechanism (Annex 4: The triggering system).

To what extent this system will exist in each Member State will depend on resources available and the perceived level of threat. A system to connect all resources in this area in EU and complement them with resources at EU level would provide a strong instrument of risk analysis. This would be a fundamental resource in the development of common perceptions of the threat formed by international event to the Member States in EU.

MS, Commission and Agencies

Checklist on Risk analysis using Intelligence and media reporting and other information sources: are the following minimal requirements in place?

- Contact with intelligence agency
- Threat assessment principles are agreed
- An inventory of resources for risk-analysis and a structure to coordinate their activities
- Resources for a timely development of a national risk analysis
- Collaboration with other national and international partners for needed information and analysis

Interoperability

Intra-Community activity leading to:

- Establishment of procedures for collaboration with a wide selection of actors in the risk analysis field
- Threat assessment principles are agreed and best practice is shared
- The Commission and technical expertise in the ECDC further develop the current tools available.
- ECDC develops structures for risk-analysis at EU level and develops capacities to strengthen national systems when requested.
- Operational links with WHO – other international required organisations: implementation of IHR.

1.3 Post-event surveillance

Outcome expected

Once an event is identified the surveillance will have to become more focused and change its priorities.

A rapid and effective system characterising the causal agent isolated from patients is in place. A reliable risk assessment will have to be made as to its potential to cause widespread outbreaks in humans. Key elements are good coverage of diagnosis for suspicious cases among humans but also reliable surveillance from other relevant sources (veterinary environment etc).

The information flow, integration of lab reporting and specific surveillance activities is established. Data are collated in one location and presented in a way that can easily be understood by the general public and the policy decision-makers.

The Member States activities at this stage co-ordinate closely at EU level with defined procedures for information exchange, co-ordination of countermeasures, evaluation of pooled data and others. Common standards for surveillance in different areas (human, veterinarian etc) are established including case-definitions.

MS, Commission and Agencies

Checklist on Post-event surveillance: are the following minimal requirements in place?

- Established links with surveillance in other-than-human areas (animal, environment).
- For CBRN-events, contacts with agency and military allowing fast and adequate dispersal assessment
- Procedures for a quick start of active surveillance and the establishment of the criteria for such as needed
- Clinical surveillance of human cases including age-specific morbidity and mortality, and rates of hospitalisation
- Epidemiological surveillance including field investigation capacity and contact-tracing
- The impact of vaccination or prevention programmes is assessed regularly.

Interoperability

Intra-Community activity leading to:

- Establishment of procedures for collaboration with a wide selection of actors in the CBRN fields
 - Procedures for dispersal assessment are shared
- An EU post event surveillance programme in ECDC with ESCON, requires the development of a systems that allows:
 - quick establishment of EU wide surveillance activities in a common format
 - evaluation screening and verification of information
 - collation, survey, analysis, evaluation and reporting medical intelligence and disease surveillance data
 - ensuring collaboration at an EU level with support to individual Member State
 - responding to established procedures and relying on necessary equipment for limiting harm and treating victims
- ECDC develops an activation mechanism, communication lines and logistics.

1.4 Clinical and laboratory diagnosis

Outcome expected

It is essential for every public health threat to achieve fast confirmation of the agent involved. Every plan addresses the identification of unknown agent, confirmation of known agents, and provides surge capacity for a Member State facing a laboratory burden.

In laboratory domain the plans consider those needs both for clinical and environmental sampling with a co-ordination mechanism between the actors if more than one is involved. In the following these dual activities (analysing clinical and environmental samples) ought to always be considered.

For the laboratory work, a structure includes procedures for laboratory reporting, confirming issues (second lab, second country), and quality assurance issues. For the clinical part, clinicians can identify the syndrome and a system supplies them quickly with the adequate guidelines.

For the unknown agents an international system for the quick agreement on laboratory procedures and collating clinical data has been proven to be essential. For known agents of high threat potential a secondary confirmation on an international level would improve the trust in the diagnosis made. For a massive surge of samples in only one country support of networking national and international laboratories will be essential. These networks also by necessity need to have common quality assurance schemes.

Laboratory support is available at Member State level, and for issues beyond the national capacity or when the national capacity is not available, a co-operation between labs within the Community is organised to optimise the use of the pooled EU resources.

MS, Commission and Agencies

Checklist on clinical and laboratory diagnosis: are the following minimal requirements in place?

- Established structures to communicate with laboratories and clinicians and assure that laboratories report diagnosed cases to their authorities.
- Procedures for a quick identification of unknown pathogens during an event in clinical and environmental samples
 - Clinical syndrome description: further examinations such as the search for pathogens and antibodies in body fluids (e.g. blood, serum, plasma, liquor, stool, lavage fluids, material from biopsies, or urine) are agreed.
 - Member States have to assure that pathogens will be handled in an adequate bio-safety-level laboratory. The bio-safety level ought to be agreed and is the same for all Member States.
- Procedures for a quick confirmation of known pathogens during an event in clinical and environmental samples
 - Member States identify and appoint reference laboratory(ies) for this pathogen. For high threat and very high threat pathogens, patient material or the isolated pathogen is sent to the reference laboratory, in order to determine the genotype and to establish proper storage of the viable isolated strain (strain collection).
- Member States have established procedures for addressing surge capacity and requirements to face important rise in demand if an epidemic is caused by a rare or by an unknown pathogen, knowing that capacities of local or even national laboratories are overwhelmed by patient samples.
- Possibilities to quickly establish and distribute guidelines for diagnosis of cases and isolation of pathogens during an event among laboratories and clinicians.
- International agreement for agents where national capacity is lacking and for the secondary confirmation of high threat pathogens.

Interoperability

Intra-Community activity leading to:

- An EU programme in ECDC with ESCON that provides a structure for the quick establishment of EU common procedures for diagnosis and confirmation of diseases and isolation of agents during an event
 - Sample taking procedures: depending on the observed syndrome, clinical and laboratory experts to advice on sampling issues

- The *bio-safety* level ought to be agreed and is the same for all Member States
- Reference laboratories for pathogens listed, and establishes links with WHO, with a view towards genotyping and proper storage of the viable isolated strain (strain collection)
- Confirmation issues: in the case of a positive laboratory diagnosis of a very high threat pathogen and where a deliberate release can not be excluded, the confirmation of the positive laboratory result is sensitive. It should be done in an independent procedure, agreed upon at Community level, including isolation of the pathogen at the reference laboratory.
- The Commission assists in setting up bilateral or multilateral agreements to assure state of the art confirmation of results and provides information and communication platforms
- Procedures to establish agreement on different aspects of laboratory assistance
- ECDC develops an activation mechanism, communication lines and logistics, support to the Commission in setting up bi- and multilateral agreements if so desired by Member States, developing and supporting training and surge capacity for laboratory burden
- Organised platforms for information collection and exchange
- An EU programme (in ECDC with ESCON) that provides a structure for the quick establishment of EU common procedures for quality assurance in order to assure high sensitivity and specificity of these usually not commercially available diagnostic devices
- An EU programme (in ECDC with ESCON) that provides a structure for the quick set up of investigation teams, in the case of request for on-site support, to assure epidemiological support for collection, collation, analysis of data during an event

1.5 Environmental sampling

Outcome expected

National plans and procedures to obtain environmental samples are in place in each Member State. These plans include protection measures for public and the investigating personnel, actors and defined roles, a list of the necessary minimum equipment and protocols for sending and analysing environmental samples in laboratories.

A Working Group installed by the Commission assists the Member States to harmonise the procedures and protocols for environmental sampling. Environmental samples collected for the purpose of determining contaminants ought to be adequately packaged, labelled, marked, and shipped according to applicable Member States and international regulations.

MS, Commission and Agencies

Checklist on environmental sampling: are the following minimal requirements in place?

- sampling strategy
 - goal of a sampling strategy is defined with regards to the objective of the investigation, including sampling method and number of samples
 - access to building plans, managers and technicians (e.g.; fans, filters, ductwork, air-conditioning systems, etc.
 - define risk limits
 - define geographical dispersion areas and mobile goods in this area to be sampled
 - define percentage of negative controls “field blanks” among the total number of samples and how to obtain these.
- Bulk Sampling: (bulk samples can help investigators characterize the presence of contamination on building materials such as carpeting, dust cakes on air filters, settled dust (e.g., rafter dusts), and office equipment. However, because extracting spores from bulk samples can pose exposure concerns for laboratory personnel, appropriate precautions (such as double-bagging of samples) ought to be taken to prevent secondary spreading of spores from contaminated bulk samples.)
 - Define detection limits
 - Define procedures to obtain bulk samples
- Surface Sampling with wipes or swabs (surface samples are collected by wiping or swabbing a moistened, absorptive medium across a nonporous surface)
 - Define media to be compatible with the laboratory’s analytical procedures
- Surface Samples collected by High-Efficiency Particulate Air (HEPA) Vacuuming (collecting samples by vacuuming offers the advantages of covering large or dusty, non-porous surfaces and porous surfaces such as carpeting, ceiling tiles, ventilation systems filters, and cloth seats)
 - Define methods for different surfaces and materials
- Air Samples

- Define procedures for collection of different contaminants

Interoperability

Intra-Community activity leading to: agreed standards on adequate sampling and subsequent decontamination procedures between public health authorities

1.6 Monitoring side-effects of actions to counter the health threat

Outcome expected

A legal framework allows the data collection in real-time. Depending on the stage of alert, depending on the medicinal products used to counter the health threat, the institutions that could provide adverse event information might be different in a number of Member States.

A system to monitor the side effects is put in place, with development of a shared database (input) and aggregated data for output, definitions (case-definitions, selection criteria, inoculation procedures, vaccines, list of contra-indications), identified variables and contact points, recommendations on potential treatment.

MS, Commission and Agencies

Checklist on adverse event monitoring: are the following minimal requirements in place?

- National plans include the set up or extension of systems to provide adverse event monitoring

Interoperability

- An EU adverse event monitoring in ECDC with ESCON is put in place in collaboration with the Member States competent authorities

1.7 Filing, documentation and archiving management

Outcome expected

During the course of an outbreak, information will evolve very fast and track keeping of response provided can become a major question. Legal questions could become apparent only after recovery, requiring adequate record keeping practices during the event. Plans describe the arrangements to ensure that relevant information is recorded and retained for use in evaluations conducted after the emergency, and for long term health monitoring and follow-up of emergency workers and members of the public who may be affected.

MS, Commission and Agencies

Checklist on filing, documentation and archiving management: are the following minimal requirements in place?

- Daily and systematic recording of incoming data and response
- Local, national, and interregional co-ordination is described

Interoperability

- Co-ordination contacts are known
- After an event, an active evaluation process of the event is done
- Community co-ordination of the existing filing systems is set up and defines the role of each Agency.
- The role of the ECDC is settled in the filing, documentation and archiving management;
- The role of the ECDC is described as central point for Community public health;
- The role of the ECDC is described in the after-event evaluation and follow-up

2 Communication

The distribution of accurate and timely information at all levels is critical in order to minimise unwanted and unforeseen social disruption and economic consequences and to maximise the effective outcome of the response. The information management as identified under the previous chapter, can only be achieved if the distribution of the information is accurate and timely respecting the following communication tasks and systems: reporting system and procedures, rules on information transmission and consultation, data communication, operational communicating and management among players, and risk-communication through media and towards public groups.

2.1 Reporting systems and procedures

Outcome expected

Who reports what to whom, along which hierarchical lines? Clear flow of data input, flow of information and data transfer, and responsibilities of each to collect analyse and report the surveillance and/or control data. SOPs, software and agreements are likely outcomes.

A coordination mechanism including communication is a key element for a general preparedness plan. This tool ought to be the main element for transmitting alerts and more largely to facilitate a regular exchange of information on a secured and available 24H/7days basis.

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Depending on the gravity of the topic addressed, two systems must be considered

- a rapid alert system
- an early warning system

In both cases, the systems must be reliable, flexible, secured and available on a 24H/7days basis. This implies following principles:

- Identification of the authorities / structures / services to report to. Inclusion of public health component in the other systems and vice versa.
- Standard Operating Procedures, including relevant algorithms, must be developed at an early stage and they must be implemented and respected by all the parties involved, with outlines for passing alerting and warning messages from local to national government
- Criteria for notification have to be agreed between parties;
- A stand-by duty officer system must be implemented;
- A bi-directional (dual) communication channel is a requisite (this would avoid any loss of information) and must involve competent authorities and 24H operational contact points;
 - Role of each: the competent authority is a high-ranked official in Ministries or Institute in charge with the power to take and implement decisions; the 24h/7d operational contact point, forwards all alerts to the competent authority
 - Apply the same principle to the specialised Commission services, acting as competent authority and the Security Office (or the upcoming central entry point ARGUS) in Brussels as the 24h/7d contact point.
- The use of the most advanced communication technologies combining rapidity of exchanges and confidentiality for the data (i.e. functional mailboxes, mobile phones, videoconference facilities, audio conference equipment, SMS, encryption, clearance of network members, PDAs, ...);
- Backup facilities must be envisaged;
- Intervention time should be set depending the target and scope of the network involved;
- The possibility of transmission of very sensitive information must be considered during the development of the system (this refers to the various type of information like unclassified information about events: sensitive information, EU, EU-restricted and EU confidential information)
- The system must show confidentiality, integrity, accountability, availability, sustainability, integrity and reliability in communication protocols (certainty that the messages arrive)
- Adapted notification forms have to be set up, taking into account the complexity of the response needed

Interoperability

Intra-Community reporting and procedures should:

- Communicate the designated competent authority and 24h contact point to the Community Alert and Early Warning mechanisms.
- Communicate the contact points in the Commission services, responsible for the Community Alert and Early Warning mechanisms and the Security Office (and/or the central entry point) in Brussels as the 24h/7d contact point to the Member State.
- Consider involvement of specialised networks on Food, Feed, Phytosanitary, Animal health, Civil Protection, Chemical and Radiological surveillance and responses bodies, law enforcement networks, and other specialised networks, etc.
 - Such networks already exist and link the Commission and the relevant Ministries in Member States, as well as international organisations involved in health protection (WHO¹, Council of Europe, OECD, IAEA, OPCW, FAO, OIE, ...).
 - The obligation for the Commission to set up a network for notifying new occurrences of organisms harmful to plants is in Article 21, point 6 of Council Directive 2000/29/EC. When related to third country imports, further procedures are developed under Commission Directive 94/3/EC.

2.2 *Obligation for information transmission and prior consultation / information on countermeasures*

Outcome expected

An EU structured framework is established to report immediately and to consult on health threats, events and countermeasures of EU and international relevance.

Communication on health threats (alerting) between authorities/structures in public health occurs in a very timely way addressing the proper authorities to make it possible for them to activate preparedness plans. A particular consideration should be given to the role and profile of the “IHR mechanisms”.

Member States inform immediately the event and countermeasures, in liaison with the Commission to the other Member States in order for them and for the EU to take timely adequate countermeasures, to contain spread to other countries. Member States adopt countermeasures, but if e.g. these measures affect persons visiting, the other Member States ought to be advised in advance.

The competent Commission services receive notification of the countermeasures to be taken and ensure the follow up with their stakeholders at Member States-level and other Commission services and their specialised structures. An EU procedure of prior information and consultation fits in the Community Institutions’ legal mandate and limitations in public health (human health). The legal frame is important since countermeasures may distress the good functioning of the Community internal market. Guidelines on levels and scales of threat and common methods and terminology are agreed.

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- Agreement on and implementation of:
 - Guidelines on levels and scales of threat and common methods and terminology.
 - A list of (mandatory notifiable / to be communicated) countermeasures.
 - A procedure on communication and consultation of countermeasures (re: in progress: Commission Decisions on Stand-by Declaration and Countermeasures)
 - Algorithms adapted to each situation
- Procedures to exchange info and co-operate between animal health – food – product – plant and human health protection services.
 - Is human health systematically involved in the relevant procedures?

¹ A particular consideration should be given to the role and profile of the “IHR focal point” which have been identified by all Member States as the national contact point

Interoperability

Transmission and consultation Intra-Community, requires:

- Set up of legal framework with 2 Com Dec, (Proposals for a Commission Decision setting up a consultation and information procedure and co-operation, and for a Commission Decision on a procedure declaring rapidly a Community alert, requiring extraordinary and temporary concerted actions at Community level under the Community Network for epidemiological surveillance and control of CD).
- Set up of arrangements with other Commission competent services to enable decisions on countermeasures that may affect trade, economy, social life,
- The competent Commission services receive notification of the countermeasures to be taken and ensure the follow up with their stakeholders at Member States-level and other relevant Commission services.
- Inclusion of WHO and revised IHR, when appropriate.

2.3 Data communication and management

Outcome expected

Clear flow of data input, flow of information and data transfer, and responsibilities of each to collect analyse and report the surveillance and/or control data from the first notification to the liaise and control structures (see Chapter 4). SOPs, software and agreements are likely outcomes. If required, security must be designed into the core of the system, along multiple lines. Its goal is to prevent, contain, and recover from network attacks. Risk analysis must be launched.

The partners at local, national, EU and international levels are identified and share the relevant information and data.

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Rapidity in the detection, but even more the prompt sharing of alerts/information is essential. Besides the communication tool and procedures one has to ensure the integrity of the information exchanged, validate the content, authenticate the sender, verify the reception of the messages sent. Pre-established notification forms may help in the rapidity of transmission as well as to the clarity of the shared information. The mechanism should integrate a searchable archiving function, as well as foresee for the Commission a role of moderator (validating, modifying, adapting, selecting, adding information, but also closing discussions or cases).

Minimal requirements to fulfil for communication tools and procedures amongst services in Member States, Commission and Agencies:

- Pre-established notification forms (purpose to transmit rapidly clear messages)?
- Establishment of adapted secured communication channels
- Authentication of the sender
- Validation of the content
- Verification of the reception of messages sent
- Security measures to ensure availability of services and data, integrity of data, authentication of nodes and the security maintenance
- Are the requirements fulfilled within the different services competent for the four kind of threats (biological; radio-nuclear; chemical)

Interoperability

Data communication and management of public health threats would require Intra-community at least to:

- Set up a platform to establish and regularly update:
 - Standards for collected epidemiological data and results (currently in development in DSN and BSN),
 - Establishment of adapted secured communication channels
 - Standards in electronic reporting of collected lab data and results,
 - Standards in routing and security of data,
 - The development of common metadata descriptions,

- The integration of information from multiple data sources, preserving linkages between entities, objects and events
- Identify the partners of this platform; the ECDC will be the EU-Public health partner, (Civil Protection, Argus, ...), WHO, IAEA...
- Liaise and control structures

2.4 *Communicating among players*

Outcome expected

Communication procedures among the players provide accurate and timely information at all levels. Public Health plays a pivotal role as the main “provider” of information.

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A good communication among all players in the event of a public health threat will require that:

- a mechanism exists for the timely and consistent distribution of information between national bodies and with regional authorities. Such information would include all available and in particular health information towards all essential services.
- a mechanism for the timely and consistent distribution of information from the regional level to the local level and to individual health care facilities exists, including emergency facilities that may be established in the community to further this information.

Interoperability

A good communication requires Intra-Community:

- Specific websites, with limited access for the health professionals and other groups (decision makers) are established.
- SOP's to analyse and inform the competent structures and authorities in order to guarantee exchange of information between Member States.
- Regularly update among the relevant stakeholders.

2.5 *Risk-communication with media and public groups*

Outcome expected

Crisis-communication and press release content within and between the different Member States are streamlined in core messages.

Public information in emergencies is the deliberate, planned and sustained effort to establish and maintain mutual understanding between those managing the response to the emergency and the community. It means ensuring answers to the questions: what is happening? what should the community do? what might happen?

It is important to involve the news media at the planning stage of emergency preparedness. With good established relationships, the media can provide significant professional assistance during the response phase, rather than become a hindrance or deterrent.

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All plans include a communication strategy that outline towards the media:

- who determines what information should be collected;
- who collects and collates information;
- who selects what information should be communicated;
- who prepares messages;
- who authorises messages;
- who contacts media.

The plans provided regional and local contact lists for media and for other crisis management authorities.

The appointed media relations officer coordinates public information and answers directly to the emergency controller or commander. The information coordinator should:

- identify persons to act as spokespersons on public health issues during an emergency for multiple audiences and formats (spokespersons representing different ethnic groups, media spokespersons, community meetings speakers, etc.)
- maintain lines of authority and responsibilities for the public information team
- establish contacts with key media personnel, understand how they work, brief them on his role, and determine how they can work together;
- liaise with the national Emergency Operations Centre (EOC) and committees;
- briefs with agency director, EOC command, and higher headquarters to update and advise on information intended for release, incident-specific policy, science, and situation;
- develop a timetable for disseminating emergency information, including advertisements for the emergency alerting processes (on radio and television) and symbol;
- present messages as a media package including features, background information and messages, with audio and/or video tapes when possible and appropriate.
- consult with emergency management authorities to identify main issues, priority issues and prepare a profile of the target audience.
- work and relief scheduling for public information team to maintain 24 hour per day operations (2-3 work shifts per day) for at least several days

Additionally, the media information need and direct public information is adequately monitored through:

- Triage of media requests and inquiries
- Response to media requests (e.g., daily press conferences, website updates)
- Production of media advisories, press releases, fact-sheets, b-roll
- Monitoring media through environmental and trend analysis (e.g., clipping service, monitoring news coverage) to determine messages needed, misinformation to be corrected, media concerns, and media interest during crisis
- Assessing the existing telephone capacity to determine the need for additional lines during an emergency
- Response to public who request information directly from the agency by telephone (e.g., hotline), in writing, or by e-mail
- Timeliness and accuracy of public website information
- Public advertising of agency contact information
- Monitoring public through environmental and trend analysis to determine messages needed, misinformation to be corrected, public concerns, and public interest during crisis.

Interoperability

The Member States and Commission agree in advance on the set up of the common information exchange mechanisms and procedures. The Commission proposes a common understanding of the wording, prepares standard texts or key messages (leaflets) about the diseases and how to address them, sets up standard information on vaccination and transport issues, prepares and disseminates information (directed to physicians, general population, etc).

During major crises, phone communication and e-mail systems could easily saturate, requiring development of alternative communication tools, such as dedicated restricted access websites and satellite / HF radio communications. The Commission and Member States set up a specific website with limited access for interfacing with media, citizen as well professionals.

Intra-Community activity leading to *Coordination on risk-communication*

- Analyse the global situation in Europe and inform HSC members on what is going on in the other Member States and their intention as regard the press.
- Transmit to the other Member States the press releases issued by the Member States concerned at first (to the media and the citizen)
- Avoid that Member States spread different information; Avoid divergences of behaviour / approach to the problem between Member States; Insure consistency in the approach to media between Member States
- Come up with some translations of the Questions/Answers published on the web
- Compare web sites contents in all Member States
- Develop contacts with airlines companies in order to get quickly the list of people who are travelling and for adjustment of traffic during crisis
- Coordinates the contacts between communication people in Member States and CEC
- Establish a common standard (common understanding of the wordings)

Intra-Community activity leading to ***Information exchange on risk-communication***, means to:

- Distribute lessons learned in Member States
- Sharing updated information about what happens in the other Member States as well their intentions as regards the press
- Dispatch press releases, briefings, information packages prepared in the other Member States
- Share media scenarios between Member States, Compiling of official press statements in the EU

Intra-Community activity leading to ***common risk-communication tools***

2.6 Political advocacy

Outcome expected

Communication procedures are necessary from the players to their political authorities to provide accurate and timely information. The political authorities know the plan and request information on events through the indicated channels before taking decisions or before answering on political issues related to the event.

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Each plan needs to take at least into account that the political hierarchy:

- Is informed and regularly updated about the plan(s), the role and competence of different players and the contact points.
- Has identified the key members of his or her emergency response team.
- Understands existing systems and processes for dealing with crisis events.
- Uses the channels providing timely and accurate information to decide.

Interoperability

Intra-Community political advocacy means:

- Council and Commission are timely informed of decisions with Community relevance;
- If needed, to accelerate relevant Council meetings for decisions of Community relevance.

3 Scientific advice

In this context, scientific advice is the process of integrating the information through rapid consultation and identifying vulnerability and possible response action through risk assessment, including support to determine corresponding control actions, countermeasures, and to identify the resources to actions and ways to implement actions.

3.1 Rapid consultation (experts, expert bodies) for advise

Outcome expected

A system to locate expertise in Member States and at EU level is in place. This system is made available to the ministries and institutes in the Member States, to provide a tool of designated national expertise, to reinforce the mutual assistance between the Member States and to facilitate a common response of the EU to public health crisis. Arrangements exist for the ad-hoc call of networks, (tele-)conferencing facilities are in place.

Expertise, potential new scientific committees (ex SARS WG) or existing committees can be put in place following existing procedures.

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Checklist on rapid consultation for incidents with public health consequences:

- Are lists available of individual expertise?
- Are lists available of contact points?
- Do reinforced procedures exist for rapid consultation of experts?
- Do these procedures include public health experts?
- Do operational links exist to consult experts in epidemiology, laboratories, animal health, plant health or experts in food safety?

Interoperability

Operational links to exchange or to consult experts Intra Community, requiring:

- Arrangements for consultation of individual expertise for each kind of incident.
 - Lists (Directory, register, inventory) of available national expertise / contact points in case of a nuclear, chemical, toxicological or biological incident.
- Including the Community contact points for requiring expertise consultation or consultation of the relevant lists.
- Definition of the role of the ECDC as a contact point for the public health expertise and its role in the management/ maintenance of the public health expertise list.
- The public health Directory will be based on at least three groups of experts: laboratory; clinical management and epidemiological / outbreak management.
- Operational links with and between the EU structures regrouping expertise bodies in animal health – plant, food, civil protection, radiological issues.
- Operational links with and between the scientific expertise available in the ECDC and the Scientific Committees in the fields of consumer safety, public health and the environment (Decision 2004/210/EC), such as the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The ECDC will provide under its mandate the necessary technical and scientific advice and support.
- Reinforced procedures to rapidly convene structures under the Decision 2119/98 like the surveillance component ESCON or to set up nominated expert groups (ex SARS WG).
- Comitology procedures under Decision 2119/98
- Operational links with WHO – other international required organisations.

Decision 2004/210/EC, Decision 2119/98/EC and the ECDC regulation (EC/851/2004) will be the basis to review the legal implications of the proposed strategy.

3.2 EU Directory of Experts

Outcome expected

A register with the inventory of available expertise is set up (Directory of Experts), with inclusion of similar registries collected by other Commission services. The register will be based on biological and chemical agents. For each biological agent, three groups of experts one for laboratory, one for clinical management and one for epidemiological/outbreak management are identified. For chemical agents, are also needed toxicologists especially with clinical experience in the management of patients exposed to the chemical and environmental experts for the decontamination and rehabilitation process. For some agents, expertise will not be needed in each group. A Member State can also express a need for expertise not already on the list and the list will then be expanded to cater to these needs, as a tool for proactive use by authorities when an event occurs. With this respect the technical possibilities, confidentiality, neutrality as well as the purpose and the content of existing systems, are appraised.

The European Centre for Disease Control (ECDC) manages the list.

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Checklist for the set up and management of an EU Directory of Experts

- Have Member States designated their experts, have experts approved to participate and is a system for consultation and use of expertise in place?
- Do Member States update and forward on a regularly basis?
- Have the necessary logistical steps been undertaken for the participation of experts: travel, reimbursement, passports, insurance?

Interoperability

Operational links for an Intra-Community consultation process and use of expertise, requiring:

- Agreement on the procedures to consult for advice or for participation at an intervention
- Agreement on the procedures and the financial rules to exchange advice or expertise Intra-Community
- Agreement on the procedures and the financial rules to exchange advice or expertise Internationally
- Agreement with WHO on the participation of the EU in international investigation
- Agreement on rules of Conduct
- Agreements to be endorsed by: ESCON, EWRS, HSC
- Inclusion of or reference to existing public health inventories, e.g. IRIDE
- Inclusion of or reference to inventories or registers under different competences: i.e. Community Civil Protection Mechanism, EFSA (*veterinary*)
- Community fund raising mechanism for participation to EU / international intervention (*Solidarity Fund*).

3.3 Forecast modelling

Outcome expected

A co-ordinated EU capability in modelling to help counter spread exists and assists by informing public health policy and planning ahead of time and provides the basis for a real time modelling capability.

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Checklist on forecast modelling for incidents with public health consequences:

- Forecast modelling is foreseen in the planning;
- System ready for obtaining and sharing the data before and during outbreaks;
- Adequate data available for initial dispersion models (airborne release, inanimate vehicles such as foodstuffs, drinks, mail items, etc);
- Expertise on mathematical modelling is identified
- Communication of results to and exchange of data, knowledge and methods with public health structures / authorities are foreseen.

Interoperability

Operational links for an Intra-Community capability on forecast modelling, requiring:

- Platform of mathematical modelling experts including expertise in all threat areas;
- Definition of role of ECDC as contact point for the public health expertise.
- Designation by the Member States, Commission and Agency experts.

- Reinforced procedure for convening meetings and presentation of model outcomes through Community Emergency Operation Facilities

3.4 Vulnerability assessment

Outcome expected

National plans include the capacity to assess vulnerability of the national structures and systems according to common standards pre-agreed on Community level. A Community mechanism to approve the quality of the application of the assessment exists.

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Checklist on vulnerability assessment for incidents with public health consequences:

- Member States indicate their experts and they participate in a system for consultation and use of this expertise. Member States develop the vulnerability assessment process taking into account the different variables, including the security and safety issues.
- Each Member State has included in its national plans the capacity to assess vulnerability of their national structures and systems. Each national assessment is mutually accepted at Community level based on common pre-agreed standards of vulnerability assessment.
- Critical infrastructures such as infrastructures on water supply, food distribution and for aerosolisable pathogens;
- Vulnerability assessment of those identified critical infrastructures;
- Set of minimal standard requirements for vulnerability assessment;
- Process of vulnerability assessment;
- Accreditation system;
- Interlinking between and co-operation with public health structures – authorities and the other structures and services;

Interoperability

Operational links for an Intra-Community capability on vulnerability assessment, requiring:

- Scientific expertise of the Scientific Committees established under Decision 2004/210/EC and the ECDC to propose on critical infrastructures and a set of minimum standards for vulnerability assessment for Member States
- Each national assessment is mutually accepted at Community level based on common pre-agreed standards of vulnerability assessment. A Community mechanism to approve the quality of the application of the assessment exists.
- Co-operation and inclusion of the proposal under the Strategy of Internal aspects of the Fight against Terrorism of the Council / Commission on critical infrastructures, lead by DG JAI. (European Programme for Critical Infrastructure Protection, EPCIP) (Communication on Critical Infrastructure Protection in the fight against terrorism 2004)
- Inclusion or amendment of the relevant legislation of the vulnerability assessment process and the accreditation mechanism.

3.5 Risk assessment and options for countermeasures (control principles)

Outcome expected

A Community mechanism and decision making process to declare an community alert and to select the best option to respond to a potential threat is laid out at EU-level. The system permits the rapid circulation of information among the Member States and the Commission. It can be used during the very first days of an emergency to convene linking of Emergency Operation Facilities, tele-conferences and rapid consultation among Member States and the Commission. A dedicated and protected mailbox or a web site will be appropriate to manage the information sharing during the evolution of the event. Public health (counter)measures for control of diseases will by necessity be different in different countries depending on the health infrastructure where they will be applied, depending on the nature of the event (biological, chemical, environmental, linked to a natural disaster or complex situation, etc.) could include identification and quarantine of contacts; measures to increase social distance; measures to

decrease the interval between onset of symptoms and isolation of ill patients; disinfection; limit travel; entry and exit screening; vector control; etc.

Scientific and epidemiological evidence as well as social, economical and logistical considerations are required to sustain implementation of public health measures. During this step towards risk management, technical and decisional groups meet in order to identify the available management options, compare and weigh various health risks along with economic, political and social factors, potentially using decision criteria, such as cost-benefit studies, cost-effectiveness analysis, risk-benefit analysis or comparative risk analysis.

Information, guidelines and scientific evidence on generic and specific control measures to be envisaged in case of public health emergency are developed.

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Checklist on risk assessment and countermeasures for incidents with public health consequences:

- Decision process for public health countermeasures based on scientific and epidemiological evidence;
 - Including public health structures;
 - Linking social, economical and logistical considerations to sustain implementation of public health measures;
- Legal back-up in other areas than public health for the implementation of countermeasures;
- International commitments of notification and co-operation, including the IHR.

Interoperability

Operational links for an Intra-Community capability to provide scientific evidence for decision takers, requiring:

- Commission Decision(s) establishing information, consultation and co-ordination procedures on measures with a view to co-ordinating the efforts to control and prevent communicable diseases through the Community Network. (Prior information Decision)
- Commission Decision on a procedure to declare rapidly a Community public health alert implying extraordinary and temporary concerted actions at Community level under the Community Network for the epidemiological surveillance and control of communicable diseases (Decision 2119/98/EC) (and under the Pharmaceutical legislation) (Stand-by Declaration)
- Common information, guidelines and scientific evidence on generic and specific control measures to be envisaged in case of public health emergency.
- Meetings under Decision 2119/98/EC (ESCON – EWRS) – Commission Decision EWRS
- Meetings with other decisional structures (Standing Veterinary Committee – HSC)
- Advice of the ECDC – Scientific Committees - EFSA – EMEA – ...
- Community Crisis Centre(s) linked with the relevant scientific structures, linkage with ARGUS, and a Central Crisis Cell within the Commission / Council. (in the meantime linkage with RELEX-crisis centre (?), MIC, ...)
- Link with Member States and Community Health Emergency Operating Centre and role of the ECDC.
- Programme on the Strategy for Internal aspects of the fight against Terrorism (Council – Commission – EU-Counter terrorism co-ordinator)
- CBRN-Programme
- Civil Protection Mechanism (Council Decision 2001/792/EC of 23/10/2001 establishing a Community mechanism to facilitate reinforced co-operation in civil protection assistance interventions)
- Co-operation with WHO through Community Network on communicable Diseases.

3.6 Determine collective protection (of international dimension)

Outcome expected

Common guidelines on generic and specific control measures to apply for embassies, international crew and transport are established. They serve the decisions to be made at different level of authorities as the threat emerges. These decisions will range from population-based recommendations, for example whether to cancel mass gatherings or close schools and public places, to individual measures like recommendation to airline crew or general public.

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Checklist on the use of the guidelines

- Communication and update of guidelines to the appropriate authorities
- Feedback foreseen to central level (Member States – Commission)

Interoperability

- Community Platform to establish common guidelines
- ECDC role in advice
- Linked with relevant Commission services in TREN – EMPL - RELEX and others.
- Linkage with WHO – IHR for fast updating.

3.7 Determine corresponding actions, resources to actions, and ways to implement actions

Outcome expected

Once the control principles are identified (see 3.5), there is value in exchanging information and resources, scientifically and logistically, on the corresponding actions, and ways to implement these. Where needed, the questions towards response are addressed with the authorities such as Civil Protection, Law enforcement, Military, etc. Previously set up and answered by Member States, the Commission fills in the gaps where a Community approach is of an added value. Lists are established of organisations working in the community, with information on their competence and capacity to be involved in emergency response and recovery activities. Lists are established with recovery items not available in the community that would need to be obtained abroad. Information can be obtained quickly on customs and taxation regulations covering the importation and transit of response and recovery (and other) items. Information is available on essential response and recovery resources that will allow a rapid response, e.g. water supply systems, sanitation systems, health networks, alternative shelter sites and materials, ports and transport networks, warehouses, and communications systems.

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Checklist for incidents with public health consequences:

- List of relief (consequence) management authorities and structures;
- List of contact points
- List on mandatory action to undertake stepwise according to the extent of the event (e.g. sample taking requires CP outfit; crime scene requires LE-intervention)
- a), b) and c) (these points above) includes link with public health structures and authorities;

Interoperability

Operational links for an Intra-Community capability to determine actions to respond, requiring:

- Lists of organisations working in the community, with information on their competence and capacity to be involved in emergency response and recovery activities,
- Lists of recovery items not available in the community that would need to be obtained abroad or could be supported by Community initiative
- Information on customs and taxation regulations covering the importation and transit of response and recovery (and other) items;
- Information on essential response and recovery resources that will allow a rapid response, e.g. water supply systems, sanitation systems, health networks, alternative shelter sites and materials, ports and transport networks, warehouses, and communications systems. (protection of Critical Infrastructures EPCIP)
- EUROPOL (Law Enforcement Network, LEN)
- Other response mechanisms: Civil Protection Mechanism, EMEA, DG-Research
- Military
- Programmes on strategies ... (see supra)
- International organisations, including WHO, OIE

4 Liaise and control structures

*A threat that has led the Community mechanism to decide to label it on a severity scale as severe (3) or major (4) health threat, activates a clear liaison and control structure (liaison & control). **This structure can be of variable capacity according to the threat activity level in the EU and the Member States.** Its purpose is to identify the minimal activities that need to be undertaken for a co-ordinated approach and their implementation. A "liaison and control" structure is developed as an adjunct to the command and control structures that will operate in each Member State. The "liaison and control structure" brings into permanent contact the different command and control structures of the Member States through their public health component. In order to be able to make clear and timely decisions at the level of the players and to have a uniform policy that is endorsed by all public health authorities and acceptable on government level, it is essential to know who is in charge of management of the threat and control and who is in charge for sub-elements of the response (like travel advisories, movement restrictions, incident and or outbreak investigations, trade bans, triage operations and enforcement of quarantine, administration of vaccines, etc).*

The appropriate tool to respond to the needs of coordination on risk management has been established within the context of the Community Network for the Surveillance and Control of Communicable Diseases (Decision 2119/98/EC) bringing into permanent communication with one another, through appropriate means, the Commission and the competent public health authorities in each Member State responsible for determining the measures which may be required to protect public health. Depending on the cause and circumstances of the threat, national authorities could identify different persons or authorities in charge of the management of particular aspects (eg. vaccine-related problem, blood-related issue, food-related threat, etc). The person in charge for dealing with the threat is denoted, for the rest of this chapter, as "Health Risk Manager" (HRM). It is essential that national plans outline the role of this person and acknowledge that the HRM has the capacity to adapt the decisions into implementing measures at national level. This HRM is not necessarily the 'decision-maker'. The HRM can be the WHO national focal points or this role can be attributed to the responsible for the warning and alert mechanisms in EU-health.

During the various stages of the event, the 'liaison and control' approach identifies the required co-ordination steps that have to be undertaken.

4.1 Trigger: deciding the response activity

Outcome expected

The procedure exists and structures are capable to acquire and forward in good time the necessary background information for triggering a response activity to a threat.

The information can lead, at Member State and Commission level, to proper decision making, in order to decide on the nature, magnitude and other features of the threat and the required action (Annex 4).

Using a system as described above, threats will be labelled and will trigger a defined level of action as of the scale of (3) (see flowchart). Examples of events allowing the activation of the trigger, provided that the threat level reaches a severity scale of (3) or (4), include a major and escalating community-wide outbreak of an unknown illness, a major chemical, biological, or radiological contamination of a transnational water supply system, a lost source or an accidental release of radiation affecting more than 1 Member State, the next influenza pandemic (although specific plans exist for this issue), a confirmed deliberate or accidental release of a serious biological agent, etc ...

The elements of a mechanism for the response activity (described in the following chapters) are based on risk assessment, risk management and communication, allowing the immediate consideration of all the necessary options for measures within the competence of relevant

services and authorities. This process involves Commission and Member States Departments and is applicable to sectors within and outside the health sector.

This mechanism allows co-ordination with and between the Member States' competent authorities and structures to enable the required activities and resources to contain the threat.

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- Checklist on trigger the response activity: are the following minimal requirements in place?
- Established clear guidelines of the responsibilities of different actors to initiate response activities
 - Procedures for timely agreement on the need to trigger the response

Interoperability

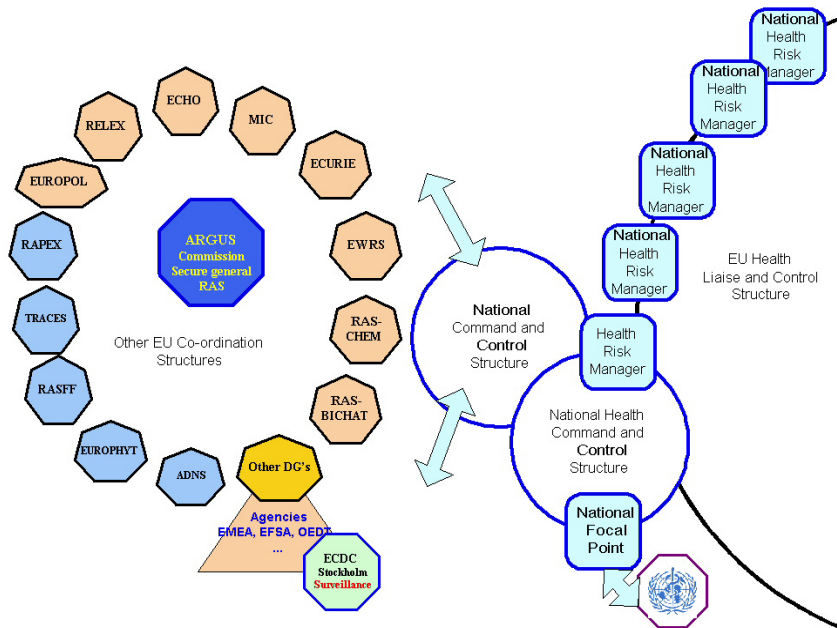
- Intra-Community activity leading to:
- Establishment of procedures for response activity
 - Unequivocal labelling of threat categories across all Member States
 - The responsibilities of ECDC in this field defined as regards activation and alert procedures, communication lines and logistics.

4.2 Liaison: linking responsible Health Risk Managers

Outcome expected

Once the triggering process (**Annex 4: The triggering system**) is completed and when the analysis of information on risks leads the Member States' or Commission's services to consider that the threat can be labelled on severity scale as severe (3) or major (4) (see flowchart), the Commission's services will contact the Member State(s) concerned to examine the situation (and with ECDC), to request information on the threat circumstances and predicted evolution of the situation.

Consequently, the liaison structure will provide a virtual or on-site co-operation capacity in order to collect and share all available relevant information, improving evaluation of the data collected and identify the appropriate risk management options. The main objective of this structure is continuous communication on every aspect of the assessment and management of the threat that is appropriate to the Health Risk Managers, avoiding their over-burdening with irrelevant or even secondary importance information.



MS, Commission and Agencies

- Checklist on the establishment of a command and control structure: Have the following minimal requirements been met to link the health risk managers?

- A command and control structure is in place and operational in each Member State, Commission and Agencies
- Plans integrate the agreed thresholds and the level of alert that lead to national activation of alert levels and introduction of stand-by measures, including the deployment of counter-measures and staff.
- National Plans integrate the Community agreed thresholds and the level of alert that lead to Community activation
- The political authority for the overall command and for individual components of the response are identified (see Political advocacy”)
- If different command and control (levels or) structures exist, what is the service (or person) designated for health risk decision-making in every level or structure?
- The national health risk manager has a defined role in the national emergency response plan and part of a national public health CCS if foreseen.
- The national health risk manager is in charge of the national public health Command and Control Structures.
- In case of EWRS: Is the health risk manager the EWRS designated authority? If not, the health risk manager’s particulars should be communicated to the EWRS to ensure rapid transmission of information in times of crises.
- Minimal requirements for command and control structures are met:
 - the hierarchical structure for each player has been described as well as the decisional role and measures to take of each department
 - the relation between health and other emergency sectors is described
 - the relation between hierarchical sectors is described
 - standard operational procedures for essential functions are described
 - field operations manuals that summarise critical procedures and contact are in place
 - communication with the national and Community Health Emergency Operations Facility (HEOF) are established, tested and are robust without risk of being overwhelmed by dense information traffic or by technical problems (server down-time, electricity grid problems etc)
 - information to facilitate performance of tasks by workers rotating into unfamiliar roles or by volunteers is provided (e.g., handbooks, pocket field guides, task orientation/standard operating procedures manuals, “cheat sheets”)
 - the chain of command for each public health player is clear and known and each receives the information he/she needs for the performance of allotted tasks (and no more) and transmits up the chain of command the information that is expected
 - the access to phone-conference, video-conference or EOC access is known to each public health player
 - the system is scalable to meet the needs of an increasingly or decreasingly resource-intensive response
 - the system is flexible to respond to unanticipated variables –health risk managers at every level have the autonomy required to respond to changing circumstances while informing the higher echelons
 - identification of suitable alternate facilities to ensure continuity of operations in case the agency’s regular facility is inaccessible
 - access to rooms, conference call or video call procedures are known to each public health player

Interoperability

Intra-Community activity leading to practical functioning of the liaison and control structure adequately linking the responsible Health Risk Managers of the involved Member States, Commission departments and Agencies, requires the Commission public health services to:

- Set up, after the evaluation triggers the necessary response or if conditions are considered to an immediate risk for the Community on the basis of the initial assessment of all relevant information available, a virtual or on-site co-operation capacity to collect and share all available relevant information in a way that is understandable and useful to all partners in the Member States, improving evaluation of the data collected and proposing appropriate risk management options.
- Immediately inform the Member States and the ECDC of the actual establishment of this liaison structure.
- Activate the link-up of all command and control structures from the Member State(s), the Commission and the agencies directly concerned (providing the necessary scientific and technical assistance).

- Ensure the provision of a continuous (24/7) function and physical presence of all personnel and experts concerned if the threat activity or the response activity level (see Annex) are raised to a defined level (levels 3-4).
- Examine the feasibility to propose a Commission Decision to set up a liaison and control structure under the Community network on CD for high level public health threats.

4.3 Operation of the liaison structure

Outcome Expected

The operation of the liaison structure has been agreed at Community level and formally endorsed in the plans taking into account the subsidiarity principles. If required, the Health Risk Managers co-operate with competent authorities and services other than human public health, as foreseen in their national plans.

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Operating the liaison structure means at least agreeing:

- Every plan includes the commitment of Community co-operation for the health risk manager or delegate.
- Every plan foresees and communicates to the Commission how to organise the 24/24 hours stand-by in this Community co-operation:
 - Set up of a national or Commission virtual facility (Emergency Operating Facility), to be linked with the Health Emergency Operating Facility (HEOF) at Commission level, currently foreseen in Luxembourg and linked to the ECDC-Stockholm EOF.
 - and
 - Attendance in the Commission HEOF or the ECDC – Stockholm EOF of one expert from each Member State who will act as liaison officer and will ensure that information and consultations are well understood in each language and jurisdiction.
- Every plan includes the principles of the Community co-operation and operation under the Liaison structure.

Interoperability

Intra-Community activity leading to adequate liaison and actions are in relation to

- Setting up a HEOF at Community level and the EOF at the ECDC and linking to existing Member States EOF.
- Organising logistical support to the liaison structure where members are present on a continuous basis throughout the threat activity. At this stage, the responsible managers or delegates are linked continuously with their own command and control structure.
- Description of involvement of the ECDC.
- Description of the principles of co-operation and collaboration with the liaison structure, such as:
 - Consideration about the expertise of other public or private persons necessary for the management of the crisis, including the permanent or ad hoc assistance of these persons or groups. Several expert groups (in previous sections) can be called upon to be associated with the work of the liaison and control structure.
 - Collection of relevant scientific data and all scientific information or other relevant data making it possible to manage the risk in question as effectively as possible.
 - Evaluation of the information available, in particular sharing of the evaluations already performed by the members; in the ECDC; or evaluations otherwise available; or organisation of the evaluation of the risk and use of the technical support of the Dedicated Surveillance Networks or ad hoc working groups.
 - The identification of the options available to prevent, eliminate or reduce to an acceptable level the risk to human health and updating of these options on the basis of the new information available and the development of the situation. In particular: the liaison structure will identify the options available, such as avoiding conflicts in the implementation of different national control strategies.
 - The organisation of the communication to the public on the risks involved and the measures taken will be organised in close link with the involved press offices.
 - The liaison structure continues until it considers that its work is completed, since the risk is under control. This opinion will be transmitted to the Commission and Member States.

- A meeting of the liaison structure members will be held after the conclusion of threat in order to evaluate the actions taken and co-ordination of these actions and the functioning of the different tools used in the management of a crisis, on the basis of the experience gained.
- Examine feasibility to propose a Commission Decision on a liaison and control structure under the Community network on CD for high level public health threats.

4.4 Situation awareness: Health Emergency Operations Facility

Outcome Expected

Health Emergency Operations Facility (HEOF) is a tool that can provide decision makers and their staff and advisers a fast and comprehensive situational awareness and analysis and allow them to exercise effective coordination of responses and of communication of commands and instructions, to transmit information and to manage operations and simulation for event analysis and training that is relevant to their responsibilities and powers.

The main existing crisis and communication structures in public health are upgraded to a Health Emergency Operations Facility as the public health hub for linkage with a centralised national / Community Crisis Management structure.

MS, Commission and Agencies

Checklist on the establishment of a Health Emergency Operations Facility: if a plan addresses the set up of HEOF, its facility ought to respond to the following minimal requirements

- Information management: fast display of data, graphs and pictures and fast transmission of early warning and alert messages. All stakeholders are able to make decisions based on the same information.
- Communication: Gathering of information and monitoring of information sources. Dissemination of validated information. Helping stakeholders with expertise.
- Tool to communicate among players. (re: Communication among players)
- Tool to exchange scientific advice: ad hoc & real-time consultations for precautionary and control measures
- Data management and communication : managerial tool of various aspects of response
- Direct and feed-back from intervention teams and on-site support, assistance in epidemiological investigations and the collection and analysis of data, as well from teams of expertise in clinical and patient isolation matters and other response aspects
- The facility can operate 24 hours per day/7 days per week

Interoperability

Intra-Community activity leading to the linking of existing Health Emergency Operations Facilities and players' Command and Control structures.

- Co-ordination between existing national Health Emergency Operations Facilities serving as the "hub".
- Co-ordination between existing Community Health Emergency Operations Facilities serving as the "hub" and a Commission Crisis Centre.
- Link up with the Early Warning and Response System (EWRS) of the Community Network for the Surveillance and Control of Communicable Diseases (European Parliament and Council Decision 2119/98/EC).
- Exchange platform for operations of planned activities on specific health threats and emergencies and response to unexpected health threats and incidents

4.5 Algorithm: approach by threat activity level and tier and level of decision making

Response Activity 1: Increased threat of concern to the EU

- Players review procedures for full operations of their command and control
- The liaison structure is put on stand-by
- Commission services assign adequate personnel to the liaison and control structure, put on stand-by

Threat Activity 2: One confirmed event² (eg. confirmed case or release incident) outside the EU

- Command and control functions are started in players structures
- The EOFs and liaison functions are put in full operation and communications occurs on a frequent basis to allow co-ordination of some activities at EU-level, such as on the need to centralise the liaison and control structure, the sending of EU-investigation or assessment team(s), the control policies and the surveillance activities in Member States

Threat Activity 3: One confirmed event (eg. confirmed case or release incident) in EU or in a country bordering to EU

- Command and control functions intensify
- Liaison functions are intensified and Member States and Agencies are requested to send their public health expert or delegate to the Commission's premises and/or activate the HEOF, and start full operation to decide on common Community policies, such as travel advisories, vaccination of target groups, tracing of contacts, administration of drugs, bans on public gatherings in confined places (theatres, cinemas, churches, sport centres etc), restriction of movement, etc.

Threat Activity 4: Several events (eg. active transmission) in EU

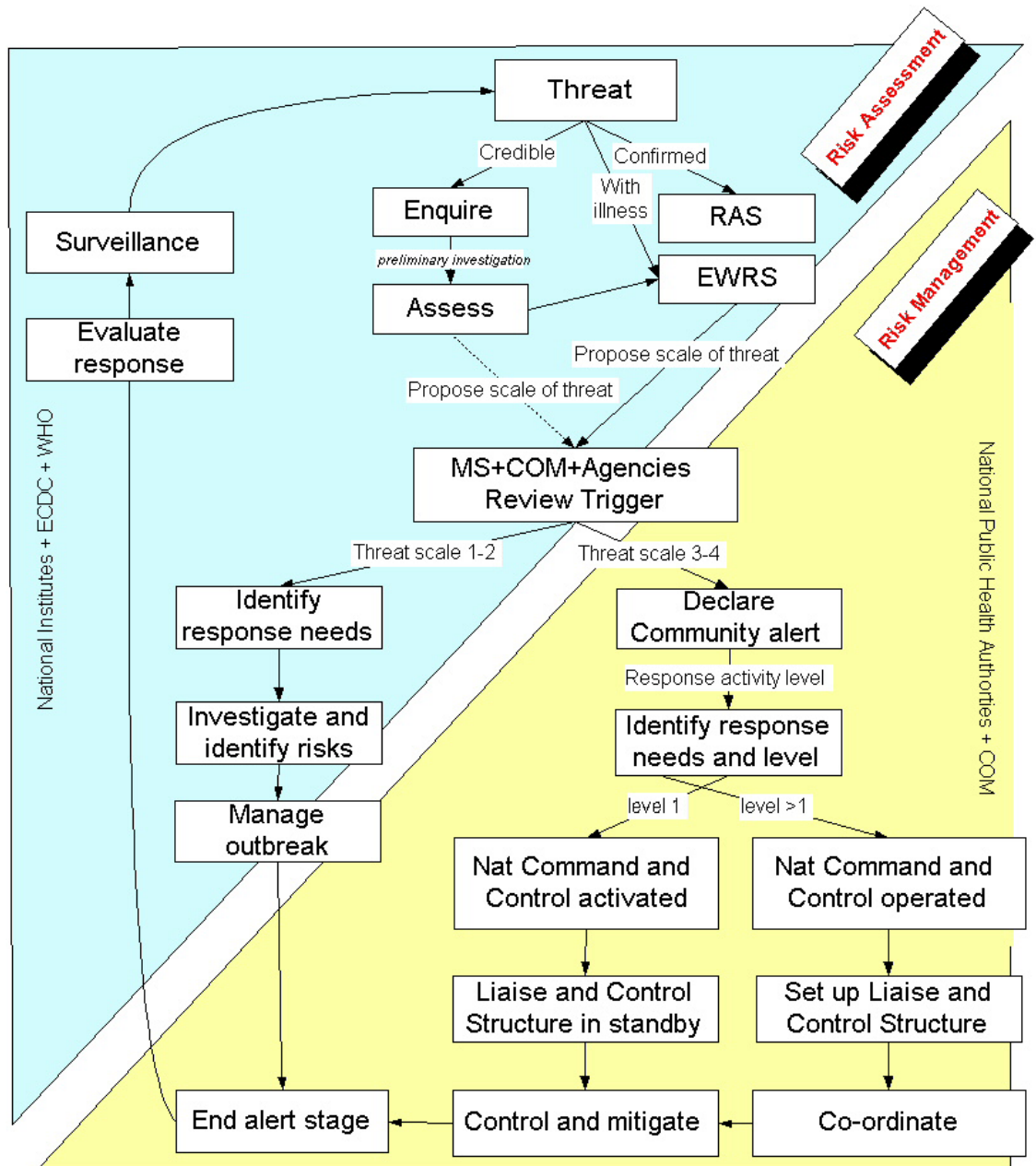
- The liaison structure is co-ordinating most activities at EU-level, such as to decisions on vaccination, proposals for restrictions etc

Threat Activity 5: Uncontrolled occurrence of events (eg. uncontrolled spread) within the EU

- The liaison structure is co-ordinating most activities at EU-level, such as to decisions on vaccination, decisions on restrictions etc
- Additional bodies / organisations / services are represented in the liaison and control structure in order to co-ordinate with other bodies (other Commission services, military, law enforcement etc).

These activities, as described in each level, need to be further elaborated for each tier in the mechanism (EU, Member States, Regional level). A proposal is developed in Annex to describe the operation of a "Threat Management Team" (**Error! Reference source not found.**).

² The definition of an event may require more fine-tuning for chemical threats



5 Preparedness beyond the health area

This section describes the processes required to deal with risk-management issues beyond the health field in order to prepare the actors to assist the public health partner, or to prepare the public health partner with mitigation issues dealt mostly by other departments, such as legal, ethical and transportation issues. Good preparedness planning will establish (public) health recommendations allowing the vital civil functions, or even recovery of these, to occur in case of a major public health threat.

5.1 Information transmission, forwarding to authorities and agencies (local, national, international)

Outcome expected

The prompt notification of alerts or information about interesting events may facilitate the handling of emergencies. Therefore, it is important that any relevant intelligence, news, advice or reports reach the right services or persons under a recognized format facilitating its handling.

This presupposes an early identification of all the relevant actors and regular testing of the communication channels as well as of the procedures laid down.

Commission will have to set up procedures with the Member States national authorities, while Member States will have to lay down their own circuits of communication and decide upon the adapted involvement of regional or/and local authorities. A list of contact persons (services) is available.

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Checklist for incidents with public health consequences:

- Crisis plans includes and identifies all actors for info transmission in a rapid way;
- List of Local, regional, national and international contact points;
- Public health information contacts are included in a) and b);
- Training and exercises.

Interoperability

Operational links for an Intra-Community information transmission, requiring:

- Co-operation procedures between the Commission services and the agencies with the Member States national authorities in each area, including international organisations.
 - According to relevant Community rules and legislation
- Co-operation procedures between Commission services (and Council?) interlinking the information forwarded under the procedures of the previous bullet point.
 - To be checked, linked and filled in.
- Introduction of Member States and Commission to ARGUS (central crisis communication) and Central Crisis Centre (at Commission level)

5.2 Stand-by operations: stand-by of agents, operators and staff

Outcome expected

Each Member State has in the national plan identified surge resources to be deployed at national level. According to the relevant Community legislation (DG-SANCO, DG-ENV, others) the Member State have also identified resources that can be shared at Community level. A procedure to start the sharing process is in place. In this phase those resources (stocks, personnel etc) ought to be placed on stand-by mode, to facilitate travel or transportation in the least time possible.

Member States will be notified via the appointed contact points in the above mentioned systems and ought to then be placed on the agreed alert mode, to be followed by deployment to the requesting Member States, soon afterwards.

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Checklist for incidents with public health consequences:

- List, inventory of surge resources in terms of personnel and material for relief – consequence management;
- Process of scaling-up and surge capacity;
- Procedure for deployment and assistance to other Member States.

Interoperability

Operational links for an Intra-Community facilitation of stand-by operations, requiring:

- Workshops / specific meetings to share or discuss topics of the national plans
 - Planners Group in the Health Security Committee.
- Stand-by mode facilitated via the alert/communication systems and their co-operation;

5.3 Information transmission, forwarding to authorities and agencies (local, national, international)

Outcome expected

The prompt notification of alerts or information about interesting events facilitates the handling of emergencies. Therefore, it is important that any relevant intelligence, news, advice or reports reach the right services or persons under a recognized format facilitating its handling.

This presupposes an early identification of all the relevant actors and regular testing of the communication channels as well as of the procedures laid down.

Commission has set up procedures with the Member States national authorities, and Member States have laid down their own circuits of communication and have decided upon the adapted involvement of regional or/and local authorities. A list of contact persons (services) is available.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- Crisis plans includes and identifies all actors for info transmission in a rapid way;
- List of Local, regional, national and international contact points;
- Public health information contacts are included in a) and b);
- Training and exercises.

Interoperability

Operational links for an Intra-Community information transmission, requiring:

- Co-operation procedures between the Commission services and the agencies with the Member States national authorities in each area, including international organisations.
 - According to relevant Community rules and legislation
- Co-operation procedures between Commission services (and Council?) interlinking the information forwarded under the procedures of the previous bullet point.
 - To be checked, linked and filled in.
- Introduction of Member States and Commission to ARGUS (central crisis communication) and Central Crisis Centre (at Commission level)

5.4 Stand-by operations: stand-by of agents, operators and staff

Outcome expected

Each Member State has in the national plan identified surge resources to be deployed at national level. According to the relevant Community legislation (Health, Civil Protection, Radio-Nuclear, Chemical, others) the Member States have also identified resources that can be shared at Community level. A procedure to start the sharing process is in place. In this phase those resources (stocks, personnel etc) ought to be placed on stand-by mode, to facilitate travel or transportation in the least time possible.

Member States will be notified via the appointed contact points in the above mentioned systems to place the surge capacities on the agreed alert mode, while waiting for deployment to the requesting Member States.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- List, inventory of surge resources in terms of personnel and material for relief – consequence management;
- Process of scaling-up and surge capacity;
- Procedure for deployment and assistance to other Member States.

Interoperability

Operational links for an Intra-Community facilitation of stand-by operations, requiring:

- Workshops / specific meetings to share or discuss topics of the national plans
 - Planners Group in the Health Security Committee.
- Stand-by mode facilitated via the alert/communication systems and their co-operation;
 - SANCO and ENV (RAS and MIC)
 - ARGUS – COM Crisis Centre
- Inventories of resources to be shared or deployed commonly;
 - Civil Protection Inventory on medical resources (under the Civil Protection Mechanism)
- Overall list of inventories on resources;
- Agreements when needed for sharing and deploying;
 - Laboratory co-operation
- International assistance where required and possible (?)
 - ECHO
- Crisis funds for enhancing the stand-by mode:
 - Solidarity Funds
 - ECHO-funds

5.5 Passenger information (traceability, information)

Outcome expected

National plans have adequate traceability measures in place for obtaining passenger information from the airline companies that have regular “slots” in airports or from travel agencies, tour operators and cruise-ship companies.

National plans also foresee providing generic information to travellers during their travel (i.e. information on the passenger checked luggage, etc) and relate this information to the airline companies, to travel agencies, tour operators and cruise-ship companies.

Internal Commission co-ordination exist to facilitate Member States in applying traceability measures. Procedures are set up with the Member States national authorities and stakeholders in the travel area. A list of contact persons (services) is available.

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Checklist for procedures to obtain or relating passenger information:

- Crisis plans includes and identifies all actors for obtaining and transmitting information in a rapid way;
- List of local, regional, national and international contact points;

Interoperability

Operational links for an Intra-Community information transmission, requiring:

- Co-operation procedures between the Commission services and the agencies with the Member States national authorities
- Based on Commission Decision(s) (Stand-by Declaration – Countermeasures)

5.6 Travel advice and entry or exit measures

Outcome expected

Travel advice to reduce the risk of infection in prospective travellers to countries involved by the epidemic has been agreed upon (response level 2 and higher). Since travel advice can have economical consequences, it is based on epidemiological – scientific advice (national public health experts – ECDC – WHO).

Statements and information for travellers and general public is made and agreed with all Member States in collaboration with the airline companies. Information for incoming traffic is made available to all EU involved services / authorities regularly and a database of contacts is established. Member States agree on a common approach to early detect imported cases and develop a joined entry/exit screening at border controls. The Commission co-ordinates and can provide translations if requested.

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Checklist for incidents with public health consequences:

- Dialogue foreseen in plans between relevant authorities and private companies in the travel sector (airline companies, travel agencies);
- Mandatory scientific advice from public health experts and back-up by public health authorities;
- Conformity with border control legislation;
- Contact-tracing by requesting lists of passengers requires back-up under privacy data protection legislation.

Interoperability

Operational links for Intra Community travel advice and measures, requiring:

- Scientific advice mechanism
 - Role and interlinking of committees and ECDC
- Decision on a Stand-by Declaration (re...)
- Based on Commission Decision(s) (Stand-by Declaration – Countermeasures)
- EU-platform for the dialogue between health, travel agencies, ... other involved stakeholders and services.
 - Common viewpoint to facilitate international dialogue
 - WHO – implementation of the IHR

5.7 Legal implication of countermeasures

Outcome expected

Countermeasures (re 2.3) may restrict movement of people, animals, plants, food, water, goods, energy flows and may have implication on data privacy protection. Those countermeasures should be momentary, ad hoc and subject to the subsidiarity principle when they affect social and economical life, or generate judicial consequences. Their implementation is necessary but difficult to grasp in a legal act before the event occurs. Since those measures touch Community competence in other areas their implementation should bear a common agreement and legal backing-up by other Community legislation.

Thus, the Community uses a mechanism for risk assessment (3.5) and prior communication (2.2) of proposed or to be implemented countermeasures. Any decision is based on the scientific value of the proposed countermeasures. If key-players are sufficiently prepared and efficiently co-ordinated for their specific role, this mechanism can be quickly and timely activated to decide on temporarily countermeasures which could hamper or restrict the free movement and which may require to divulge medical and other personal data (addresses for traceability purposes).

According to the threat level, the Liaise and control structure recommends on countermeasures.

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Checklist for incidents with public health consequences:

- Procedures or at least a dialogue mechanism foreseen in plans;
- List of relevant authorities according to the measures to be taken
 - E.g. customs – trade - economical affairs; external – internal affairs; tourism; animal, plant, food, human health - health inspections;
- Mandatory scientific advice from public health experts and back-up by public health authorities;
- Conformity with identified relevant legislation in case of implementation of the countermeasure;

Interoperability

Operational links for an Intra-Community legal facilitation to implement countermeasures, requiring:

- Scientific advice mechanism
 - Role and interlinking of committees and ECDC
- Decision on a Stand-by Declaration (re...)
- Commission Decision(s) (Stand-by Declaration – Countermeasures)
- EU-platform for the dialogue.
 - Commission Crisis Centre
 - Common viewpoint to facilitate international dialogue
 - WHO – implementation of the IHR

5.8 Ethical implication of countermeasures

Outcome expected

Ethical issues are closely related to the legal issues as mentioned above and are part of the normative framework needed to assess the cultural acceptability of measures like quarantine or selective immunisation of pre-defined risk groups.

National plans include a leading ethical framework for responses to public health crisis and national plans include a verification processes to assure that the ethical aspects of policy decisions to be used during the response to an outbreak balance individual and population rights.

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Checklist on ethical implication of countermeasures

- National plans address ethical questions related to limiting the availability of a scarce resource, such as rationed diagnostic laboratory tests, vaccines or anti-viral drugs.
- National plans address questions related to compulsory vaccination for first care providers, health care workers and essential community service providers
- National plans address issues related to limiting personal freedom, such as may occur with isolation and quarantine
- National plans address establishment of an ethical framework for research, especially when this involves human subjects.

Interoperability

Intra-Community activity leading to:

- Platform between Commission services and relevant stakeholders:
 - To identify issues leading to ethical implications

- To provide frame for assessment of inclusion of ethical aspects.
- To issue recommendations.

5.9 Transport of samples

Outcome expected

Member States foresee in their plans how to transport dangerous pathogens in and if needed outside the country. Agreements exist between laboratories endorsed by the competent authority for this transport. Customs are informed about eligible transport between designated national laboratories for public health emergencies.

The relevant Community legislation takes into account the transport of patient and environmental samples in case of public health emergencies. Community and national legislation on the transport of dangerous substances is regularly adapted to the evolving scientific and technological circumstances issued by the international organisations.

Legislation or guidelines on protective measures do exist.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- Transport safety measures (according to international standards);
- Agreements between laboratories, with transportation companies;
- Legislation takes into account the emergency situation:
 - Customs
 - Transport
 - Designated laboratories

Interoperability

Operational links for an Intra-Community transport, requiring

- Prior information Decision (re...)
- Decision on a Stand-by Declaration (re...)
- Declaration, as basis justifying transport Intra Community
- Agreements and support by Commission
- Relevant Community legislation takes into account the transport of patient and environmental samples in case of public health emergencies.
- Transport of dangerous substances;
- Legislation or guidelines on protective measures;
- Discussion at international level: IATA, WHO, ...

5.10 Requisition of property (land, vehicles, facilities such as labs, hospitals, centres, pharmaceuticals)

Outcome expected

Member States foresee in their plans (legislation if required) a worst case scenario where the authorities have to requisition those facilities to support their consequence management.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- Legal possibility for requisition exists
 - Civil protection, Military, Law enforcement
- Plans include this requisition possibility
- Decision is based on scientific evidence

Interoperability

Operational links for an Intra-Community travel advice and measures, requiring:

- Decision on a Stand-by Declaration (re...)
- Prior information Decision (re...)

- Training, workshops.

5.11 Medical and law enforcement interventions

Outcome expected

Member States have installed coordination and communication mechanisms between the national Health, the Law Enforcement and the Civil Protection authorities in order to enforce public health measures. Each competent authority keeps its counterparts in the Member States updated in liaison with the Commission.

Member States coincide epidemiological and law enforcement investigation in their plans.

The Commission supports the initiative of co-operation since a lot of the countermeasures will involve legal enforcement and civil protection intervention. The command & control structure at national level and the liaison and control structure at EU-level, support this role.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- Co-ordination and communication with the relief and consequence management services and authorities, including health, LE and CP.
- In the *pre-incident phase*, public health planning, training, and equipping for emergencies exists towards first responder law enforcement agencies for incidents involving hazardous agents and includes:
 - Solutions towards possible jurisdictional problems between law enforcement agencies
 - Interaction between law enforcement personnel with fire and emergency medical personnel
 - Threat intelligence information to first responders and their supervisors
 - Hazardous agent mitigation by primary law enforcement agency
 - CBRN training facility(s) responsible for training law enforcement personnel
 - personal protective equipment for first responders of the law enforcement personnel
 - Procedures for maintenance, upgrade, and/or replacement of this protective equipment
 - Emergency self-decontamination
- In the immediate on-scene response phase, public health is involved in the planning towards law-enforcement including:
 - Procedures to install an incident command system
 - Procedures for on-scene responders to establish control of an incident scene
 - Procedures for responders to decide what type or size of perimeter to establish
 - Procedures for responders to decide on evacuation and/or shelter-in place
 - Procedures in place to bring in additional law enforcement personnel into the affected area
 - Procedures in place to protect/secure an evacuated area
 - Procedures in place to protect/secure evacuated or sheltered personnel
 - Procedures in place to safeguard evidence at a hazardous agent incident scene
 - System to account for the number and location of personnel at an incident scene
 - Procedure in place to protect responders working at an incident scene
 - Procedures to communicate with fire, emergency medical, and hazardous materials responders
- In the detailed response phase, public health is involved in assisting planning towards law-enforcement including:
 - Procedures to allow for transition from a local to a National level of command responsibility
 - Procedures to allow interoperability between specialised response teams with other specialised response assets from other sectors of government
 - Defined responsibilities for collecting health findings and forensic evidence in a contaminated environment
 - Procedures for rotating personnel into the incident site
 - Procedures for additional on-scene surge needs
- In the consequence management phase, planning towards law-enforcement include:
 - Procedures in place to decontaminate mission-essential equipment
 - Definition of role do your law enforcement agencies have in consequence management plans
 - Procedures to conduct medical monitoring of law enforcement personnel after potential exposure to hazardous agents and public health reporting

- Forwarding and reporting between specific forensic laboratories and public health laboratories for suspected hazardous agent materials
- Forensic analysis procedures consistent with legal requirements for public health laboratories

Interoperability

Operational links for an Intra-Community support to medical and law enforcement interventions, requiring

- Update of Member States via Commission through the relevant communication channels;
- Role of a Command and control structure;
- Training, exercises on a regular basis.

5.12 Defining cordoned area radius and safe distances

Outcome expected

National arrangements exist for defining for radiological, biological, chemical or radio-nuclear releases the adequate area cordoning and safe distance definitions. Public health personnel have adequate knowledge and training on precautions and handling within these cordoned areas. Personnel have passing permits to access defined zones.

National arrangements exist for taking agricultural countermeasures within the food restriction radius, implementation of temporary relocation (for areas with territory near a threat category I or II nuclear facility) and management of radiation waste.

The choice of the radii represents a judgment of the distance to which making advanced arrangements is reasonable in order to ensure effective response. In a particular emergency, protective actions may have been warranted only in a small part of the zones. For the worst possible emergencies, protective actions might need to be taken beyond the radii suggested. The sizes are defined in terms of a radius of a circle centred at the source of the potential release or criticality. However, the actual boundary of the zones should not be a circle but should be established to conform to geographical features such as roads, rivers, or political boundaries.

MS, Commission and Agencies

National plans include adequate provisions of definitions of zones:

- Precautionary action zone is the area within which arrangements ought to be made to implement precautionary urgent protective actions before or shortly after a severe release with the aim of preventing or reducing the occurrence of severe deterministic effects.
- Urgent protective action planning zone applies to nuclear facilities in threat categories I and II and is the area where preparations are made to promptly shelter in place, perform environmental monitoring and implement urgent protective actions based on the results of monitoring within a few hours following a release
- Food restriction planning radius (threat category V distance) is the area where preparations for effective implementation of protective actions to reduce the risk of stochastic health effects from the ingestion of locally grown food ought to be developed in advance.

Interoperability

Operational links for an Intra-Community defining areas in the case of nuclear events, requiring:

- Cross border coordination

5.13 Environmental decontamination, waste management and disposal interventions

Outcome expected

All national plans foresee methods of decontamination (microbiological and chemical) of waste and of the waste water as well as transport arrangements of waste and storage. EU-legislation supports the national plans where relevant.

The purpose is to emphasise environmental protection. Arrangements for cross-border aid are made.

The Member States and the Commission have identified the issues and areas where a common approach is of EU-added value. Where needed, the Commission should set up a required collaboration.

MS, Commission and Agencies

Checklist for incidents with public health consequences:

- Plans foresee methods, decontamination measures and equipment;
- Plans foresee the competent services (Civil protection, ...)
- Arrangements for cross-border aid

Interoperability

Operational links for an Intra-Community support to emphasis environmental protection, requiring:

- Scenarios and exercises to identify issues and areas for a common approach;
- Workshops and discussions;
- Guidelines;
- Support for arrangements for cross-border aid.

5.14 Distribution

Outcome expected

National plans have foreseen the necessary distribution plans for medical goods, supply, minimal hospital supplies for essential hospitalisation services (food, drugs, ...)

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Checklist on distribution capacity: are the following minimal requirements in place?

- an agreement exists with an adequate private or public logistics provider to carry out the distribution functions
- the command and control structure has a reliable single point of 24/7 contact to alert the entity.
- the logistics provider uses tethers or a call-down system ensuring all drivers can muster at once.
- the logistics provider has 24/7 arrangements for fuel, repair, and recovery services.
- the logistics provider has means for its drivers to purchase fuel from commercial sources.
- the drivers have credentials that will allow access to all sites without interference.
- identity markings for the logistics provider vehicles is arranged for use to facilitate site access
- drivers will be outfitted with communication devices to allow dispatch.
- security is arranged to protect entity vehicles to and from delivery points.
- police have agreed to escort distribution vehicles from staging to delivery points.
- transportation experts have cited the best delivery routes and any detouring needed, including
- drivers to treatment centres have gotten controlled substance protocols & orientation, invoicing and other record keeping SOPs.

Interoperability

Intra-Community activity leading to:

- Lists of contact points and companies to fill in the gaps (previously established)
- DG ENV-CP / Community Civil Protection mechanism for assistance
- Commission Crisis Centre / Solidarity Fund

5.15 Maintenance interventions

Outcome expected

Essential services are the ones that are required for essential processes to keep the country running. Priorities may differ in countries but examples are power and drinking water delivery, transport and telecommunication. Consideration of the effect of a pandemic on essential

services is an important part of pandemic planning. Much of the planning ought to be undertaken by the services themselves, as part of their existing emergency plans

Do you have an idea of how a widespread outbreak may affect the delivery of essential services? Have you identified people / organisations that are responsible for maintaining these services? Have you developed contingency plans for coping with shortages of workers in these services during a pandemic? Are these plans legally and ethically acceptable?

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Checklist on maintenance intervention: are the following minimal requirements in place in national plans to:

- identify a procedure for looking at the advantages and disadvantages of the declaration of a community alert during a major public health crises
- nominate a lead agency for coordinating the maintenance of essential services during a major public health crises and have clearly defined the role of public health authorities and institutes
- develop a list of essential community services and consequently the corresponding personnel, whose diminution or absence would pose a serious threat to public safety or would significantly interfere with response to the crises.
- develop for these personnel from these essential services procedures for eventual preventive drug administration or allocation of PPE
- an estimation of the minimum number necessary for a sustained crises response
- discuss with professional organisations and unions regarding people working outside their areas of training and competence during a crises
- identify personnel who may be available to assist in an essential non-health care role with maintenance of essential services during a crises (military, retired people, people employed in other areas or voluntary organisations, etc)
- develop protocols for accepting and training volunteers and workers from other fields for defined essential service roles
- ensure that liability, insurance and temporary licensing issues for volunteers and workers from other fields are addressed and consider ethical aspects of your plans.
- develop existing emergency contingency plans so that they could be applied to a crises, such as emergency shifts and workers compensation

Interoperability

Intra-Community activity leading to:

- Civil protection
- Solidarity fund

5.16 Recovery interventions

Outcome expected

After the public health crisis is over, it can be expected the many people will be affected in one way or another: many persons may have lost friends or relatives, will suffer from fatigue or may have financial losses due to interruption of business due to absenteeism, isolation or quarantine requirements. National plans ensure that concerns can be addressed and to support 'rebuilding the society' and ensure the quick revitalisation of the Member State. National plans foresee a mechanism in place to assess economical losses and to provide financial support to affected groups.

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Checklist for incidents with public health consequences:

- national plans ensure that concerns can be addressed and to support 'rebuilding the society' and ensure the quick revitalisation of the Member State.
- national plans foresee a mechanism in place to assess economical losses and to provide financial support to affected groups.
- list of relief services and authorities, such as civil protection
- list of required material and safety measures
- essential services have developed company-recovery plans

- national plans define responsibilities for social, psychological and practical support for affected families and companies. If needed, organise trainings and education for personnel involved.
- national plans assess how existing community groups (religious groups/churches, sports groups, can contribute to rebuilding the society. Identify contact persons for these groups.
- national plans consider whether recovery after a public health threat needs financial support from the government and develop criteria for financial support and availability of funds

Interoperability

Operational links for an Intra-Community support to recovery interventions, requiring:

- Scenarios and exercises to identify issues and areas for a common approach;
- Workshops and discussions;
- Guidelines on safety measures or required material.

6 Health sector preparedness

A public health event will in almost all instances put an added strain on the health sector and preparedness and planning is needed when adapting to the new requirements. Principles for management of cases will, by necessity, vary according to different countries depending on the health infrastructure where they will be applied, and the adaptation to managing extensive public health event will also differ. Even so in the principles of planning there will be many similarities and there will be a value in exchanging information. Furthermore when there is a need for support across borders a need will arise for the understanding of the procedures employed in the receiving country. To achieve this understanding, cross-communication networks should be created between countries and sharing information on planned activities would be useful, as would the assistance in the development of new national plans and in developing principles for sharing resources (human, planning and information) between countries.

6.1 Incident management outside hospitals

6.1.1 Investigation and response teams

Outcome expected

The investigation of the event and the evaluation of the response needed is a prerequisite to deal with a public health threat. The resources to do this are identified before an incident and procedures to utilise them are developed. Since few member states have sufficient quantities and qualities of these resources and structures, pooling the investigating resources enhances the preparedness. Pooled resources also significantly strengthen the possibilities for an international response to a major event outside the EU.

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Checklist on Investigation and response teams:

- National plans include provisions for fast deployment of investigation and response teams
- Guiding principles for international operations are endorsed
- Who are the competent authorities / structures?
- Are other than Public health issues integrated in case of an incident? Such as the police, security others?
- Do operational links exist and are used with WHO – other international public health organisations?

Interoperability

Intra-Community activity leading to:

- An EU-response capacity is made operational for EU and international activities
- Operational links with ESCON.
- Operational links with WHO/GOARN – other international required organisations: implementation of IHR.
- Operational links with EU mechanisms on animal health – plant, food, civil protection, radiological issues, law enforcement - EUROPOL.
- ECDC role as coordinator and evaluator of the process is clearly defined
- ECDC develops an activation mechanism, communication lines and logistics.
- ECDC sets up a mechanism to identify terms of reference and teams on an ad-hoc basis.

6.1.2 Decontamination of Patients and Environment

Outcome Expected

Decontamination of exposed individuals prior to receiving them in the healthcare facility may be necessary to ensure the safety of patients and staff while providing care. Procedures to determine the need for decontamination and capabilities to carry out decided measures are developed by Member States. Criteria for decontamination and procedures used will vary but

sharing of the information would strengthen the development in Member States where such is planned and guide the possibilities to share the resources for decontamination across borders.

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Checklist on Decontamination of Patients and Environment:

- Are the following minimal requirements fulfilled?
 - National plans include guidelines and procedures to be used for decontamination
 - Chosen methods of decontamination are validated
 - Timeliness and other aspects of the preparedness is tested in regular exercises
 - Information on the capacity for decontamination is aggregated at National level
- Who are the competent authorities / structures?
- Are other than Public health issues integrated in case of an incident? Such as the police sampling teams others?

Interoperability

Intra-Community activity leading to:

- Sharing of guidelines and decontamination methods among Member States possibly leading to some best practises
- Sharing of validation data on decontamination methods
- Evaluation of the possibilities of sharing resources across borders
- ECDC role as coordinator and evaluator of the process are clearly defined

6.1.3 Triage and management of large number of cases

Outcome Expected

A large number of cases can either be handled by the health system in emergency rooms or other locations to where patients are directed or at the site of a possible or real exposure. Triage and triage procedures are essential to give adequate care to large number of people irrespective of the location. Triage procedures are closely connected to ambulance services that provides the next link in the chain to give the cases the necessary care. Plans for ambulance utilisation will be closely linked to plans for triage and ought to be seen as a block of activities for which the same developments and collaboration is needed. While emergency medicine has developed well defined procedures for large scale accidents and exposures causing acute illness the management of large numbers of people exposed to biological agents are in many instances less well developed. Procedures will be different in different member states depending on local traditions and health systems present. The Member States have agreed on minimal requirements to foresee in their plans. The Commission supports the border areas in developing plans for collaborative management of major events including hospitals.

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Checklist on triage and management of large number of cases:

- Are the following minimal requirements fulfilled?
 - Triage procedures are established among national emergency medicine specialists
 - Opportunities for the training of these methods for all staff exists
 - The procedures are developed for a wide range of threats (e.g. CBRN)
 - Hospitals in border areas have developed collaboration with neighbouring health authorities
- Are other than Public health issues integrated in case of an incident? Such as the police sampling teams others?

Interoperability

Intra-Community activity leading to:

- Supporting border areas in developing plans for collaborative management of major events
- ECDC role as coordinator and evaluator of the process clearly defined

6.1.4 Contact tracing

Outcome Expected

Contact tracing procedures are an important connection between health care activities and surveillance. It involves a wide range of activities and actors depending on scenario and agents involved. It will both be involved in finding the cause of the incident and minimise the future effects. There are extensive experiences in Member States in doing contact tracing and the exact procedures will be heavily dependant on national systems. International spread of disease adds an extra level of complications to the system where there are experiences for some diseases.

The activities in international events are coordinated, the differences in the systems are understood and acknowledged and definitions have been agreed for the contacts to be traced. Procedures are established to enable contact tracing among people travelling between countries and continents and enhance the EU preparedness.

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Checklist on Contact tracing:

- Are the following minimal requirements fulfilled?
 - Incidents where contact tracing should be done are defined
 - Responsibilities are defined
 - International contacts established for international contact tracing
- Are other than Public health issues integrated in case of an incident? Such as the police others?

Interoperability

Intra-Community activity leading to:

- Procedures for international contact tracing established
- Quickly coordinate EU wide tracing established (EWRS, ESCON)

6.1.5 Crisis support

Outcome Expected

The experience from national and international crises has stressed the fact that the population in general and healthcare personnel in particular, especially those belonging to the first responders, suffer significant stress during and after an incident. Through all phases of the crisis situation i.e. preparation, during and the aftermath, counselling services are readily available in order to maintain confidence among the population and adequate staffing levels for the health sector.

National resources are needed during a major event and regional plans cover this aspect. Information from national and regional authorities is an important part of this procedure. These activities will be closely adapted to a local situation. Possibilities to share resources across borders will be limited during crisis situation. Exercises are organised on sharing experiences of the planning and on the actual execution of the plans to provide these resources.

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Checklist on Crisis support: are the following minimal requirements fulfilled?

- National resources and guidelines available

Interoperability

Intra-Community activity leading to:

- Develop guidelines and share experiences in crisis support
- ECDC role as coordinator and evaluator of the process clearly defined

6.2 *Hospital preparedness*

6.2.1 Emergency departments

Outcome Expected

Emergency Departments in most Member States might be first responders to a large incident. The division of work between the Emergency Departments and the Intensive care unit might vary considerably as will other aspects. National differences are considerable. Important parts are the integration with and access to other parts of the flow of patients and with experts on the agents. The coordination of the triage activities described above is also important.

The possibilities to move ED resources, due to the extensive differences in systems, are of limited value. The flow of individuals between Member States that work in EDs in different countries shows that some resources can be moved. The organisation of national systems has been shared and the feasibility of movements of resources is identified.

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Checklist on Emergency Departments:

- Are the following minimal requirements fulfilled?
 - Plans exists in Emergency Departments for the handling of major public health incidents
 - Structures are in place to coordinate Emergency Departments activities with other activities to control an incident
- Are other than Public health issues integrated in case of an incident? Such as the Civil Protection teams and others?

Interoperability

Intra-Community activity leading to:

- Sharing of descriptions of the Emergency Departments role in the national systems
- Evaluation of possibilities of sharing resources in defined scenarios

6.2.2 Treatment capacity

Outcome Expected

The health sector (hospitals, GP etc) is the end recipient of casualties after any event. In the case of a large number of casualties, the treatment capacity of the hospital or healthcare facility will be overwhelmed. In the face of large increases in demand, resources and equipment will be probably left in short supply. In many countries the main limiting factor will be the availability of personnel.

In small-scale events, routine facility patient placement procedures will be followed. Advance planning according to given guidelines is done, to apply alternatives when the number of patients presenting to a healthcare facility is too large, such as cohorting patients who present with similar syndromes (i.e., grouping affected patients into a designated facility) or setting up alternative treatment modalities. The guidelines also include how to reallocate personnel and how big the extra capacity needs to be. Guidelines exist for health facilities on how to establish priorities when it comes to which patient-groups that will be treated in different facilities.

Transfer of patients between Member States has already started both for acute care (mainly burn victims) and for planned procedures. Transferring resources such as mobile hospitals is mainly developed in the military field. If these resources would be large and timely enough to actually assist a Member States during a major event needs to be investigated.

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Checklist on Treatment capacity: are the following minimal requirements fulfilled?

- Guidelines for surge capacity established
- Policy for the percentage of the normal care that is needed developed
- Procedures for patient movements between countries established with data on the numbers involved
- National plans foresee co-ordination and communication with treatment facilities and have:
 - identified area treatment centres most likely to care for symptomatic casualties.
 - identified alternate treatment facilities to care for symptomatic casualties.
 - a system to allow prompt ongoing reporting of the numbers of diagnosed and suspect cases to the local authority in a bioterrorism event.

- progress tracking of reporting systems at treatment centres that not currently able to promptly report the ongoing numbers of diagnosed and suspect cases to the local authority in a bioterrorism event.
- epidemiologists identified who, in case of need, could go to treatment centres that have inefficient reporting systems to report the numbers of diagnosed and suspect cases to the local authority in a bioterrorism event.
- communication devices that could be employed to ensure prompt reporting of case numbers from treatment centres in a bioterrorism event.
- identified a coordinator at each treatment centres with whom to communicate.

Interoperability

Intra-Community activity leading to:

- Procedures for international transfers established with a focus on acute transfers

6.2.3 Intensive care units

Outcome Expected

Intensive Care Units (ICU) have a clear role in many of the scenarios that a preparedness plan ought to cover. It is a limited resource with expensive equipment that requires a significant amount of highly trained and capable staff for each patient. The knowledge on treatment of mass casualties by unusual agents is usually very limited. It can be foreseen that the demand will often be much higher than the resources available. In each national setting there is a need to have plans for extending these resources to the maximum and possibly have stocks of additional equipment to be used in an emergency. Even with these possibilities there will be a need to have plans to make priorities between different groups of patients.

National guidelines define to what extent hospitals might be required to extend their capabilities to treat patients in intensive care and how priorities can be made. Adapting resources to the management of mass casualties need national coordination to become effective and international sharing of experiences is organised. Sharing resources has been considered between Member States for smaller number of patients in border areas and then procedures for these transfers are established. Mobile resources might be the choice in some settings and the possibilities to share them at an international level could then be explored.

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Checklist on Intensive care units: are the following minimal requirements fulfilled?

- National guidelines on the role of ICUs in extensive events
- Hospitals in border areas have developed collaboration with neighbouring health authorities

Interoperability

Intra-Community activity leading to:

- A planning process to identify agreement and conditions with other Member States for sharing resources and staff.
- Networking among ICUs in the field of mass casualties and containment measures
- ECDC role as coordinator and evaluator of the process clearly defined

6.2.4 Infection control / Personal Protective Measures

Outcome Expected

With many of the agents to consider when planning for a public health event there are additional concerns about personal protective measures and infection control. Some of the agents will be unknown and for others the transmission routes might be others than previously seen. Special precautions may be needed to reduce the likelihood for transmission and for specific diseases additional isolation requirements might be needed. Knowledge and evaluation of additional procedures is collected and further developed at EU-level. The use of methods developed are adapted to national settings. These methods might in some instances

mean the use of specialised equipment or pharmaceuticals for pre and post-exposure prophylaxes. Here national guidelines and resources are issued for storing this equipment and developing training programs in their use. For major events requiring mutual support, international agreements on the use of such equipment is foreseen.

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Checklist on Infection control / Personal Protective Measures: re the following minimal requirements fulfilled?

- National guidelines on the infection control and personal protective equipment in public health events involving specific agents
- Hospitals in border areas have developed collaboration with neighbouring health authorities

Interoperability

Intra-Community activity leading to:

- A planning process to identify agreement and conditions with other Member States for sharing resources and staff.
- Networking among Member States in development of procedures and guidelines for specific agents
- ECDC with ESCON role as coordinator and evaluator of the process clearly defined and develops agreed list of pre-and post-exposure prophylaxis scheme
- Guidelines for infection control practitioners (currently in EC-funded project EUNID)

6.2.5 Isolation procedures

Outcome Expected

For a number of agents considered as threats for public health events isolation of patients is an important countermeasure. This will limit the spread of disease to personal and other patients. Procedures for the isolation including definition of cases to be isolated and when they can be released are for some diseases already available and need to be developed for others. In some areas specialised resources will be needed and national guidelines on the amount needed have been drafted. For new diseases procedures are in place to quickly develop guidelines based on a common consensus at EU level even if national adaptations are needed.

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Checklist on Isolation procedures: are the following minimal requirements fulfilled?

- National guidelines available
- Data available on national resources for isolation

Interoperability

Intra-Community activity leading to:

- Share guidelines for isolation procedures
- ECDC with ESCON role as coordinator and evaluator of the process clearly defined
- Support from projects to allow sharing and developing of guidelines (EUNID)

6.2.6 Poison Control Centres

Outcome Expected

A provision of expertise from Poison Information Centres improves the response and treatment capacity in case of chemical incidents. They can provide specific expertise to first line responders and to other emergency departments, ICU etc and can assist in additional antidote procurement”.

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Checklist on Poison control centres: are the following minimal requirements fulfilled?

- Plans include dedicated poison control centres.

Interoperability

Intra-Community activity leading to:

- A planning process to identify agreement and conditions with other Member States for sharing resources, knowledge and staff.
- Networking among Member States in development of procedures and guidelines for specific agents

6.2.7 Ensuring sufficient critical supplies for the health sector

Outcome Expected

The national plans for health facilities will ensure that all different kinds of supplies needed will be available even during a time of crisis. Types and amounts of supplies needs to be discussed with local authorities to ensure that the needs of health facilities are included in general preparedness plans for the society as a whole.

The input of public health is needed when preparedness issues for the society is discussed both at national and EU level.

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Checklist on ensuring sufficient supplies for the health sector: are the following minimal requirements fulfilled?

- National guidelines on supplies to health facilities in emergencies developed
- General preparedness plans includes provision to health facilities during a crisis
- Plans address the options for stockpiling extra medical supplies, including personal protective equipment, and identify sources for additional supplies
- Plans have determined a range of essential drugs for disease which will be *additionally* required (antibiotics, cardiovascular drugs, ...) that will be useful for treatment of *complications*
- Plans have determine the level of care that could be provided in alternative health care facilities and develop a contingency plan for providing these alternative facilities with the equipment and supplies adequate for the level of care that will be provided.

Interoperability

Intra-Community activity leading to:

- ECDC role as coordinator and evaluator of the process clearly defined
- Community mechanism and involvement in the operational issues of stockpile (with EMEA, DG-ENV, ...)

6.2.8 Ensuring medical outreach capacity for the health sector

Outcome Expected

The national plans ensure for health facilities that prophylactic measures, drugs and supplies needed will be made available quickly and maintained in outreach settings, such as primary care clinics or mobile clinics with medical or paramedical personnel. Logistics to bring these supplies to the agreed facilities has been discussed with local authorities to ensure that the needs of health facilities are included in general preparedness plans for the society as a whole.

The input of public health is needed when preparedness issues for the society is discussed both at national and EU level.

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Checklist on ensuring sufficient supply dispensing for the health sector in an outreach setting: are the following minimal requirements fulfilled?

- National guidelines on dispensing supplies to outreach settings in emergencies developed
- General preparedness plans includes provision to dispense supplies to outreach settings during a crisis
 - Plans have determined a strategy for the distribution of stockpiled supplies and medication.
 - dispensing sites
 - a decision has been made about providing prophylactic medication and PPE to first responders
 - accessibility for impaired, homeless and similar groups is included
 - decision is made on dispensing agency(ies)
 - decision made on how many days of prophylaxis will be initially dispensed

- teams and team managers are identified for each dispensing
- feedback on supply availability is organised
- procedures for patient tracking are developed
- the staff of the dispensing sites has received orientation and training for their roles.
- legal aspects for drug dispensing have been properly addressed
- an outreach plan for making homeless & similar groups aware of dispensing sites
- a communication campaign has been planned to tell people where to go for prophylaxis
- security is arranged to protect the staff at each dispensing site
- crowd control services are arranged to help maintain order at each dispensing site.
- transportation is arranged for symptomatic persons who present to dispensing sites to be transported to a treatment centre
- arranged for mental health professionals to be assigned to dispensing sites

Interoperability

Intra-Community activity leading to:

- Share experience
- Develop public health input when preparedness issues are discussed at EU level.

6.2.9 Ensuring general hospital preparedness plans

Outcome Expected

National plans identify and verify the commonly agreed EU minimal requirements for health care facilities. Emergency management for healthcare facilities includes elements of mitigation, preparedness, response, and recovery. These plans ought to take into account such factors as the appropriateness and adequacy of physical facilities, organizational structures, human resources, and communication systems.

The checklist is designed to provide facilities with questions that stimulate assessment and dialogue with key stakeholders both within the facilities as well as at the local level and beyond. Utilizing this checklist process, the Infection Control Practitioner can assist in identifying both thought and action leaders. Although the checklist divides the assessment into sections, many of them overlap and may be grouped in differing manners according to the organization and operation of individual facilities. Although comprehensive, the facility assessment will undoubtedly identify new questions and considerations.

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Checklist on ensuring minimal requirements in the preparedness planning for health care facilities: are the following minimal requirements fulfilled (see details in Checklist 7: Checklist for Healthcare Facilities)?

- presence of a disaster plan?
- surveillance
- identification of authorized personnel:
- activation of the plan:
- alerting system:
- response:
- hospital disaster control command centre:
- security
- communications systems:
- internal traffic flow and control:
- external traffic flow and control:
- visitors:
- media:
- reception of casualties and victims:
- hospital evacuation:
- relocation of patients and staff:
- hospital out of communication or cut off from resources:
- equipment, services, facility, and laboratory assessment
- pharmaceuticals:
- post disaster recovery:

- education and training:
- key internal personnel phone contact list
- key external personnel/agencies contacts
- incident command system
- exercising the disaster planning program

6.3 *Fatality management*

Outcome Expected

Fatality management in the event of multiple casualty incidents requires consideration of several aspects. Plans ensure that extra resources can be put in place when the number of cases overwhelm the system. The agents causing the fatalities might demand special handling of the bodies to protect personnel and ensure that the agent is not further spread in the environment. Finally nationals from many different countries might be involved, and therefore each national plan takes into account the management of casualties according to specificities of other Member States legislation.

Coordination of these activities at EU level and the relevant formalities for this is developed

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Checklist on management of fatalities:

- Are the following minimal requirements fulfilled?
 - National guidelines on the management on large numbers of fatalities exists
 - National plans address post-mortem care and informing pathology departments and clinical laboratories on submitting specimens for examination or disposal and use of personal protective equipment and standards
 - Guidelines on handling fatalities from transmissible agents exists

Interoperability

Intra-Community activity leading to:

- ECDC role as coordinator and evaluator of the process clearly defined

6.4 *Research issues*

6.4.1 Research on management of health threats

Outcome expected

The management of health threats goes through several steps like identification of the threat; treatment of those affected, limiting the spread of the disease / eradication of the threat.

Research is needed to evaluate the tools existing to handle these steps and in many cases to develop new tools needed. These tools are often not developed in ordinary research programs or often at least needs to be adapted to the special needs of the management of health threats. Special procedures are developed for programs to identify the special needs, to find applications that can be used and adapt them to health threat management.

Some of this research can be done in the preparatory phase but due to the very special and unforeseeable nature of new threats much research needs to be done during and after an emergency. Plans foresee this development and include fast availability of financial resources.

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Checklist on research on management of health threats: are the following minimal requirements in place?

- in the Member States:
 - a program in place to direct research efforts needed to improve preparedness with the necessary financial incentives attached

Interoperability

Intra-Community activity leading to:

- DG SANCO, DG RESEARCH and DG ENTR
 - a program in place to direct research efforts needed to improve preparedness with the necessary financial incentives attached
- Agencies:
 - EMEA for regulatory issues
 - ECDC for a role in co-ordination of research in Member States and funded by EC,

6.4.2 Medicinal product development

Outcome expected

A special area of research is the development of new medicinal products. For many health threats there is a lack of adequate medicinal products but the development has been slow, due to a lack of market perspective, consequently a failure to attract sufficient interest of industry, biotech and academia to invest in the development of such products. Furthermore when potential new products are becoming available there is no mechanism to assure the access of these products to all actors.

An EU-wide policy/strategy for the development and production of priority medicinal products against major health threats exists, consisting of:

- 1) An EU-wide mechanism to identify and ensure equitable access to existing essential medicinal products against major health threats
- 2) An EU-wide policy/strategy for the development and production of priority medicinal products against major health threats in collaboration with the pharmaceutical industry.

When a new product is identified there is also a need for a system to find a consensus on the use of the product e.g. targeting groups, dosing etc in the special setting of a health threat.

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Checklist on medicinal product development: are the following minimal requirements in place?

- in the Member States:
 - review application of existing EU-legislation
 - a system for the collaboration with regulatory agencies, public health institutions with product development capabilities and academia to further development of new medicinal products
 - a system to fund these activities
 - a system to evaluate the needs of medicinal products in the preparedness for health threats

Interoperability

Intra-Community activity leading to:

- Adaptation of EU-legislation to remove temporary liability from manufacturers in an emergency situation and to accommodate the potential use of unlicensed products (egg. first generation smallpox vaccines, new pandemic influenza vaccine): amendment to Art 5 of Directive 2001/83/EC.
- Promoting innovation through pricing and regulatory reforms
- The establishment of a Technology Platform to accelerate the development process of medicines with established public health value.
- DG SANCO, DG Research and DG Enterprise
 - A structure for collaboration between commission services
 - Possibilities to coordinate and fund activities in Member States
- Agencies:
 - EMEA for regulatory issues
 - ECDC for a role in co-ordination of multi-country phase IV post marketing surveillance studies),

7 Co-ordination of actions within Commission

A clear definition of roles, tasks and consultation process between the different partners (Commission services and agencies) has to be set out.

In essence, reference is made to issues like the public health Community legislation / public health mechanisms for alert and response when:

- Community legislation foresees exceptions such as public policy, security, health...
- Community legislation / initiatives / plans deal with situations that might affect or involve the health of the EU-citizen.

Conversely, public health initiatives and activities ought to meticulously consider the partners in the Community Institutions that need to be addressed to ensure adequate response to a threat. The previous issues in the planning process have identified already several mechanisms and Community legislation or services where co-operation is a requisite. Hereafter we try to identify in a more detailed way the implication of several of the players.

The Commission can act in a variety of other sectors of policy. Coordination across all such policies will bring significant benefits to the efforts of the Member States to respond effectively to health threats.

The aim with this Strategy document for the Commission is to identify our common areas in case of emergencies with threat to the health of the EU-citizen, to look closer to any vulnerability due to gaps in legislation or to identify where co-operation could be enhanced and to plan to prepare co-operation as much as possible.

This paper sums up already a number of key-actors, with whom the services competent for response to health threats already dealt with during real crises or in the preparation against deliberate releases of biological, chemical and radio-nuclear agents (Health Security). It is intended that the competent Commission services identify and specify, according to their past experience:

- The common areas when response to a public health threat occurs;
- The vulnerabilities in the co-operation to reach rapid response;
- How they identify what would be needed to improve and to prepare better (Interoperability)
- What 'tools' (legislation, platform, ...) the public health sector should provide for them to make rapid response feasible within their area.

By way of example we provide you already with a frame started on public health.

- 7.1 Commission competent services dealing with Civil Protection**
- 7.2 Commission competent services dealing with humanitarian operations**
- 7.3 Commission competent services dealing with trade**
- 7.4 Commission competent services dealing with transport and energy**
- 7.5 Commission competent services dealing with justice, freedom and security**
- 7.6 Commission competent services dealing with enterprise**
- 7.7 Commission competent services dealing with research**
- 7.8 Commission competent services dealing with external relations**
- 7.9 Joint Research Centre**
- 7.10 Commission competent services dealing with EuropeAID or development**
- 7.11 Commission competent services dealing with regional aid**
- 7.12 Commission competent services dealing with Information Society**
- 7.13 Commission competent services dealing with employment and worker's health**
- 7.14 Commission competent services dealing with health and consumer protection**

Most of the other services have far more stretching legal implications in the field of their competences than the Community competence on the “human health” aspects. Nevertheless, the protection of human health is a prerequisite. Vice versa human health protection has to consider animal health, plant, food safety, civil protection, Full respect and co-operation of

each other mechanisms and tools to respond quickly to any event is required. The human health services dealing with health threats should provide a frame for other policy areas to be able to prepare for and to decide rapidly when an event occurs. This frame should provide EU-decisions by public health authorities on the likelihood of the threat and the seriousness of the event based on scientific evidence, in order to give other competent areas a solid basis for action within their legislation.

Interoperability

- Review co-operation between the services of DG SANCO and with the other DG's within the scope of the relevant legislation on each role to threats where a joint response is required.
- Ensure co-operation between the scientific committees
- Ensure co-operation with the relevant agencies, such as ECDC, EMEA, EFSA and EU-OSHA
- Proposal for legislation based on Decision 2119/98/EC on the Community Network of Communicable Diseases, and in particular on a declaration of an emergency alert (Stand-by Declaration) and on the communication and consultation of adequate countermeasures.
- Proposal for a HEOF, Health Emergency Operating Facility in Luxembourg (and at the ECDC) serving as the enhanced tool allowing SANCO to fulfil obligations under Decision 2119/98, the Health Security Programme and the Solidarity clause of the Draft Treaty establishing a Constitution for Europe calling for increased solidarity and cooperation between the Member States in the field of prevention and protection against terrorism. All three documents refer inter-alia mechanisms for information and cooperation, coordination of actions and bringing into permanent communication with one another, through appropriate means, the Commission and the competent public health authorities in each Member State responsible for determining the measures which may be required to protect public health.
- Examine proposals to deliver rapid response to health threats under the Programme of Community action in the field of Health and Consumer protection 2007-2013:
 - Actions to prepare the Community to effectively react to health security threats and plan carefully for anticipated events, such as an influenza pandemic;
 - Actions to contain quickly and adequately the public health risks for EU citizens, following a health disaster or crisis, mitigating the health consequences of epidemics and releases of biological, chemical and radiological agents and restoring key health system functions.
 - Actions to establish and maintain a trained and permanently available core group of public health experts for global rapid deployment to places of major health crises together with mobile laboratories, protective equipment and isolation facilities.

7.15 Co-ordination of Commission services

Due to the complex nature of the response to public health threats, there is a clear need to co-ordinate the activities among the involved Commission services. To this end, an ad-hoc inter-service coordination group could be established that can be convened at short notice in the event of an emergency. The terms of reference defining competences and operational modalities are established in advance of such an event. It is important that the role of each service is mutually understood, in particular scope and limitation of competences. It should also be clarified how the conclusions and the outcome of the involved Commission services' meetings which are convened in the event of an emergency can be linked to the results of the consultations which will be held with the Member States' representatives.

The Commission is in the process of proposing several common mechanisms which could facilitate co-ordination in the event of health threats.

Interoperability

- A consolidation of the emergency systems managed by the Commission is proposed, named ARGUS. The Commission needs to ensure that relevant information is shared forthwith with all its services and national authorities concerned.
- The new system will respect the specific characteristics, competence and expertise of the individual and specialised systems which will continue to carry out their current functions.
- A central Crisis Centre in the Commission is proposed to bring together representatives of all relevant Commission services during an emergency. This crisis centre would coordinate efforts so as to evaluate the best practicable options for action and to decide on the appropriate response measures. A comprehensive emergency system in place at EU level requires that associated with

each degree of risk there be a uniform approach to risk analysis (assessments, security levels, response actions etc).

8 Management of plans

This section describes the processes required to deal with the established plans, allowing careful and mutual sharing, evaluation, training, distribution and testing.

8.1 Follow-up and verification process of plans

Outcome expected

This suggested planning process is to be followed by actions to ensure that the necessary structures, legislation, arrangements and resources are in place. It ought to be clear who holds responsibility for the plan and a mechanism and frequency for reviewing and updating the plan ought to be agreed. A distribution list ought to be maintained in order to communicate any update. This Community planning may provide as a template for event-specific plans or as template for developing or updating national/regional plans which obviously should not be in conflict. Therefore plans should refer to each other. The responsible(s) for this planning should oversee and ensure the existence of national plans and should be involved in the development or updating of such plans. Therefore it will be advisable that all national plans will be shared and validated through an agreed mechanism.

The level of scrutiny of plans in the EU requires carefully consideration since it is political sensitive.

A confidence building strategy has been agreed upon and the Commission has installed a peer review platform. This platform brings small geographical groups together and considers key parameters that are used to assess plans. The objective is that neighbouring countries feel confident in each other preparation.

MS, Commission and Agencies

Checklist on follow-up of plans: are the following minimal requirements in place?

- Public health authorities take actions to ensure that the necessary structures, legislation, arrangements and resources for national planning are in place
- Responsibility for the plan and a mechanism and frequency for reviews are agreed
- National plans include and maintain up to date a distribution list
- Public health authorities present the different plans in a peer setting to ensure that national/regional plans are not in conflict to plans at different levels
- Inventory/database/portal for national plans and agreed mechanism for validation of national plans

Interoperability

Intra-Community activity leading to:

- Public health authorities share the plans and present the different plans in a peer setting to ensure that national/regional plans are not in conflict to plans in the different Member States.
- Inventory and database for national plans is provided
- Member States agree on a mechanism for validation of national plans

8.2 Training

Outcome expected

At EU level the most appropriate concept for training may be to ‘train-the-trainers’ to help relevant courses at national level. This would help to fill possible gaps that may exist in training material (courses, slides, case-studies) and/or trainers. Therefore, procedures and structures are developed and training material share, a “directory of trainers” exists and courses are available also to ‘non-nationals’.

MS, Commission and Agencies

Checklist on training: are the following minimal requirements in place?

- Plans include relevant training programmes for all involved levels

Interoperability

Intra-Community activity leading to:

- 'train-the-trainers' modules to assist relevant courses at national level and provide training material (courses, slides, case-studies)
- procedures and structures to develop training material and a "directory of trainers" available to support in training materials and plan development

8.3 Testing and evaluation of plans

Outcome expected

After finalising structure and content of any preparedness plan, an important step is to test and evaluate the plan. To verify coherence and feasibility of the planning exercises are regularly set up.

A first exercise would be to go structured through the plan 'rehearsing' recent experiences (e.g. SARS) with different key players that were involved. In fact, recent experiences with SARS and (avian) influenza helped in developing the current document on preparedness planning.

Another step may be to go through the plan with the key players and simulate different scenario's (biological, chemical, radiological, etc.). In fact, preparations are made to do this kind of exercise at EU level. Similar exercises should be undertaken for national/regional plans.

MS, Commission and Agencies

Checklist on testing and evaluation of plans

- Plans include exercise processes and integrated learned lessons
- Exercise(s) that allow(s) players involved to test and evaluate the proposed plans

Interoperability

Intra-Community activity leading to:

- Regular EU-wide testing of scenario's
- As many as possible players should be identified in plan (local, regional, EU level, global partners)
- Sharing of learned lessons
- Develop opportunities to establish good practice and guidelines in the Community

8.4 Response time objectives

Outcome expected

Response time objectives mean suggested time frames for selected critical response functions or tasks. They form part of the objectives for a response capability once established and ought to be used as evaluation criterion in exercises.

MS, Commission and Agencies

Checklist on response time objectives: are the following minimal requirements in place?

- Plans include proper indicators and response time objectives, including testing response time on:
 - establishing emergency management operations
 - EOF activation
 - EOF fully functional (all organizations represented)
 - notify local, national and EU
 - initiate mitigation actions and provide technical assistance to the on-site responders
 - cordoning off an area
 - recommend urgent protective actions for the public
 - preparing patient isolation functions in a hospital
- Response time is tested at different levels

Interoperability

Intra-Community activity leading to:

- Sharing of lessons learned and plan efficacies

8.5 Coverage objectives

Outcome expected

Coverage objectives for selected critical response functions or tasks allow verification of the implementation of the cross-department implementations of plans. They form part of the objectives for a response capability once established and ought to be used as evaluation criterion. The coverage of specific professional target groups in national plans for specific illnesses (e.g. influenza vaccine, availability of collective and Personal Protective Equipment, etc...) allow plan managers to evaluate how well plans have been implemented.

MS, Commission and Agencies

Checklist on coverage objectives: are the following minimal requirements in place?

- Plans include proper indicators and coverage objectives, including measuring procedures:
 - coverage among emergency management operations
 - coverage among target professional groups (e.g. civil protection, transport, ...)
- Time to achieve these objectives is tested at different levels

Interoperability

Intra-Community activity leading to:

- Sharing of lessons learned and plan efficacies

Annex 1: Scenario

Sometime in the future...

The 24th of December 2006 a level 3 alert message is circulated to the EU Member States by the Early Warning and Response System, that links the Public Health Authorities responsible for measures to control communicable diseases in EU: a tourist returning from South East Asia has been hospitalized under BSL 3 conditions in a Capital of a small EU Member State, bordering several other Member States. The patient has an unusually severe respiratory illness. SARS has been suspected because a travel history in an area at potential risk of SARS transmission and recent contacts with persons with acute respiratory disease.

WHO outbreak verification list reports that since the beginning of December SARS suspected cases have been notified from South East Asia; an investigation is in course and confirmation of diagnosis of these cases is expected soon.

The patient, who spent two days in another Capital in EU while flying back, has been hospitalized two days after the arrival at home. No special measures of isolation and containment during the consultation have been taken and the patient has been isolated the day after the admission to the hospital. Respiratory specimens collected from the patient are tested at the national laboratory and are found to be positive for SARS coronavirus. Diagnosis is delayed because there was no pre-existing reference laboratory and agreements with other reference laboratories for confirmation were not finalised.

A EWRS message reporting the results is circulated to member states in EU and WHO is informed.

The day after WHO reports that a cluster of several cases of SARS has been confirmed in South East Asia and that other two bordering countries are reporting suspected cases. SARS coronavirus, after two years of silence, begins to make headlines in every major newspaper and becomes the lead story on major news networks. Key government officials throughout the world are briefed on a daily basis about the evolution of the situation.

In the meanwhile the patient dies and the national public health authorities are bombarded with thousands of telephone call by citizens who fear a SARS catastrophe.

As soon as the first EWRS message has been circulated among the EU Member States the emergency has been called to update the Public Health Authorities at Community level about the evolution of the situation and to share the strategy and the measures undertaken by each country. The following issues are raised and discussed: available expertise on SARS in the field of clinical management, infection control measures, laboratory procedures, public health measures; technical guidance documents on several topics; risks for blood donation; operational procedures for communicating among Member States and the Commission; case definitions; influenza differential diagnosis; restriction of travels; quarantine; previous reports and results of the questionnaire on 'measures undertaken by Members States, EFTA and Accessing Countries to control the outbreak of SARS'; web sites; road map for actions...

The National health authority of the victim's country starts all the procedures to quarantine all the health care workers who were in contact with the patient and they activate the operation for contact tracing of all the people who have been in contact with him: they all remain in the hospital. All the member of the family and the persons who visited the patient during the two days he stayed at home are quarantined in their own houses. A public health service, in collaboration with the local health authorities is managing the assistance and the monitoring of the people in quarantine. 32 selected passengers who travelled with the patient on the same airplane during the return flight will be included in the list. Unfortunately the airline company delayed the transfer of the passenger list for two days. They need to be contacted in 7 Member States, in Canada (1 case) and in US (2 persons). Contact tracing will be carried out by means of a GSM identifying system and on the basis of the personal history, in close collaboration with the police department.

Some of the people traced back refuse to be quarantined and says that there is no law that can oblige them to stay at home. Some other people fear that their pets will be killed. Two adolescents arrive to escape. An elderly man commits a suicide. A total of 379 people are quarantined and monitored on a daily basis, but many are from neighbouring countries, creating problems to their families and raising important concern for legal and ethical issues.

Soon after the case has been officially confirmed the Ministers of Health in Member States agree to call an extraordinary meeting of the Council to evaluate the action undertaken to respond to the event and to envisage future actions and measures to limit the spread of the outbreak at Community level.

The same day another EU Member State communicates that two patients are hospitalised and isolated because of an acute respiratory disease developed after returning back from South East Asia. A flight attendant who was on the same airplane of the first patient develops fever without respiratory symptoms and she is promptly isolated.

Two weeks after the notification of the event a Member States is communicating that a batch of eggs contaminated by a *Salmonella* strain has been widely distributed in EU and that at least 7 Member States are concerned by the distribution. The information does not receive proper attention because of the SARS event and because in Member States several systems for catching up early warning and response information are not adapted to such a situation. As a result 125 persons are currently hospitalized with severe *Salmonella* spp. Infections and 12 elderly people died. The outbreak is linked to consumption of contaminated food and it is now spreading.

One month after the notification of the first SARS case 3 Member States are involved with local transmission of SARS and 15 Member States are reporting cases by SARS affected areas. In South Asia the situation is apparently uncontrolled and the number of new cases are growing day after day. Cases are reported also in Canada, US, Brazil and Australia.

Public health officials are rapidly overburdened by the event. The Commission calls a team of experts to help the co-ordination of the emergency at central level but the National Health Authorities in Member States regret to inform that they are not in a position to send people to Luxembourg and Brussels because of lack of personnel. Only four people are recruited to help the Public Health Directorate staff dealing with the file. The new European Centre for Disease Prevention and Control is starting its activities and has all its limited manpower on the subject.

The rate of spread appears to be more rapid compared with the 2003 outbreak and all Member States begin to implement travel restrictions, quarantine measures and closures of educational institutions.

Selected hospitals in several Member States decide to activate their code for emergency situation. This is done in different ways depending by the country but usually means that the involved hospitals suspend non-essential services. They are also required to limit visitors, create isolation units for potential SARS patients, and implement protective clothing for exposed staff (i.e., gowns, masks, and goggles). Four days later this decision is extended to other hospitals. Later Health Authorities from five Member States communicate formally that this kind of measure is not justified. The massive number of cancelled services could cause collateral casualties from the suspension of health care activities and the impact of these events may never be fully measured. Other harms are more subtle, including hardship caused by restrictions on visits between families and patients hospitalized with conditions other than SARS. A harsh polemic starts between Member States. Unfortunately there is no scientific evidence to support the two different approaches. A Member State announces that it will derogate from the Schengen agreements if nothing is done to protect citizens at Community level.

National experts are called by their authorities to establish a SARS surveillance system; it is rapidly clear that physical and human resources are insufficient. Mainly the reporting structures are unclear and the appointed authority is unable to provide optimal support for outbreak investigation and management. There are also frequent requests for data for the regional and national government's daily press conference. The national infectious disease

tracking and outbreak management software are out-date and in some Member States also archaic, used in the late eighties and they can not be adapted for SARS.

Widespread panic begins because a therapy and a vaccine is not available. Media is attacking the industries, the different governments and the EU because they have ‘the main responsibility of the lack of vaccine and anti-viral drugs.

The influenza season is at its peak and people with acute respiratory disease are panicking and consulting the hospital services. Hospital structures are overburden and additional support to manage the still worsening emergency situation is severely limited.

Over the next two months cluster of cases are reported in other 5 Member States.

Worldwide the situation is worsening. Rates of absenteeism in schools and businesses begin to rise also in non affected countries. Phones at health departments are ringing constantly. The spread of SARS continues to be the major news item in print and electronic media. Citizens begin to clamour for vaccine and everybody wear masks. The Hong Kong scenario is reappearing in Europe.

Annex 2: List of abbreviations used

BICHAT	Task Force for Biological and Chemical Agents
BSN	Basic Surveillance Network
CBRN	Chemical Biological and Radiological/Nuclear events
DG	Directorate General
DSN	Dedicated Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ECHO	European Community Humanitarian Office
ED	Emergency Department
EDQM	European Department for the Quality of Medicines
EFSA	European Food and Safety Authority
EISS	European Influenza Surveillance Scheme
EMA	European Agency for the Evaluation of Medicinal Products
EMS	Emergency Medical Services
EOF	Emergency Operations Facility
EPCIP	European Programme for Critical Infrastructure Protection
ESCON	Epidemiological Surveillance Component of the Community Network
EU	European Union
EUNID	European Network of Infectious Diseases Physicians
EUPHIN	European Public Health Information Network
EWRS	Early Warning and Response System
HSC	Health Security Committee
HSSCD	Health Surveillance Scheme for Communicable Diseases
HTU	Health Threat Unit
ICU	Intensive Care Unit
IHR	International Health Regulations
IRIDE	Inventory of Resources of Infectious Diseases in Europe
MIC	Monitoring and Information Centre
MP	Medicinal Products
MS	Member States
NATO	Northern Atlantic Treaty Organisation
NGO	Non-Governmental Organisation
OIE	International Office for Epizootics
PPE	Personal Protective Equipment
RAS- BICHAT	Rapid Alert System on Biological and Chemical Agents Attacks
RAS-CHEM	Rapid Alert System on Chemicals
RD	Research and Development

SANCO	Health and Consumer Protection (Santé et Protection des Consommateurs)
SARS	Severe Acute Respiratory Syndrome
SOPs	Standard Operating Procedures
EVM	European Vaccine Manufacturers
WG	Working Group
WHO	World Health Organisation

Annex 3: Definitions

<u>Authentication of sender</u>	establishes identity of the electronic information provider.
<u>Authorisation of a user</u>	establishes what that a user is allowed to do. The operating principle applied is one of least privilege—participants, whether human or machine, will have only the privileges required to fulfil their duties. This approach prevents information over-load and adverse effects from leaks or unauthorised circulation or disclosure of sensitive information and maximises patient privacy as personal data are transmitted through the network.
<u>Closure of premises</u>	Measure to minimise contacts between persons might include closing of public areas such as schools certain work places etc.
<u>Contacts</u>	Contacts are persons who have been in touch with a confirmed or probable case during a period starting 24 hours before the start of symptoms and up to the time the scabs fall of. Another group of contacts are persons who have been in contact with contagious materials. Contacts can be divided in two groups A Household contacts and persons who have been in face-to-face contact with the case. Contacts with infectious material B Persons who spent time in the same environment or shared the same air-conditioning system as cases. This includes passengers in the same aircraft
<u>Cordon sanitaire</u>	Establishing a barrier around a defined potentially infected geographical area to prevent the movement of people in and sometimes also out of the area.
<u>Decontamination</u>	Decontamination is a process of removing or reducing the concentration of harmful substances
<u>Evacuation</u>	Measure to move a population in a geographical area to another place to restrict the spread of the disease.
<u>High-risk exposure groups</u>	In some plans called first responders, which is a term most often reserved for the special groups created to manage initial cases of smallpox. It is anybody that can be identified as likely to be the first to meet cases of smallpox in a country. Normally this includes health-staff mainly in emergency departments and ambulance personnel. Depending on the scenarios that are considered likely other groups should be considered such as the police, customs and other border-officials.
<u>Integrity of information</u>	implies that the information passing through, or residing on the system, is genuine and remains unadulterated. For transmission of data, random corruption should be handled on the protocol level with in-built error correction. To counter intentional corruption of transmissions, the operating principle will be that every communication transmission has to be encrypted, because of the dynamic, peer-to-peer nature of the networks.
<u>Isolation</u>	The separation of patients with a disease in from other people to prevent the further spread of the disease to the community or health workers.
<u>Mass emergency</u>	A major incident with a large number of people involved, causing an exceptional disproportion (in size or in time) between the medical and psycho-social needs on the one hand and the response capacity to these needs on the other hand
<u>Disaster</u>	A mass emergency in which disruption of facilities, infrastructure and/or service causes a huge and long lasting disparity between the medical and psycho-social needs and the response capacity to these needs

<u>Medical intelligence</u>	That category of intelligence resulting from collection, evaluation, analysis, and interpretation of foreign medical, bio-scientific, and environmental information and other information related to human or animal health that is of interest to strategic planning and to military medical planning and operations for the conservation of the fighting strength of friendly forces and the formation of assessments of foreign medical capabilities in both military and civilian sectors.
<u>Preparedness planning</u>	Factoring in plans the local, national and EU dimension in various sectors that impinge on emergency plans: provide a backbone structure for developing core elements to the different types of health threats and improve the inter-operability of such plans, addressing threats and emergencies which are threatening or are likely to threaten public health in more than one Member State.
<u>Player</u>	Administrative departments and authorities, institutes, companies, and community services (e.g. Hospitals, rescue workers, EMS departments, ...) at any level of functioning, providing an essential role in the event assessment and management
<u>Priority medicines</u>	Priority Medicines is a collective term for those medicinal products which are needed from a public health /care perspective, but are not existing nor being developed due to lack of market perspective. The term includes orphan drugs, medicines for children and the elderly and vaccines against major health threats caused by communicable diseases and bio-terrorism.
<u>Public Health Threat</u>	Is an event (incident), condition or agent, which by its presence has the potential to rapidly harm, directly or indirectly, an exposed population, sufficiently to lead to a crisis.
<u>Public Health Crisis</u>	A sequence of events following a public health threat, where the limited time available for deciding and the large degree of uncertainty leads to overburdening the normal response capacity and undermining of authority.
<u>Quarantine</u>	Measures to restrict the movements or activities of groups of people who are presumed to have been exposed to a disease. In some plans referred to as keeping people under observation. Can either be done by collecting people in one place (centralised quarantine) or by asking people to stay at home with regular contacts with a public health staff (decentralised quarantine).
<u>Risk management</u>	A process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for health protection of consumers and for the promotion of fair trade practices, and if needed selecting appropriate prevention and control options.
<u>Risk assessment</u>	A scientifically based process consisting of the following steps: I) hazard identification, ii) hazard characterization, iii) exposure assessment, and iv) risk characterization
<u>Restriction of movement</u>	Measures such as closure of public transport (airports, railways etc) to inhibit the spread of the disease.
<u>Ring-vaccination or Search and Contain strategy</u>	The strategy developed by WHO during the eradication of smallpox more adequately called a search and containment strategy. The mainstay is the early identification and isolation of cases, active search for and vaccination of all contacts and monitoring of these contacts to identify early signs of diseases to be able to isolate them at an early stage.
<u>Secondary contacts or Contacts to contacts</u>	Person with a household- or face to face contact with a type A contact
<u>Standing group</u>	Group available for very immediate meeting (within a 24 hour period).
<u>Threat area</u>	The technical area such as environment and expertise that may be

required to deal with the consequences of the threat: biological, chemical, radio-nuclear.

Tier

A group key players operating at a certain administrative level. During a wide spread incident, there is often a need to establish a national level, which manages wider than national strategic issues. For major incidents this would be the Health Threat Unit, DG SANCO.

In the current context of the above there are four tiers that need to be considered for action:

- EU co-ordinating structures and committees
- Member State; e.g.: Ministries of Health, Institutes of Public Health, other “competent bodies”, laboratories, academia
- Regional, provincial or country level: to be addressed by the each Member State

Local level or unit level e.g.: operational units such as hospital

Annex 4: The triggering system

1. is the event worth further consideration (*importance*)?

For an EU-wide context, this question depends on the pathogen, on the chemical on the type of release suspected. It can be answered through the score an illness would attain in the matrix. A tool will be developed to allow to this question to be answered “on the spot” such as a small computer programme to analyse the input.

Proposal: an illness which constitutes a reasonable (3), high (4) or very threat (5), as a result from analysis in the matrix, should be further examined. Unknown and unlisted disease should be tentatively entered and scored.

2. does analyses of surveillance data indicate any uncommon findings (*unexpectedness*)?

A threat generating at least the suspicion that it might be unexpected should be further examined. More precise questions to assist the decision making can be developed.

3. how credible is the threat (*credibility*)?

A manifestation of illness does not need further evaluation, since its mere presence already confirms the threat, be it from natural, accidental or man-made source. But this question becomes more relevant when the threat is expressed as a potential contamination or spread.

Initially three levels will be used:

- (0) Hoax (the threat is not deemed credible)
- (1) Probable/Possible (potentially credible, awaiting further information)
- (2) Likely/Confirmed

A positive answer to any of the threat assessment questions should lead to further consider the threat as probable, hence severe.

4. how big is the threat (*scale*)?

Scales that categorises events into four different classes has been developed in the Global health Security collaboration. This scale gives the possible approximation of the impact of the event. This would make it possible to have a common way of describing events with implications on/the resources needed to manage them. The table below describes the different levels. This table is taken from the incident scale developed in the Global health security network

Class of incident	Score	Description
Scale 4 Major incident	20-	Widespread/major presence of the hazard: very large impact on health/ environmental. All countermeasures deployed and aid/assistance requested/required
Scale 3 Serious incident	9-19	Significant presence of hazard: full implementation of countermeasures needed in affected localities.
Scale 2 Moderate incident	3-8	Moderate presence of hazard: requires partial implementation of countermeasures. Full countermeasures on alert. Serious/significant risk to health within immediate locality.
Scale 1 Minor incident	0-2	Minor presence of hazard with serious health effects likely to be restricted to immediate locality only. Public exposure within controllable limits and local countermeasures being implemented.

In order to assist the scoring of a threat into scale an event describing the severity, a scoring grid: the event is assessed and given a score according to the evaluation of 19 variables, using a set of predefined questions, each with predefined weights.

5. what is the extent of the threat (*response activity*)?

Threat Activity 0: No known cases anywhere

Threat Activity 1: Increased threat in the world

Threat Activity 2: One confirmed event (e.g. confirmed case) outside the EU

Threat Activity 3: One confirmed event (e.g. confirmed case) in EU or in a country bordering to EU

Threat Activity 4: Several events (e.g. active transmission) in EU

Threat Activity 5: Uncontrolled occurrence of events (e.g. uncontrolled spread) within the EU

Annex 5: Levels of threat and response

Scales that categorises events into four different classes has been developed in the Global health Security collaboration. This score gives an estimate of how big is the threat is and the same scoring system should be included in national preparedness plans.

Levels of threat activity (s) are of use when:

- Vaccinations/prevention measures of first responders or other groups
- Distribution of supplies
- Restriction of movements of populations
- Closing of borders and public transport
- Mass vaccination campaigns

Common EU threat activity levels would not necessarily replace the levels established by Member States in their plans. Instead they could serve the purpose of making it possible to “translate” the levels in one plan to the levels of another plan. This would make it easier to understand what activities are triggered by what events in different Member States.

The common threat activity levels would also provide a background needed for the development of a strategy on common EU activities. In the same way as activities in Member States needs to be related to certain events activities proposed by the Commission need to be connected happenings during an event. For countries that have not yet developed plans a common set of threat activity levels could form the basis for their own levels.

Based on what Member States and other countries developed the following set of threat activity levels is suggested. They are based on wish for a minimal amount of levels and a need to have them detailed enough so that the timing of the envisioned activities can be specified

Threat Activity 0: No known cases anywhere

The levels start at the present situation where no cases in the world are reported neither confirmed nor suspected. Most countries would at this level restrict themselves to preparatory activities.

Threat Activity 1: Increased threat in the world

The next level is when an increased level threat exists in the world probably through the identification of a probable or suspected case or through intelligence information. Findings of the transmitted pathogen with indication that they could be used for deliberate releases would be another sign of an increased threat. At this level the preparedness would be increased and some operational activities might be instituted like the vaccination of first responders if not already performed.

Examples of response: at this level the preparedness would be increased and some operational activities might be instituted like the vaccination of first responders if not already performed.

Co-ordination of some activities at EU-level, such as:

- Protect first-responders
- Start adverse event monitoring
- Alert web-page
- Case-definitions
- Prepare (syndrome-) surveillance
- Training material development for Member States
- Developing Guidelines

Threat Activity 2: One confirmed case outside the EU

Level 2 would be reached when a confirmed case is found outside the EU. This level takes into account the risk of exposed persons turning up in an EU country. The risk would correspond to the number of people are coming from the affected region in a given time-period. Some EU countries have extensive exchanges with neighbouring countries that are not in the EU, which is taken into account. There might also be cases when other countries also have a lot of contacts bit these details is impossible to take into account in a simple model.

Examples of response: co-ordination of some activities at EU-level, such as

- Send EU-investigation or assessment team
- MP development
- Stockpile assessment / re-evaluation
- Adopt policy on non-residents
- Agree on policy for contact-tracing
- Start surveillance at Member States

Threat Activity 3: One confirmed case in EU or in a country bordering to EU

Level 3 is when a case is found in the EU. The travel between EU countries is unrestricted and often encompasses big amounts of people everyday. This implies a real risk that persons exposed very quickly could appear anywhere within the EU.

Examples of response: co-ordination of some activities at EU-level, such as

- Schengen
- Restriction of movement

Threat Activity 4: Active transmission in EU

At level 4 there has been a confirmed transmission in one or several EU countries. This implies a situation where there is not just the occasional traveller that arrives with the disease but that cases have escaped attention long enough to transmit the disease.

Examples of response: co-ordination of most activities at EU-level, such as

- decision on mass-vaccination
- decision on closing borders

Threat Activity 5: Uncontrolled spread within the EU

Level 5 is reached when the spread is uncontrolled. The definition varies slightly but usually this would mean that cases appear where the time and place of infection cannot be verified. It could also be the simultaneous appearance of unrelated cases in several places in the same country. The level is often interpreted, as a stage when the counter-measures employed does not control the epidemic.

Examples of response: co-ordination of most activities at EU-level, such as

- mass-vaccination
- decontamination
- distribution of food / daily functions organisations ...

Annex 6: National Plans and relevant focus areas

The following table gives a possible national plan outline and an indication of relevant focus areas. Most elements of the Generic Preparedness Planning find a place in this table, but some other elements have been added, referring to activities from the individual players, without a need to have included these in the Generic Preparedness Planning process. The purpose of this table is merely informative, providing a comprehensive list of issues, each time with a relevance indicator to a specific biological, chemical or radio-nuclear focus, marked as “x”.

Relevance	Biological	Chemical	Radio-Nuclear	Terrorist
1. INTRODUCTION				
1.1 Purpose <i>Describe the purpose of the plan</i>	X	X	X	X
1.2 Participating organisations <i>List all organisations participating in the plan. This should include all national level organisations and also non-governmental organisations (NGOs), that may be a significant part of a response to an emergency involving a radiation hazard, and should include those responsible for response to conventional emergencies and criminal activities.</i>	X	X	X	X
1.3 Scope <i>Describe the scope of the plan, for example: “The plan addresses the response to an actual or perceived radiation hazard involving a national response in order to:</i> 1. <i>provide co-ordination of a response involving multi-jurisdictions or significant national responsibilities; or</i> 2. <i>provide national support to local governments. The plan does not provide sufficient detail for an adequate response. This level of detail should be contained in procedures that are developed based on the plan.</i>	X	X	X	X
1.4 Legal basis <i>List the national laws, codes or statutes that define responsibility for planning, decisions and actions governing the response to radiation and conventional emergencies and terrorist or criminal activities</i>	X	X	X	X
1.5 Related plans and documents <i>Give a brief description of how the plan relates to other major national plans that may be used along with the plan, including those for response to conventional emergencies and terrorist or criminal activities. Provide a complete list of all the supporting documents in an appendix.</i>	X	X	X	X
2. PLANNING BASIS				
2.1 Types of threats <i>Give a brief description of the different threats that were considered in developing the plan. This should be a summary of the results of the threat assessment and other appropriate threats. In appendices or other referenced documents list and show on a map any vulnerable facilities and local jurisdictions which fall within emergency zones or food restriction planning radius.</i>	X	X	X	X
2.2 Terms <i>Refer to an appendix for standard definitions of terms that should be used consistently in other plans and procedures in order to promote co-ordination. Where possible, the terms used by the organisations involved in the response to conventional emergencies should be adopted.</i>	X	X	X	X
2.3 Response roles and responsibilities <i>Describe the roles and responsibilities of national and local response organisation, in particular the public health authorities. This could be accomplished by a table showing the organisations: 1) responsible for authorizing/activating the national response, 2) directing the total national response, and 3) responsible for the different functional areas. This table should show how responsibilities could differ under different conditions such as: the source of the hazards (e.g. licensed practice/material, natural material, international, military, unknown); or simultaneous involvement of other emergency plans or hazards (e.g. major natural disaster or criminal activity). This could be based on the result of the allocation of responsibilities. Describe how responsibilities are delegated or transferred and the responsibilities of local response organisations and conditions when</i>	X	X	X	X

<i>these may change.</i>				
2.4 Response organisation <i>Provide a block diagram of the national level response organisation components (sections, groups and teams) with a brief description of responsibilities of each “block” and where the organisational element will probably perform. The emergency response organisation structure should be used for the national and local response organisations to foster integration. It should show how the national level response interfaces with the response of other organisations.</i>	X	X	X	X
2.5 Response facilities <i>Describe the response facilities that may be functional during a response.</i>	X	X	X	X
2.6 Response communications <i>Describe the communications system to be used during an emergency, which should include provision to ensure continued inter-compatibility with those used by other response organisations.</i>	X	X	X	X
2.7. Logistics/resource commitments <i>Describe the arrangements, including the organisational component responsible during a response for providing logistics support, for prompt procurement of needed supplies and services, possibly bypassing normal procurement arrangements. Describe the resources of government agencies and other organisations that will be made available to meet their obligations under the plan or that could be provided as assistance to local governments or other States. Describe the conditions under which resources will be provided.</i>	X	X	X	X
2.8 Concept of operations <i>Give a brief description of the ideal response to the various types of emergencies and the set up of the Health Operation Facility.</i>	X	X	X	X
2.9 Financing operation <i>Describe the system for financing of operations and reimbursement of organisations that provide support during a response. This could be that the cost of each government agency's participation in support of the plan is the responsibility of that organisation, unless other agreements exist.</i>	X	X	X	X
3. EMERGENCY RESPONSE PROCESS				
<i>Describe the national response arrangements process to perform the response functions listed in the subsections below, providing an appendix with detailed information needed by other organisations to develop compatible response arrangements. Identify which organisational component (section, group, team or position) within the response organisation will be responsible for all or part of the performance of these functions.</i>	X	X	X	X
3.1 Information Management Notification, activation and request for assistance				
<i>Describe the arrangements and process for notification, activation, and deployment of national response resource. This should include how decisions will be made to activate or deploy for: 1) emergency class declaration or notification of an emergency; 2) a request for assistance; 3) an event not addressed in the plans and 4) notification. Describe arrangements to receive and authenticate the notification (notification points, warning points) and trigger the response. Describe the arrangements for local governments to request national assistance. Describe the arrangements, the systems and links towards the health authorities.</i>	X	X	X	X
3.1.1 Pre-event surveillance (<i>see section 1</i>)	X	X	X	X
3.1.2 Risk analysis using intelligence and media reporting and other information sources (<i>see section 1</i>)	X	X	X	X
3.1.3 Trigger the response activity (<i>see section 1</i>)	X	X	X	X
3.1.4 Post-event surveillance (<i>see section 1</i>)	X	X	X	X
3.1.5 Monitoring side-effects of actions to counter the health threat (<i>see section 1</i>)	X	X	X	X
3.1.6 Clinical and laboratory diagnosis (<i>see section 1</i>)	X	X	X	X
3.1.7 Environmental sampling (<i>see section 1</i>)	X	X	X	X
3.1.8 Filing, documentation and archiving management (<i>see section 1</i>)	X	X	X	X
3.2 Communication				
3.2.1 Reporting systems and procedures (<i>see section 2</i>)	X	X	X	X
3.2.3 Data communication and management (<i>see section 2</i>)	X	X	X	X

3.2.4 Communicating among players (<i>see section 2</i>)	X	X	X	X
3.2.5 Risk-communication with media and public groups <i>Describe the arrangements for co-ordinating information from the national level with that from local government to national governments to communicate to the EU in order to ensure the information provided to the public through the media is timely, consistent and helpful. This is best accomplished by use of a single spokesperson or joint briefings at a public information centre near the scene of the emergency as soon as possible.</i>	X	X	X	X
3.2.6 Providing warnings and instructions to the public <i>Describe the national role in providing information, warnings or instruction to the public for regional or national emergencies such as for a large release or loss of a dangerous source.</i>	X	X	X	X
3.3 Scientific advice				
3.3.1 Rapid consultation (experts, expert bodies) for advise	X	X	X	X
3.2.7 Performing mitigation <i>Describe the arrangements to provide expertise and services promptly to assist local officials and first responders in mitigation (e.g. an uncontrolled source emergency).</i>	X	X	X	X
3.3.2 Directory of Experts	X	X	X	
3.3.3 Forecast modelling	X	X	X	X
3.3.4 Vulnerability assessment	X	X	X	X
3.3.5 Risk assessment and options for countermeasures	X	X	X	X
3.3.6 Determine collective protection (of international dimension)	X	X	X	X
3.3.7 Determine corresponding actions, resources to actions, and ways to implement actions	X	X	X	X
3.3.8 Taking urgent protective action <i>Describe the arrangements for providing support to local officials taking urgent protective actions. Any national role must support prompt decision-making. Local officials should make these decisions in most cases.</i>	X X	X X	X X	X X
3.4 Liaise and control structures				
3.4.1 Emergency management <i>Describe the command and control system used to manage the response, including responses involving several different national (e.g. for response to conventional emergencies and criminal activity), international and local plans. The system should have a unified command system (ICS),, which should be used at all levels (national–local) to allow maximum flexibility. Describe how authority would be transferred.</i>	X X	X X	X X	X X
3.4.2 Health Emergency Operations Facility	X	X	X	X
3.4.3 Operational procedures of the liaison structure	X	X	X	X
3.4.4 Approach by threat activity level and tier	X	X	X	X
3.5 Preparedness beyond the health area				
3.5.1 Information transmission, forwarding to authorities and agencies (local, national, international)	X	X	X	X
3.5.2 Stand-by operations: stand-by of agents, operators and staff	X	X	X	X
3.5.3 Assessing the initial phase <i>Describe the national arrangements for providing support to local officials in assessing the situation during the initial phase of an emergency.</i>	X X	X X	X X	X X
3.5.4 Passenger information (traceability, information)	X	X	X	X
3.5.5 Travel advice and entry or exit measures	X	X	X	X
3.5.6 Legal implication of countermeasures	X	X	X	X
3.5.7 Ethical implication of countermeasures	X	X	X	X
3.5.8 Transport of samples	X	X	X	X
3.5.9 Requisition of property (land, vehicles, facilities such as labs, hospitals, centres, pharmaceuticals)	X	X	X	X
3.5.10 Medical and law enforcement interventions	X	X	X	X
3.5.11 Defining cordoned area radius and safe distances <i>Describe the national arrangements for: taking agricultural countermeasures within the food restriction radius; implementation of temporary relocation; and management of waste.</i>	X	X X	X X	X X
3.5.12 Environmental decontamination, waste management and disposal interventions	X	X	X	X
3.5.13 Distribution	X	X	X	X
3.5.14 Maintenance interventions	X	X	X	X
3.5.15 Recovery interventions	X	X	X	X

<i>Describe the arrangements for the transition from emergency phase operations to routine long term recovery operations and for cancelling restrictions and other arrangements imposed during the emergency phase of the response</i>	X	X	X	X
3.6 Health sector preparedness				
3.6.1 Incident management outside hospitals	X	X	X	X
3.6.2 Protecting emergency workers <i>Describe the arrangements for protecting emergency workers (including those responding to the scene from agencies with no expertise or who are recruited during the response) and for supporting local governments in protecting their workers. Provide the criteria in an appendix. Describe the arrangements for providing for ethical and legal protection (e.g. protection from being personally liable for actions taken while responding) and social welfare (e.g. compensation for injuries) of responders.</i>	X X	X X	X X	X X
3.6.3 Hospital preparedness	X	X	X	X
3.6.4 Provide medical assistance and mitigating consequences <i>Describe the arrangements to make medical personnel nationwide aware of the medical symptoms following exposure and of the appropriate immediate action. Describe the arrangements to treat people who may suffer severe deterministic health effects from exposure or contamination. Describe the arrangements to assess exposure incurred by members of the public and workers and to make the results publicly available. Describe arrangements for identification, tracking and long term medical monitoring and treatment for those groups of people who are at greater risk of getting disease as a result of exposure. Describe the arrangements for responding to concern, anxiety, distress and inappropriate actions on the part of workers and the public. Describe the arrangements for requesting international assistance in providing treatment of severely exposed/contaminated individuals.</i>	X X	X X	X X	X X
3.6. Fatality management	X	X	X	X
3.6. Research issues	X	X		
4. EMERGENCY PREPAREDNESS PROCESS				
<i>Describe the arrangements used to perform the preparedness functions listed, which are needed to develop and maintain the capability to respond to an emergency. Identify which organisational component (section, group, team or position) within the response organisation will be responsible for all or part of the performance of these functions.</i>	X	X	X	X
4.1 Authorities and responsibilities <i>Describe the arrangements for developing and maintaining the plan and supporting infrastructure.</i>	X	X	X	X
4.2 Organisation <i>Describe the arrangements for selection and recruitment of adequate numbers response personnel</i>	X	X	X	X
4.3 Co-ordination <i>Describe the arrangements used to ensure that planning is continually co-ordinated with other planning efforts at the national and local level. This should include co-ordination with the planning for response to conventional emergencies and criminal activities and provision to ensure that interoperability of equipment (e.g. communication frequencies), concepts (e.g. command and control) and methods (e.g. monitoring) is maintained where appropriate. This should include the designation of a national coordinating authority and possibly an “emergency preparedness committee” which ensures the co-ordination of all planning efforts between ministries, local governments, agencies, facilities and operators.</i>	X	X	X	X
4.4 Plans and procedures <i>Describe the arrangements for production, distribution and maintenance of the plan and supporting procedures and documents.</i>	X	X	X	X
4.5 Logistical support and facilities <i>Describe the arrangements for ensuring the availability of the logistical support and facilities needed to execute the plan. A list of the resources available and the agencies/organisations that provide them should be provided in an appendix.</i>	X	X	X	X
4.6 Training <i>Describe the arrangements for ensuring adequate training for personnel responding under the plan.</i>	X	X	X	X
4.7 Exercises				

<i>Describe the arrangements for the preparation and conduct of emergency preparedness exercises.</i>	x	x	x	x
4.8 Quality assurance and programme maintenance <i>Describe the arrangements to ensure a high degree of availability and reliability of all personnel, training, supplies, equipment, communication systems and facilities necessary to perform the functions specified in the plan and the arrangements to maintain, review and update the plan, procedures and other arrangements and to incorporate lessons learned from research, operating experience (such as response to emergencies) and emergency drills and exercises.</i>	x	x	x	x
4.9 Follow-up <i>Describe the follow-up and verification process of plans. Describe the results of the time tests against the objectives</i>	x	x	x	x
REFERENCES				
LIST OF ABBREVIATIONS				
DISTRIBUTION LIST <i>List (and distribute to) all individuals/organisations that are parties to the plan or that will be developing response arrangements that should be consistent with the plan.</i>	x	x	x	x

Annex 7: EU list of high threat pathogens

The establishment of a list of agents was foreseen in the plan for the EU Health Security Programme: “Elaboration of an agreed updateable list of biological and chemical agents that are susceptible to be used in attacks or threats of attack, together with their characteristics and associated symptoms and diseases and indications that permit their timely detection and identification/diagnosis with agreed levels of certainty.”

Similar lists have been developed elsewhere with a more or less defined goal of identifying the most dangerous agents for which certain activities, like export control, need to be implemented. Other lists aim for the most dangerous pathogens if used against humans or the agents that have most potential to be developed into a bio-weapon. In order to do this a number of variables have obviously been examined and this has been described more or less openly. There is medical literature, when it comes to the CDC list but less obvious for other lists. These lists were obtained from analysing the vulnerability along many variables.

List of diseases	Agents with VERY HIGH threat
Anthrax	<i>Bacillus anthracis</i>
Botulism	<i>Clostridium botulinum</i> toxin
Glanders	<i>Burkholderia mallei</i>
Haemorrhagic fever	Congo-Crimean haemorrhagic fever virus Ebola virus Guanarito Junin virus Lassa fever virus Machupo virus Marburg virus Omsk Haemorrhagic Fever Virus Sabia
Plague	<i>Yersinia pestis</i>
Smallpox	Variola major
Toxic syndromes	Ricin Tetrodotoxin Viscum album lectin 1 (Viscumin)
Tularemia	<i>Francisella tularensis</i>
List of diseases	Agents with HIGH threat
Brucellosis	<i>Brucella abortus</i> <i>Brucella melitensis</i> <i>Brucella spp</i> <i>Brucella suis</i>
Cholera	<i>Vibrio cholerae</i>
Coccidioidomycosis	<i>Coccidioides immitis</i>
Diphtheria	<i>Corynebacterium diphtheriae</i>
Dysentery	<i>Shigella dysenteriae</i>
Fever	Chikungunya virus
Hantavirus pulmonary syndrome	Hantaan virus
Haemorrhagic fever	Nipah Rift Valley fever virus
Histoplasmosis	<i>Histoplasma capsulatum</i>
HUS	<i>E. coli</i> 0157:H7
Influenza	Influenza virus (new strain)
Legionellosis	<i>Legionella pneumophila</i>
Melioidosis	<i>Burkholderia pseudomallei</i>
Meningitis	<i>Neisseria meningitidis</i>

Monkey pox fever	Monkey pox
Neurological syndrome	Palytoxin
Paratyphoid fever	<i>Salmonella paratyphi</i>
Psittacosis	<i>Chlamydia psittaci</i>
Q fever	<i>Coxiella burnetii</i>
Rocky mountain spotted fever	<i>Rickettsia rickettsii</i>
Scrub typhus	<i>Oriente tsutsugamushi</i>
Toxic syndrome	Conotoxin
	Microcystin (Cyanginosin)
	Saxitoxin
Tuberculosis	<i>Mycobacterium tuberculosis</i>
Typhoid fever	<i>Salmonella typhi</i>
Typhus fever	<i>Rickettsia prowazekii</i>
(Epidemic louseborne typhus)	
Viral encephalitis	Eastern equine encephalitis virus
	Getah Virus
	Hendra (formely: Equine Morbilli Virus)
	Herpesvirus simiae (B virus)
	Japanese encephalitis virus
	Kyasanur Forest Virus
	LaCrosse
	Louping III Virus
	Lymphocytic choriomeningitis virus
	Murray Valley Encephalitis Virus
	Powassan Virus
	Rocio Virus
	St. Louis Encephalitis Virus
	Tick-borne encephalitis virus
	Toscana
	Venezuelan equine encephalitis virus
	West Nile
	Western equine encephalitis virus
Yellow fever	Yellow fever virus

Annex 8: Guiding principles for interventions

1. Public health threats are rapidly verified and information is shared with partners quickly.
2. Member States all designated network institutes contribute to the necessary resources to rapidly respond to requests for assistance from affected state(s).
3. EC and Member States, decide commonly on the type of support, sending a team and terms of references for the investigation/support.
3. When a team is decided, under the direction of the designated team leader, the EU-team integrates and coordinates activities to support national efforts and existing public health infrastructure.
4. The most appropriate experts reach the field in the least possible time to carry out coordinated and effective outbreak control activities.
5. There is fair and equitable participation of all designated network institutes in the international responses.
6. There is strong technical leadership and coordination in the field.
7. There is commitment to national and regional capacity building as a follow up to international outbreak responses to improve preparedness and reduce future vulnerability to epidemic prone diseases.
8. Responses will be used as a mechanism to build EU capacity by the involvement of participants in training programs relevant to outbreak response, such as the exercises by the Commission Civil protection, EPIET, etc.
9. All responses will proceed with full respect for ethical standards, human rights, national and local laws and cultural sensitivities and traditions

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