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**NOTE**

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from : Council Secretariat

to : Attachés/Counsellor on Bio-preparedness

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Subject : Draft inventory of EU instruments in the area of bio-preparedness relevant for the Council conclusions on addressing Chemical, Biological, Radiological and Nuclear risks and on Bio-preparedness

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1. Delegations will find attached a draft inventory of the EU-instruments that are relevant for the draft Council conclusions on addressing Chemical, Biological, Radiological and Nuclear risks and on Bio-preparedness<sup>1</sup>.

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<sup>1</sup> 14744/07.

2. This version was established by several services of the Council Secretariat in consultation with several other services of the Commission. It is by no means a complete document, the consultations having not yet been finalized as yet. It is nevertheless felt to be useful to inform delegations so that they can make their contributions and comments at an early stage.

It is the intention that the final product become "an inventory established under the responsibility of the Presidency by the Services of the Commission and the Council Secretariat."

3. This draft is based upon the CBRN-inventory<sup>2</sup> that accompanied the CBRN Programme of 2002<sup>3</sup>, upon the 1st Presidency report of 2003<sup>4</sup> and the 2nd Presidency report of 2005<sup>5</sup>.
4. This inventory only covers bio-preparedness. It is however the intention to expand it so as to cover chemical, radiological and nuclear risks as well. This task will be undertaken in the 1st semester of 2008.
5. The present draft has the "LIMITE" status but the final version of the Inventory is bound to be public.
6. Delegations are invited to notify the General Secretariat, with copy to the Presidency, before Friday 16 November 2007, close of business, of any comments, suggestions or contributions they may have on this draft (mail to lieven.vermote@consilium.europa.eu and jbs@reper-portugal.be).

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<sup>2</sup> 15873/02.  
<sup>3</sup> 14627/02.  
<sup>4</sup> 16285/03.  
<sup>5</sup> 8988/05.

**DRAFT**

**INVENTORY OF EU-INSTRUMENTS**

**RELEVANT FOR**

**THE COUNCIL CONCLUSIONS OF .....**

**ON ADDRESSING CHEMICAL, BIOLOGICAL,**

**RADIOLOGICAL AND NUCLEAR RISKS AND ON**

**BIO-PREPAREDNESS <sup>6</sup>**

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<sup>6</sup> 14744/07.

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**INVENTORY OF EU-INSTRUMENTS RELEVANT FOR  
THE COUNCIL CONCLUSIONS OF ... ON ADDRESSING CHEMICAL,  
BIOLOGICAL, RADIOLOGICAL AND NUCLEAR RISKS AND  
ON BIO-PREPAREDNESS**

**A. INTRODUCTORY PART**

**I. BASES FOR THIS COMPILATION**

1. This inventory of EU instruments relevant for the Council conclusions of .... on addressing Chemical, Biological, Radiological and Nuclear risks and on bio-preparedness is basically an update of the bio-preparedness elements contained in the Inventory <sup>7</sup> of EU Instruments relevant for the Council and Commission programme of 20 December 2002 on preventing and managing the consequences of CBRN threats (CBRN Programme) <sup>8</sup>.
2. The CBRN Programme has been overtaken by the EU Solidarity Programme of the Council of 2 December 2004 on the consequences of terrorist threats and attacks (revised/widened CBRN Programme). <sup>9</sup> On its turn, the Solidarity Programme has become part of the EU Action plan on combating terrorism. <sup>10</sup>
3. This description of EU-instruments concerns the areas of :
  - I. civil protection,
  - II. human health protection,
  - III. pharmaceuticals for human use,
  - IV. safety of feed and food,
  - V. animal health protection,
  - VI. plant protection and plant health,
  - VII. environment,
  - VIII. critical infrastructure protection
  - IX. non-proliferation, global disarmament and arms control
  - X. customs,
  - XI. police, security and intelligence,
  - XII. military assistance
  - XIII. research.
  - XIV. overall coordination

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<sup>7</sup> 15873/02 + COR 1 + COR 2.

<sup>8</sup> 14627/02.

<sup>9</sup> 15480/04.

<sup>10</sup> The latest version of the EU Action Plan on combating terrorism is contained in 7233/1/07 REV 1.

4. This inventory was established under the responsibility of the Presidency and under the supervision of a Counsellors/Attachés Group on bio-preparedness by the General Secretariat of the Council in cooperation with the Services of the Commission, the Counter-Terrorism Coordinator, the HR's Personal Representative for non-proliferation and the Chairmen of the following contributing working parties and committees of the Council :
- the Civil Protection Working Party (ProCiv),
  - the Working Party on Public Health and Medical Devices (SAN),
  - the Working Party on Pharmaceuticals and Medical Devices (PHARM),
  - the "Friends of the Presidency" Working Party (Food Safety),
  - the Working Party of Veterinary Experts (VETER),
  - the Working Party on Plant Health (PHYTOSAN),
  - the Environment Working Party(ENV),
  - the Working Party on Transport (Intermodal Questions and Networks) (TRANS),
  - the Working Party on Global Disarmament and Arms Control (CODUN),
  - the Working Party on Non-Proliferation (CONOP),
  - the Working Party on dual use goods (COMER),
  - the Working Party on Terrorism (3rd pillar) (ENFOPOL),
  - the Working Party on Terrorism (2nd pillar) (COTER),
  - the European Union Military Committee (EUMC),
  - the Research Working Party (RECH).

## II. SECTORS THAT ARE VULNERABLE FOR CBRN THREATS

### A. Health

5. The Health sector is highly exposed to biological threats. These threats might arise from naturally occurring diseases, especially if they develop into pandemic, deliberate releases of biological agents to cause harm, or from accidents in which harmful biological agents are involved. Terrorist acts aiming, directly or indirectly, at inflicting harm on human health may often be carried out in a covert way using biological, chemical or radiological agents.
6. Mitigating the effects of covert releases requires early agent detection or case recognition of victims, followed by a prompt activation of an effective multi-sector response.
7. Health authorities and health services have a crucial role in identifying agents released in various environmental compartments, including built-up environments such as buildings, underground train and other transport infrastructures, and distribution chains such as for food, water, air and post. They must establish effective surveillance for unusual clinical syndromes or unexpected patterns of occurrence of more common syndromes, for making clinicians aware of the syndromes to look out for and for notifying promptly and appropriately the authorities in charge of collecting and evaluating epidemiological information and co-ordinating public health responses.

Identification and clinical recognition rely on high quality laboratory diagnostic tests based on previously prepared protocols so that deliberate releases can be rapidly confirmed or excluded. Laboratory expertise and capacity must be available to cope with high-threat agents and complex technology and methods as well as a surge in demand in case of multiple threats or attacks. Proper and safe arrangements are in place for transportation of samples, reagents and specimens. However, further improvements to reduce the burden of administrative issues are required. Chemical and radiological agents would require separate specialised laboratories and adaptable methods of environmental sampling.

8. Field investigation must be rapidly available to analyse relationships between cases and to establish common environmental exposures, and co-ordinate additional case finding. This is key to determining potentially exposed groups of people who would require antibiotic prophylaxis, vaccination and/or monitoring depending on the agent. Tracing the source of covert deliberate releases would require combining data from human and environmental epidemiology with information from security services. Finally, the public health system would have to be prepared for conducting, as required at the local, regional or national level, triage, contact tracing, testing, diagnosis, treatment, and prophylaxis for large numbers of people, and for providing advice to health professionals and the public.
9. Health authorities and health services would undertake preventive, remedial and treatment action, such as decontaminating exposed persons, taking swabs for analysis or administering prophylactic treatments. They have to be shielded from direct or indirect effects of attacks and be strengthened to cope with the upsurge in demand that will follow an attack with many victims and to withstand the pressures from the occurrence of multiple attacks or incidents. They have to undergo drills and ensure the smooth interdisciplinary working between clinicians, microbiologists, toxicologists, epidemiologists, communicable disease control physicians, and radiation biologists and physicists in order to mount an effective and proportional response. They need to be properly equipped and have recourse to sufficient quantities of medicines, other medical supplies, protective and decontamination equipment, detection kits and sampling equipment, and laboratory and medical services. They will have to rely on tested emergency plans based on appropriate scenarios and modelling which takes account of geographical characteristics and allow for a surge in demand and circumstances of disruption of vital utilities and transport.

## **B. The food chain (food production, animals and plants)**

10. Throughout the whole food chain, food contamination is a real threat to EU food sources and should be appropriately addressed. In fact, food and feed could be the target of terrorist acts and this threat has to be carefully considered, assessed and handled both at national and Community level. Food production is extremely complex. Products of animal and plant origin present intrinsic hazards, due to microbiological and chemical contamination. Food systems can be very complex and unfortunately microbes, toxins, [chemicals and heavy metals] can be deliberately used to contaminate food sources on the farm, during feed and food processing, during storage and transportation or in the restaurant during food preparation. These types of activities can cause of extensive morbidity and mortality as well as economic destruction of agricultural and food manufacturers industries and a disruption of consumers' confidence.

11. In the area of animal health, the seriousness and spreading potential of certain pathogens are obvious threats to stock farming in all countries. Epizootiological agents of this kind not only adversely affect animal health and stockfarming and thus cause major economic disruption by destabilising national and international markets, but also create social problems and divert the public's attention from the goals of combating campaigns. Their effects can also lead to food shortages, and some of them are zoonotic, thus threatening human health. The biological agents in question, e.g. African and classical swine fevers, foot and mouth disease, avian influenza, Rift Valley fever etc. are listed by the OIE (World Organisation for Animal Health) as having a potential for very rapid spread and serious economic consequences. The nature and properties of a number of these pathogen agents mean that they could be used for terrorist purposes. Because of their media impact, certain diseases less contagious but highly harmful for human health, notably anthrax, botulism, brucellosis or tularaemia, could also be effectively used by terrorist groups. The OIE recently issued comments regarding bio-preparedness, including a list of animal diseases from potential bioterrorists agents.
12. On plant protection, products which are used to protect crops against diseases and pests can basically be abused by terrorists in destroying crops by using herbicides, intentionally poisoning the population or livestock, replacing packages of plant protection products by more harmful substances in distribution centres and contaminating cultures of microbial plant protection products with human pathogens. Plant pests and diseases may be caused by insects, mites, nematodes, bacteria, fungi or viruses. They could be harmful to plants and plant products and they are not infectious to human beings. They could be abused by terrorists in destroying crops. They could also cause significant yield losses in agricultural plant production and damages in forests, public green and wild flora. Outbreaks are often caused by special climatic conditions which favour one organism and render it possibilities to spread more than usually, or because organisms are introduced into areas where they find favourable conditions that allow spreading and establishing of the relevant harmful organism.

**C. Environment**

13. Particular attention should be paid to the vulnerability of drinking water.

**D. Critical infrastructures**

14. *(to be inserted)*

### **III. ROLE OF THE DIFFERENT POLICIES CONDUCTED IN THE EU IN RESPONSE TO CBRN THREATS**

#### **A. Civil Protection**

15. Civil Protection at Community and Member States level basically prepares for consequence management to limit the consequences of disasters. Civil protection also contributes to prevention and monitoring. At the level of the Community, the main instrument for reaching these objectives are the Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument,<sup>11</sup> and the Council Decision ..../EC/Euratom of ...2007 establishing a Community Civil Protection Mechanism<sup>12</sup> hereafter referred to as "the Mechanism".
16. The Financial Instrument and the Mechanism, which are implemented by the Commission, basically aim at facilitating the use of the civil protection resources of the Member States with a view to preventing disasters and to assisting other Member States and third countries in case of an emergency.

#### **B. Health**

17. To reduce the vulnerability of the health sector and enhance its capacity to deal effectively with covert releases, it is essential, in a space such as the European Union where people, products and services circulate freely, that appropriate mechanisms and arrangements are put in place to ensure prompt notification and exchange of information in case of threats and attacks, action at source to stem the spread of disease and environmental contamination, and mutual assistance for diagnosis and management of cases, laboratory and epidemiological investigations, and public health response as detailed above. This, in turn, requires sharing of knowledge and good practice, laboratory facilities, equipment and products, and experts and intervention personnel across Europe. It would be important to ensure that Bio-preparedness issues are properly included in national public health laws.
18. *The Health Security Programme* agreed upon on 17 December 2001 by the Health Security Committee aims at
  - (1) setting up a mechanism for information exchange, consultation and coordination for the handling of health-related issues related to attacks in which biological and chemical agents might be used or have been used,
  - (2) creating a EU-wide capability for the timely detection and identification of biological and chemical agents,
  - (3) creating a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available,
  - (4) drawing up rules and disseminating guidance to authorities, health professionals and to the public on facing-up to attacks from the health point of view and coordinating the EU response and links with third countries and international organisations.

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<sup>11</sup> OJ L 71, 10.3.2007, p. 9.

<sup>12</sup> OJ L .....

19. The *Mandate* of the Health Security Committee was re-established in February 2007, following a Communication from the Commission, enlarging its scope until a general review of all the legal provisions and other arrangements in the area of health threats is carried out and covering also pandemic influenza and generic preparedness and response planning.<sup>13</sup>

**C. Pharmaceuticals**

20. On pharmaceuticals, the starting points are the priorities set out in the Presidency conclusions on bioterrorism at the Health Council of 15 November 2001 (paragraph 4) to "(3) Set up a mechanism for information on the availability of serums, vaccines and antibiotics, including concerted strategies for developing and using those resources; to (5) Promote the development of vaccines, medicines and treatments".

**D. Protection of feed and food**

21. Feed and food operators, including growers of crops intended for feed and food, have primary responsibility for food safety. They are at the front line for ensuring food safety and protecting the public. However, the responsibility for food safety belongs to everybody who is a part of the food chain.
22. The current legal framework and operational set-up has in general afforded the EU consumer a high level of health protection. The problem has not been that much the lack of legal instruments, but the broad disparity in the means to respond to situations in specific sectors, or the multiplicity of actions which need to be triggered in the case where a problem spills over from one sector to another.

**E. Protection of animals**

23. Within the framework of the Community's exclusive competence, numerous regulatory measures have been adopted at Member State and European Union level to keep animal diseases at bay and to combat any outbreaks that do occur. These measures apply whether the origin of an epidemic is accidental or the result of terrorist action. The EC new Animal Health Strategy for 2007-2010 thoroughly enhances that aspect and the essential link of any policy with relevant international standards.

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<sup>13</sup> Council conclusions of 5 February 2007 on the Communication from the Commission to the Council on the transitional prolongation and extension of the mandate of the Health Security Committee in view of a future general revision of the structures dealing with health threats at EU level,(5862/07).

**F. Plant health**

24. Plant health forms the basis for the production of food and feed stuff in the EU. The structures to prevent the abuse of plant protection products are already in place in the Community (including, for example, a frequent sampling) to prevent or discover unintended contamination. The efficiency of these structures was recently demonstrated in the case of Nitrofen.
25. Within the framework of the Community's plant health legislation, numerous provisions have been adopted at Member State and European Union level to prevent the introduction into and the spread within the Community of organisms harmful to plants or plant products.

**G. Environment**

26. EU environmental policy may contribute effectively to the protection of the environment and of human health against pandemics and biological accidents, disasters and terrorism. Coordination, exchange of information and cooperation mechanisms in the field of the environment, existing within and between the Member States, should be expanded and sped up as appropriate, in order to reinforce the EU's capacity of reaction towards biological and chemical terrorist threats.

**H. Critical infrastructure protection**

27. An EPCIP ("European Programme for Critical Infrastructure Protection") policy package was put forward by the Commission in December 2006. It is composed of a Communication and a proposal for a Directive. The communication sets forth the horizontal framework for the protection of critical infrastructures in the EU.

**I. Non-proliferation, global disarmament and arms control**

28. The EU-strategy endorsed by the European Council of 12 December 2003 against the proliferation of weapons of mass destruction i.a. aims at preventing third countries and terrorists to acquire CBRN-materials and their means of delivery<sup>14</sup> and by seeking an effective multilateral response to this threat.

**J. Customs**

29. p.m.

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<sup>14</sup> 15656/03.

## **K. Police, Security and Intelligence**

30. In the framework of the Police and Judicial Cooperation in Criminal Matters and of the Common Foreign and Security Policy, a wide range of terrorism-related issues are discussed, including also issues related to terrorists' use of CBRN substances, such as exchange of information, assessment of terrorist threats, strategic and operational analyses and specialised projects.

## **L. Military capabilities**

31. p.m.  
Description of
- the database of military assets and capabilities relevant to the protection of civilian populations, created in 2003<sup>15</sup>
  - the general framework of 2006 for the use of Member States military or military chartered transportation assets and ESDP coordination tools in support of EU disaster response<sup>16</sup>
  - the arrangements of 2006 for military support to EU disaster response<sup>17</sup>

## **M. Research**

32. *The Sixth Framework Programme for Research and Development*, adopted on 27 June 2002, will provide support to research activities in this area, in particular under the 'scientific support to policies' where the section dealing with health and security has been expanded to include "issues related to civil protection (including biosecurity and protection against risks arising from terrorist attacks) and crisis management."

## **B. ACTIVITIES UNDERTAKEN IN THE DIFFERENT POLICY AREAS**

33. This part explores, for the different policy areas described in II above, the activities that have been undertaken for the 7 strategic objectives of :

- A. threat and risk analysis and assessment,<sup>18</sup>  
*Threat analysis assesses the activity of threatening actors.*  
*Risk analysis concerns the vulnerability of the possible targets and the potential effects of disasters on the society, economy and environment.*

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<sup>15</sup> 6644/4/04.

<sup>16</sup> 8976/06.

<sup>17</sup> 9462/3/06 (limite)

<sup>18</sup> The definitions are derived from the EU Solidarity Programme of 2 December 2004 on the consequences of terrorist threats and attacks (15480/04) and, to a lesser extent, from the Programme of 20 December 2002 to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats (CBRN Programme) (14627/02).

- B. prevention (or reduction of vulnerability),  
*Prevention concerns upfront measures to decrease the vulnerability of potential targets or to increase their protection.*
- C. monitoring, detection, identification and alert ~~of attacks~~,  
*This strategic objective concerns the putting in place of adequate mechanisms for a quick detection and identification of an actual threat and for alerting professionals and the public in appropriate ways.*
- D. preparedness  
*Preparedness concerns putting in place and enhancing all capabilities that are needed for mitigating and remedying the impacts of a threat and for facilitating the return to normal conditions so that they are ready for immediate use in case of threat or disaster.*
- E. consequence management,  
*This concerns the establishment and operation of the structures and procedures for mobilising and using the capabilities that are necessary and available for mitigating the impact of a disaster.*
- F. international cooperation,  
*International cooperation may contribute to the provision, exchange and coordination of vital information and to supplementing prevention policies and national consequence management capacities in the affected country.*
- G. overall coordination and implementation.  
*This concerns the effective coordination and monitoring of the implementation of the above 6 strategic objectives.*

## I. **CIVIL PROTECTION**

### A. **Generalities**

34. The main instruments in civil protection are the Council Decision of 5 March 2007 establishing a Civil Protection Financial Instrument (the "*Financial Instrument*")<sup>19</sup>, which succeeds to the civil protection action programmes of 1997 and 1999, and the Council Decision 2007 (EC, Euratom) of .. November 2007 establishing a Community Civil Protection Mechanism (the "*Mechanism*")<sup>20</sup>. Taken together, those two acts will improve significantly the technical and financial resources for the prevention of disasters within the EU, and for the preparedness and joint response of the civil protection assets of the EU Member States.
35. The *Financial Instrument* contributes to :
- the further development and establishment of forecasting, detection and early warning systems,
  - training, networking, exercises and exchanges of experts and expertise,
  - the education, disaster awareness and self-protection of the populations.

<sup>19</sup> OJ L 71, 10.3.2007, p. 9.

<sup>20</sup> 11163/1/07 REV 1.

36. *The Civil Protection Mechanism* will contribute to :
- the creation of self-sufficient and autonomous civil protection assistance intervention capabilities or teams of the Member States that are able to undertake certain pre-defined tasks, such as fire fighting and rescue operations ("modules"), and aim to be trained and interoperable,
  - the development of the Monitoring and Information Centre (MIC) managed by the Commission into a framework for collecting and sharing validated emergency information and for mobilising and pooling personnel, equipment, transport and other resources of the Member States,
  - the improved coordination of the assets of the Member States at headquarter and field level.

The *Mechanism* has been used very intensively in the past, both inside and outside the EU. It was e.g. called upon to intervene during the forest fires in the Mediterranean in summer 2007, arranging for the provision of fire-fighting planes, helicopters, equipment, expertise and satellite images.

## **B. Risk analysis and assessment**

37. The experts from the Member States and from the Commission will, within the framework of the Civil Protection Action Programme and the Mechanism, consider several CBRN threats and the most appropriate response and identify in particular where mutual help may be possible.
38. Within the framework of the *Civil Protection Action Programme*, the call for proposal 2003-2004 identifies a major project on the comparison of risk assessment and/or risk management methodologies in the sector of NBC threats. The project should establish an inventory of existing methodologies, elaborate best practise, draft common recommendations to be addressed to the Member States, and take into account scientific knowledge.

## **C. Prevention/ Vulnerability reduction**

### **- Public information**

39. The Commission recommends guidelines and techniques for public information which pay special attention to CBRN threats.
40. Within the framework of the *Civil Protection Financial Instrument* <sup>21</sup>, the call for proposal 2003-2004 identifies a major project on self-protection, in the section "information to the public". The project should focus on accident prevention and preparedness, including CBRN risks, in private households. The project should establish best practices for the appropriate behaviour in the case of an accident and major emergency. Moreover, the project should give recommendations for a basic life support kit for the European citizen at home.

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<sup>21</sup> Council Decision of 5 March 2007 establishing a Civil Protection Financial Instrument, OJ L 71, 10.3.2007, p. 9.

The support kit should encompass the necessary physical first-aid equipment for daily risks, disasters and CBRN threats.

41. Furthermore, a Communication, which address the question of natural and technological hazards, is in preparation. It presents in particular the arguments in favour of improving information provided to populations likely to be affected by the consequences of a disaster.

#### **D. Monitoring**

##### **1) The 112 Single European Emergency Call number**

42. *Council Decision 91/396/EEC of 29 July 1991 on the introduction of a single European emergency call number*<sup>22</sup> and the *Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services*<sup>23</sup>, introduce, in particular the Single European emergency call number (112). This enables the public to transmit direct warnings to the police and the civil protection authorities of the Member States.

##### **2) The Monitoring and Information Centre**

43. *The Monitoring and Information Centre set up under the Civil Protection Mechanism* and operated by the Commission may, with the support of CECIS (see 49 below), serve as the nerve centre of the mechanism as it is here that information is received from the various networks and the Member States. This enables the Centre to speed up and facilitate the selection of the most appropriate means of intervention and to ensure ongoing coordination while liaising with the national authorities.
44. Moreover, the human resources available to the Centre have been reinforced, in particular through the support of experts seconded by the Member States. As a result, the personnel on standby have doubled since 1 April 2002. At the same time, the Commission has substantially increased the staff that is to be mobilised to implement the mechanism in particular in emergency situations.
45. The Centre also serves as an interface with other Community networks likely to be involved in dealing with an emergency. In this framework, appropriate measures are underway to continue to guarantee optimum coordination between the civil protection network and other networks such as the Rapid Alert System BICHAT of the Health Sector, as well as ECURIE (European Community Urgent Radiological Information Exchange).
46. The centre will of course cooperate with appropriate international organisations in accordance with the operative rules of the Civil Protection Mechanism.

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<sup>22</sup> OJ L 217, 6.8.1991, p. 31.

<sup>23</sup> OJ L 108, 24.4.2002, p. 51.

### 3) 24h Contact points

47. The Monitoring and Information Centre's work is based on the round-the-clock network of contacts set up very rapidly by the Commission to ensure uninterrupted links with the civil protection centres of the Member States. Through this network there is immediate access to essential information on the expertise available to control the effects of CBRN attacks.
48. To date, the fifteen Member States, Norway and nine candidate countries have supplied this information which will prove to be of crucial importance in the event of a CBRN attack. The information is constantly up dated.

### 4) Dedicated and reliable Common Emergency Communication and Information System (CECIS)

49. The Member States will have the possibility of exchanging urgent messages through the Common Emergency Communication and Information System (CECIS) of the Mechanism if they wish, without being under an obligation to do so <sup>24</sup>.
50. The Commission and the Member States have adopted the technical procedures and security constraints of the dedicated communication network that will be established in the framework of the Mechanism in particular to enable urgent information to be exchanged among the Community in response to CBRN threats. Establishing a communication system that is powerful and reliable even in emergencies is a formidable challenge, which should be met within the framework of the mechanism. The solution adopted will specifically guarantee the authenticity, integrity and confidentiality of information exchanged among Member States under routine conditions and in emergencies.
51. Provision has of course been made by the Commission for inter-linking this communication system with other Commission networks, in particular for radiological and health emergencies. The interconnections will be tested and validated through exercises.
52. In order, more specifically, to validate and test communication among operational centres, from alert detection to intervention team mobilisation, the Commission organises, with the relevant services of the Member States, communication exercises covering CBRN aspects.

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<sup>24</sup> CECIS is the follow-up to the *PROCIV-NET (Civil Protection and Environmental Emergencies European Network) project*, planned by the Commission's services (DG ENVIRONMENT) in cooperation with the Member States and with financial and technical support from the IDA programme. PROCIV-NET seeks to establish the interconnection of National Authorities with responsibility for the protection of citizens from natural and technological hazards. The PROCIV-NET project is to be implemented in three stages over the coming years.

## **E. Preparedness**

### **1) Disaster Medicine**

53. In the framework of the Civil Protection Financial Instrument, a dedicated workshop will be organised to improve the understanding of CBRN threats in a disaster medicine context, allowing the actors in this field to improve their preparedness.

### **2) Network of CBRN experts of the Member States**

54. The Commission and the Member States have now available under the Mechanism a list of national contact points for networks of CBRN experts in the Member States and in EEA and candidate countries with the necessary qualifications in CBRN emergency fields. These experts can be consulted or sent at the request of the Member States concerned to the scene whenever necessary.

### **3) Predetermined intervention teams and other means that can be made available by the Member States**

55. The Member States have identified, within the framework of the Mechanism, civil protection capacities that may be provided by the Member States on a case by case basis. To ensure that optimum use can be made of these capacities, a preliminary inventory has provided an overview of the means currently available for various types of interventions (including the response to CBRN risks). This inventory will help identifying the capacities that are needed but are not sufficiently covered.
56. In collecting the information necessary to draw up the inventory of specific means such as serums and vaccines, the Commission has established an efficient cooperation with the pharmaceutical sector. These activities are described in more detail in the section devoted to pharmaceuticals.
57. In response to the request put forward by the June European Council, and after consultation with the EU Counter-Terrorism Coordinator, the Commission has initiated a new process designed to assess the civil protection capabilities that are available at European level to assist countries affected by a major terrorist attack. This exercise is not intended to provide a realistic picture of all national civil protection resources available within the participating countries, but focuses specifically on the assets and capabilities that could be made available to assist other countries in the event of a major terrorist attack.

The Commission has taken a scenario-based approach to identify both the needs for assistance at EU level and the resources available in such cases. These scenarios cover the following types of attacks: a massive explosion affecting critical infrastructure in the affected country, the dispersal of a chemical agent, the dispersal of a biological agent, the dispersal of radiological material (N and R-scenario), an attack against a sea-going tanker, agri-terrorism and the deliberate contamination of food.

Based on the scenarios, the Commission has developed a consolidated list of the civil protection assets and capabilities required to handle the consequences of major terrorist attacks in Europe, and a comprehensive questionnaire focusing both on quantitative and qualitative information. The Commission has requested the 30 countries participating in the Community Mechanism to provide information on the civil protection assistance they could offer in each of these scenarios. In the meantime, the European Union Military Staff has started upgrading the military database on the basis of the consolidated list and questionnaire developed by the Commission.

**4) Predetermination of teams of experts for assessment and for the coordination of interventions**

58. The added value of the Mechanism also largely derives from the availability of experts capable of assessing needs and of organising and coordinating intervention teams made available by the Member States.
59. In order to enable the Commission and the Member States to properly select the experts required and to ensure that the abilities of these experts are recognised by all concerned, it has been necessary to develop and agree, in the framework of the comitology procedure, on the selection criteria that will be used by the Member States in compiling and supplying lists of experts.

**5) Training and exercises for intervention and assessment/coordination teams**

60. An ongoing training programme has been set up by the Commission under the Mechanism in order to create a reserve of highly qualified teams and personnel with proper experience and trained to working together in a European context. This training will concern all levels, from the head of a national intervention team up to the senior official responsible for coordinating the action of different national teams. The first training courses will start in the end of 2002.
61. In addition, the Commission organises with the relevant services of the Member States full-scale simulation exercises in the field of chemical, biological, radiological and nuclear terrorist attacks.
62. Moreover, a programme for exchanging CBRN experts will be set up under the Mechanism during fall 2002 to disseminate national best practices more effectively and to enable information transfer among Member States.
63. A special workshop and a full-scale exercise have been organised end 2002 to take stock of the action taken by the Member States and the Commission one year after the attacks of 11 September. They have focussed on the level of preparedness and response of the services concerned and highlighted any additional action required. The first workshop has tested the CBRN network in the Member States and the Monitoring and Information Centre placed in the Commission. A second workshop will take place beginning 2003.

64. In the period 2004/05, in the framework of the Community Civil Protection Mechanism, the Commission funded five exercises, accompanied by workshops. While not uniquely devoted to terrorist threats, one exercise deals with an explosion in a petrochemical plant and two of them are on the release of dangerous CBRN materials as the result of an earthquake. The Austrian exercise EUDREX 2004, for instance, will involve search and rescue activities in full protective gear due to the release of R, B and C agents. The mitigation measures under these scenarios are very much the same as would be needed following a terrorist attack.

The call for proposals launched in May 2004 requested proposals for exercises simulating either terrorist attacks or natural disasters. Unfortunately, none of the proposals submitted involves a terrorist scenario. Based on this experience, the 2005 call for proposals may focus exclusively on terrorist scenarios.

## **F. Consequence management**

### **1) Assistance through the Community Civil Protection Mechanism**

65. The Member States may seek assistance from each others through the Monitoring and Information Centre of the Mechanism. In particular, thanks to the sound cooperation among all the Member States and efficient coordination of work and resources available in the various areas, a country hit by a disaster can now count on national resources in all fields that have been predetermined in the framework of the Mechanism.
66. The means and tools for coordination and information exchange among Member States and between the Member States and the Commission have been improved drastically in recent months.
67. Finally, it should be noted that all the efforts made to respond specifically to the new threats in the CBRN field will, of course, also enhance the capacity to respond and the quality of such response to any natural disaster or major technological accident in and outside the Union.

## **G. International cooperation**

68. The Community works in close cooperation with other relevant international organisations and third countries in order to establish adequate information exchange and rapid alert systems and to avoid duplication of work.
69. *p.m. : Reference to the arrangement between Cion and UN-OCHA of 2003*
70. On 19 May 2004, an Administrative Arrangement was signed by the Commission with the Russian Federation Ministry for Civil Defence, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM of Russia) on cooperation between the Monitoring and Information Centre and the Operational Centre of EMERCOM of Russia in order to facilitate the rapid exchange of information in emergencies.

## H. Coordination

71. pm. to be inserted.

## II. HUMAN HEALTH PROTECTION

### A. Generalities

#### 1) **The Health Security Committee**

72. To provide an effective mechanism of co-ordination on preparedness and response to deliberate releases of biological and chemical agents, the *Health Security Committee (HSC)* was set up following the conclusions which the Health Ministers drew at their meeting on 15 November 2001. The HSC is comprised of high-level representatives of the Member States charged with improving cooperation on preparedness to biological and chemical agent attacks, raising the alert in case of attack, exchanging information rapidly and coordinating health responses in case of emergency following a deliberate release of biological or chemical agents to cause harm.

73. On 16 November 2006, the Commission submitted to the Council the Communication on the transitional prolongation and extension of the mandate of the Health Security Committee in view of a future general revision of the structures dealing with health threats at EU level.<sup>25</sup> In 2007, the Council of the European Union agreed that the mandate of the Health Security Committee was temporarily prolonged covering also pandemic influenza and generic preparedness and response planning and the general revision of the structures dealing with health threats at EU level.

#### 2) **The Health Security Programme**

74. Moreover, following a proposal by the Commission, the HSC agreed on 17 December 2001 *a programme of cooperation on preparedness and response to biological and chemical agent attacks (health security)* as requested by the EU Health Ministers at their meeting of 15 November 2001. The programme comprises 25 actions grouped under 4 objectives.

The programme aims to ensure an EU-wide capability for the timely detection and identification of biological and chemical agents in laboratories, the rapid and reliable determination and diagnosis of relevant human disease cases, the availability of medicines, the co-ordination of emergency plans and the drafting and dissemination of rules and guidance on facing-up to attacks from the health point of view. The Communication reflects the progress made in carrying out the 25 actions which form the health security programme and describes the outlook for continuation of action at Community level in this field. Health security is a major component in the Commission's "stability and security" objective for 2003 and 2004.

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<sup>25</sup> COM/2006/0699 final.

75. A Communication on progress with the implementation of the Health Security Programme was published on 2 June 2003.<sup>26</sup>

### 3) The Health Security Task Force

76. A-Task Force composed of seconded experts from Member States and public health officials dispatched by the European Commission, was set-up with the European Commission's, Health and Consumer Protection Directorate-General of the Commission to implement the Health Security Programme. The Task Force was integrated into the newly created Health Threats Unit in 2003.

### 4) The Health Action Plans and Strategy

77. In May 2002, the European Parliament and the Council reached an agreement regarding a new *programme of Community action in the field of public health 2003-2008* of which the promotion of actions to respond rapidly and in a coordinated fashion to health threats is one part. This new programme contributed, for example, to the exchange of information concerning strategies in order to counter health threats from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts and developing and using, when appropriate, Community approaches and mechanisms.

78. The Commission will adopt a new Health Strategy in 2007 setting broad objectives for health during the next decade promoting health across all policies and tackling global health issues.<sup>27</sup> A new EU Programme on Health 2008-2013 is presently being discussed in the European Parliament and the Council. The draft new Programme also includes a part on health security.

## B. Risk analysis and assessment

79. To enhance the Community public health systems preparedness for CBRN terrorism, the focus is on strengthening risk assessment, communication and management of all kinds of health threats. Preparedness for threats to health has to cover the whole spectrum of activities. This ranges from a simple threat or suspicion of a deliberate release designed to cause harm all the way up to mass casualties and interdiction of movement that might require law enforcement and civil protection interventions.

80. The Commission has already devised a system for the classification of CBRN incidents. *For infectious diseases, this led to a classification in very high and high threat pathogens.*

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<sup>26</sup> 10327/03 - COM(2003) 320 final  
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<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/747&format=HTML&aged=0&language=EN&guiLanguage=en>

<http://europa.eu/scadplus/leg/en/cha/c11503c.htm>

It has also envisaged scenarios of releases of each of the different categories of CBRN agents under different circumstances and corresponding algorithms for introducing counter-measures and for informing partners in the Rapid Alert System RAS-BICHAT and the communication system between the Global Health Security Initiative partners (Canada, France, Germany, Japan, Italy, Mexico, United Kingdom, United States, the World Health Organisation, and the Commission).

### C. Monitoring

81. The majority of Member States have surveillance systems in place for monitoring the occurrence of infectious diseases. In most Member States, it are these existing systems that would be used to monitor a deliberate release of bio agents. In conjunction with this, Member States are developing new diagnostics for rapid detection and have expertise in risk analysis, which is used to prepare for outbreaks.
  - 1) **Surveillance systems network for the epidemiological surveillance and control of communicable diseases and Rapid Alert System - BICHAT**
82. There are existing networks at European and international level for many infectious diseases. Under the *European Parliament and Council Decision 2119/98/EC of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community*, effective co-ordination of national networks of bioagents is taking place. To ensure progressive coverage of bioagents, which will now be extended to some pathogens that may be used in bioterrorist attacks, the Commission has adopted *Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision 2119/98/EC*.
83. Since 1999, monitoring and alert of ~~some~~ events due to communicable diseases relevant at Community level are taking place under *Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC of the European Parliament and of the Council*. The mechanism is operated by an informatics tool called Early Warning and Response System (EWRS) and provides for notifications and exchange of information on responses, including coordination of public health measures between Member States, Candidate countries, EEA countries and the European Centre for Disease Prevention and Control (ECDC). In addition, since the entry into force of the new revised International Health Regulation, the World Health Organisation is part of the system.
84. To provide a proper system for notifying incidents and threats involving the deliberate release of biological and chemical agents, a system for alert notifications and co-ordination of first responses has become operational under the first objective of the Health Security programme. This aims at setting up a comprehensive mechanism for information exchange, consultation and coordination for the handling of health-related issues related deliberate releases and providing a common platform for sharing information on preparedness and response plans.

The Health Security Committee members are linked via direct lines and a 24hour/7 day-a-week alert system of contact points in the Member States and the Commission (*Rapid Alert System BICHAT*). *In situ* visits, tests and joint exercises as well as training (internal and external) are being conducted to ensure the system works reliably and effectively.

## 2) Rapid detection, identification of CBRN agents and diagnostics

85. Detection and identification of agents is covered under the second objective of the health security programme, namely, creating an EU-wide capability for the timely detection and identification of biological and chemical agents. The agents that have been prioritised, in this context, comprise those adopted by the US Centres for Disease Control that are included in *Commission Decision 2002/253/EC laying down case definitions for diseases to be covered by the EU communicable disease network* (that Commission Decision was taken under the *Council Decision 2119/98/EC on the surveillance of communicable diseases*). In addition, tularaemia, Q-fever and smallpox have been given priority.
86. In 2007, an initiative was made by the Network Committee under Decision 2119/89/EC to include 3 new diseases as Human Flu in Humans, West Nile Virus and the Severe Acute Respiratory Syndrome – SARS. Furthermore, the scientific approach of case definitions is currently under review with the support of ECDC. The Decision 2119/89/EC itself will be examined in order to elaborate the smooth collaboration with the new WHO International Health Regulation 2005.
87. In order to enhance capabilities in detection and identification by clinicians and laboratories, working groups on clinical diagnosis guidelines and on laboratory capacity and cooperation have been set up under the HSC. In addition, Commission funded laboratory networks cover most of the very high threat pathogens (as defined and adopted by the HSC<sup>28</sup>) such as viral hemorrhagic fever viruses. Further improvement is needed with regards to bacterial pathogens. Moreover, to cater for the specific requirements of chemical agents, an ad hoc group has been set up, also under the auspices of the HSC.
88. The detection of deliberate releases of biological agents relies first and foremost on Member States' surveillance systems for monitoring the occurrence of infectious diseases. Co-ordination of these surveillance systems at EU level, especially for notification and exchange of information on outbreaks, is conducted in the framework of Decision 2119/98/EC on the surveillance and control of communicable diseases and its specific executive Commission Decision on case definitions for potential BT-pathogens.<sup>29</sup>

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<sup>28</sup> Van Loock MATRIX

<sup>29</sup> Commission Decision 2003/534/EC, of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable - OJ L 184 , 23/07/2003 P. 0035 - 0039.

Inventories of laboratories and their diagnostic capabilities were compiled to ensure the reliable and timely detection of agents likely to be used in a bio-terrorist attack.

89. The Commission services have evaluated the means available to diagnose some of the "very high and high threat" pathogens in some Member States. To do this, projects have been launched on laboratory networking to ensure state of the art diagnosis of those pathogens likely to be used in a terrorist attack. A laboratory-working group has been established under the Health Security Committee (HSC). The mandate of the group is to provide a sensitive and reliable diagnosis of rare pathogens, including ortho-poxes, in each Member State through officially appointed laboratories and to reach agreement on methods and protocols. Quality Assurance Schemes have been developed and ring test have been carried out. In the same field, the Commission is developing supporting equipment.

### 3) The Health Emergency Operations Facility (HEOF)

90. The Health Emergency Operations Facility (HEOF) management arrangements are dealing with major health incidents which are defined as *"Any event (happening with or without warning) causing or threatening death or injury, damage to property or the environment or disruption to the community, which because of the scale of its effects cannot be dealt with by the emergency services and local authorities as part of their day-to-day activities."*
91. HEOF covers self-limiting as well as unlimited disasters—be they natural or man-made. It is activated by a decision by senior management to apply the Public Health Emergency Management structure. HEOF's role is to provide the Commission with an overview of pandemic and epidemic phenomena, related data and information, measurements taken and the health related situational awareness information. It should facilitate communication among crisis managers<sup>30</sup> in Member states and other associated countries, international health organisations and health emergency professionals. Enhanced communication will increase the Community's capability to respond to and to prepare for health related emergencies. HEOF should enable the Commission to "play a role"<sup>31</sup> in the coordination of large-scale (i.e. cross-border) health related emergencies and Bio-chemical terrorist attacks. HEOF is a place to communicate (listen and speak).

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<sup>30</sup> HEOF network of communication includes the 27 Member States, the EEA countries (Iceland, Lichtenstein, Norway), the Candidate countries (Croatia, Turkey), the Global Health Security Network (Canada, Japan Mexico, United States, WHO), other Rapid Alert Systems run by the Commission [ECURIE (Radio-nuclear); MIC (Civil Protection); RASFF (Food and Feed), RAPEX, EUROPHYT (plants), ADNS (animal health) and TRACES ], JLS, EU agencies [ECDC; EMEA; EUROPOL, EFSA] and Commission central crisis structure ARGUS. Switzerland has applied for official membership.

<sup>31</sup> The importance of this role is not completely defined, nor is it stable. It is possible that the EC will play a more important coordination role in the future if the member states agree that more centralized coordination activities could be beneficial to them. For the time being, Public Health not being an exclusive Community competence, HEOF will be used to facilitate the coordination of the involved actors and provide them with the information they need in order to take coordinated measures.

Commission positions are decided by a distinct process, which will involve people who should not be in HEOF.

92. As regards decision making, the procedures laid down in the Public Health Emergency Management structure will apply, notably as regards Senior Management. The HEOF (LUX and BXL) is a key part of the general infrastructure of SANCO's response to public health emergencies, which itself is linked to the Commission's crisis management system ARGUS. All of these are for improving rapid communication and do not change decision making responsibilities.
93. HEOF uses the following sources of information:
- a) ECDC
    - daily roundtable report (See in [Sanco-lux-onduty@ec.europa.eu](mailto:Sanco-lux-onduty@ec.europa.eu) )
    - weekly report
    - ECDC website [ <http://www.ecdc.eu.int/> ]
  - b) WHO
    - weekly Outbreak verification list [ <http://www.who.int/csr/outbreaknetwork/en/> ]
    - GOARN <http://www.who.int/csr/outbreaknetwork/en/>
  - c) INVS Weekly international epidemiological bulletin
  - d) INVS (l'Institut de veille sanitaire) is the public institution in France in charge with surveillance; monitoring and early warning and covers all kind of health emergencies.
    - [http://www.invs.sante.fr/liste\\_diffusion/index.htm](http://www.invs.sante.fr/liste_diffusion/index.htm)
  - e) EUROSURVEILLANCE - <http://www.eurosurveillance.org/>  
Eurosurveillance is a leading independent European scientific journal devoted to the epidemiology, surveillance, prevention and control of communicable diseases. It is published by the European Centre for Disease Prevention and Control (ECDC) in Stockholm, Sweden. Eurosurveillance is available in three separate formats: a weekly online release, concentrating on timely dissemination of preliminary and short outbreak reports, and new developments concerning communicable diseases relevant to Europe; a monthly online release, which features longer, in-depth analyses of outbreaks and the epidemiology of infectious diseases as well as articles on policies and guidance for the prevention of communicable diseases; and a quarterly print edition, which compiles material from the monthly and weekly releases. In addition, e-alerts are sometimes released on events that need to be urgently communicated to the readers for rapid public health action.

- f) PROMED website [ <http://www.promedmail.org/>].  
 ProMED-mail - the Program for Monitoring Emerging Diseases - is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases and acute exposures to toxins that affect human health, including those in animals and in plants grown for food or animal feed. Electronic communications enable ProMED-mail to provide up-to-date and reliable news about threats to human, animal, and food plant health around the world, seven days a week.
- g) EMM – European Media monitor  
<http://press.jrc.it/NewsBrief/alertedition/en/CommunicableDiseases.html>  
 The NewsExplorer automatically generates daily news summaries, allowing users
- a) to see the major news stories (news cluster) in various languages for any specific day (The clusters are ranked according to the number of articles contained in the cluster.)
  - b) to compare how the same events have been reported in the media written in different languages.
- h) Tariqa – It is equivalent software to MedISys run for DG RELEX. It concentrates on Humanitarian Aid, Conflicts, Security abroad, Terrorists activities and cooperation matters. [ <http://158.166.117.10/tariqa/terrorism.html>]
- i) GPHIN website and messages [ <http://gphin-rmisp.hc-sc.gc.ca> ]  
 The Global Public Health Intelligence Network (GPHIN) is a secure, Internet-based "early warning" system that gathers preliminary reports of public health significance in seven languages on a real-time, 24/7 basis. GPHIN has a broad scope. It tracks topics such as disease outbreaks, infectious diseases, contaminated food and water, bio-terrorism and exposure to chemical and radio-nuclear agents, and natural disasters. It also monitors issues related to the safety of products, drugs and medical devices. Information contained in this system is integrated in HEDIS and all news alerts can be found in the functional mailbox INFO BICHAT.
- j) Lexis Nexis [ <https://www.nexis.com/> ]  
 LexisNexis is a popular searchable archive of content from newspapers, magazines, legal documents and other printed sources. LexisNexis claims to be the "world's largest collection of public records, unpublished opinions, forms, legal, news, and business information" while offering their products to a wide range of professionals in the legal, risk management, corporate, government, law enforcement, accounting and academic markets.

- k) MedISys alerts  
 MedISys (Medical Intelligence System) is an internet monitoring and analysing system developed by the European Commission Joint Research Centre (JRC) for the Health and Consumer Protection directorate General (DGSANCO) to rapidly identify potential threats to the public health. These threats include both communicable diseases (including unknown ones) and chemical, biological and radio-nuclear threats. The information processed by MedISys is widely derived from the Europe Media Monitor (EMM - <http://emm.jrc.org>) monitoring about 1000 new websites in 35 languages.
- l) Messages circulating through the various warning systems (EWRS, RAS BICHAT, RAS CHEM, ECURIE, MIC, RASFF, ...)
- m) The Global Health Security Initiative (GHSAG) public and restricted website.  
 Open website: <http://www.ghsi.ca/english/index.asp>.  
 - URL: <http://www.ghsn-rssm.org/ev.php>
- n) Search engines  
 - URL: [www.google.com](http://www.google.com)  
 - URL: [www.clusty.com](http://www.clusty.com)
- o) News and press agencies  
 Traditional media and press agency have their own fast information flows. It is not rare that they are the first ones informed of certain events. Links as the following ones can be of interest:  
 - BBC News Health [ <http://news.bbc.co.uk/2/hi/health/default.stm>]  
 - CNN: [www.cnn.com](http://www.cnn.com)  
 - Reuters AlertNet (Alerting humanitarians to emergencies [ <http://www.alertnet.org/thenews/newsdesk/index.htm> ])  
 - Reuters: [www.reuters.com](http://www.reuters.com),  
 - International Herald Tribune: □
- p) Dedicated Surveillance Networks: via ECDC  
 Several Surveillance Networks are funded by the European Commission. National Institutes from different MS carry out systematic surveillance on specific diseases.
- q) ENAC [IAEA- International Atomic Energy Agency]  
 Under its Emergency Notification and Assistance Convention, the International Atomic Energy Agency offers a secure exchange of emergency information through this official protected Early Notification and Assistance Conventions Website for:  
 - Submission of initial notification, advisory messages and changes of emergency class by relevant contact points, together with attached electronic documents;

- Accessing messages and downloading relevant documents submitted by contact points; and
  - Contact points to confirm to the ERC that they have taken note of a particular message
  - URL: <https://www-emergency.iaea.org/login.asp>
  - 
  - r) IAEA - First Responders"
 

This section of the IAEA/IEC website is based on the "Manual for First Responders to a Radiological Emergency" and provides practical guidance to first responders in dealing with a radiological emergency. The site/pages are accessible via <http://www-ns.iaea.org/tech-areas/emergency/emergency-response-actions.asp>.

In addition, a "Manual for First Responders to a Radiological Emergency" in PDF format can be downloaded.
  - 
  - s) IPCS – International programme on chemical safety provides "Chemical Safety Information from Intergovernmental Organizations", called INCHEM [<http://www.inchem.org/> ]
- IPCS INCHEM is a tool for those concerned with chemical safety and the management of chemicals. Produced through cooperation between the International Programme on Chemical Safety (IPCS) and the Canadian Centre for Occupational Health and Safety (CCOHS), IPCS INCHEM directly responds to one of the Intergovernmental Forum on Chemical Safety (IFCS) priority actions to consolidate current, internationally peer-reviewed chemical safety-related publications and database records from international bodies, for public access. to documents on chemical risks and the management of chemicals, helping countries fulfil their commitments under UNCED's Agenda 21, Chapter 19.
- t) Jane's
    - o CHEMBIO WEB [ <http://chembio.janes.com/>
    - o Geopolitical Library
    - o RUSI/Jane's Homeland and Resilience Motor
  - u) ARGUS
 

[<https://intracomm.cec.eu.int/argus/event/> ]

ARGUS is the General Rapid Alert System i.e. the internal communication network allowing the DG's and services of the Commission to share key information in the event of a crisis

and finally

- v) HEDIS (Health Emergency & Disease Information System)
 

HEDIS has been developed by the European Commission Joint Research Centre (JRC) in order to support DG SANCO and Member States during health emergencies. HEDIS is a web-based portal with restricted access offering a central destination derived from various sources (with real-time updates from MediSys, WHO, OIE and others); communication tools, access to Geographic Information Systems (GIS) and modelling applications.

94. The following warning systems are currently in place in HEOF:
- a) EWRS – Early Warning and Response System [ Communicable Diseases]
  - b) RAS BICHAT – Rapid Alert System for Biological, Chemicals agents and threats [CBRN]
  - c) RAS CHEM – Rapid Alert System for chemical threats
  - d) GHSAG – Global Health Security Action Group (CBRN, system run by Canadian Public Health Agency for the Global Health Security Network)

#### **4) European Centre for Disease Prevention and Control**

95. *Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control*<sup>32</sup> provides that this Centre, which is a Community Agency and is based in Stockholm, will enhance the capacity of the European Community and the Member States to protect human health through prevention and control of human diseases, by:
- identifying and assessing current and emerging threats to human health from communicable diseases;
  - ensuring the integrated operation of the dedicated surveillance networks designated under Decision 2119/98/EC establishing a Communicable Diseases Network, including its Early Warning and Response System (EWRS);
  - collecting, collating, evaluating, and disseminating relevant scientific and technical data, information and best practices;
  - coordinating European networking.

#### **D. Preparedness**

##### **1) Classification of events and emergency planning**

96. Work on classification of events and incidents under various scenarios and modelling to predict effects and impact of counter-measures as part of preparedness plans has started and is intended to intensify in the next months so as to permit the refinement and strengthening of emergency and contingency plans for threats and attacks.

##### **2) Dissemination of rules**

97. These aspects are dealt with under the fourth objective of the health security programme, i.e. drawing up rules and disseminating guidance to authorities, health professionals and to the public on facing-up to attacks from the health point of view and coordinating the EU response and links with third countries and international organisations.

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<sup>32</sup> OJ L 142, 30.4.2004, p. 1.

EU rules applicable to circulation of persons, products, produce and services, as well as on animal and plant safety have been under review and will be considered in other parts of the joint Council-Commission programme. Guidelines for case management and decontamination following attacks are being prepared as part of the work of the Task Force set up by the HSC.

### 3) Scenario approach

98. In the area of health *security*, the Commission has established a system of CBRN classification of incidents based on scenarios and algorithms for action developed with the Member States and the Global Health Security Initiative partners. These scenarios and algorithms have resulted in a classification system in RAS BICHAT and in GHSAG (Global Health Security Action Group) communications and serve for the formulation and testing of emergency plans in Member States. Scenarios have also been developed for exercises evaluating response plans for smallpox and anthrax outbreaks.

### 4) Generic preparedness planning

99. At the request of the Council, in 2003 the Commission services prepared a blueprint for work to start on Generic Preparedness Planning for Community level health threats. This has been the subject of consultation with the Member States in the framework of the Health Security Committee. Once updated and developed, it will be presented in 2005 as a Commission Communication.

The goal of the EU in generic preparedness planning is to assist Member States in factoring in their plans the EU dimension with its body of laws in various sectors that impinge on emergency plans and to make possible the inter-operability of such plan, mainly by the setting up of a co-ordination mechanism that enhance co-operation between key Member States' and Commission-players. By doing so the draft for discussion of a Planning contains different chapters aiming to identify shortcomings, vulnerabilities and incompatibilities between national and/or EU systems, policies and co-ordination.

### 5) Coordination and evaluation of emergency plans

100. It has become a necessity to intensify work on emergency planning, in particular through modelling, to permit the refinement and strengthening of current plans. A detailed comparison of smallpox plans of all 15 the Member States ~~has been~~ *was* carried out and the issues of the interface and Community dimension have been identified for action.

*This will be further updated with the data from the 12 new MS. A large exercise on the testing of preparedness capacity was held in October 2005 (exercise "New Watchman" on smallpox preparedness) and November 2005 on pandemic influenza preparedness (exercise "Common Ground).*

The Commission jointly with EUROPOL has developed a training module on interaction between Public Health and Law Enforcement to develop understanding of relevant laws and common approaches, using the "train-the-trainers" strategy.

## 6) Influenza pandemic planning

101. The 2-3 June 2004 Council (EPSCO) adopted *Conclusions on Community Influenza Pandemic Preparedness Planning*<sup>33</sup> which inter alia invited the Commission and the Health Ministers to extend the mandate of the Health Security Committee<sup>34</sup> so as to cover the area of Community influenza pandemic preparedness and response planning for a temporary transitional period of one year to the end of May 2005 and then to review its mandate once the European Centre for Disease Prevention and Control has become operational.
102. The Commission proposed at a meeting of the Health Security Committee on 27-28 June 2007 to establish a priority working programme, on which its comments are awaited for the next meeting scheduled for November 2007. In addition, it was proposed and accepted to create three sections for the Committee to look into issues of concern (chemical, biological and radio-nuclear preparedness and response, generic preparedness and response and influenza preparedness and response) and these sections will meet for the first time in the Autumn, 2007.

## 7) Organisation of workshops and exercises

103. In the area of health protection, numerous workshops, conferences and seminars have been organised by the Commission, including on forensic epidemiology with Europol, on deliberate releases of chemical agents, on vaccines and antivirals, and on the interoperability of emergency plans. *Further E-wide exercises are planned by the Commission in 2008 and 2009.*

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<sup>33</sup> 9507/04.

<sup>34</sup> The Health Security Committee was established as an informal co-operation and co-ordination body by the Health Ministers and the European Commissioner for Health and Consumer Protection on 28 October 2001. It is composed of high-level accredited representatives of the Health Ministers and of the European Commission. Its terms of reference are to exchange information on health-related threats from acts of terrorism or any deliberate release of biological or other agents with intent to harm health; share information and experience on preparedness and response plans and crisis management strategies; be able to communicate rapidly in case of health-related crises; advise Health Ministers and the European Commission services on preparedness and response as well as on co-ordination of emergency planning at EU level; share and co-ordinate health-related crisis responses by Member States and the Commission; and facilitate and support co-ordination and cooperation efforts and initiatives undertaken at EU level and help and contribute to their implementation at national level.

## **E. International relations**

### **1) G 7**

104. Following a meeting in Ottawa, Canada, on 7 November 2001, of Health Ministers from G7 countries together with the Health Minister from Mexico, Commissioner Byrne and representatives from the World Health Organisation, a Global Health Security Network of high level officials acting as contact points was set up to provide an alert mechanism and a forum for consultation in case of a crisis at international level. In addition, a Global Health Security Action Group was formed to implement the concerted global action plan agreed at Ottawa to strengthen the public health response to the threat of international biological, chemical and radio-nuclear terrorism. A follow up meeting to the Ottawa session was held in London on 14 March 2002 where they agreed a number of actions concerning, inter alia, laboratory collaboration, the conduct of a joint exercise and exchanging experience on dealing with chemical incidents and attacks.
105. An incident scale for risk communication and rules for response in various CBRN scenarios have been developed between the parties to the initiative and shared with all the EU Member States. Workshops have been held on smallpox, using the "training-the-trainers" approach. *In the remits of the Global Health Security Initiative (GHSI)*, workshops on smallpox vaccines and patient isolation have been carried out. Inter-laboratory tests have been carried out on smallpox and anthrax. Groups have been set up on laboratory collaboration, risk communication and co-ordination, field investigation, radio-nuclear terrorist events and chemical terrorist events and influenza.
106. In September 2003, a smallpox plan evaluation exercise (Global Mercury) was conducted. Ministers and the Commissioner for Health and Consumer Protection meet regularly to review progress. At a meeting of the GHSI in Berlin on 7 November, the Commission was tasked with the establishment of a co-operation platform on bio-safety research. The Ministers and the Commissioner *met* in Paris on 10 December 2004. Further sessions have been taken place in Tokyo, Paris, Berlin, Rome and Washington in order to address recent needs. In this context also numerous meetings of working groups and workshops have been conducted.

### **2) International Health Regulations**

107. The International Health Regulations are an international legal instrument which is legally binding on all WHO Member States who have not rejected them (or, subject to the procedure foreseen in the IHR, who have made reservations) and on all Non-Member States of WHO that have agreed to be bound by them.

The International Health Regulations adopted in 1969 applied only apply to three infectious diseases: cholera, plague and yellow fever, revised by the WHO Member States.

108. In May 2005, the World Health Assembly adopted the [revised International Health Regulations](#). IHR(2005) came into force on 15 June 2007, also for the 25 EU MS as well as for Bulgaria and Romania. The EU itself is not a party to the IHR, but the IHR recognizes the role of “regional economic integration organizations” such as the EU. The purpose and scope of the IHR(2005) are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. The IHR(2005) also establish a single code of procedures and practices for routine public health measures at international airports and ports and some ground crossings.
109. In order to maximize efficiency the Commission has proposed the following working practices<sup>35</sup>:
- (1) Nominating the same national focal point for EWRS as for IHR.
  - (2) Simultaneously informing EWRS and WHO about events within their territory which are notifiable under IHR but which are not potential PHEICs (Public Health Emergency of International Concern).
  - (3) Informing the EU Communicable Disease Network in advance of making a formal IHR notification of a potential PHEIC.
  - (4) Particularly for multi-state outbreaks, using EWRS and / or the Health Security Committee to help coordinate health risk management and response prior to communicating with WHO.

## **F. Coordination and implementation**

110. It is, however, important to assess thoroughly the various tasks performed by the temporary structures set up under the Health Security Programme in order to determine which activities that could be either discontinued or continued within already existing mechanisms and what tasks that would require the development of new Community approaches and mechanisms.

The "Employment, Social Policy, Health and Consumers Affairs" Council of 2–3 December 2002 has, in this respect, taken note of the Commission's intention to put forward a communication on preventing and limiting the consequences of possible chemical or biological threats in the field of public health.

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<sup>35</sup> COM(2006) 552 final, Brussels, 26.9.2006

### III. PHARMACEUTICALS FOR HUMAN USE

#### A. Preparedness

##### 1) **Mechanism for information on the availability of serums, vaccines and antibiotics**

111. The ability and capacity to manufacture vaccines and other medicinal products and to stockpile and supply those (for human as well as for animal use) are of pivotal importance for any plan to counter CBRN attacks.
112. Storage of medicines is dealt with under the third objective of the Health Security Programme, namely creating a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available. The joint Commission-pharmaceutical industry task force, set up by Commissioners Byrne and Liikanen, and the specific network of the Pharmaceutical Committee of the EU, carried out an assessment of stockpiles in the Member States.
113. The ongoing work in the joint Commission-Pharmaceutical Industry Task Force has given rise to a number as yet unresolved questions and sensitive issues, in particular drawing up an inventory of the availability and capacities of manufacture, stockpiles and distribution of sera, vaccines and antibiotics likely to be used to counter any biological attack. Crucial questions discussed in this connection include the desirability and possibility of creating or pooling strategic stockpiles, evaluating manufacturing capacity for vaccines, sera and antibiotics, and developing new medicines and vaccines. The Commission continues to examine possible options for creating strategic stockpiles at EU level.
114. At the request of the Commission, the *European Medicines Evaluation Agency (EMEA)* had established two expert groups: one to develop guidance on the use of medicines against potential pathogens and the other to develop specific recommendations and guidance with respect to vaccines, in particular vaccines against small pox. These initiatives have had the following results:
- An inventory has been drawn up of medicines available in the EU to treat or protect against a number of pathogens which could be used in a bioterrorist attack. As far as possible, the inventory includes the authorisation status in the Member States. This is complemented by guidance developed by the EMEA and its scientific committee, the CPMP, on the recommended use of these medicines. The latter is published on the websites of the EMEA and the Commission.
  - There are existing and planned national stockpiles of vaccines, antibiotics, antivirals and antitoxins. The only smallpox vaccines currently available are unauthorised and most of these vaccines have been in storage since the 1970s in government agencies and laboratories in a number of Member States. Studies on dilution for such vaccines are planned which may result in an increase in numbers of available units should an emergency arise.

New vaccines using different strains are being developed, the first of which is expected to be available in the last quarter of 2002, although it is not expected that clinical trials will be completed before the end of 2003. For smallpox vaccines, production capabilities for the new vaccines will probably be sufficient to meet demands, based on a strategy of ring vaccination. Currently, the Member States focus on national stockpiles and there is no support for an EU-level stockpile of smallpox vaccines.

- For antibiotics, production capabilities are sufficient to meet demands in the event of an emergency, and careful consideration is being given to increasing production and ensuring effective distribution to meet demands in case of crisis. Sera and antitoxins have been singled out as the target of collaborative efforts, which will be pursued in the context of the health security programme. However, stockpiling at EU level or under EU auspices of vaccines or other medicines is not considered necessary by Member State representatives at this stage. Nevertheless, there has been a discussion of a common effort to be undertaken towards the research and development of medicines in short supply such as vaccinia immunoglobulins and anthrax vaccines.

115. A Working Group on medicinal product development set up under the Health Security Committee investigates the capabilities of Member States for the development and production of medicinal products (including vaccines) against bio-terror agents.

A study has been completed on the dilution of existing smallpox vaccines and on vaccine immuno-globulin development. The study showed that dilution of first generation vaccines will be difficult in case of urgent need.

## 2) Concerted strategies for developing pharmaceutical resources

116. In the abovementioned *conclusions on the influenza pandemic*, the Council (EPSCO) of 2-3 June 2004 asked the Health Security Committee to assess the desirability or otherwise of any future collective negotiation process with the pharmaceutical industry for the development and purchase of vaccines and anti-virals.
117. The EMEA *expert* group has prepared and published guidance on the development of new small pox vaccines.
118. *The Council conclusions of 6 December 2004 on a European response to emerging zoonotic diseases*<sup>36</sup> welcome the Commission's intention to propose a European Plan for zoonoses preparedness and control that would implement an inter-sectoral and responsive Community strategy including integrated public health and animal health policy measures to emerging threats from zoonotic diseases.

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<sup>36</sup> 16051/04.

### 3) **Concerted strategies for using pharmaceutical resources**

119. Clinical guidelines for the recognition and case management of diseases related to the pathogens that may be used in deliberate releases have been developed on the basis of a consensus process and peer review. Ten manuscripts have been prepared and will be published, on anthrax, smallpox, botulism, plague, tularaemia, haemorrhagic fever viruses, brucella, Q fever, encephalitis viruses, glanders and melioidosis.

### 4) **Regulatory aspects**

120. Parliament and Council adopted on 31 March 2004<sup>37</sup>:

- *Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinarian use and establishing a European Medicines Agency*; Its Article 57(1)(q) entrusts the European Medicines Agency with the task of compiling scientific information concerning pathogenic agents which might be used in biological warfare, including the existence of vaccines and other medicinal products available to prevent, or to treat, the effects of such agents;
- *Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, whose Article 5 authorises Member States to allow, on a temporary basis, the distribution of unauthorised medicinal products in response to an attack involving the spread of pathogenic agents, toxins, chemical agents or nuclear radiation.

## **B. Implementation**

121. Finally, the Commission could be invited to introduce legislative or budget proposals concerning medicinal products that the Commission considered would facilitate the response to bioterrorist threats further. A proposal from the Commission would enable the Council and the European Parliament to adopt a position towards some of the, as yet, unresolved and sensitive issues mentioned in 133 above.

## **IV. SAFETY OF FEED AND FOOD**

### **A. Generalities**

122. Feed and food operators have primary responsibility for food safety. They are at the front line for ensuring food safety and protecting the public. However, the responsibility for food safety belongs to everybody who is a part of the food chain. Awareness of this responsibility can be improved by means of education and enhanced cooperation.

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<sup>37</sup> See OJ L 136, 30.4.2004.

Feed and food operators should therefore take into consideration the risks of bio-terrorism and should implement procedures to identify, assess and tackle these risks. These procedures, based on the principles used to develop the *HACCP-system (Hazard Analysis and Critical Control Points)* are already a legal obligation for all food operators with the exception of primary production in accordance with Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

123. National authorities and agencies should, of course, collaborate and work together with farmers, food processors, distributors and retailers to address food safety and security from farm to the table in particular implementing monitoring programmes and controls.
124. There is a sufficiently well developed EU body of rules for alerts and contingency plans of action, both in health and economic terms, to face up to an epidemic of criminal origin in the food chain. The various means that have been established in order to guarantee safety throughout the whole food chain have functioned well in general, and the ability to respond to crises has been tested in numerous occasions.

The aspect of the fight against bioterrorism that needs developing in the future is the organisation of upstream information, investigation and information-gathering within the territory of the Community and third countries as well as an improved cooperation between authorities and those working in the food chain. Emphasis should also be given to cooperation between the food sector and other sectors of the society. In particular, the role of education in guaranteeing safety throughout the food chain must be underlined.

125. The EU has a broad body of legislation which covers primary production of agricultural products and industrial production of processed food. The legislation has evolved over the last thirty years, reflecting a blend of scientific, societal, political and economic forces.
126. The current legal framework and operational set-up has in general afforded the EU consumer a high level of health protection. The problem has not been that much the lack of legal instruments, but the broad disparity in the means to respond to situations in specific sectors, or the multiplicity of actions which need to be triggered in the case where a problem spills over from one sector to another.

## **B. Prevention**

127. The existing legislative framework of the EC already provides for:
  - general obligation for operators to take necessary measures to ensure that their products are safe for the consumer;

- legislative means for the competent authorities to control EU borders, to take emergency measures when food or feed products may be harmful, to take and analyse samples, to control operators and to start investigations when necessary;
  - a rapid alert system for food and feed, which organises the transmission of information throughout the Community in cases where human health may be in danger. The system involves a network consisting of the Member States, the *European Food Safety Authority (EFSA)* and the Commission, which is responsible for the management of the system. The system is triggered by a member of the network, on the basis of any information on a serious risk to human health deriving from food. This network, which has been in place for several years and has well proved its efficiency, can be activated 24 hours a day;
  - a network of technical competencies and share of scientific information, notably through national and Community reference laboratories and through Scientific Committees.
128. In addition, laboratories for the official control of foodstuffs and feedstuffs are approved under the scope of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. For those laboratories, an accreditation following the prescriptions of ISO standard 17025 is mandatory.

A number of Community Reference Laboratories (CRLs), operating with Community financial support, have been established. These laboratories have an important role in ensuring a high standard of food safety and consumer protection. They provide national reference laboratories, for example, with details of analytical methods, organise comparative testing, coordinate research into new analytical methods, conduct training courses and provide technical assistance to the Commission. CRLs exist at present for residue testing (four laboratories), milk testing, biotoxins in molluscs and testing molluscan shellfish for absence of harmful virus and for the control of zoonoses (salmonella).

129. In the framework of EU food safety legislation, a number of legislative instruments have the aim of improving and completing the existing system.

In particular, a new *Regulation 178/2002/EC of 28.01.2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* establishes over-arching principles, definitions and requirements on which all new food law in Europe is based.

Modalities are laid down in Regulation 178/2002/EC to ensure optimum coordination and to strengthen the Community's overall capacity to identify the most effective measures to prevent, reduce or eliminate a risk for human health.

130. On the overarching objectives of food law, the Regulation complements the EC Treaty requirements in relation to food and the Community's responsibilities to ensure a high level of human health protection in the definition and implementation of Community policies and activities.

**C. Risk Analysis**

131. On the scientific basics to food law, the Regulation establishes the principles of risk analysis in relation to food law and establishes the structures and mechanisms in relation to the scientific and technical evaluation which will be, in the main, undertaken by the European Food Safety Authority (Authority).

**D. Prevention (2)**

132. The new regulation also contains the concept of **risk management**. Risk management is the process of weighing policy alternatives in the light of the results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the European Community.

In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment, including for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and environmental impact. The new Regulation establishes the principle that risk management actions are not just based on scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration.

133. The following new specific provisions will enter in force from 1 January 2005 that improve the safety and control of the food chain.

**1) Traceability**

134. The identification of the origin of feed, food, ingredients and food sources is of prime importance for the *protection of consumers* particularly when products are found to be faulty. Traceability facilitates the *withdrawal* of foods and enables consumers to be provided with targeted and accurate information concerning implicated products. The new Regulation provides for traceability of all food and feed as they move between businesses, with information on the traceability of the food or feed being made available to the competent authorities if requested. Importers are similarly affected, as they will be required to identify from whom the product was exported in the third country. This measure is limited to ensuring that businesses are at the least able to identify the one step in the food supply 'above' them and the one step 'below', unless specific provisions exist for further traceability.

## 2) Responsibilities

135. The new Regulation establishes the basic principle that the *primary responsibility* for ensuring compliance with food law *rests with the food business*. Similarly this principle is applied to feed businesses. To complement and support this principle, there must be adequate and effective controls, as well as cooperation between different authorities, organised by the competent authorities of the Member States.

## 3) Food safety requirements

136. The new Regulation establishes a food safety requirement, which comprises two elements: i) food should not be injurious to health or ii) unfit for human consumption. Only one of these elements has to be in place for the food to be considered as unsafe.

The new Regulation also makes it obligatory for food businesses to withdraw unsafe foods from the market, and provide accurate information to the consumers when this is done. Feed and food operators must also inform the competent authorities when they have a suspicion that their products may be harmful. The Regulation requires food safety to be considered at all stages that may have an impact on food safety.

## 4) Food hygiene

137. Regarding food hygiene, EP and Council adopted:
- Regulation (EC) No 852/2004 of 29 April 2004 of the hygiene of foodstuffs;<sup>38</sup>
  - Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin;<sup>39</sup>
  - Regulation (EC) No 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;<sup>40</sup>
  - Regulation (EC) No 882 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;<sup>41</sup>
  - Regulation (EC) No 183/2005 of 8 February 2005 laying down requirements for feed hygiene<sup>42</sup>.

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<sup>38</sup> OJ L 139, 30.4.2004, p. 1.

<sup>39</sup> OJ L 139, 30.4.2004, p. 55.

<sup>40</sup> OJ L 139, 30.4.2004, p. 206.

<sup>41</sup> OJ L 165, 30.4.2004, p. 1, replaced by corrigendum in OJ L 191, 28.5.2004, p. 1.

<sup>42</sup> 3677/04.

138. The aim of the hygiene package is to provide a unified and consolidated Community legislation regarding both the rules for feed hygiene and food hygiene. These texts introduce food safety rules at all stages of the food chain ("from farm to fork" approach) and the application by food business operators of a food safety management system by the introduction of the Hazard Analysis and Critical Control Point (HACCP) system.

## **E. Monitoring**

139. The Rapid Alert System for Food and Feed (RASFF) is a network for notification of a direct or indirect risk to human health deriving from food or feed and was established in 2002.

This present extended system specifically addresses products intended for human consumption and for animal feed in a network that will include the Commission, Member States and the Authority.

It involves Member States, the Commission and the European Food Safety Authority. Where a member of the network has any information on a serious direct or indirect risk to human health deriving from food or feed, this information must be immediately notified to the Commission under the rapid alert system. The Commission immediately transmits the notification to members of the network, together with any supplementary information on measures to restrict placing on the market, or forcing withdrawal from the market, etc.

140. The *European Food Law Regulation 178/2002* (see above) is the legal basis of the new extended Rapid Alert System for Food and Feed. It replaces the relevant provisions of the General Product Safety Directive, in so far as they related to the rapid exchange of information concerning food.

The scope of the system has been considerably clarified and extended to: direct or indirect risk to human health (no longer reference to "immediate"), risk deriving from food and feed.

141. The EFSA will be fully part of the network and will be able to input technical or scientific information to help taking decisions.

Alert notifications are sent when the food or feed presenting a direct or indirect risk to human health is on the market and immediate action is required.

The RASFF also covers the rejection of a consignment of food or feed following an inspection at a Border Inspection Post (BIP) in order to avoid attempts to import it through another point of entry. This prevents the placing on the market of food or feed, which presents a risk to the consumer.

142. The RASSF is an effective tool for:  
risk prevention,  
identification of food safety problems in Member States and third countries,  
identification of new issues,  
triggering changes to legislation,

detecting divergences in application of EU legislation,  
input for priority setting by the Food and Veterinary Office (FVO).

143. The Council of 17 November 2003 had, pending the 1st reading of the EP, an orientation debate on *the proposal on official feed and food controls*, which aims at bringing together in a single Community framework all the food safety control rules currently applied, in particular by grouping together all the existing veterinary, animal feed and foodstuffs legislation, and whose Article 13 reinstates the requirement for contingency plans.

#### **E. Consequence management**

144. On procedures for managing emergencies and crises in the field of the safety of feed and food, the new tools laid down in Regulation 178/2002 include the definition of a crisis management plan and provide for the Commission to establish, where necessary, a crisis unit in which the Authority will participate. The Authority will give scientific and technical support to the crisis unit, the Commission remaining responsible for the management measures. The crisis unit will be responsible for communication during the time of crisis. Regulation 178/2002/EC gives also provision for adopting emergency procedures very quickly, when necessary, through the comitology procedure.
145. Emergency measures could be adopted for each stage of the food chain. A general plan for food/feed crisis management was adopted on 29 April 2004 by the Commission.<sup>43</sup> The plan focuses not only on the management of crises, but also on tools to prevent a difficult situation from developing into a real crisis.

#### **G. International relations**

146. The new Regulation 178/2002/EC acknowledges the Community's commitment to its international obligations particularly in relation to the Sanitary and Phyto-Sanitary (SPS) and the Technical Barriers to Trade Agreements (TBT) under the auspices of the World Trade Organisation (WTO). It underscores the European Community's commitment to the development of international technical standards for foods. It also recognises the Community's obligation to consider international standards such as those established in the framework of the *Codex Alimentarius Commission* and *Office International des Epizoöties (OIE)* within both of these agreements but balances this with the Treaty requirement for a high level of health protection, and with the other objectives of food law established in this proposal. International standards will only be considered where the high level of health protection, as established by the Community, or the other objectives of food law are not compromised. Other international conventions like *the Nuclear Safety Convention*, *the Chemical Weapons Convention* and *the Biological Weapons Convention* are also relevant in the combat against terrorist activities which may have an impact to the food chain.

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<sup>43</sup> Commission Decision 2004/478/EC

## **H. Coordination and implementation**

147. The measures that would be taken in response to a terrorist act in the food sector are not fundamentally different from those adopted by the Community in response to accidents in the recent past. There is consequently a sufficiently well developed body of rules for alerts and contingency plan action (both health and economic) in the event of an epidemic of criminal origin (the only differences between a terrorist act and an accidental epidemic would undoubtedly be the dimension of the initial phase and the number of primary outbreaks).

The various means that have been established in order to guarantee safety throughout the whole food chain has functioned and functions in general well. Its ability to respond to crises has been tested in numerous occasions. Therefore, there is no need to establish new systems, but rather to adjust the current mechanisms in order to improve their functioning taking into account the threat of bioterrorism. Should a crisis occur, an efficient communication plan is of utmost importance in order to address societal concerns.

The aspect of the fight against bioterrorism that needs developing in the future is the organisation of upstream information, investigation and information gathering within the territory of the Community and third countries as well as an improved cooperation between authorities and people working in the food chain and their education. Emphasis should also be given to cooperation between the food sector and other sectors of the society. In particular, the role of education in guaranteeing safety throughout the food chain must be underlined.

## **V. ANIMAL HEALTH PROTECTION**

(including pharmaceuticals for use on animals)

### **A. Generalities**

148. Numerous regulatory measures have been adopted at European Union level to keep animal diseases at bay and to combat outbreaks, including a Community notification system and a vaccine bank. Furthermore, Member States contingency plans approved at Community level ensure a fast and harmonised response to the most serious epidemics. All measures to combat diseases are taken and coordinated at Community level following comitology procedure. These measures apply whether the origin of an epidemic is accidental or the result of terrorist action. As is the case for food safety, there is no need to establish new systems, but rather to adjust the current mechanisms taking into account the threat of bioterrorism.
149. Within the framework of the Community's exclusive competencies, a comprehensive set of legislative texts is in place to keep animal diseases at bay and to combat any outbreaks that do occur. These measures apply whether the origin of an epidemic is accidental or the result of terrorist action.
150. Decisions are taken collegially and as swiftly as necessary, through the Standing Committee on the Food Chain and Animal Health (SCOFAH), under the responsibility of DG SANCO D1.

The implementation of these measures is checked by the Commission through its Food and Veterinary Office (DG SANCO F), both within the EU and in the third countries, guaranteeing a high level of safety to all animals and animal products that are placed on the EU market.

151. In this favourable context, which enabled solving the latest animal health crises, and in order to place prevention at the top of the agenda, the Commission prepared a new EU Animal Health Strategy (2007-2013), which includes: the prioritisation of EU intervention; a modern and appropriate animal health framework; the strengthening of EU active influence on international standards; better prevention, surveillance and crisis preparedness, especially biosecurity measures at farm level, on animal movements and at borders and EU animal disease surveillance and emergency preparedness; science, innovation and research. This new strategy "prevention is better than cure" will also improve the bio-preparedness of EU.

## **B. Prevention**

### **1) Internal market**

152. The harmonised rules regarding intra-Community trade and placing on the market of live animals<sup>44</sup> and animal products have been amended several times following certain animal health crises and will now be reorganised in a more comprehensive and global legislation, still including emergency policies.

### **2) International trade**

153. Rules have been defined for substantially all products and animals under the Community's harmonisation policy in import-related matters. They establish harmonised animal and public health conditions for the import of live animals and animal products into the Community. This legal framework ensures that the same principles for importation of live animals and animal products are applied in all the Member States and that animals or their products that carry unacceptable health risks do not enter the EU territory. Safeguard measures taken in response to outbreaks of serious pathologies are adopted by the Commission as protection against health crises. These rules follow the international standards, guidelines and recommendations of the OIE, which has a crucial role and importance in the safeguard of international trade of animal and animal products and in the prevention and control of the spread of transboundary animal diseases.

### **3) Import controls**

154. Product and animal imports are subject to strict controls. However, imports of commercial consignments are not the real risk as far as bioterrorism is concerned. Checks on passengers and postal consignments to prevent the import of biological agents in packaged form are more to the point, as well as epidemiological surveillance and rapid answer in case of crisis.

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<sup>44</sup> [http://ec.europa.eu/food/animal/liveanimals/index\\_en.htm](http://ec.europa.eu/food/animal/liveanimals/index_en.htm)

## C. Monitoring

### 1) **Epidemiological surveillance and notification**

155. Specific measures have been laid down in the EU legislation<sup>45</sup> to survey and control the spread of known and present animal diseases of major health and economic importance in the EU. In addition, there is a risk management procedure in place to detect exotic and emerging risks and react towards them:
- Collection and analysis of data, such as biological analyses by Community Reference Laboratories;
  - Risk analysis by Community agencies such as EFSA and ECDC;
  - Risk notification by existing EU systems;
  - Contingency plans developed by Member States and approved by the Commission.
156. Member States have to actively monitor the animal health situation by setting up a system of surveillance networks. These national networks are to be linked at EU level to provide an overall surveillance of the EU territory. Each Member State should have a national laboratories capable of diagnosing the agents representing a bio-threat. The national laboratories are linked to and in contact with the Community Reference Laboratories which are responsible in particular for collecting and preserving the various strains and types of viruses that cause diseases. That preservation role should be stressed as it is central to the detection of fresh outbreaks of diseases, whether in or out of the EU, including exotic diseases or diseases that have supposedly been eradicated (e.g. Rinderpest, as it is in human health for smallpox).
157. The competent authority of a Member State concerned by an outbreak of one of the 25 listed contagious animal diseases has to notify the Commission and the other Member States within 24 hours, notably through the Animal Disease Notification System, under the responsibility of DG SANCO D1.

### 2) **Epidemiological investigations; traceability measures and systems: animal identification and registration**

158. The purpose of the investigation is both to identify the source of an outbreak of disease (trace up) and to determine whether and where the disease has spread from the primary source of the outbreak. (trace down). This requires a high level of traceability, and would be of the utmost importance in case of a bioterrorist emergency.
- The EU traceability framework consists of two basic elements:
- Animal identification and registration systems<sup>46</sup> ensure the traceability of animal movements primarily at national level and
  - TRACES (Community Trade Control and Expert System)<sup>47</sup> ensures the traceability of animals and their products with particular view to intra-Community trade, import or transit.

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<sup>45</sup> [http://ec.europa.eu/food/animal/diseases/controlmeasures/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/controlmeasures/index_en.htm)

<sup>46</sup> [http://ec.europa.eu/food/animal/identification/index\\_en.htm](http://ec.europa.eu/food/animal/identification/index_en.htm)

<sup>47</sup> [http://ec.europa.eu/food/animal/diseases/animo/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/animo/index_en.htm)

## **D. Consequence management**

159. In the interests of a rapid and coordinated response, Member States have to draw up contingency plans for all notifiable diseases.
160. The rules provide in certain cases for the establishment of control or crisis centres with associated experts to coordinate the fight, in relation with the Commission. Recent crisis management of FMD, classical swine fever, Newcastle disease and avian flu led to the updating of these responses and eventually demonstrated the usefulness and effectiveness of such plans.
161. As for emergency vaccination needs, vaccine banks and banks of antigens capable of being converted into vaccine in less than three days, have been established. Costs for these stockpiling are borne by the Community through a dedicated budget.

## **E. International relations**

### **1) International notification of diseases**

162. All 170 Member Countries of the OIE (of which every EU Member State) are obliged to report the suspicion of a highly contagious disease and of certain diseases of economic or public health importance. This information is then forwarded by the OIE to the Commission and the Member States. Third countries which engage in trade in animal products also notify the Commission of any suspected outbreak of disease. Following this information is of the utmost importance in the emergency preparedness.

### **2) International activities**

163. The raising importance of the OIE in the international activity related to animal health management, including bio-preparedness, is one of the reasons why the activity of the Community in this organisation is more and more intense. Not only the Community coordinates in depth its comments to the draft standards and guidelines, with the purpose of having them as much harmonised as possible with EU Legislation, but its experts participate to a number of *ad hoc* working groups to assist in the further development of OIE policy. The Commission's observer status in the OIE is effective at keeping all Member States informed and working together on matters of common interest. The OIE is also an important platform of experience exchange with third countries, especially in terms of bio-preparedness.

## VI. PLANT PROTECTION AND PLANT HEALTH

### A. Prevention

164. The use of plant protection products (including pesticides) on crops are part of the food chain management. The Rapid Alert System for Foodstuffs is covering pesticide residues on food and feed. *Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC* fix maximum limits for Pesticide Residues and provide for the monitoring of Pesticide Residues of feed and food on the market. *Council Directive 91/414/EEC on the use and marketing of plant protection products* provides for control measures to prevent the use of unauthorised plant protection products. It also prevents pesticides with potential risks for human and animal health and the environment to be marketed, e.g. high risk chemicals.
165. As far as the prevention of the introduction into or spread within the Community of harmful organisms is concerned, the basic legal instrument is *Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community and related regulations*.
166. An important measure consists in listing the particularly dangerous harmful organisms whose introduction into the Community must be prohibited and also the harmful organisms whose introduction into the Community must be prohibited when carried by certain plants or plant products.
167. Inspections for presence of harmful organisms are conducted as random checks in the field, as stratified inspections in nurseries as well as at the outer borders of EU. Nurseries are responsible for notifying the local Authority if specified harmful organisms are found.

Plants intended for planting and specified plant products from third countries must be inspected in the third country or origin, have to fulfil specified Community phytosanitary requirements and must be accompanied by a phytosanitary certificate with a view to their import into the EU.

### B. Consequence Management

168. There is also a system for temporary safeguard measures in the case of an imminent danger of the introduction or spread of harmful organisms.

### C. Monitoring

169. Phytosanitary laboratories exist in the Member States in order to provide expert assistance in the identification of plant pests and diseases as well as for regular inspection of certain crops (e.g. potatoes).

#### **D. Prevention (2)**

170. For Pesticide Residues, *Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC, as well as Regulation (EC) No 396/2005*, fix maximum limits for Pesticide Residues and provide for the monitoring of Pesticide Residues of feed and food on the market. Member states are obliged to do a minimum of check sampling. The Commission co-ordinates part of the activities of the Member States by making a yearly Monitoring Recommendation which results in the covering of the major pesticide crop combinations over a period of 3 years. The Commission is regularly organising proficiency tests in order to achieve a uniform quality of analytical results. To that end, guidance documents are developed and published on the website. The FVO is monitoring the activities of the Member States by regular missions and thereby discussing the individual results and policies. *Council Directive 91/414/EEC on the use and marketing of plant protection products* provides for control measures to prevent the use of unauthorised plant protection products.

#### **E. Monitoring (2)**

171. In the framework of EU, harmful organisms are a major issue and a notification system is on force. Each country also implements surveillance systems for pests and diseases that form a particular phytosanitary threat to crops in their territory.

#### **F. Prevention (3)**

172. There are also international obligations to take into account International Standards on Phytosanitary Measures such as those established in the framework of the *International Plant Protection Convention*.

#### **G. Consequence management (2)**

173. A notification scheme, EUROPHYT, operates within the Community on the basis of faxes and e-mails; in each country, the Authorities sends and receives warnings to and from the other Member States when a harmful organism has been recorded or when commodities are found not to comply with EU Phytosanitary requirements. Crops may be destroyed if the harmful organisms cannot be controlled in situ. Special attention is paid to plants and plant products that enter the EU.

#### **H. Prevention (4)**

174. *Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC, as well as Regulation (EC) No 396/2005*, fix maximum limits for Pesticide Residues and provide for the monitoring of Pesticide Residues of feed and food on the market. Violations of MRLs are reported in the framework Rapid Alert System for Foodstuffs. Before a Rapid alert is issued, an exposure assessment is done by the Commission to see if there is a risk to any specific consumer group.

To that end, a guidance document is developed for the Rapid Alert System for Foodstuffs specifically to make rapid decisions about the risk of findings of Pesticide Residues. The efficiency of these structures was recently demonstrated in the case of Nitrofen and a few other pesticides.

## **VII. ENVIRONMENT**

### **A. General principles**

175. Environmental policy may contribute effectively to the protection of the environment and of human health against acts of biological and chemical terrorism. As a matter of priority, an assessment should be made of the instruments available under the existing legislation, in the light of concerns raised by biological and chemical threats, and of any need to adapt that legislation accordingly.

### **B. Risk analysis**

176. The Council [started work on] the Commission proposal for a Directive establishing an infrastructure of spatial information in the Community (INSPIRE)<sup>48</sup>, that aims at acquiring environmental data through spatial monitoring, which could support the prevention policies, the response and recovery of CBRN threats and the operation of emergency services.

### **C. Prevention**

177. *Directive 90/219/EC on the contained use of genetically modified micro-organisms* as amended by Directive 98/81/EC could also be relevant as it:

- requires activities involving genetically modified micro-organisms to be carried out under conditions of containment. These activities are regulated at national level, rather than at Community level, by the appointed competent authorities. National competent authorities therefore have a duty to decide, after consultations with the applicant, the information relating to these activities that should remain confidential.
- requires the operators to inform immediately the competent authorities of any incident. For their part, the latter have the obligation of drawing up emergency plans.
- finally provides for consultations with other involved Member States and information of the Commission.

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<sup>48</sup> 11781/04.

178. The European Parliament and the Council adopted, on 15 July 2003, a *Regulation on transboundary movements of genetically modified organisms*. Under Article 14, Member States shall take appropriate measures to prevent unintentional transboundary movements of GMOs. As soon as they are aware of such a movement that is likely to have significant adverse effects, they must inform the public and the Commission and consult the affected or potentially affected States to enable them to determine appropriate responses (OJ L 287, 5.11.2003, p. 1).

**D. Monitoring**

179. *Directives 80/778/EC and 98/83/EC on the quality of drinking water and Directive 75/440/EC on the quality of surface waters used for drinking water abstraction* provide for constant monitoring of drinking water. Other instruments provide for the monitoring of the air.

**E. Consequence management**

180. *to be inserted.*

**F. International relations**

181. *to be inserted.*

**VIII. CRITICAL INFRASTRUCTURE PROTECTION**

**A. Generalities**

182. An EPCIP ("European Programme for Critical Infrastructure Protection") policy package was put forward by the Commission in December 2006. It is composed of a Communication and a proposal for a Directive. The communication sets forth the horizontal framework for the protection of critical infrastructures in the EU. This framework is composed of :

- i) Measures designed to facilitate the implementation of EPCIP including an EPCIP Action Plan, the Critical Infrastructure Warning Information Network (CIWIN), the use of CIP expert groups at EU level, CIP information sharing processes and the identification and analysis of interdependencies.
- ii) Support for Member States concerning National Critical Infrastructures (NCI) which could optionally be used by the Member States.
- iii) Contingency planning
- iv) An external dimension
- v) Accompanying financial measures and in particular the proposed EU programme on "Prevention, Preparedness and Consequence Management of Terrorism and other Security Related Risks" for the period 2007-2013, which will provide funding opportunities for CIP related measures having a potential for EU transferability.

- vi) A procedure on the identification and designation of European Critical Infrastructure and the assessment of the need to improve their protection (addressed in detail by way of the proposed Directive).
183. The proposed Directive focuses on the procedure for the identification and designation of European Critical Infrastructure (including a definition of European Critical Infrastructure). It also puts forward two concrete obligations on the owners/operators of those infrastructures designated as European Critical Infrastructures – the elaboration of an Operator Security Plan (an advanced business continuity plan) and the designation of a Security Liaison Officer (linking the owner/operator with the national authority responsible for critical infrastructure protection). Each Member State will inform the Commission at a generic level of the threats, vulnerability and risks present in particular critical infrastructure sectors. Any measures that should emerge out of these assessment will be done on an "ad hoc" basis, i.e. only where necessary and with the use of appropriate binding or non-binding tools.
184. Work in being undertaken in parallel on the establishment of the CIWIN system which will facilitate the exchange of information concerning EU trans-boundary critical infrastructures. Since the end of 2006, a study is being conducted on the development of a CIWIN prototype. The putting into place of CIWIN has been postponed to 2008 since the results of the study will only be collected by the end of 2007.

## **B. Vulnerability analysis**

185. In the chemicals sector (a so-called critical infrastructure) the Commission is working on a methodology to identify the sensitive areas within an industrial installation in order make operators more aware of the potential weaknesses of their safety and security systems.
- As far as the vulnerability of the population is concerned, the Commission is developing a method for the definition of areas at risk from attacks on hazardous installations.
- In 2002, the Commission, taking into account scientific and social developments, performed a prospective study which identifies, explains and evaluates the ways in which EU society is or may become significantly vulnerable to attack by terrorists using infective and toxic agents. Due to the sensitivity of its content, access to the final report has been restricted.

## **IX. NON-PROLIFERATION, GLOBAL DISARMAMENT AND ARMS CONTROL**

186. The EU actions in the area of non-proliferation and disarmament are guided by the EU strategy against proliferation of weapons and mass destruction (and their means of delivery) and the deliberations of the Council of the EU.
187. The Strategy defines the EU policies and measures to respond to existing and emerging CBRN risks, threats and challenges, which are associated both with the state programmes and the activities of non-state actors, such as terrorists and other criminals. The strategy's main aim is to prevent those threats to materialise.

188. The Strategy's approach is based on three principles:

- **Supporting effective multilateralism by**

- a) promoting universalisation, national implementation and the strengthening of international non-proliferation and disarmament treaties, instruments and relevant UNSCRs. This has already been translated into a number of J.A. (IAEA<sup>49</sup>, CTBTO<sup>50</sup>, OPCW<sup>51</sup>, BTWC<sup>52</sup>, UNSCR<sup>53</sup> 1540), Common Positions<sup>54</sup>, Action Plans<sup>55</sup>, etc;
- b) enhancing export controls by improving the European system on export controls (Peer Review and regular updating of dual-use Regulation) and participating actively in multilateral export control regimes;
- c) providing assistance to requesting states to enhance their national capacity of control and ability to effectively prevent, deter and halt proliferation of WMD related materials, equipment, means of delivery as well as the know-how;
- d) closing the loophole in the non-proliferation regimes through multilateral initiatives such as PSI<sup>56</sup> (The Council and all EU MS endorsed the interdiction principles of the PSI), GINCT (The EU institutions enjoy the observer status).

- **Cooperating with key international partners by**

- a) implementing specific joint statements and work-plans with third countries (US, Japan<sup>57</sup>, Russia<sup>58</sup>, China<sup>59</sup>);
- b) maintaining staff-to-staff contacts with international and regional organisations on non-proliferation and disarmament issues (UN ODA, WHO, NATO);

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<sup>49</sup> International Atomic Energy Agency, OJ L 165/20, p. 1, OJ L 193/44, p. 1, OJ L 182/46, p. 1.  
<sup>50</sup> Comprehensive Nuclear Test Ban Treaty Organisation, OJ L 176/31, p. 1, OJ L 88/68, p. 1.  
<sup>51</sup> Organisation for the Prohibition of Chemical Weapons, OJ L 85/10, p. 1, OJ L 331/34, p. 1, OJ L 349/63, p. 1.  
<sup>52</sup> Convention of the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological), and Toxin Weapons and on their Destruction, OJ L 65/51, p. 1.  
<sup>53</sup> United Nations Security Council Resolutions, OJ L 165/30, p. 1.  
<sup>54</sup> See Common Position on OJ L 106/32, p. 1, OJ L 176/39, p. 1, OJ L 61/49, p. 1, OJ L 88/65, p. 1, OJ L 302/34, p. 1.  
<sup>55</sup> See Action Plan on OJ L 57/1  
<sup>56</sup> Security Proliferation Initiative. See 9211/04 and 10052/04.  
<sup>57</sup> 1101/1/04 REV 1.  
<sup>58</sup> 15061/04.  
<sup>59</sup> 15065/04

- c) streamlining non-proliferation issues into EU relations with third countries through the inclusion of so-called non-proliferation clauses in the cooperation and association agreements (The clause is included in new agreements with more than 90 countries) and into the work of relevant organisations (e.g. the issue of proliferation finance in the FAFT).
- **supporting regional approaches to security** (e.g. through the establishment of regional WMD free zones)

189. Further details on the Implementation of the Strategy can be found in the half-yearly reports established by the Council Secretariat<sup>60</sup> in cooperation with the Commission and endorsed by the Council.

## X. **CUSTOMS**

190. The Customs Cooperation Working Party agreed, in September 2004, an action plan aiming i.a. at promoting the detection and prevention of the smuggling of CBRN goods.<sup>61</sup>

191. The Council adopted, on 30 March 2004, a Decision concerning the conclusion of an agreement with the USA on intensifying and broadening the Agreement on customs cooperation and mutual assistance in customs matters to include cooperation on container security and related matters.<sup>62</sup>

## XI. **POLICE, SECURITY AND INTELLIGENCE**

### A. **Generalities**

192. In July 2007, the Commission issued a Green Paper on biopreparedness. This Green Paper intends to stimulate a debate and launch a process of consultation at European level on how to reduce biological risks and to enhance preparedness and response.

In order to improve the ability of the EU to prevent, respond to and recover from a biological incident or attack, the coherence of actions in different policy sectors requires that all relevant stakeholders in Member States and at EU level be consulted e.g. national authorities responsible for risk prevention and response, human, animal and plant health, customs, civil protection, law enforcement authorities, the military, bio-industry, epidemiological and health communities, academic institutions and bioresearch institutes.

The objective of combating bio-terrorism cuts across a wide range of challenges. These include:

- tracking shipments of lethal biological agents;
- enforcing international sanctions;

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<sup>60</sup> 10448/04, 15246/04.

<sup>61</sup> 10238/2/04.

<sup>62</sup> 7113/04.

- coordinating verification and information exchanges among law enforcement agencies, customs authorities and the scientific community;
- reorienting research and development funds toward prevention; setting up of common lists of dangerous pathogens;
- boosting security at virological research facilities; EU and/or MS certification of facilities harbouring pathogens and/or of researchers; codes of conduct on researchers not disclosing dangerous results;
- raising public awareness;
- stockpiling and harmonising sufficient quantities of vaccines and prophylactics that could be shared between nations as well as
- improving communications and coordination between public and private actors, including the interaction between civil and military authorities.

## **B. Risk analysis and assessment**

### **1) Third pillar (JHA) activities**

193. Issues in relation to the fight against terrorism are discussed and prepared by the Terrorism Working Group (Third Pillar). The members of the working group are composed of representatives from the police and security/intelligence services of the Member States and of officials from the ministries responsible for the fight against terrorism in the individual countries under the responsibility of the Council (Justice and Home Affairs).

In the Terrorism Working Group, which reports to the Article 36 Committee, a wide range of terrorism related issues are dealt with, including also issues related to terrorists' use of chemical, biological, radiological and nuclear substances.

194. An important part of the work of the Terrorism Working Group consists of the exchange of information on terrorism related incidents in the Member States.

This exchange mainly consists in an oral exchange of information in the form of a "tour de table" at each meeting. Here all Member States have the opportunity to give an account of terrorist related incidents or steps within the sphere of the Member State during the period since the latest meeting. The accounts comprise both descriptions of terrorist incidents that have taken place, and preventive measures in the form of arrests or other measures that have prevented the execution of a terrorist action.

Apart from this, a system has been established between the Member States – as adopted by the Council at the extraordinary Council meeting (Justice and Home Affairs) on 20 September 2001 – concerning rapid exchange of certain information on terrorist incidents within the European Union. The system ensures a rapid exchange of certain defined terrorist related incidents as far as possible within 12 hours after they took place. The reports are sent through a special communications network that can handle confidential material.

195. Based on these reports and on contributions from the Member States a summary and assessment of the terrorist threat in Europe is prepared under each Presidency. In addition to this, Europol prepares an assessment of the terrorist threat in Europe. The latest edition of this threat assessment [...] has a special section that assesses the possibility for attacks with CBRN weapons/material. Both threat assessments are confidential and are submitted to the Council for information. The Terrorism Working Group will also in future be very aware of possible threats of attacks with CBRN weapons/materials.
196. Each year the Presidency also prepares a public document that reviews the terror situation in the European Union during the last twelve months.
197. On 6 November 2003, the Council started the operational project entitled "*multinational ad hoc teams for exchanging information on terrorism*".

## **2) 2nd pillar (CFSP) activities**

198. Furthermore, the Council's Terrorism Working Group (COTER, second pillar) is assessing the terrorist threat in specified countries and regions.

*COTER* has produced three new Regional Threat Assessments (Central and Latin America, South Asia and South East Asia). Fourteen new country threat assessments have also been finalised. The compilation now encompasses 9 regions and 55 countries such as Indonesia, Pakistan, and India. Progress has also been achieved in updating and reviewing the existing assessments. The updating process is ongoing.

199. Following discussions at the Council (General Affairs and External Relations) in October 2002, a group of Ministers' personal representatives was commissioned to submit an analysis of the phenomenon of extreme fundamentalism and terrorism. Between December 2002 and May 2003, *the Extreme Fundamentalism and Terrorism* group met four times (once in Copenhagen, twice in Brussels and once in Athens). The final report has been submitted and will be further discussed within the Council with a view to taking forward its recommendations.

## **3) Cross-pillar activities**

200. The EU is developing a more co-ordinated and cross-pillar approach to the fight against terrorism. The CFSP COTER Working Party and the JHA Working Party on Terrorism have produced a EU Compendium of Threat Assessments in the fight against terrorism. This common document presents the overall threat to the EU interests both internally and internationally. Proposals have been made during the CFSP/JHA joint meeting on terrorism to enhance the cross-pillar approach. (SN 200/03) It has been agreed that further versions of the compendium will focus on specific regions or themes. The second version of the compendium pays specific attention to terrorism from Northern Africa.

201. The Council has adopted in December 2001 a first list of the most significant terrorists and terrorist organisations <sup>63</sup> and has regularly updated that list. <sup>64</sup>

#### **4) Europol/Cepol**

202. A core activity for Europol is to provide the Member States with analytical services. Europol carry out a number of projects concerning terrorism, including strategic and operational analysis and more specialised projects, e.g. concerning the use of forged documents, propaganda material, suicide terrorists and security measures adopted in the Member States.

203. In addition, Europol held a conference on CBRN in January 2002, and is following up on a number of areas identified by the conference. Furthermore, Europol work on strategic analysis just as the EU reaction to the anthrax dissemination in the USA last year is being examined in detail.

204. Based on contribution from the Member States, Europol has also prepared a report on the security measures taken in the Member States after 7 October 2002. The report was presented to the Council for information on 13 June 2002.

205. As regards CBRN, Europol is becoming part of the EU rapid alert system ("RAS-BICHAT") and is also becoming part of the interface between law enforcement and health sectors in the Member States.

#### **5) European Commission**

206. In the field of threat assessment and scenario analysis for emergency planning, the Commission is preparing to classify terrorist actions (both CBRN and conventional) into scenarios and to model their impact on the population. It is also working on assessment of the effects of potential countermeasures. Moreover, the Commission is participating in the development of "Probabilistic Risk Assessment: ASTRA" in the context of anti-fraud and on "Assessment of threats in country profiles" in the field of non-proliferation.

#### **6) Joint Situation Centre**

207. Under the authority of the Secretary General/High Representative an assessment of the CBRN-terrorism threat has been prepared by the *Joint Situation Center of the Council (Sitcen)* <sup>65</sup> in accordance with the Seville Declaration.

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<sup>63</sup> OJ L 344, 28.12.21001, p. 93.

<sup>64</sup> The latest update is contained in OJ L 229, 13.9.2003, p. 22.

<sup>65</sup> The Joint Situation Centre has been developed to enhance the capacity of the Council Secretariat to analyse and make use of intelligence material and other information made available by Member States and to increase the sharing of intelligence and other information.

208. Sitcen establishes threat assessments about or including bio-terrorism aspects. In this respect, it updated, in connection with the Committee on Terrorism (2nd pillar) (COTER), a study on Al Quaida and the resulting consolidated document will aim at providing political guidance.
209. Sitcen also has a role in response as it manages the Crisis Coordination Arrangements (CCA), established by the Council in 2005. Sitcen provides the necessary infrastructure, human resources and Standard Operating Procedures for CCA.
210. The CCA is tested through annual exercises. In 2007, the exercise concerned a scenario of bio-terrorism. Moreover, the Presidency, with the support of the two forthcoming Presidencies (SI + FR) agreed on using this exercise to create a kind of check-list of measures to be taken at EU level should an event of this type occur, in line with what was decided by Coreper in the context of the exercise.

### C. Prevention

211. The above data have been communicated to trusted contact points in the Member States, who used the above assessments in the different sectors, adjusted their overall protecting system under conditions of strict confidentiality, and encouraged sectors that are vulnerable to CBRN attacks to include in their risk assessments the relevant information they received from them, so as to monitor and protect vulnerable infrastructures or activities.
212. The assessments by COTER contain recommendations for an EU strategy towards the countries and regions in question as well as follow-up action. Efforts are being made to streamline and clarify these recommendations included in these reports. Methods of streamlining the recommendations will be agreed upon under the Italian Presidency.
213. A peer assessment of anti terrorist arrangements in Member States has started in 2003 at the Terrorism Working Party. The accession countries will be examined in the second half of 2004 and first half of 2005.
214. The Council took note, on 3 December 2004, of an *Interim Report on the Evaluation of National Anti-Terrorist Arrangements*, established by Article 36 Committee in association with the Counter Terrorist Coordinator<sup>66</sup>. This report i.a. contains certain suggestions for national consequence management preparedness and training programmes, for the reduction of the vulnerability of critical infrastructures, for national crisis arrangements and for public communication and information.

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<sup>66</sup> 14306/3/04 REV 3.

## **E. Monitoring**

215. In September 2006, the Commission adopted a Green paper on detection technologies in the work of law enforcement, customs and other security authorities. Modern detection technologies have an important role to play in the fight against crime and terrorism. This Green Paper aims at further stimulating the public-private dialogue and partnership, allowing for better focussing of investment in standardisation, research, certification or interoperability of detection systems and for transforming research results into useful and applicable tools.
216. The Green Paper addresses the following issues:
- Standardisation;
  - Certification of detection tools;
  - Information and experience exchange on the use of new and innovative detection tools;
  - integrated detection systems (multi-sensor systems);
  - procedures of how best to deploy and use detection tools;
  - Improvement of the protection of mass events.

## **E. International cooperation**

217. As noted by the 12th EU-Russia summit held in Rome on 6 November 2003, cooperation will continue to combat terrorism in all its forms and to prevent the proliferation of weapons of mass-destruction. Contacts are also undertaken to explore possible cooperation in the field of civil protection and long-haul air transport for crisis management. (13990/03)
218. The Declaration on combating terrorism adopted at the EU-US Summit of Dromoland, of 26 June 2004, confirmed the intention of the EU and the US to work together to develop further their capabilities to deal with the consequences of terrorist attacks.<sup>67</sup>

## **XII. RESEARCH**

### **A. Generalities**

219. The Commission has set up a group of national experts to compile an inventory of research efforts in the field of BC-terrorism within the Framework Programme 5 to determine gaps and define needs and opportunities. Its report was submitted to the Council on 8 July 2002<sup>68</sup>.

*Regarding the on-going research activities in Member States, the inventory noted that the R & D programmes and capabilities vary significantly between Member States. Where some Member States have specific research programmes on countering the effects of biological and chemical terrorism in place, these are generally linked to defence research, are publicly funded and undertaken in*

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<sup>67</sup> 10809/04.

<sup>68</sup> 10842/02 RECH 128 PROCIV 49 SEC(2002) 698.

Government research institutions.

There was substantially more research taking place to counter biological terrorism than chemical events.

220. The Council adopted, on 22 December 2003, *a resolution on strengthening Community cooperation in the field of civil protection research*, in particular by stepping up civil protection participation in existing and future Community research programmes on reducing natural or man-made accidents and risks and by fostering links between researchers and all those involved in civil protection (14782/03).
221. The Research and Development Expert Group on Countering the Effects of Biological and Chemical Terrorism has met six times. The inventory of research activities in Member States discussed by this group is being updated in the second half of 2004.

**B. Threat and risk analysis and assessment, prevention, monitoring, preparedness and consequence management**

**1) The 5th R&D Programme**

222. There are no specific key actions in the 5th R&D Programme aimed at countering the effects of chemical and bio terrorism. However within the four thematic programmes some research which may be of relevance is supported. For example:
  - The Energy, Environment and Sustainable Development programmes include research on risk assessment and biological hazards.
  - The Quality of Life programme includes research on detection of food borne pathogens, vaccines development and mechanisms for control of infectious diseases etc.
  - The Competitive and Sustainable Growth Thematic programme includes projects on measurement and testing aimed at fighting fraud and crime.

**2) The 6th R&D Programme**

223. The Sixth Research and Development Framework Programme provides for studies and research on issues related to civil protection, crisis management, life sciences, radiation emergency management, genomics and biotechnology for health, food quality and safety (including traceability of food and food components with regard to malicious introduction of pathogens), bio-security and protection against risks arising from terrorist attacks.
224. In the context of "Scientific Support for Policies", six co-ordination activities are currently being implemented following the launch of two calls for proposals in 2002 and 2003, in the following areas:
  - detection of haemorrhagic fever viruses and variola virus and their use in diagnostics;
  - European research networking activities to develop safe products and policies to protect citizens from the threat of anthrax attacks and other agents of bio-terrorism;

- assessment of the vulnerabilities of modern societies to terrorist acts employing radiological, biochemical or chemical agents with a view to helping develop preventive and suppressive crisis management strategies;
- transmission modelling and risk assessment for released or newly emergent infectious disease agents;
- crop bio-security as a means of preventing and preparing for bio-terrorism;
- a European approach to nuclear and radiological emergency management and rehabilitation strategies, to provide better coherence and transparency in decision-making processes on local, national and cross-border operations.

225. Under "Support for Policies", a third call for research proposals has been launched. It will cover topics in the areas of protection, cure, biology of pathogens, and policy.

### 3) The Security Research Programme

226. In 2004, the Commission launched a three-year "Preparatory Action for Security Research (PASR)" in the field of Security Research. With three annual budgets of € 15 million, the Preparatory Action was a first step towards a new Security theme in the 7th RTD Framework Programme (FP7). Under PASR, 39 projects<sup>69</sup> have been funded.

227. Building on PASR, the 7<sup>th</sup> RTD Framework Programme (FP7, 2007-2013) saw a substantial increase of the budget for Security Research to 1,4 Billion € including the protection against CBRN terrorism.

228. In parallel, a European Security Research and Innovation Forum (ESRIF) has been created<sup>70</sup>. ESRIF will build on the work already done by the Group of Personalities<sup>71</sup> and the European Security Research Advisory Board (ESRAB)<sup>72</sup>.

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<sup>69</sup> A description of the 39 PASR research projects, including final and intermediate results, can be found on:

[http://ec.europa.eu/enterprise/security/articles/article\\_2007-02-23\\_en.htm](http://ec.europa.eu/enterprise/security/articles/article_2007-02-23_en.htm)

<sup>70</sup> The creation of ESRIF was announced in the Commission Communication on a public-private dialogue in the field of European security research and innovation (COM(2007)511 final) of 11.9.2007.

<sup>71</sup> The 'Group of Personalities' (GoP) was set up in 2003. In its final report (Research for a Secure Europe: Report of the Group of Personalities in the field of Security Research, 15 March 2004, [http://ec.europa.eu/enterprise/security/doc/gop\\_en.pdf](http://ec.europa.eu/enterprise/security/doc/gop_en.pdf)), the GoP recommended the launch of a security research theme in FP7 with a minimum threshold of € 1 billion per annum as well as the creation of the 'European Security Research Advisory Board' (ESRAB).

<sup>72</sup> The ESRAB Board was created by Commission Decision [2005/516/EC](#) on 22 April 2005 and published its final report on 22 September 2006. It recommends that multidisciplinary mission-oriented research should be undertaken. It should combine end-users and suppliers in project definition and execution. The report identified a number of areas, including security of infrastructures, to stimulate innovation and improve the use of research in procured products and services. Finally, the ESRAB report also suggested 'the creation of a European Security Board (the later ESRIF), to foster greater dialogue and a shared view of European security needs. The board should bring together, in a non-bureaucratic manner, authoritative senior representatives from the public and private communities to jointly develop a strategic security

The objective of the ESRIF is to support civil security policy-making with the appropriate technology and knowledge base by establishing a mid- and long-term Joint Security Research Agenda that will involve all European stakeholders from both the supply and the demand sides. This agenda should contain a research roadmap based on the future needs of the public and private end-users and the state-of-the-art security technologies.

229. The Joint Security Research Agenda will aim to be the reference document for security research programming for the next coming years, at national, regional and industrial level, taking into account the research that will be carried out at European level as decided in the 7th RTD Framework Programme and beyond.

#### **4) Activities of the Joint Research Centre**

230. The Joint Research Center's activities include two new prospective studies launched in January 2002 on:

- Scientific aspects of biological and chemical terrorism
- Social, economic and psychological vulnerabilities of modern society to terrorism.

Initial results are expected in mid summer 2002 with final results available by the end of 2002.

231. The JRC has established a Bioresponse Working Group including Member States experts to assess possible scenarios involving the introduction of deliberately transformed organisms for terrorist purposes (e.g. agri-food chain) and to evaluate the potential consequences. The JRC is also currently in the process of updating its on-line database relevant to biological and chemical terrorism. This database would be available to all authorised competent authorities of EU Member States at their request.

#### **5) GMES and INSPIRE**

232. In the context of GMES (Global Monitoring for Environment and Security), a Network of Excellence in support of Security, GMOSS (Global Monitoring for Security and Stability), started in March. The objective of this project is to work towards enhancing European monitoring capability, based on earth observation, for civil applications such as humanitarian aid, reconstruction, verification of compliance with non-proliferation treaties, policing operations, including vulnerability assessment, and developing stability beyond EU's borders.

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agenda and act as a possible reference body for the implementation of existing programmes and initiatives'.

In addition to INSPIRE (Infrastructure for Spatial Information In Europe), a specific support action has been introduced to the Work Programme on Space on data harmonisation in order to increase the level of interoperability among geospatial information systems. The development of common standards and specifications for data documentation, collection, and exchange is central to the successful technical implementation of INSPIRE.

## **6) Ethical questions**

233. The Commission services have started an initiative on exploring the ethical implications of scientific research on bio-weapons and prevention of bio-terrorism, which addresses issues such as the science/security dilemma and raising the awareness of scientists regarding the possible dual use of their findings. A conference on ethical implications took place in Brussels in February 2004. As part of the follow-up, a research topic on "The Science-Security Dilemma (SSD) and its implications for research on or with possible spin-offs for bio-terrorism" is planned for inclusion in the Call for Proposals on Scientific Support to Policies (to be launched in October 2004).

## **7) Decontamination techniques**

234. Based on lessons learnt from previous disasters, accidents and acts of terrorism, the Commission reviews the available techniques of decontamination following attacks involving dangerous substances. Furthermore, it models the dispersion of radioactive materials and estimates dose rates by using the software simulation code, combined with digital maps and satellite information.

## **C. International relations**

235. The Commission is involved in European Safeguards Research and Development Association (ESARDA) networking, e.g. working group on verification technologies and methodologies, physical protection in the Containment Surveillance Working group.
236. Coordination of European defence research is primarily through Western European Union, and the Research panel of the Western European Armament Group (WEAG). Within the EUCLID research programme carried out by the WEAG, the CEPA 13 (Common European Priority Area) deals with Radiological, Chemical and Biological Defence. Otherwise, NATO has also its own science programme which provides support for international collaboration between scientists from countries of the Euro-Atlantic Partnership Council (EAPC).

### **XIII. MILITARY SUPPORT**

#### **A. Consequence management**

237. In the framework of the Mechanism, some Member States resources declared that, in order to face major emergencies, their civil protection resources will include national military resources under civilian coordination. These resources, who are encompassing a broad extent of assistance possibilities, will complete the civil protection resources while avoiding unnecessary duplication of work.
238. A database of military assets and capabilities relevant to the protection of civilian populations against the effects of terrorist attacks, including CBRN was set up in accordance with conclusions of the Council of 8 December 2003. This database, kept by the EUMS, is the military equivalent of the civil protection database kept by the Commission. The content of this database has been made available to the Community Civil Protection Mechanism, in accordance with the modalities, procedures and criteria endorsed by the Council on 17 May 2004<sup>73</sup>. On this basis, work on deepening and widening this military database started in autumn 2004. The conceptual Framework on the ESDP dimension of the fight against terrorism<sup>74</sup>, adopted by the Council on 22 November 2004 and annexed to the December 2004 EDPS Presidency report, requested the PSC to consolidate work in this field by identifying a set of recommendations to the Council on the role of this database in the wider context of the Headline Goal 2010 and on possible more systematic updates.
239. *To be inserted : Description of*
- *the database of military assets and capabilities relevant to the protection of civilian populations, created in 2003<sup>75</sup>*
  - *the general framework of 2006 for the use of Member States military or military chartered transportation assets and ESDP coordination tools in support of EU disaster response<sup>76</sup>*
  - *the arrangements of 2006 for military support to EU disaster response.*

#### **B. International cooperation**

240. At informal meetings between the EU and NATO staff on the urgent civilian reactions in crisis management, there were exchanges of information about non-binding standards for the protection of civilian populations against CBRN-risks.
241. Both organisations have additionally increased transparency through the exchange of inventories listing their respective activities and capabilities for protection of civilian populations against CBRN terrorist attacks.

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<sup>73</sup> 15564/03.

<sup>74</sup> 14797/04.

<sup>75</sup> 6644/4/04.

<sup>76</sup> 8976/06. 6644/4/04.

<sup>76</sup> 8976/06.

## **XIV. HORIZONTAL ACTIONS AND OVERALL COORDINATION**

### **1) ARGUS**

242. The general rapid alert system called ARGUS has two main functions: to provide an internal platform to exchange, in real time, relevant information between Commission services and to ensure political coordination at high level in case of a major multisectoral crisis. Thus, Commission services can improve their coordination and ensure a coherent and efficient response. However, the response to crisis in specific fields stays under the responsibility of sectoral RAS. Each RAS manages crisis through their own networks, procedures and expertise and respecting their own mandate. A specific coordination process can be launched to manage a rapid, coordinated and coherent Commission response, based on all relevant information, in its domains of competence and in cooperation with the other institutions.

### **2) The Crisis Coordination Arrangements (CCA).**

243. Following the remits given by the Hague Programme and the Council Declaration on the EU response to the London bombings, the Council has endorsed, on 13 June 2007, the operational EU emergency and crisis coordination manual<sup>77</sup> drawn up by the Presidency in close cooperation with the Commission and the Council Secretariat in order to ensure that the Union can react more effectively and lend assistance when major emergencies occur inside or outside the Union. This manual is composed of the following elements:

- First, the manual contains internal arrangements for political coordination in Brussels for major emergencies inside or outside the European Union by providing input for coordinated action or decisions by COREPER or the Council.
- Second, the manual pre-identifies a list of default contact points of the EU Institutions, of all Member States and of the relevant organisations that can be used when needed at any time (24/7) to help in response to an emergency/crisis. The information provided by this list will enable the Member States to respond rapidly to crisis situations by giving practical and operational support to the above mentioned crisis coordination arrangements and by facilitating cooperation between Member States.

The manual will be updated by the forthcoming Presidencies in cooperation with the Council Secretariat, the Commission and the Member States in the light of tests to be undertaken, experience and practice.

### **3) Horizontal cooperation among services**

244. The Presidency organised, in The Hague, on 7-8 July 2004, a seminar on cooperation between services on the civil preparedness for possible attacks against the civilian population with CBRN agents<sup>78</sup>.

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<sup>77</sup> <http://register.consilium.europa.eu/pdf/en/07/st10/st10011-re01.en07.pdf>

<sup>78</sup> 11919/04.

Several of its recommendations found their way to the Solidarity Programme of the Council and the Commission of 3 December 2004 on the consequences of terrorist threats and attacks <sup>79</sup>, that has now succeeded to the 2002 CBRN Programme.

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<sup>79</sup> 15480/04.

LIST OF INSTRUMENTS

Civil Protection

1. *Council Decision 91/396/EEC of 29 July 1991 on the introduction of a single European emergency call number*<sup>80</sup>
2. *Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument*<sup>81</sup>
3. *Council Decision ..../EC, Euratom of ...November 2007 establishing a Community Civil Protection Mechanism.*<sup>82</sup>

Health protection

4. *European Parliament and Council Decision 2119/98/EC of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community*
5. *Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision 2119/98/EC*
6. *Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC of the European Parliament and of the Council*
7. *Commission Decision 2002/253/EC laying down case definitions for diseases to be covered by the EU communicable disease network*
8. *Health Security Programme* agreed upon on 17 December 2001 by the Health Security Committee.
9. *Programme of Community action in the field of public health 2003-2008*

Pharmaceuticals for human use

10. p.m.

Food protection

11. *Directive 89/397/EEC on the official control of foodstuffs*
12. *Directive 93/43/EEC on the hygiene of foodstuffs*

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<sup>80</sup> OJ L 217, 6.8.1991, p. 31.

<sup>81</sup> OJ L 71, 10.3.2007, p. 9.

<sup>82</sup> 11163/1/07.

13. *Regulation 178/2002/EC of 28.01.2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*

#### Animal protection

14. *Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine*
15. *Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community*
16. *Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot- and-mouth disease*
17. *Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market*
18. *Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines, as amended by Decision 2001/181,*
19. *Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals*
20. *Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness*
21. *Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza*
22. *Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease*
23. *Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease*
24. *Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the liability of beef and beef products and repealing Council Regulation (EC) no. 820/97.*
25. *Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue*
26. *Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever.*

27. *Commission Regulation (EC) 466/2001 setting maximum levels for certain contaminants in food*
28. *Directive of the European Parliament and the Council 2002/32/EC of 7 May 2002 on undesirable substances in animal feed*
29. *Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97*
30. *Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing*
31. *Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes*

#### Plant safety

32. *Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC fixing maximum limits for Pesticide Residues on feed and foodstuffs*
33. *Council Directive 91/414/EEC on the marketing of plant protection products*
34. *Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community and related regulations.*
35. *International Plant Protection Convention.*

#### Environment protection

36. *Directive 75/440/EC on the quality of surface waters used for drinking water*
37. *Directives 80/778/EC and 98/83/EC on the quality of drinking water*
38. *Directive 90/219/EC on the contained use of genetically modified micro-organisms as amended by Directive 98/81/EC.*

#### Non-proliferation, Global disarmament and arms control

39. *Treaty on the Non-Proliferation of Nuclear Weapons*
40. *Chemical Weapons Convention*
41. *Biological Weapons Convention*

### Customs

42. *Council Regulation 1334/2000/EC setting up a Community regime for the control of exports of dual-use items and technology,*

### Police

43. *p.m.*

### Military support

44. *p.m.*

### Research

45. *[Decision 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to Innovation (2002 to 2006).]*

### Horizontal actions and overall coordination

46. *p.m.*
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