



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 5 June 2008**

**10382/08**

**PROCIV 88  
JAI 310  
AGRI 173  
AGRILEG 97  
ATO 50  
CODUN 14  
CONOP 35  
COSDP 495  
COTER 41  
DENLEG 65  
ENFOPOL 113  
ENV 354  
PHARM 2  
RECH 204  
SAN 119  
VETER 12**

**I/A ITEM NOTE**

---

from : the Presidency

to : Coreper / Council

---

No. prev. doc. : 79653/07 PROCIV 71 JAI 259 AGRI 145 AGRILEG 84 ATO 46 CODUN 7  
CONOP 28 COSDP 416 COTER 33 DENLEG 53 ENFOPOL 99 ENV 309  
PHARM 1 RECH181 SAN 90 VETER 8 + COR 1

---

Subject : Inventory of EU instruments relevant for addressing Chemical, Biological,  
Radiological and Nuclear risks ("CBRN Inventory")

---

1. Coreper and Council will find in the Annex an Inventory of the EU instruments that are relevant for addressing Chemical, Biological, Radiological and Nuclear risks. This Inventory was established in order to meet a request by the Council in its conclusions of 6 December 2007 on addressing chemical, biological, radiological and nuclear (CBRN) risks and on bio-preparedness<sup>1</sup>.

---

<sup>1</sup> 16589/07, sub (e), 5 and 13.

As the Council said, it should enable it "to take stock of the capabilities and needs in this area in the course of 2008." It should also help the Commission in proposing, as indicated in no. 7 of those conclusions, relevant policy measures on CBRN risks in 2009.

2. This Inventory is an update of the CBRN Inventory of 2002<sup>2</sup> and of the draft Bio Inventory of 2007<sup>3</sup>, taking into account comments on the latter made by several delegations. It also takes into account the 1st Presidency report of 2003<sup>4</sup> and the 2nd Presidency report of 2005<sup>5</sup> on the implementation of the CBRN Programme.

This Inventory was established under the responsibility of the Presidency by the General Secretariat of the Council and the Commission services, under the general supervision of the Civil Protection Working Party (ProCiv) and in consultation with the Counter-Terrorism Coordinator and the HR's Personal Representative for non-proliferation.

3. This Inventory was noted by the Political and Security Committee (PSC) on 2 June 2008.
4. As requested in no. 5 of the abovementioned conclusions, the Commission and the General Secretariat will update this Inventory biennially.
5. It is suggested that, under I/A items on their agendas, Coreper invite Council to take note of this Inventory.

---

<sup>2</sup> Inventory of the EU instruments relevant for the Council and Commission 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), 15873/02 + COR 1 + COR 2.

<sup>3</sup> 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, 14802/07 + ADD 1.

<sup>4</sup> 16285/03.

<sup>5</sup> 8988/05.

**INVENTORY OF EU INSTRUMENTS  
RELEVANT FOR ADDRESSING  
CHEMICAL, BIOLOGICAL, RADIOLOGICAL  
AND NUCLEAR RISKS  
("CBRN INVENTORY")**

*(established under the responsibility of the Presidency  
by the General Secretariat of the Council and the Commission services)*

*Brussels, 5 June 2008*

*(Blank page)*

## TABLE OF CONTENTS

### PART A. INTRODUCTORY PART

I.	BACKGROUND TO THIS INVENTORY.....	6
II.	SECTORS THAT ARE VULNERABLE TO CBRN THREATS.....	9
III.	ROLE OF THE DIFFERENT POLICIES CONDUCTED IN THE EU IN RESPONSE TO CBRN THREATS.....	10

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

#### a) THREAT REDUCTION

I.	POLICE, SECURITY AND INTELLIGENCE.....	17
II.	NON-PROLIFERATION, GLOBAL DISARMAMENT, ARMS CONTROL AND CUSTOMS.....	21

#### b) RISK AND VULNERABILITY REDUCTION

III.	HUMAN HEALTH PROTECTION.....	23
IV.	FEED AND FOOD.....	38
V.	ANIMAL HEALTH PROTECTION.....	45
VI.	PLANT PROTECTION AND PLANT HEALTH.....	49
VII.	GENETICALLY MODIFIED ORGANISMS (GMOs) AND BIOLOGICAL AGENTS.....	51
VIII.	ENVIRONMENT (WATER AND AIR).....	54
IX.	PROTECTION AGAINST CHEMICALS AND DANGEROUS SUBSTANCES.....	55
X.	RADIOLOGICAL AND NUCLEAR PROTECTION.....	61
XI.	CRITICAL INFRASTRUCTURE PROTECTION.....	68

#### c) RESPONSE AND PREPAREDNESS

XII.	CIVIL PROTECTION.....	70
XIII.	PHARMACEUTICALS FOR HUMAN USE.....	77
XIV.	MILITARY SUPPORT TO EU CONSEQUENCE MANAGEMENT.....	80

#### d) CROSS-CUTTING

XV.	RESEARCH.....	81
XVI.	OVERALL COORDINATION.....	86

### PART C. LIST OF INSTRUMENTS

List of instruments.....	88
--------------------------	----

**INVENTORY OF EU-INSTRUMENTS**  
**RELEVANT FOR ADDRESSING**  
**CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR RISKS** <sup>6</sup>

**PART A.**

**INTRODUCTORY PART**

**I. BACKGROUND TO THIS INVENTORY**

1. The EU's concern over chemical, biological, radiological and nuclear (CBRN) threats is not new. Already at a very early stage, the EU has taken numerous measures to help protect the populations of its Member States against accidents, pandemics or natural events involving CBRN substances.
2. Following the Anthrax letters that were circulated shortly after the terrorist attacks on the United States on 9 September 2001, the Council and the Commission jointly adopted, on 20 December 2002, their programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats (*CBRN Programme*)<sup>7</sup>. At the same time, the Council took note of an Inventory of EU Instruments relevant for the CBRN Programme, that was established under the responsibility of the Presidency<sup>8</sup>. The CBRN Programme was integrated into the *EU Solidarity Programme* adopted by the Council on 2 December 2004<sup>9</sup> which widened the CBRN Programme to all terrorist threats and attacks. The Solidarity Programme itself was integrated in the *EU Action Plan on Combating Terrorism*, which is a rolling Action Plan that was created shortly after the attacks of 11 September 2001 and which is updated every year.<sup>10</sup>
3. As witnessed by the 1st Presidency report of 2003<sup>11</sup> and the 2nd Presidency report of 2005 on the implementation of the CBRN programme,<sup>12</sup> the CBRN Programme, and its continuation under the Solidarity Programme of 2004, led to major practical improvements in the areas covered by their seven strategic objectives of 1) Threat and risk assessment, 2) Prevention and **risk and** vulnerability reduction, 3) Monitoring and identification of the agents used, 4) preparedness for and management of the response, 5) research and development, 6) international relations and 7) overall coordination.

---

<sup>6</sup> *The changes to 9653/08 + COR 1 are in **bold** or empty brackets [ ]).*

<sup>7</sup> 14627/02.

<sup>8</sup> Inventory of the EU instruments relevant for the Council and Commission 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), 15873/02 + COR 1 + COR 2.

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

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

<sup>11</sup> 16285/03.

<sup>12</sup> 8988/05.

4. The Commission's Green Paper of July 2007 on bio-preparedness<sup>13</sup> led to increased awareness of CBRN risks and threats and launched a process of consultation at European level on how to reduce biological risks and enhance preparedness and response. However, where the CBRN programme had concentrated on the terrorist threat, the bio-preparedness Green Paper followed an all-hazards approach, also targeting risks deriving from natural disasters, accidents and pandemics, while giving priority to the terrorist threat.
5. On the basis of the Commission's Green Paper, the Council adopted its Conclusions of 6 December 2007 on addressing chemical, biological, radiological and nuclear risks and on bio-preparedness<sup>14</sup> which show the way forward for addressing, during the years 2008 and 2009, CBRN risks of natural or man-made origin under an all-hazards approach while giving priority to the terrorist threat, and covering both the "safety" (**prevention of the risks of accidents, pandemics, natural disasters**) and "security" aspects (protection against malicious acts), **under the understanding that security is building on the proper implementation of safety measures** :
- The Commission will provide the Council with an analysis of the responses received to the Green Paper on bio-preparedness in spring 2008.
  - The Commission will, in the follow-up to the consultations on that Green Paper, continue, in 2008, its work in the CBRN field together with the Member States and relevant public and private stakeholders, avoiding duplications and building on good practices across Member States.
  - The Commission, the Member States and the Council Secretariat will, within the framework of their respective competences, strengthen interoperability and improve the exchange of information between the different rapid alert and response systems and structures while taking due care to preserve their specificity and effectiveness.
  - The EU Counter-Terrorism Coordinator and the SG/HR's Personal Representative for non-proliferation will work together and with Member States and the Commission, in accordance with their respective competences, with a view to identifying ways and means of mitigating the risk that terrorists might in the future obtain, directly or indirectly, CBRN materials.
  - The Commission and the Member States will continue to organise regular exercises addressing CBRN risks.
  - The Commission will propose relevant policy measures in 2009.
  - Coreper, supported by the competent Council Working Party/ies, will monitor the implementation of these conclusions.
  - The Council will remain seized of the matter.
6. At the same time, the Council of 6 December 2007 took note of a draft Inventory of EU instruments relevant for addressing Chemical, Biological, Radiological and Nuclear risks and on bio-preparedness ("Bio Inventory")<sup>15</sup> which was drawn up by the Council Secretariat and the Commission services.

---

<sup>13</sup> 11951/07.

<sup>14</sup> 16589/07.

<sup>15</sup> 14802/07 + ADD 1.

This Inventory addressed prevention, preparedness and response to biological risks existing in the areas of human **health (including occupational health and safety)**, animal and plant health, police, research, environment, civil protection, etc. and was established on the basis of the relevant sections of the 2002 CBRN Inventory.

In its conclusions, the Council asked the Commission and the Secretariat General of the Council to use the 2007 Bio Inventory in order to update the CBRN Inventory of 2002 which outlined the many EU instruments that can be used to counter CBRN risks and threats so that the Council can, on this basis, take stock of the capabilities and needs in this area in the course of 2008. The Council also asked the Commission and the General Secretariat of the Council to update this inventory biennially.

7. This Inventory of EU instruments relevant for addressing Chemical, Biological, Radiological and Nuclear risks ("CBRN Inventory") contains:

- In this PART A : Introductory Part :
  - this Section I: Background to this Inventory,
  - Section II below: Sectors that are vulnerable to CBRN threats,
  - Section III below: The role of the different policies conducted in the EU in response to CBRN threats and risks,
- in PART B: Activities undertaken in different policy areas:
  - a) Threat reduction
    - I. Police, security and intelligence,
    - II. Non-proliferation, global disarmament and arms control
  - b) Risk and vulnerability reduction
    - III. Human health protection,
    - IV. Safety of feed and food,
    - V. Animal health protection,
    - VI. Plant protection and plant health,
    - VII. Genetically Modified Organisms (GMOs) **and biological agents**,
    - VIII. Environment (water, air),
    - IX. Protection against chemical and dangerous substances ("Seveso" undertakings, trade, transport),
    - X. Radiological and nuclear protection,
    - XI. Critical infrastructure protection,
  - c) Preparedness and response
    - XII. Civil protection,
    - XIII. Pharmaceuticals for human use,
    - XIV. Military assistance,
  - d) Cross-cutting
    - XV. Research,
    - XVI. Overall coordination,
- in Part C : the list of relevant instruments.



8. The intention is that this Inventory will become a useful tool for establishing and implementing the renewed CBRN policy. It could, in particular, be of use for the public-private task force that the Commission has created in order to prepare the CBRN policy package of 2009.

## II. SECTORS THAT ARE VULNERABLE TO CBRN THREATS

### 1) Human Health

9. Human health is highly exposed to biological, **chemical, radiological and nuclear** threats. **Biological** threats might arise from naturally occurring diseases, especially if they develop into pandemics, 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 [ ] be carried out in a covert way using biological, chemical or radiological agents.

### 2) Feed and food

10. Throughout the whole food chain, food contamination is a real threat to EU food sources and should be addressed appropriately. Food production and food systems are extremely complex. Products of animal and plant origin present intrinsic hazards, due to microbiological and chemical contamination 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. 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. These types of activities could cause extensive morbidity and mortality as well as economic destruction of agricultural and food manufacturing industries and undermine consumer confidence.

### 3) Animals

11. In the area of animal health, the seriousness and spreading potential of certain pathogens are obvious threats to stock farming in all countries. The real presence of epizootiological agents of this kind or even the risk of its presence 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 campaigns for combating animal diseases. 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. Their effects can also lead to food shortages, and some of them are zoonotic, thus threatening human health. The nature and properties of a number of these pathogen agents mean that they could be used for terrorist purposes.

[ ] Certain diseases that are less contagious but highly harmful for human health, notably anthrax, botulism, brucellosis or tularaemia, could also be [ ] used by terrorist groups. The OIE issued comments regarding bio-preparedness, including a list of animal diseases from potential bioterrorist agents.

**Like for human health, not only bio-agents but also chemical and radiological agents can contaminate animals, as well as plants.**

#### 4) Plants

12. In the areas of plant health and of plant protection, attention must be paid to the risks inherent in the placing on the market of plant protection products and to the spread of organisms that are harmful to plants.

Concerning plant health, plant pests and diseases may be caused by insects, mites, nematodes, bacteria, fungi or viruses. These could be harmful to plants and plant products without being 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 damage to forests, public parks and wild flora. Outbreaks are often caused by special climatic conditions which favour one organism and allow it to spread more rapidly than usual, or because organisms are introduced into areas where they find favourable conditions that allow the relevant harmful organism to spread and become established.

With regard to plant protection, products which are used to protect crops against diseases and pests can 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.

#### 5) Environment (water and air)

13. Particular attention should be paid to the vulnerability of drinking water. But also the air can carry dangerous substances creating large numbers of victims as could be witnessed following the disaster of Bhopal on 3 December 1984.

#### 6) Dangerous and radioactive substances and the facilities and transports handling them

14. Dangerous and radioactive substances and the facilities and transports handling them, as well as certain critical infrastructures, are not only subject to threats increasing their vulnerability and requiring measures to enhancing their security; they also carry an inherent safety risk because of their very nature; Both the safety and security aspects are covered by this Inventory.

#### 7) Critical infrastructures

15. In addition to the special protection of facilities handling the **dangerous and radioactive substances** mentioned above, it is important to provide a more general protection in favour of certain infrastructure that could be, on the passive side, the target of CBRN threats or risks or, on the active side, the originator of CBRN disasters.

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

16. *EU policies can contribute to (a) threat reduction, to (b) **risk and vulnerability reduction** of the potential victims or to (c) response after a CBRN disaster has occurred. Although the various EU policies all contribute to all of those factors, they often have a prevailing role in one of them, which explains their classification in one or other of those categories.*

a) **Threat Reduction**

**A. Police, Security and Intelligence**

17. In the framework of 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.

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

18. The EU strategy endorsed by the European Council of 12 December 2003<sup>16</sup> against the proliferation of weapons of mass destruction i.a. aims at preventing third countries and terrorists from acquiring CBRN materials and their means of delivery and at seeking an effective multilateral response to this threat.

b) **Risk and Vulnerability Reduction**

**C. Human health**

19. To reduce the vulnerability of human health and to enhance the capacity of the health sector 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 early detection of threats and 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 a public health response as detailed above. This, in turn, requires, **on the basis of occupational health and safety measures implemented in accordance with Directive 2000/54/EC<sup>17</sup>**, a 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.
20. *The Health Security Programme* agreed upon on 17 December 2001 by the Health Security Committee aims at :
- setting up a mechanism for information exchange, consultation and coordination for the handling of health-related issues,
  - 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 dealing with attacks from the health point of view and
  - the co-ordination of emergency plans.

---

<sup>16</sup> 15656/03.

<sup>17</sup> **Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from the risks related to exposure to biological agents at work (OJ L 262, 17.10.2000, p. 21).**

21. On 22 February 2007, the Council of the European Union agreed that the mandate of the Health Security Committee should be temporarily prolonged to cover pandemic influenza and generic preparedness and response planning, pending the general revision of the structures dealing with health threats at EU level.

**D. Protection of feed and food**

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

**E. Protection of animals**

24. 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 Commission's new Animal Health Strategy for the European Union (2007-2013) thoroughly enhances that aspect and the essential link of any policy with relevant international standards.

**F. Plant health**

25. Plant health protection forms the basis for the sustainable production of plants and arable crops and 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. Additionally, there are food and feed controls on residues and contaminants (including, for example, frequent sampling) to prevent or discover unintended contamination.
26. Within the framework of the Community's plant health legislation, numerous phytosanitary 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. Genetically Modified Organisms (GMOs) and biological agents**

27. The EU has established a **comprehensive** set of precautionary measures aiming at avoiding the **possible** adverse effects of **GMOs and biological agents** on human health, the workplace or the environment. These measures are to be taken at the levels of the culture of GMOs, their storage, transport, use, deliberate release, destruction, placing on the market, traceability, transboundary movement.

## **H. Environment**

28. The EU environmental policy can 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, can reinforce the EU's capacity of reaction to biological and chemical terrorist threats.

## **I. Chemicals and dangerous goods, their industries and transport**

29. The existing instruments under the Seveso II Directive relating to risk assessment/scenarios and risk management go a long way towards providing sufficient protection. However, there are some gaps still to be filled (e.g. through EPCIP –see below).
30. The circulation, registration, authorisation, classification, marketing, packaging and labelling, export and import of dangerous substances and chemicals is subject to strict controls under the "REACH" Regulation, the 76/769/EEC "marketing and use" Directive and the Rotterdam Convention.
31. In accordance with Title V of the EC Treaty, one of the main aims of the Community transport policy is to improve transport safety, in particular for the transport of dangerous goods. This safety concern also implies protection of neighbouring populations, monitoring of dangerous goods carried, measures to be taken in the case of emergency situations and exchange of information among the competent authorities of the Member States concerned. Numerous measures adopted and implemented in this context could, albeit indirectly, provide for adequate instruments that could be used in the case of a terrorist threat. Since 11 September 2001, there has been considerable focus on specific measures relating to security of transport. It has to be noted however that the essential competence in this respect lies with Member States, not least in sectors concerned with the second and third pillars.

## **J. Radiological and nuclear protection**

32. In addition to measures already taken at national level, numerous Community instruments relevant to threats affecting the security of nuclear facilities, the use and transport of radioactive waste and substances and their consequences on populations, are already in place.

## **K. Critical infrastructure protection**

33. A "European Programme for Critical Infrastructure Protection (EPCIP)" policy package was put forward by the Commission in December 2006. It comprised a Communication and a proposal for a Directive. The communication and the relevant Council conclusions set forth the horizontal framework for the protection of critical infrastructures in the EU. Measures currently under discussion within the Council aim at increasing the protection of infrastructure (including CBRN-relevant infrastructure) whose destruction or disruption would have cross-boundary effects.

### c) Response and Preparedness

#### L. Civil Protection

34. Civil Protection at Community and Member State level basically prepares for consequence management to limit the consequences of disasters. Civil protection also contributes to prevention and monitoring.
35. At the level of the Community, the main instruments for reaching these objectives are Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument<sup>18</sup> and Council Decision 2007/779/EC/Euratom of 8 November 2007 establishing a Community Civil Protection Mechanism (recast)<sup>19</sup>, hereafter referred to as "the Mechanism". Both instruments apply to CBRN disasters.
36. 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 assisting other Member States and third countries in case of an emergency. Civil Protection can also help prevent disasters through public information.

#### M. Pharmaceuticals

37. With regard to pharmaceuticals, the starting points are the priorities set out in the Presidency conclusions on bioterrorism at the Health Council of 15 November 2001, namely 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".

#### N. Using military assets and ESDP coordination tools in support of EU disaster response

38. In February 2003, the Political and Security Committee agreed, in accordance with the Seville Declaration on the contribution of the CFSP, including the ESDP, to the fight against terrorism, on the establishment of a database of military assets and capabilities relevant to the protection of civilian populations against the effects of terrorist attacks, including CBRN. The Commission has access to the content of the database based on the arrangements developed in 2004 in accordance with the Council conclusions of 8 December 2003.<sup>20</sup>
39. In 2006, the Council welcomed the work on improving the EU's ability to respond to disasters, notably on military support to EU disaster response in the context of the Hampton Court follow-up and the proposals put forward by the SG/HR in March 2006.
40. The Council recalled that helping citizens in an emergency, crisis or disaster, whether natural or man-made, requires rapid and effective delivery of assistance. Military means may be essential to complement civilian capabilities in order to save lives and allow for speed of action.

---

<sup>18</sup> OJ L 71, 10.3.2007, p. 9.

<sup>19</sup> OJ L 314, 1.12.2007, p. 9. Declarations for the minutes : 13459/07.

<sup>20</sup> 6644/4/04.

41. In this framework, the Council noted the document on "Military support to EU disaster relief – identification and coordination of available assets and capabilities"<sup>21</sup> as a living document, and agreed on its way ahead. The arrangements set out therein are designed to enhance the rapidity and effectiveness of the EU's response to disasters with military support. They will be subject to review, as necessary, in the light of experience gained.
42. One of the recommendations was to keep the database regularly updated and to expand its content to cover responses to natural and man-made disasters.
43. Work is also ongoing within the European Defence Agency, notably in the field of the Integrated Development Team (IDT) "Protect", currently dealing with CBRN: protection against Improvised Explosive Devices and Detection and Identification and Monitoring capabilities.

d) **Cross-Cutting**

**O. Research**

44. The *Sixth Framework Programme for Research and Development*, adopted on 27 June 2002, provides support to research activities in the CBRN area, in particular under "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."
45. The Preparatory Action on "Enhancement of the European industrial potential in the field of Security Research 2004-2006 -*Preparatory Action for Security Research (PASR)*-" constituted the Commission's contribution to the wider EU agenda for addressing key security challenges facing Europe and her partners. The PASR led to 6 projects related to CBRN.
46. *The Seventh Framework Programme for Research and Development*, adopted on 18 December 2006, provides support to cooperative research activities related to Security (Theme 10 of the Cooperation Specific Programme). The objective is to develop technologies and knowledge for building the capabilities needed to ensure the security of citizens from threats, such as acts of terrorism and (organised) crime, natural disasters and industrial accidents while respecting fundamental human rights including privacy.
47. One of the challenges of this activity is to contribute to the detection, tracking, tracing, *identification* and neutralisation of CBRN, both "traditional" and "home grown".
48. Another *challenge* is to contribute to ensuring that societies are better prepared prior to unpredictable catastrophic incidents and that they respond and recover more effectively both during, and after an incident, also in the case of pandemics.

**P. Overall coordination**

49. The main instruments for overall coordination of the response in case of disaster are, for the Commission, the ARGUS network and, for the Council, the Crisis Coordination Arrangements.

---

<sup>21</sup> 9462/3/06.

## PART B.

### ACTIVITIES UNDERTAKEN IN THE DIFFERENT POLICY AREAS

50. This part explores, for the policy areas in A.III above, the activities that have been undertaken for the 7 strategic objectives of:
- A. Threat and risk analysis and assessment,<sup>22</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.*
  - B. Prevention (or reduction of **risks and** vulnerability),  
*Prevention concerns upfront measures to increase the protection of potential targets and to decrease their **risks and** vulnerability.*
  - C. Monitoring, detection, identification and alert,  
*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 these capabilities 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.*

---

<sup>22</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).



a) **THREAT REDUCTION**

51. The reduction of CBRN threats dealt with in this sub-section basically concerns security, whereas **risk and** vulnerability reduction (sub-section below) mainly concerns safety.<sup>23</sup>

**I. POLICE, SECURITY AND INTELLIGENCE**

**A. General Information**

52. The objective of combating CBRN-terrorism cuts across a wide range of challenges. In order to improve the ability of the EU to prevent, respond to and recover from a CBRN 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.

53. For Police, Security and Intelligence, the challenges include:

- a) tracking shipments of [ ] biological agents **that pose a security concern**,
- b) enforcing international sanctions;
- c) coordinating verification and information exchanges among law enforcement agencies, customs authorities and the scientific community;
- d) boosting security at facilities **handling biological agents that pose a security concern**; security certification **checks** of facilities harbouring **such** pathogens and/or of **persons handling such agents**; **professional** codes of conduct **raising awareness of risks and threats, including the possible misuse of scientific results for weapons and terrorist activities**;
- e) raising public awareness;
- f) improving communications and coordination with public and private actors, including civil and military authorities.

**B. Risk analysis and assessment**

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

54. 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 comprise representatives of the police and security/intelligence services of the Member States and 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 issues related to terrorists' use of chemical, biological, radiological and nuclear substances.

---

<sup>23</sup> The OECD defines "Biosecurity" as "Measures to protect against the malicious use of pathogens, parts of them or their toxins in direct or indirect acts against humans, livestock or crops."

The OECD defines "Biosafety" as "The safe handling practices, procedures and proper use of containment facilities to prevent accidental harm caused by living organisms either directly or indirectly to individuals within laboratories or to the environment."

55. 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 taken by the Member State in 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 – for the 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 have taken place. The reports are sent through a special communications network that can handle confidential material.

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

56. 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.

## **3. Cross-pillar activities**

57. In December 2001, the Council adopted an initial list of the most significant terrorists and terrorist organisations<sup>24</sup> and has regularly updated that list.<sup>25</sup>

## **4. Europol**

58. 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.
59. In addition to this, Europol prepares regular assessment of the terrorist threats in Europe. They usually have a special section that assesses the possibility for attacks with CBRN weapons/material.<sup>26</sup>

---

<sup>24</sup> Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism (OJ L 344, 28.12.2001, p. 93).

<sup>25</sup> The latest update is contained in OJ L 340, 22.12.2007, p. 100.

<sup>26</sup> See the regular non-confidential reports of Europol on "Terrorist activity in the European Union - Situation and Trends Reports (TE-SAT), the latest one being in 8195/1/06.

60. Europol can also participate in the Joint Investigation Teams that have been set up under Council Framework Decision 2002/465/JHA <sup>27</sup>.
61. Finally, Europol has become part of the EU rapid alert system for biological and chemical threats ("RAS-BICHAT") and of the interface between law enforcement and health sectors in the Member States.

## **5. European Commission**

62. 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 the 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 (Sitcen)**

63. 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.
64. Under the authority of the Secretary General/High Representative an assessment of the CBRN terrorism threat has been prepared by the *Joint Situation Centre of the Council (Sitcen)* in accordance with the Seville Declaration.
65. Sitcen establishes threat assessments in relation to 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.
66. Sitcen also has a role in response as it manages the Crisis Coordination Arrangements (CCA), established by the Council in 2006. Sitcen provides the necessary infrastructure, human resources and Standard Operating Procedures for CCA.
67. The CCA are tested through annual exercises. In 2007, the exercise dealt with a bioterrorism scenario . Moreover, the then PT Presidency, with the support of the two forthcoming Presidencies (SI + FR) agreed on using this exercise to create an informal check-list of measures to be considered at EU level should an event of this type occur, in line with what was discussed by Coreper in the context of the exercise.

---

<sup>27</sup> Council Framework Decision 2002/465/JHA of 13 June 2002 on Joint Investigation Teams' (OJ L 162, 20.6.2002, p. 1); Council Agreement 2003/C 1212/01 of 8 May 2003 on a model agreement for setting up joint investigation teams (JIT) (OJ C 121, 25.3.2003, p. 1).

### **C. Prevention**

68. 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 general protection systems 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.
69. Under Council Decision 2002/996/JHA<sup>28</sup>, a first peer assessment of anti-terrorist arrangements in Member States and accession countries was undertaken between 2003 and 2007 under the coordination of COTER. A second round was started in 2007.

### **D. Monitoring (operational analysis)**

70. 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.
71. 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 for how best to deploy and use detection tools;
  - improvement of the protection of mass events.

### **E. International cooperation**

72. 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.
73. 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 further develop their capabilities for dealing with the consequences of terrorist attacks, including attacks using CBRN contaminants.<sup>29</sup>

---

<sup>28</sup> Council Decision 2002/996/JHA of 28 November 2002 establishing a mechanism for evaluating the legal systems and their implementation at national level in the fight against terrorism (OJ L 349, 24.12.2002, p. 1).

<sup>29</sup> 10809/04.

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

### **– Prevention**

74. 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.
75. The Strategy defines the EU policies and measures for responding 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 from materialising.
76. The Strategy's approach is based on three principles:
- i) 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 Joint Actions (IAEA<sup>30</sup>, CTBTO<sup>31</sup>, OPCW<sup>32</sup>, BTWC<sup>33</sup>, UNSCR 1540<sup>34</sup>, WHO<sup>35</sup>), Common Positions<sup>36</sup>, Action Plans<sup>37</sup> etc;
    - b) enhancing export controls by improving the European system for export controls (Peer Review and regular updating of dual-use Regulation) and participating actively in multilateral export control regimes;

---

<sup>30</sup> International Atomic Energy Agency : OJ L 165, 17.6.2006, p. 20; OJ L 193, 23.7.2005, p. 44; OJ L 182, 19.5.2004, p. 46.

<sup>31</sup> Comprehensive Nuclear Test Ban Treaty Organisation : OJ L 176, 6.7.2007, p. 31; OJ L 88, 25.3.2006, p. 68.

<sup>32</sup> Organisation for the Prohibition of Chemical Weapons : OJ L 85, 27.3.2007, p. 10; L 331, 17.12.2005, p. 34; OJ L 349, 25.11.2004, p. 63.

<sup>33</sup> Council Joint Action 2006/184/CFSP of February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction (OJ L 65, 7.3.2006, p. 51).

<sup>34</sup> Council Joint Action 2006/419/CFSP in support of the implementation of United Nations Security Council Resolution 1540 (2004) and in the framework of the implementation of the EU Strategy against the proliferation of Weapons of Mass Destruction (OJ L 165, 17.6.2006, p. 30).

<sup>35</sup> Council Joint Action 2008/307/CFSP of 14 April 2008 in support of World Health Organisation activities in the area of laboratory bio-safety and bio-security in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction (OJ L 106, 16.4.2008, p. 17).

<sup>36</sup> See Common Positions in OJ 176, 6.7.2007, p. 39, (CWC); OJ L 61, 28.2.2007, p. 49, (Iran); OJ L 88, 25.3.2006, p. 65, (BTW); OJ L 106, 27.4.2005, p. 32, (NPT); OJ L 302, 20.11.2003, p. 34 (universalisation).

<sup>37</sup> See EU Action Plan on biological and toxin weapons, complementary to the EU Action Plan in support of BTWC (OJ C 57, 9.3.2006, p. 1).

- c) providing assistance to requesting States in enhancing their national controls 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 Proliferation Security Initiative <sup>38</sup> (the Council and all EU MS endorsed the interdiction principles of the PSI) and GINCT (the EU institutions enjoy observer status).

**ii) Cooperating with key international partners by**

- (a) implementing specific joint statements and work-plans with third countries (US, Japan<sup>39</sup>, Russia<sup>40</sup>, China<sup>41</sup>);
- (b) maintaining staff-to-staff contacts with international and regional organisations on non-proliferation and disarmament issues (UN ODA, WHO, NATO);
- (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 has been 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).

**iii) supporting regional approaches to security** (e.g. through the establishment of regional WMD-free zones)

- 77. Further details on the implementation of the Strategy can be found in the six-monthly reports established by the Council Secretariat <sup>42</sup> in cooperation with the Commission and endorsed by the Council.
- 78. The Customs Cooperation Working Party agreed, in September 2004, on an action plan aiming i.a. at promoting the detection and prevention of the smuggling of CBRN goods. <sup>43</sup>
- 79. 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>44</sup>

---

<sup>38</sup> Proliferation Security Initiative. See 9211/04 and 10052/04.

<sup>39</sup> 1101/1/04 REV 1.

<sup>40</sup> 15061/04.

<sup>41</sup> 15065/04.

<sup>42</sup> Latest report in 16411/07.

<sup>43</sup> 10238/2/04.

<sup>44</sup> 7113/04.

b) **RISK AND VULNERABILITY REDUCTION**

**III. HUMAN HEALTH PROTECTION**  
**(including occupational health and safety aspects)**

**A. General structures**

**1) Role of the health services in general**

80. Mitigating the effects of covert releases requires early agent and events detection or the case recognition of victims, followed by the prompt activation of an effective multi-sector response.
81. Health authorities and health services have a crucial role in the early detection of events which could represent a threat to health and 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 the 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.

82. 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.
83. 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 smooth interdisciplinary collaboration 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 for a disruption in vital utilities and transport.

## 2) The Health Action Plans and Strategy

84. In May 2002, the European Parliament and the Council adopted its first *programme of Community action in the field of public health 2003-2008*<sup>45</sup> of which the promotion of actions to respond rapidly and in a coordinated fashion to health threats is one part. This 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 as well as to developing and using, where appropriate, Community approaches and mechanisms.

85. A new EU Programme on Health 2008-2013 was adopted by the European Parliament and the Council in 2007<sup>46</sup>. The new Programme also includes a part on health security which aims at protecting citizens against health threats by developing strategies and mechanisms for:

### a) **Risk and Vulnerability reduction :**

- developing risk management capacity and procedures,
- supporting the development of *prevention, vaccination and immunisation* policies;
- helping to enhance the safety, quality, availability, accessibility and traceability of organs and substances of human origin, blood, and blood derivatives for medical use,
- promoting the *early identification of risks* and their potential impact;
- developing risk communication and consultation procedures on counter-measures.

### b) **Threat reduction, preparedness and response :**

- preventing, exchanging information on and responding to *health threats*;
- ensuring high-quality diagnostic cooperation between Member States' laboratories and a network of Community reference laboratories;
- improving *preparedness* and planning for health emergencies;
- promoting the cooperation and improvement of existing response capacity and assets;
- drawing up and improving general contingency and specific health *emergency plans* and improving their inter-operability between Member States.

---

<sup>45</sup> Decision 1786/2002/EC of the European Parliament and of the Council, of 23 September 2002, establishing a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002, p. 1.

<sup>46</sup> Decision 1350/2007/EC of the European Parliament and of the Council, of 23 October 2007, establishing a second programme of Community action in the field of public health (2008-2013), OJ L 301, 20.11.2007, p. 3.



86. The Commission adopted a new Health Strategy in 2007 setting strategic objectives and fundamental principles for EC action on health for the period 2008-2013<sup>47</sup>. The Council adopted, on 5-6 December 2007, conclusions which i.a. recognize the existence of new health threats and environmental risks such as pandemics and climate change, and the need to strengthen EU work to address them.<sup>48</sup>

### 3) The Health Security Programme

87. Following a proposal by the Commission, the Health Security Committee (HSC) (see below) agreed on 17 December 2001 on 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<sup>49</sup>. The programme comprises 25 actions grouped under 4 objectives.

The programme 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 an 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.
88. A Communication on progress with the implementation of the Health Security Programme was published on 2 June 2003.<sup>50</sup> 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.

### 4) The Health Security Committee

89. To provide an effective coordination mechanism of 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 accredited representatives of the Health Ministers 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.

---

<sup>47</sup> Commission White Paper : "Together for Health : A Strategic Approach for the EU, 2008-2013" (14689/07 COM(2007) 630 final.

<sup>48</sup> Council conclusions of 6 December 2007 on the Commission White Paper: "Together for Health : A Strategic Approach for the EU, 2008-2013", 15611/07.

<sup>49</sup> Council conclusions of 15 December 2001 on bioterrorism, 13826/01, p. 12.

<sup>50</sup> 10327/03 – COM(2003) 320 final

90. 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>51</sup>

On 22 February 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, pending the general revision of the structures dealing with health threats at EU level, which should be undertaken in any case at the latest within two years after the submission of the report on the achievements of the European Centre for Disease Prevention and Control (ECDC).<sup>52</sup> The Council established the terms of reference of the HSC, i.e. 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 coordination of emergency planning at EU level;
- share and coordinate health-related crisis responses by Member States and the Commission;
- facilitate and support coordination and cooperation efforts and initiatives undertaken at EU and international level and help and contribute to their implementation at national level.

In November 2007, the Commission submitted to the Council an activity report on the HSC work for the period October 2006 – November 2007.<sup>53</sup>

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

91. To enhance the Community public health systems preparedness for threats to health, in particular 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.
92. The HSC Committee members exchange information on health-related threats to ensure rapid communication in case of major health-related crises, advising on preparedness and response as well as on co-ordination of emergency planning at EU level.

---

<sup>51</sup> 15561/06, COM/2006/0699 final.

<sup>52</sup> Council conclusions of 22 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.

<sup>53</sup> 15789/07.

## C. Prevention

93. *Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work*<sup>54</sup> introduces measures to encourage improvements in the safety and health of workers at work. To that end, it contains general principles concerning the prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors, the information, consultation, balanced participation in accordance with national laws and/or practices and training of workers and their representatives, as well as general guidelines for the implementation of the said principles.

## D. Monitoring

94. 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.

### 1) **Surveillance systems network for the epidemiological surveillance and control of communicable diseases and Rapid Alert Systems – RAS-BICHAT and EWRS**

95. 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.
96. 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 second objective of the Health Security programme, i.e. the Rapid alert system in case of biological and chemical threats (RAS-BICHAT).
97. 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 of communicable diseases, is conducted in the framework of Decision 2119/98/EC of the *European Parliament and Council Decision of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community*,<sup>55</sup> and its implementing measures, in particular Commission Decision 2003/534/EC on case definitions for pathogens **specifically engineered for the purpose of maximising morbidity and/or mortality upon deliberate release**<sup>56</sup>.

---

<sup>54</sup> OJ L 183, 29.6.1989, p. 1.

<sup>55</sup> OJ L 268, 3.10.1988, p. 1. Decision at last amended by Commission Decision 2007/875/EC (OJ L 344, 28.12.2007, p. 48)

<sup>56</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 diseases (OJ L 184 , 23/07/2003, p. 35).

98. The mechanism for the prevention and control of communicable diseases is operated by an informatics tool called *Early Warning and Response System (EWRS)*<sup>57</sup> 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 Regulations, the World Health Organisation is part of the system.

## 2) Pathogens covered

99. 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*<sup>58</sup>.

100. 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*.<sup>59</sup> In addition, tularaemia, Q-fever and smallpox have been given priority. On 28 April 2008, the European Commission updated a series of legislative texts intended to reinforce co-ordination measures and to strengthen the control of communicable diseases in Europe. The first of these texts concerns the EU Early Warning and Response System<sup>60</sup>. A new link between the EU alert system and the international level will now bring the EU and the World Health Organisation's reporting requirements into line.

---

<sup>57</sup> Commission Decision 2000/57/EC of 22 December 1999 on early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 21, 26.1.2000, p. 32 Decision as amended by Commission Decision 2008/351/EC of 28 April 2008 (OJ L 117, 1.5.2008, p. 40).

See also the Report from the Commission to the Council and the European Parliament on the operation of the Early Warning and Response System (EWRS) of the Community Network for the epidemiological surveillance and control of communicable diseases during years 2004-2005 (Decision 2000/57/EC) (7723/07, COM (2007) 121 final).

<sup>58</sup> OJ L 28, 3.2.2000, p. 50. Decision as last amended by Commission Decision 2007/875/EC (OJ L 344, 28.12.2007, p. 48).

<sup>59</sup> OJ L 86, 3.4.2002, p. 44. Decision as last amended by Commission Decision 2003/534/EC of 17 July 2003, OJ L 184, 23.7.2003, p. 35.

<sup>60</sup> Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases (OJ L 117, 1.5.2008, p. 40).

The second text updates the list of diseases subject to EU notification <sup>61</sup>. New communicable diseases like the Severe Acute Respiratory Syndrome (SARS), the avian influenza in humans and the West Nile virus infection in humans are now part of a list of 47 diseases. Finally, case definitions <sup>62</sup> for the 47 communicable diseases which must be notified under EU law have been updated taking into account the newest scientific knowledge.

### 3) Identification of CBRN agents and diagnostics

101. 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>63</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.
102. 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.
103. 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 orthopoxes, 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.

### 4) European Centre for Disease Prevention and Control (ECDC)

104. *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>64</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;

---

<sup>61</sup> Commission Decision 2007/875/EC of 18 December 2008 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 (OJ L 344, 28.12.2007, p. 48).

<sup>62</sup> Commission Decision ... of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision 2119/98/EC of the European Parliament and of the Council (OJ L ..., ..., p. ...).

<sup>63</sup> A. Tegnell, F. Van Loock, A. Baka, S. Wallyn, J. Hendriks, A. Werner and G. Gouvras. Development of a matrix to evaluate the threat of biological agents used for bioterrorism. [Cell Mol Life Sci](#). 2006 Oct. 63(19-20): 2223-8,2006.

<sup>64</sup> OJ L 142, 30.4.2004, p. 1.

- 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.

## **E. Preparedness**

### **1) Dissemination of rules**

105. 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 dealing with attacks from the health point of view and coordinating the EU response and links with third countries and international organisations.

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 projects funded under the Public Health Programme.

### **2) Organisation of workshops and exercises**

106. 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 EU-wide exercises are planned by the Commission from 2008 to 2011.

## **F. Consequence Management**

### **1) Planning**

#### ***a) Scenario approach***

107. 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.

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

108. 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 course of 2008 so as to permit the refinement and strengthening of emergency and contingency plans for threats and attacks.

109. 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.

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 Commission and the World Health Organisation).

*c) Generic preparedness planning*

110. On 28 November 2005, the Commission adopted a communication on EU Generic preparedness planning<sup>65</sup> to address threats and emergencies affecting or likely to affect public health in more than one EU country. The process of planning provides a structure to address different types of health threat, whether they are foreseen (such as pandemic influenza) or unforeseen (e.g. a SARS-type epidemic), involve biological, chemical, physical or radionuclear agents, or are caused by deliberate acts, accidents or natural events.

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 a plan, mainly by the setting up of a co-ordination mechanism that enhances co-operation between key Member States and Commission players.

The communication contains different chapters aiming to identify shortcomings, vulnerabilities and incompatibilities between national and/or EU systems, policies and co-ordination.

*d) Coordination and evaluation of emergency plans*

111. 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 the 15 old Member States was carried out and the issues of the interface and the Community dimension have been singled out for action.

This will be further updated with the data from the 12 new MS. A large-scale 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.

---

<sup>65</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, of 28 November 2005, on strengthening coordination on generic preparedness planning for public health emergencies at EU level (15123/05, COM 2005 (605) final).

**e) Influenza pandemic planning**

112. The 2-3 June 2004 Council (EPSCO) adopted *Conclusions on Community Influenza Pandemic Preparedness Planning*<sup>66</sup> which inter alia invited the Commission and the Health Ministers to extend the mandate of the Health Security Committee so as to cover the area of Community influenza pandemic preparedness and response planning.
113. On 28 November 2005, the Commission adopted a communication on influenza pandemic preparedness planning<sup>67</sup> to update the planning taking account of recommendations issued by the WHO and the establishment of the European Centre for Disease Prevention and Control (ECDC).
114. The Commission proposed at a meeting of the Health Security Committee on 27-28 June 2007 a priority working programme. In addition, it was proposed and accepted to create three groups 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 groups met for the first time in the Autumn 2007. The Health Security Committee adopted its priority working programme on 23 January 2008 which also deals with influenza pandemic planning.

**2) Response management**

**a) Health Security Committee**

115. The terms of reference of the Health Security Committee are i.a. 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.
116. The Health Security Committee members are linked via direct lines and a 24 hour/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.

---

<sup>66</sup> 9507/04.

<sup>67</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on Pandemic Influenza Preparedness and Response Planning in the European Community (COM2005 (607) final)



**b) The Health Emergency Operations Facility (HEOF)**

117. 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."*
118. 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 health-related situational awareness information. It should facilitate communication among crisis managers<sup>68</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>69</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).

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

119. 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.

---

<sup>68</sup> The 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 the Commission central crisis structure ARGUS. Switzerland has applied for official membership.

<sup>69</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 actors involved and provide them with the information they need in order to take coordinated measures.

120. HEOF uses the following sources of information:

- a) **MedISys**  
MedISys (Medical Intelligence System) is an internet monitoring and analysis system developed by the European Commission Joint Research Centre (JRC) for the Health and Consumer Protection Directorate-General (DG SANCO) 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 1500 news websites and newswires in 42 languages.
- b) **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/> ]
- c) **WHO**
  - weekly Outbreak verification list  
[ <http://www.who.int/csr/outbreaknetwork/en/> ]
  - GOARN <http://www.who.int/csr/outbreaknetwork/en/>
- d) **INVS** Weekly international epidemiological bulletin

INVS (l'Institut de veille sanitaire) is the public institution in France in charge of surveillance; monitoring and early warning and covers all kinds 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 in different languages.
- h) **Tariqa** – This 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 is of 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 relating to the safety of products, drugs and medical devices. Information contained in this system is integrated into HEDIS and all news alerts can be found in the functional mailbox INFO BICHAT.
- j) **Lexis Nexis** [<https://www.lexis.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) Messages circulating through the various warning systems (**EWRS, RAS BICHAT, RAS CHEM, ECURIE, MIC, RASFF, ...**)
- l) The Global Health Security Initiative (**GHSAG**) public and restricted website.  
 Open website: <http://www.ghsi.ca/english/index.asp>.  
 o URL: <http://www.ghsn-rssm.org/ev.php>
- m) 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.

- n) **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>

- o) **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.

- p) **IPCS – International Programme on Chemical Safety**  
provides "Chemical Safety Information from Intergovernmental Organizations", called INCHEM  
[\[http://www.inchem.org/ \]](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.

- q) **ARGUS**  
ARGUS is the General Rapid Alert System i.e. the internal communication network allowing the DGs and services of the Commission to share key information in the event of a crisis

and finally,

- r) **HEDIS** (Health Emergency & Disease Information System)  
HEDIS, developed by the European Commission Joint Research Centre (JRC), is the main interface of the EU Health Emergency Operations Facility (HEOF) run by the Health Threat Unit in DG SANCO with its external stakeholders (Ministries of Health in the Member States, specialised EU agencies and crisis centres). HEDIS is designed to provide accurate situation reports during health emergencies, to ensure that all stakeholders have the same level of information and to facilitate the relevant coordination and crisis management activities.

121. 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, Chemical Agent Attacks 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).

## **G. International relations**

### **1) Global Health Security Initiative (GHSI)**

122. 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 the 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. Ministers and the Commissioner for Health and Consumer Protection meet regularly to review progress concerning the laboratory collaboration, risk management and communication, the conduct of a joint exercise and exchanging experience on dealing with chemical incidents and attacks.

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

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

The International Health Regulations adopted in 1969 applied to only three infectious diseases (cholera, plague and yellow fever).

124. On 23 May 2005, the World Health Assembly adopted the [revised International Health Regulations](#)<sup>70</sup>. IHR(2005) came into force on 15 June 2007, for the 27 EU Member States. The EU itself is not a party to the IHR, but the IHR recognises 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.

---

<sup>70</sup> Resolution WHA 58.3.

Commission Decision 2007/875/EC <sup>71</sup> provides an obligation to communicate to Community network cases of "communicable diseases which may lead to potential emergencies of international concern identified according to Annex 2 of the International Health Regulations".

In addition Commission Decision 2008/351/EC <sup>72</sup> adds to events to be reported within the EWRS "manifestation of a disease or an occurrence that creates a potential for a disease pursuant to article 1 of the International Health Regulations (2005) which is a communicable disease pursuant to Annex of Decision No 2119/98/EC and related measures to be notified to the World Health Organisation under Article 6 of the International Health Regulations (2005)."

## **H. Coordination and implementation**

125. The HSC is dealing, in addition to the coordination role, with crisis management.

## **IV. FEED AND FOOD**

### **A. General information**

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

Feed and food operators should therefore take into consideration risks of all kinds such as those 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.

127. 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 table, in particular implementing monitoring programmes and controls.

128. 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.

---

<sup>71</sup> Commission Decision 2007/875/EC of 18 December 2008 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 (OJ L 344, 28.12.2007, p. 48).

<sup>72</sup> Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases (OJ L 117, 1.5.2008, p. 40).

129. 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 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 on numerous occasions.
130. 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 so much the lack of legal instruments as the wide disparity in the means of responding to situations in specific sectors, or the multiplicity of actions which need to be triggered where a problem spills over from one sector to another.
131. 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 in third countries as well as improved cooperation between authorities and those working in the food chain. Emphasis should also be put on cooperation between the food sector and other sectors of society. In particular, the role of education in guaranteeing safety throughout the food chain must be underlined.
132. In the framework of EU food safety legislation, a number of legislative instruments aim to improve and complete the existing system.

In particular, *Regulation (EC) No 178/2002 of the EP and of the Council of 28 January 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*<sup>73</sup> establishes over-arching principles, definitions and requirements on which all new food law in Europe is based.

Procedures are laid down in Regulation (EC) No 178/2002 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 to human health.

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

---

<sup>73</sup> OJ L 31, 1.2.2002, p. 1. Regulation amended by Regulation (EC) No 1642/2003, OJ L 245, 29.9.2003, p. 4.

See also Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of EP and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission, OJ L 379, 24.12.2004, p. 64.

## **B. Risk Analysis**

134. On the scientific basis for food law, Regulation (EC) No 178/2002 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 undertaken, in the main, by the European Food Safety Authority ("the Authority").

## **C. Prevention**

135. The following new specific provisions which improve the safety and control of the food chain entered into force on 1 January 2005.

### **1) General overview**

136. The existing legislative framework of the EC provides for:

- a general obligation for operators to take the 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 amply proved its efficiency, can be activated 24 hours a day;
- a network of technical competencies and sharing of scientific information, notably through national and Community reference laboratories and through Scientific Committees.

137. 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, accreditation in line with 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. 17 CRLs exist at present in the field of food and feed and 13 in the field of animal health i.e. for residue testing (four laboratories), milk testing, biotoxins in molluscs and testing molluscan shellfish for harmful viruses and for the control of zoonoses (salmonella).<sup>74</sup>

## 2) Risk management

138. Regulation (EC) No 178/2002 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 in order to ensure the high level of health protection determined as appropriate in the European Community.
139. 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.

## 3) Traceability

140. 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 products implicated. Regulation (EC) No 178/2002 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 least able to identify the step in the food supply immediately 'above' them and the step immediately 'below', unless specific provisions exist for further traceability.

## 4) Responsibilities

141. Regulation (EC) No 178/2002 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.

---

<sup>74</sup> Commission Regulation (EC) No 776/2006 of 23 May 2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and the Council as regards Community reference laboratories, OJ L 136, 24.5.2006, p. 3.

## 5) Food safety requirements

142. Regulation (EC) No 178/2002 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 Regulation also makes it obligatory for food businesses to withdraw unsafe foods from the market, and provide accurate information for 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.

## 6) Food and feed hygiene

143. The aim of the hygiene package of 2004 is to provide unified and consolidated Community legislation regarding the rules for both 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 through the introduction of the Hazard Analysis and Critical Control Point (HACCP) system.

144. Regarding food hygiene, EP and Council adopted:

- Regulation (EC) No 852/2004 of 29 April 2004 on the hygiene of foodstuffs; <sup>75</sup>
- Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin; <sup>76</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>77</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>78</sup>;

145. Regarding feed hygiene, Council Regulation (EC) No 183/2005 of 8 February 2005 laying down requirements for feed hygiene <sup>79</sup> covers:

- the activities of feed business operators at all stages, from primary production up to placing on the market;
- the feeding of food producing animals;
- imports and exports of feed to and from third countries.

---

<sup>75</sup> OJ L 139, 30.4.2004, p. 1.

<sup>76</sup> OJ L 139, 30.4.2004, p. 55.

<sup>77</sup> OJ L 139, 30.4.2004, p. 206.

<sup>78</sup> OJ L 165, 30.4.2004, p. 1, replaced by corrigendum in OJ L 191, 28.5.2004, p. 1.

<sup>79</sup> 3677/04.

The Regulation is aimed at increasing responsibility for feed business operators responsibility ensure that controls are carried out in accordance with Community legislation and for farmers to take measures in order to keep the risk of contamination of feed and animals at a low level. Moreover it sets up requirements on registration, transport, storage, handling and delivery of primary products. The Regulation seeks also to ensure that imported feed attains an equivalent standard to feed produced in the Community.

#### **D. Monitoring**

146. The Rapid Alert System for Food and Feed (RASFF), which is also based upon the Food Law Regulation No. 178/2002/EC, is a network for notification of a direct or indirect risk to human health deriving from food or feed and was established in 2002.

The 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.

147. 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.
148. The RASFF 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).
149. On 29 April 2004 the European Parliament and the Council adopted Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules<sup>80</sup>, which brought together in a single Community framework all the food safety control rules that had been applied before, in particular by grouping together all the existing veterinary, animal feed and foodstuffs legislation. Article 13 of this Regulation reinstates the requirement for contingency plans.

---

<sup>80</sup> OJ L 191, 28.5.2004, p. 1.

## **E. Consequence management**

150. On procedures for managing emergencies and crises in the field of the safety of feed and food, the tools laid down in Regulation (EC) No 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 (EC) No 178/2002 also provides for adopting emergency procedures very quickly, when necessary, through the committee procedure.
151. Emergency measures could be adopted for each stage of the food chain. A general plan for food/feed crisis management was adopted by the Commission on 29 April 2004.<sup>81</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.

## **F. International relations**

152. Regulation (EC) No 178/2002 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<sup>82</sup> and *Office International des Epizooties (International Office of Epizootics) (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 such as *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 on the food chain.

---

<sup>81</sup> Commission Decision 2004/478/EC

<sup>82</sup> The Community has been a member of the Codex Alimentarius Commission since 2003 (13089/03 + 13073/03 ADD 1 + ADD 2). The object of the Codex Alimentarius Commission is inter alia to develop and harmonise world-wide health standards and to issue guidelines and recommendations on agricultural and fishery products, foodstuffs, food additives and contaminants, feedstuffs, veterinary drugs, pesticides, including labelling, methods of analysis and sampling, codes of ethics and good agricultural practice and guidelines of hygiene practice, with a view to protecting consumer health and ensuring fair practices in international trade.

## **G. Coordination and implementation**

153. 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. (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).

In general, the various means that have been established in order to guarantee safety throughout the whole food chain have functioned and are functioning well. Their ability to respond to crises has been tested on 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 the utmost importance in order to address societal concerns.

## **V. ANIMAL HEALTH PROTECTION**

(including pharmaceuticals for use on animals)

### **A. General information**

154. Numerous regulatory measures have been adopted at European Union level to keep animal diseases at bay and to combat any outbreaks that do occur, including a Community notification system and vaccine banks. 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 in accordance with the committee 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.
155. Decisions are taken collegially and as swiftly as necessary, through the Standing Committee on the Food Chain and Animal Health (SCOFCAH), under the responsibility of the Commission.

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

156. In this favourable context which made it possible to solve the latest animal health crises, and in order to place prevention at the top of the agenda, the Commission prepared a new Animal Health Strategy for the European Union (2007-2013)<sup>83</sup>, 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, in relation to 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 the EU.

---

<sup>83</sup> 13292/07.

157. In its conclusions of 17-19 December 2007, the Council accordingly invited the Commission to present an action plan as envisaged in the Strategy, to propose a legal framework for the Animal Health Law and to propose the definition of priorities for more effective use of resources.<sup>84</sup>

## **B. Prevention**

### **1) Internal market**

158. The harmonised rules regarding intra-Community trade and placing on the market of live animals<sup>85</sup> and animal products have been amended several times following certain animal health crises and will now be reorganised in more comprehensive and global legislation, still including emergency policies.

### **2) International trade**

159. Rules have been defined for practically 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 diseases are adopted by the Commission as protection against health crises. These rules follow the international standards, guidelines and recommendations of the OIE, which plays a crucial role and is of crucial importance in the safeguarding of international trade in animal and animal products and in the prevention and control of the spread of transboundary animal diseases.

### **3) Import controls**

160. Product and animal imports are subject to strict controls.<sup>86</sup> 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 response in the case of a crisis.

---

<sup>84</sup> 15481/07 + ADD 1 or 16373/01/07.

<sup>85</sup> [http://ec.europa.eu/food/animal/liveanimals/index\\_en.htm](http://ec.europa.eu/food/animal/liveanimals/index_en.htm)

<sup>86</sup> Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24 , 30.01.1998, p. 9)

## C. Monitoring

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

161. Specific measures have been laid down in EU legislation<sup>87</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 to 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.
162. Member States are required 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 overall surveillance of EU territory. Each Member State should have 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. This role should be stressed as it is central to the detection of outbreaks of diseases, whether inside or outside the EU, including exotic diseases or diseases that have supposedly been eradicated (e.g. Rinderpest), as is the case in human health for smallpox.
163. The competent authority of a Member State concerned by an outbreak of one of the 25 listed contagious animal diseases is required to notify the Commission and the other Member States within 24 hours, notably through the Animal Disease Notification System (ADNS), under the responsibility of the Commission.<sup>88</sup>

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

164. The purpose of the investigation is both to identify the source of an outbreak of disease (trace upwards) and to determine whether and where the disease has spread from the primary source of the outbreak (trace downwards). This requires a high level of traceability, and would be of the utmost importance in the case of a bioterrorist emergency.

The EU traceability framework<sup>89</sup> consists of two basic elements:

- Animal identification and registration systems<sup>90</sup> ensure the traceability of animal movements primarily at national level and

---

<sup>87</sup> [http://ec.europa.eu/food/animal/diseases/controlmeasures/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/controlmeasures/index_en.htm)

<sup>88</sup> See Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58). Directive last amended by Commission Directive 2004/21/EC of 1 March 2004 (OJ L 67, 5.3.2004, p. 27).

<sup>89</sup> Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC, OJ L 5, 9.1.2004, p. 8.

<sup>90</sup> [http://ec.europa.eu/food/animal/identification/index\\_en.htm](http://ec.europa.eu/food/animal/identification/index_en.htm)

- TRACES (Community Trade Control and Expert System)<sup>91</sup> in particular ensures the control of the movement of animals and their products particularly with a view to intra-Community trade, import or transit. It also allows for rapid reaction in alert cases.

### 3) **Monitoring of zoonoses and zoonotic agents**

165. Zoonoses, i.e. diseases and infections transmissible directly or indirectly between animals and humans, are a matter of increasing concern. Directive 2003/99/EC<sup>92</sup> aims to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources.

#### **D. Preparedness**

166. 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 this stockpiling are borne by the Community through a dedicated budget.
167. Article 8 of Directive 2001/82/EC on a Community Code relating to veterinary medicinal products<sup>93</sup> authorises Member States to allow the distribution of unauthorised medicinal products, on a temporary basis, in response to an attack involving the spread of pathogenic agents, toxins, chemical agents or nuclear radiation. This provision is similar to Article 4 of *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, referred to in the previous chapter on pharmaceuticals for human use.

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

168. In the interests of a rapid and coordinated response, Member States are required to draw up contingency plans for all notifiable diseases.
169. The rules provide in certain cases for the establishment of control or crisis centres with associated experts to coordinate the fight, in conjunction with the Commission. Several cases of crisis management of Foot and Mouth Disease (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.

---

<sup>91</sup> [http://ec.europa.eu/food/animal/diseases/animo/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/animo/index_en.htm)

<sup>92</sup> Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

<sup>93</sup> Directive 2001/82/EC of the EP and of the Council of 6 November 2001 on a Community Code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1, amended by Directive 2004/28/EC of 31 March 2004 (OJ L 136, 30.4.2004, p. 58).



## **F. International relations**

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

170. All 172 Member Countries of the Office International des Epizoöties (OIE) (including every EU Member State) are obliged to report any suspicion of a highly contagious animal 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. Monitoring this information is of the utmost importance in emergency preparedness.

### **2) Community action within OIE**

171. The increasing importance of the OIE in international activity relating 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 does the Community coordinate its comments on the draft standards and guidelines in depth, with a view to having them harmonised as much as possible with EU Legislation, but its experts participate in 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 for exchange of experience with third countries, especially in terms of bio-preparedness.

## **VI. PLANT PROTECTION AND PLANT HEALTH**

172. The use of plant protection products (including pesticides) on crops is part of food chain management. The Rapid Alert System for Foodstuffs covers pesticide residues on food and feed.

### **A. Prevention**

173. For pesticide residues, Regulation (EC) No 396/2005 of the European Parliament and the Council of 23 February 2005 on *maximum residue levels of pesticides in or on food and feed of plant and animal origin* and amending Council Directive 91/414/EEC<sup>94</sup> fixes maximum limits for Pesticide Residues and provides for the monitoring of Pesticide Residues in or on feed and food on the market. Member States are obliged to meet a minimum sampling requirement. The Commission coordinates part of the activities of the Member States by making an annual Monitoring Recommendation which covers the major pesticide crop combinations over a period of 3 years. The Commission regularly organises proficiency tests in order to achieve uniform quality of analytical results. To that end, guidance documents are developed and published on the website. The Food and Veterinary Office of the EU (FVO) monitors the activities of the Member States through regular missions and thus discusses the individual results and policies.

---

<sup>94</sup> OJ L 70, 16.3.2005, p. 1.

174. Council Directive 91/414/EEC of 15 July 1997 concerning the placing of plant protection products on the market <sup>95</sup> provides for control measures to prevent the use of unauthorised plant protection products. It also prevents plant protection products with risks for human and animal health and the environment from being marketed, e.g. high risk chemicals.
175. 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*<sup>96</sup> and related regulations.
176. 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.
177. Inspections for the presence of harmful organisms are conducted as random checks in the field and as stratified inspections in nurseries as well as at the outer borders of EU. Nurseries are responsible for notifying the local Authority if regulated harmful organisms are found.

Plants intended for planting and specified plant products from third countries must be inspected in the third country of 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. Monitoring**

178. In the framework of the EU, harmful organisms are a major issue and a notification system is in force. Each country also implements surveillance systems for pests and diseases that represent a particular phytosanitary threat to crops in their territory.
179. 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).
180. A notification scheme, EUROPHYT, operates within the Community on the basis of faxes and e-mails; in each country, the Authorities send and receive 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.
181. *Regulation (EC) No 396/2005* fixes maximum limits for Pesticide Residues and provides for the monitoring of Pesticide Residues of feed and food on the market. Violations of Maximum Residue Levels (MRLs) are reported in the framework of the 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.

---

<sup>95</sup> OJ L 230, 19.8.1991, p. 1.

<sup>96</sup> OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission **Directive 2007/41/EC of 28 June 2007, OJ L 169, 29.6.2007, p. 51.**

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

### **C. Consequence management**

182. There is also a system for temporary safeguard measures in the case of an imminent danger of the introduction or spread of harmful organisms.
183. Under the EUROPHYT notification scheme, 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.

### **D. International cooperation**

184. 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 signed at Rome on 6 December 1951 under the aegis of FAO, e.g. the international standard for pest risk analysis (PRA)*.

## **VII. GENETICALLY MODIFIED ORGANISMS (GMOs) AND BIOLOGICAL AGENTS**

### **A. Prevention**

185. Directive 2001/18/EC of the European Parliament and of the Council on the *deliberate release into the environment of genetically modified organisms* and repealing Council Directive 90/220/EEC <sup>97</sup>:

Under this Directive, Member States, in accordance with the precautionary principle, shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.

Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

On its own initiative or at the request of a Member State, the Commission shall consult the relevant Scientific Committee(s) on any matter under this Directive that may have an adverse effect on human health and the environment."

---

<sup>97</sup> OJ L 106, 17.4.2001, p. 1.

186. Under Council Directive 90/219/EEC of 23 April 1990 on the *contained use of genetically modified micro-organisms*<sup>98</sup>, any activity in which micro-organisms are genetically modified or in which genetically modified micro-organisms (GMMs) are cultured, stored, transported, destroyed, disposed of or used in any other way, should limit their contact with, and provide a high level of safety for, the general population and the environment; To this end, the user **shall** carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may pose. The user must apply general principles and the appropriate containment and other protective measures so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level corresponding to the class of the contained use so that a high level of safety is ensured. An emergency plan must be drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment. In the event of an accident, the user is required to inform the competent authority immediately.

Directive 90/219/EEC has been amended several times and is currently being revised under the "recast procedure".<sup>99</sup>

187. **Under Directive 2000/54/EC on the protection of workers from biological risks**<sup>100</sup>, any activity in which biological agents are cultured, stored, transported, destroyed, disposed of or of use in any other way, should limit the exposure and provide a high level of safety for the employees, the general population and the environment (unintended release). To this end, the employer must carry out a risk assessment and establish feasible precautionary measures. The impact on human health and on the environment of the measures used should be checked. For his part, the user must apply certain general principles and the appropriate containment measures (containment level 1 - 4) or comparable measures and other protective measures so as to keep work-place and environmental exposure at any adequate level according to the class of containment (BSL 1 - 4).

188. On 15 July 2003, the European Parliament and the Council adopted *Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms*.<sup>101</sup> Under its Article 14, Member States must 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.

---

<sup>98</sup> OJ L 117, 8.5.1990, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>99</sup> Proposal for a Directive of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (Recast), 15782/07 COM(2007) 736 final.

<sup>100</sup> **Directive 2000/54/EC of the European Parliament and the Council, of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (OJ L 262, 17.10.2000, p. 21).**

<sup>101</sup> OJ L 287, 5.11.2003, p. 1.

189. Regulation (EC) No 1830/2003 *on the traceability and labelling of GMOs*<sup>102</sup> requires the operators placing GMOs on the market or receiving a GMO to ensure the traceability of those GMOs.
190. Regulation (EC) No 1829/2003 of the EP and of the Council, of 22 September 2003 *on genetically modified food and feed*<sup>103</sup> requires genetically modified food and feed to be authorised by the Commission under the Committee procedure, and following an opinion by the European Food Safety Authority. In addition, the words "genetically modified" must appear in the labelling of the product.
191. For the purpose of traceability, each GMO authorised for placing on the market must be given a unique identifier number, as laid down in Commission Regulation (EC) No 65/2004.<sup>104</sup>

## **B. International relations**

192. The abovementioned Regulation (EC) No 1946/2003 implements the Cartagena Protocol of 29 January 2000 on *Biosafety*, which was concluded by the Community under Decision 2002/628/EC<sup>105</sup>. This Protocol is based on the precautionary principle and applies to all Living Modified Organisms (LMOs) resulting from modern technology that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account risks to human health. It excludes however pharmaceuticals for humans that are addressed by other international agreements or organisations.

The "Advance Informed Agreement" (AIA) procedure ensures that the Party of import is notified and can take a decision or give its consent before the first movement actually takes place. This procedure applies to LMOs intended for direct introduction into the environment (e.g. seeds and plants). As regards LMOs which are not intended for direct introduction into the environment but intended for food, feed or for processing (so-called LMO commodities), the exporting countries will in advance share information on domestic approvals with potential importing countries via a Biosafety Clearing House.

In the case of unintentional transboundary movements likely to have significant adverse effects, each party must take appropriate measures to notify affected or potentially affected States, to enable them to determine appropriate responses and initiate necessary action, including emergency measures in order to minimise any significant adverse effects, the Biosafety Clearing-House and, where appropriate, relevant international organisations, and consult with the affected or potentially affected countries.

Each Member State shall establish a national contact point for notification of unintentional transboundary movements and shall inform the BCH and the Commission about its contact details.

---

<sup>102</sup> Regulation (EC) No 1830/2003 of the EP and of the Council, of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268, 18.10.2003, p. 24.

<sup>103</sup> OJ L 268, 18.10.2003, p. 1.

<sup>104</sup> Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, OJ L 10, 16.1.2004, p. 5.

<sup>105</sup> Council Decision 2002/628/EC of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety, OJ L 201, 31.7.2002, p. 48.

## VIII. ENVIRONMENT – WATER AND AIR

### A. General principles

193. Environmental policy may contribute effectively to the protection of the environment and of human health against **disasters of natural or human origin, including** acts of biological and chemical terrorism.

### B. Risk analysis

194. On 14 March 2007, the EP and the Council adopted a Directive establishing *an infrastructure of spatial information in the European Community (INSPIRE)*<sup>106</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. INSPIRE specifically focuses on information needed in order to monitor and improve the state of the environment, in particular regarding air, water, soil and the natural landscape, but it is also open for use by other sectors such as civil protection, agriculture, transport and energy.

### C. Prevention

195. The Commission's proposal of 12 February 2007 for a Directive of the EP and of the Council *on the protection of the environment through criminal law*<sup>107</sup> aims at establishing a minimum set of serious environmental offences that should be considered criminal throughout the Community when committed intentionally or at least with serious negligence. An annex is envisaged mentioning certain instruments referred to in this Inventory such as those on GMOs, the Seveso Directive and the protection of groundwater.

### D. Monitoring

196. *Directive 75/440/EC concerning the quality required of surface water intended for the abstraction of drinking water*<sup>108</sup>, *Directive 98/83/EC on the quality of water intended for human consumption*<sup>109</sup> and *Directive 2000/60/EC*<sup>110</sup> provide for constant monitoring of drinking water as well as for strict minimum requirements for its quality.

---

<sup>106</sup> Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE), OJ L 108, 25.4.2007, p. 1).

<sup>107</sup> 6297/07, COM (2007) 51 final. The proposal aims at replacing Council Framework Decision 2003/80/JHA of 27.1.2003 (OJ L 29, 5.2.2003, p. 55) which was quashed by the Court of Justice. See Council draft in 6749/08.

<sup>108</sup> Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States, OJ L 194, 25.7.1975, p. 26.

<sup>109</sup> Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, OJ L 330, 5.12.1998, p. 32.

<sup>110</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. (OJ L 327, 22.12.2000, p. 1).

197. Other instruments provide for the monitoring of the air as well as for alerts when a specified threshold is exceeded:

- a) Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management, OJ L 296, 21.11.1996, p. 55 ("air quality framework directive").
- b) Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air, OJ L 163, 29.6.1999, p. 41 ("first daughter directive").
- c) Directive 2002/3/EC of the EP and of the Council of 12 February 2002 relating to ozone in ambient air, OJ L 67, 9.3.2002, p. 14.

The legislative acts in a, b and c will be repealed within 2 years by the Directive 2008/.../EC of the European Parliament and of the Council of 14 April 2008 on ambient air quality and cleaner air for Europe (PE-CONS 3696/1/07, 7690/1/08))

- d) Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, OJ L 23/3, 26.1.2005 ("Fourth Daughter Directive")
- e) Directive 2001/81/EC of the EP and the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants, OJ L 309, 27.11.2001, p. 22.

## **E. Response**

198. Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC<sup>111</sup> provides, in its Article 7, paragraph 4, that, without prejudice to any specific obligation laid down by Community legislation, Member States shall take the necessary measures to ensure that, in the event of an imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information held by or for public authorities which could enable the public likely to be affected to take measures to prevent or mitigate harm arising from the threat is disseminated, immediately and without delay.<sup>112</sup>

## **IX. PROTECTION AGAINST CHEMICALS AND DANGEROUS SUBSTANCES** (Seveso industries, circulation of dangerous substances, transport of dangerous goods)

### **A. Analysis of vulnerabilities**

199. 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 to make operators more aware of the potential weaknesses of their safety and security systems.

---

<sup>111</sup> OJ L 41 , 14/02/2003, p. 26.

<sup>112</sup> This provision implements Article 5 of the Aarhus Convention on access to information, public participation in decision making process and access to justice regarding environmental matters and Amendment to Aarhus Convention (ratified by European Community in 2005 year).

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. Owing to the sensitivity of its content, access to the final report has been restricted.

The Commission has also undertaken a study on the issue of the security of supply of various strategic products. This document consists of an inventory describing in detail the current situation as regards inter alia security of supply at European Union level in the health sector, the energy and transport sector, as well as civil protection and communication.

## **B. Prevention, consequence management and international relations**

### **1) The "Seveso Directive" and the Convention on Industrial Accidents**

200. Council Directive 96/82/EC of 9 December 1996 on *the control of major-accident hazards involving dangerous substances*<sup>113</sup>, as amended by Council Directive 2003/105/EC of 12 December 2003<sup>114</sup> ("Seveso II Directive"), requires operators of establishments that have dangerous substances present above certain thresholds to take all measures to prevent major accidents and to limit their consequences for man and the environment. The Directive provides in particular for the following:

- All operators of establishments falling under the scope of the directive have the obligation to notify the competent authorities, to establish a major-accident prevention policy, and to inform the competent authorities of the safety plans and any major accident that may have occurred. In addition, operators of upper-tier establishment need to draw up a safety report and a safety management system and an internal emergency plan. In identifying and evaluating major accident risks and prevention methods the operator is required to assess major accident scenarios including causes that may be internal or external to the installation.
- The competent authorities must prohibit any installation where the prevention and mitigation measures are seriously deficient, draw up external safety emergency plans, take into account accident prevention and consequence limitation in their land-use planning (including appropriate distances between the establishments covered by the Directive and other areas) provide information on safety measures and on the requisite behaviour in the event of an accident to all persons and all establishments serving the public liable to be affected by a major accident originating in a "Seveso" establishment, and inform the Commission of any accidents that may have occurred.
- The Commission will organise the exchange of information among Member States on major accidents that have occurred.

201. There is general agreement that the requirements of this amended Directive, such as risk analysis/risk scenarios, risk management, including the protection of access to chemical sites and external emergency planning, are broadly appropriate should a Seveso site become a target for a terrorist attack.

---

<sup>113</sup> OJ L 10, 14.1.1997, p. 13.

<sup>114</sup> OJ L 345, 31.12.2003, p. 97.



However, the Directive basically addresses the safety of installations rather than their "security". The Directive does not require security analyses, nor does it impose additional security measures for installations that are either particularly vulnerable to terrorist attacks or that are potential targets of attacks. It should, nevertheless, be noted that the requirements related to the mitigation of the consequences of accidents, and in particular the formulation in advance of emergency plans, will help with the consequences of a terrorist attack targeting a Seveso installation.

202. The Community is a party to the UN/ECE Convention on the *transboundary effects of industrial accidents*<sup>115</sup>. This Convention applies to the prevention of, preparedness for, and response to industrial accidents at sites where hazardous activities take place that are capable of causing transboundary effects. EU Directive 96/82/EC, as amended by Directive 2003/105/EC, is considered to be the legal and technical instrument fulfilling the Community's obligations under the Convention.

## 2) Protection of workers handling chemical agents

203. **Council Directive 98/24/EC on the protection of workers against chemical risks<sup>116</sup> lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.**

## 3) Circulation, registration, authorisation, classification, marketing, packaging and labelling of dangerous substances and chemicals

204. The 2006 Regulation concerning *the registration, evaluation, authorisation and restriction of chemicals (REACH)*<sup>117</sup> aims at avoiding chemical contamination of air, water, soil and the human environment in order to preserve biodiversity and to safeguard workers' and citizens' health and safety. It seeks to balance health and environmental benefits with the need to sustain a competitive, innovative and job-creating European industry and the proper functioning of the internal market. REACH applies to all substances manufactured or imported in quantities over 1 tonne per year. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

---

<sup>115</sup> Council Decision of 23 March 1998 concerning the conclusion of the Convention on the Transboundary Effects of Industrial Accidents (98/685/EC), OJ L 326, 3.12.1998, p. 1.

<sup>116</sup> **Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).**

<sup>117</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 136, 29.5.2007, p. 1.

Substances on their own, in preparations or in articles must not be manufactured in the Community or placed on the market unless they have been registered with the European Chemicals Agency of Helsinki where this is required. A chemical safety assessment must be performed and a chemical safety report completed for all substances subject to registration in accordance with Chapter 1 of the Regulation in quantities of 10 tonnes or more per year per registrant. The Agency will assign a submission number to each registration, The supplier of a substance or a preparation must provide the recipient of the substance or preparation with a safety data sheet. For substances for which a safety data sheet is not required any other available and relevant information should be provided about the substance that is necessary to enable appropriate risk management measures to be identified and applied. A manufacturer, importer or downstream user may not place a substance on the market for a use or use it himself if that substance is included in a list of carcinogenic, mutagenic, toxic, and very persistent and very bioaccumulative substances, unless he has been duly authorised or exempted by the Commission.

205. Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to *restrictions on marketing and use of certain dangerous substances and preparations*<sup>118</sup> establishes a framework for harmonised rules throughout the European Union concerning the placing on the market and use of dangerous substances and preparations. Directive 76/769/EEC is used to manage the risks to human health and the environment from dangerous substances. Dangerous substances and preparations listed in Annex I to Directive 76/769/EEC may only be placed on the market and used under specified conditions.

The EP and the Council are currently examining an amendment to the Directive aimed at restricting the marketing of ammonium nitrate, which can be used in explosives.<sup>119</sup>

206. Other relevant instruments are:

- Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to *the classification, packaging and labelling of dangerous substances*<sup>120</sup>,
- Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to *the classification, packaging and labelling of dangerous preparations*<sup>121</sup>.

---

<sup>118</sup> OJ L 262, 27.9.1976 p. 201. Directive as last amended by Commission Decision 2006/139/EC (OJ L 384, 29.12.2006, p. 94)

<sup>119</sup> 13530/07 (COM (2007) 559 final).

<sup>120</sup> OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36), as last amended by D 2006/121/EC of 18.12.2006 in order to be adapted to Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006).

<sup>121</sup> OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5), as last amended by Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006).

The Council and the EP are currently examining a Commission proposal aimed at replacing Directive 67/548/EEC as of 2010 and Directive 1999/45/EC as of 2015.<sup>122</sup>

#### 4) Export and import of dangerous chemicals and the Rotterdam Convention

207. Regulation (EC) No 304/2003 of the EP and of the Council of 28 January 2003 concerning the *export and import of dangerous chemicals*<sup>123</sup> make dangerous chemicals exported from, or imported into, the EU subject to notifications by the exporter or importer to the designated authorities of the Member States who will then inform the Commission or third country concerned.

These may then take an import decision, or export decision, concerning the chemical concerned. This Regulation enabled the Community to become a Party to the *Rotterdam Convention on certain hazardous chemicals in international trade*.<sup>124</sup>

208. The Court of Justice quashed Regulation (EC) No 304/2003 for formal reasons while maintaining its effects until the adoption of a new regulation founded on appropriate legal bases. Parliament and Council reached agreement on a Commission proposal which has basically the same contents as the Regulation annulled, which was should be finally adopted by the Council on 5 June 2008.<sup>125</sup>

#### 5) Transport of dangerous goods

209. On 7 April 2008 the Council adopted its common position with a view to the adoption of a Directive of the European Parliament and of the Council on the *inland transport of dangerous goods*<sup>126</sup>. The Directive updates the existing four Council (and EP) Directives and four Commission Decisions on the transport of dangerous goods, integrating them into a single piece of legislation and extending the scope of the EU rules to cover not only road and rail transport but also inland waterway transport.<sup>127</sup>

---

<sup>122</sup> Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, 11497/07, COM 2007 (355)

<sup>123</sup> OJ L 63, 6.3.2003, p. 1.

<sup>124</sup> Council Decision 2003/106/EC of 19 December 2002 concerning the approval, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade, OJ L 63, 6.3.2003, p. 27.

<sup>125</sup> PE-CONS 3604/08.

<sup>126</sup> 6920/3/08 REV 3+ ADD 1, OJ C 117E, 14.5.2008, p. 1.

<sup>127</sup> The substituted Directives are the following :

- Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2006/89/EC (OJ L 305, 4.11.2006, p. 4).
- Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail<sup>2</sup> OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2006/90/EC (OJ L 305, 4.11.2006, p. 6).

The proposal also brings the existing rules for international transport into Community law and extends the application of international rules to national transport.

The draft Directive provides that the transport of dangerous goods between Member States and third countries will be authorised, unless otherwise indicated, insofar as it complies with the requirements of

- the European Agreement concerning the International Carriage of Dangerous Goods by Road, concluded at Geneva on 30 September 1957, as amended (ADR),
- the Regulations concerning the International Carriage of Dangerous Goods by Rail, appearing as Appendix C to the Convention concerning International Carriage by Rail (COTIF) concluded at Vilnius on 3 June 1999, as amended (RID), and
- the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways, concluded at Geneva on 26 May 2000, as amended (ADN).

The ADR, RID and ADN lay down uniform rules for the safe international transport of dangerous goods. Such rules are also extended to national transport in order to harmonise across the Community the conditions under which dangerous goods are transported and to ensure the proper functioning of the common transport market.

210. In addition, a great many measures have been adopted in order to enhance the safety or security of transport operations in general, the main ones being:

- Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC, OJ L 208, 5.8.2002, p. 10,
- Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security, OJ L 129, 29.4.2004, p. 6.
- Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security, 3629/3/05,
- Regulation (EC) No 300/2008 of the EP and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002, OJ L 97, 9.4.2008, p. 72.<sup>128</sup>

- 
- Council Directive 96/35/EC of 3 June 1996 on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway, OJ L 145, 19.6.1996, p. 10.
  - Directive 2000/18/EC of the European Parliament and of the Council of 17 April 2000 on minimum examination requirements for safety advisers for the transport of dangerous goods by road, rail or inland waterway, OJ L 118, 19.5.2000, p. 41.  
As a consequence the following Decisions will lapse as well :
  - Commission Decision 2005/263/EC of 4 March 2005 authorising Member States to adopt certain derogations pursuant to Directive 94/55/EC with regard to the transport of dangerous goods by road, OJ L 85, 2.4.2005, p. 58. Decision as last amended by Decision 2007/447/EC (OJ L 169, 29.6.2007, p. 64).
  - Commission Decision 2005/180/EC of 4 March 2005 authorising Member States to adopt certain derogations pursuant to Council Directive 96/49/EC with regard to the transport of dangerous goods by rail. OJ L 61, 8.3.2005, p. 41. Decision as amended by Decision 2005/777/EC (OJ L 293, 9.11.2005, p. 23).

<sup>128</sup> This Regulation replaces Regulation (EC) No 2320/2002 of the European Parliament and of the Council of 16 December 2002 establishing common rules in the field of civil aviation security (OJ L 355, 30.12.2002, p. 1. Regulation as amended by Regulation (EC)

## **X. RADIOLOGICAL AND NUCLEAR PROTECTION**

### **A. General information**

211. The responsibility for protecting the population, property and the environment against threats affecting nuclear facilities or materials lies primarily with Member States, subject to existing Community competencies. This includes the measures aimed at preparing for protection against such threats, reducing their consequences and facilitating the return to normal conditions. Measures to prepare for and reduce the consequences of such threats must be based on the procedures that exist in each Member State for dealing with the various types of radiological or nuclear emergency.
212. Several initiatives and measures were taken to reduce the vulnerability of nuclear industries to terrorist attacks and ensure greater security in the use of nuclear materials and radioactive sources.

### **B. Prevention**

213. In addition to measures already taken at national level, Community instruments relating to threats affecting the security of nuclear facilities and the use and transport of radioactive waste and substances and to their consequences for the population, are already in place.
214. The measures below were primarily intended to address safety and non-proliferation issues by ensuring that practices using radioactive materials are subject to reporting to national authorities or authorisation by national authorities, that nuclear and radioactive materials are properly accounted for and controlled and that competent authorities are made aware of relevant transfers. Ensuring that nuclear and radioactive materials do not bypass proper regulatory control also ensures that they are not available to those with malicious intentions.

#### **1) Basic Safety Standards for workers and the general public**

215. Council Directive 96/29/Euratom of 13 May 1996 laying down *basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation* and repealing and replacing Council Directive 80/836/Euratom of 15 July 1980<sup>129</sup> and Council Directive 84/467/Euratom of 3 September 1984<sup>130</sup> (OJ L 159, 29 June 1996, p. 1).

Communication 98/C133/03 from the Commission concerning the implementation of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ C 133, 30.4.1998 p. 3).

216. Council Directive 90/641/Euratom of 4 December 1990 on *the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas* (OJ L 349, 13.12.1990 p. 21).

---

No 849/2004 (OJ L 158, 30.4.2004, p. 1).

<sup>129</sup> OJ L 246, 17.9.1980, p. 1.

<sup>130</sup> OJ L 265, 5.10.1984 p. 4.

## 2) Control of radioactive sources

217. Council Directive 2003/122/Euratom of 22 December 2003 on *the control of high-activity sealed radioactive sources and orphan sources* (OJ L 346, 31.12.2003, p. 57) aims at harmonizing controls by defining specific requirements ensuring that each source is kept under control and should significantly improve the traceability of nuclear materials in the EU. This Directive is intended to contribute to higher security for European citizens against the risks associated with the handling and storage of highly radioactive sources and to help prevent illicit trafficking of radioactive sources. Enhanced traceability of sources will reduce the risk of radioactive sources being misused, e.g. for criminal purposes, and will prevent sources from bypassing regulatory control.

## 3) Nuclear Safeguards

218. On the basis of a Council Decision of 29 April 2004 enabling the Commission to adopt a Regulation on the *application of EURATOM safeguards* (7768/3/04 REV 3), the Commission adopted its Regulation (Euratom) No 302/2005 of 8 February 2005 on the application of Euratom safeguards (OJ L 54, 28.2.2005, p. 1). The Directive provides inter alia for prompt notification to competent authorities in the case of theft, loss or unauthorised use of such sources.

Commission Recommendation of 15 December 2005 on guidelines for the application of Regulation (Euratom) No 302/2005 on the application of Euratom safeguards (OJ L 28, 1.2.2006, p. 1)

219. Building on the European Council Conclusions of 9 March 2007<sup>131</sup> and in particular on paragraph 11 of the European Council Action Plan on an Energy Policy for Europe (2007-2009) attached to those conclusions, the Commission established a High Level Group on Nuclear Safety and Waste Management (See Commission Decision of 17 July 2007 establishing the European High Level Group on Nuclear Safety and Waste Management (OJ L 195, 27.7.2007, p. 44).

On the basis of two revised Commission proposals for Council Directives laying down basic obligations and general principles on the *safety of nuclear facilities* and the *safe management of spent fuel and radioactive waste*, submitted to the Council in September 2004<sup>132</sup>, the Council set out an "Action Plan on Nuclear Safety and the Safe Management of Spent Fuel and Radioactive Waste" in its Conclusions of 28 June 2004<sup>133</sup> and June 2007<sup>134</sup>.

The Council Working Party on Nuclear Safety prepared a report<sup>135</sup>. The main outcome of the report is to suggest the creation of an EU expert group on nuclear safety, a proposal taken up by the Nuclear Illustrative Programme and by the Council Presidency.

---

<sup>131</sup> 7224/1/07.

<sup>132</sup> 12368/04, COM(2004) 526 of 8.9.2004.

<sup>133</sup> 10823/04.

<sup>134</sup> 8784/07.

<sup>135</sup> CS/2006/16737-1 of 15.12.2006

#### 4) Shipments of radioactive waste and substances

220. Council Directive 2006/117/Euratom of 20 November 2006 *on the supervision and control of shipments of radioactive waste and spent fuel* (OJ L 337, 5.12.2006, p. 21) [establishes a strict authorisation regime and, in certain cases, prohibition regime for transboundary shipments inside the EU or between the EU and third countries].

This Directive will replace, with effect from 25 December 2008, Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community, (OJ L 35, 12.2.1992, p. 24).

This Directive was implemented by:

- Commission Decision 93/552/Euratom of 1 October 1993 establishing the standard document for the supervision and control of shipments of radioactive waste referred to in Council Directive 92/3/Euratom (OJ L 268, 29.10.1993, p. 83);
- Commission Communication No. 94/C224/02 concerning Council Directive 92/3/Euratom (OJ C 224, 12.8.1994, p. 2);
- Commission Decision of 1 October 1993 establishing the standard document for the supervision and control of shipments of radioactive waste referred to in Council Directive 92/3/Euratom (OJ L 268, 29.10.1993, p. 83).

221. Council Regulation (Euratom) No 1493/93 of 8 June 1993 on *shipments of radioactive substances between Member States* (OJ L 148, 19.6.1993, p. 1);

Commission Communication No. 93/C335/02 concerning Council Regulation (Euratom) No 1493/93 (OJ C 335, 10.12.1993, p. 2);

Commission Communication 2002/C40/04 concerning Council Regulation (Euratom) No 1493/93 on shipments of radioactive substances between Member States (OJ C 40, 14.2.2002, p. 4);

222. Communication from the Commission of 19 April 1996 on *illicit trafficking in nuclear materials and radioactive substances*, COM(96) 171 final – not published in the OJ.

#### C. Monitoring

##### 1) **Monitoring obligations set up by the Euratom Treaty**

223. *Articles 35, 36 and 37 of the Euratom Treaty*: Chapter 3, Health and Safety, of Title II of the Euratom Treaty is concerned on the one hand with the establishment of Basic Safety Standards for the protection of the health of workers and members of the public (Articles 30 – 33) and, on the other hand, specifically with levels of radioactivity in the air, water and soil as laid down in Articles 35 – 38 (to some extent also Article 34, on "particularly dangerous experiments", i.e. weapons testing).

With regard to levels of radioactivity, in addition to the requirements of the standards, the main tasks of the Commission over five decades have concerned the application of Article 36 (collection and publication of data on levels of radioactivity to which the public is exposed as transmitted by Member States on the basis of measurement facilities established by them in accordance with Article 35, first paragraph) and Article 37 (Commission Opinions given on whether plans for the disposal of radioactive waste submitted by Member States are liable to affect other Member States).

224. Communication 2006/C/155/02 from the Commission *on Verification of environmental radioactivity monitoring facilities under the terms of Article 35 of the Euratom Treaty — Practical arrangements for the conduct of verification visits in Member States* (OJ C 155, 4.7.2006, p. 2);

Commission Recommendation 2004/2/Euratom of 18 December 2003 *on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation* (OJ L 2, 6.1.2004, p. 36);

225. Commission Recommendation 2000/473/Euratom of 8 June 2000 on the application of Article 36 of the Euratom Treaty concerning *the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole*, (OJ L 191, 27.7.2000, p. 37);
226. Commission Recommendation 99/829/Euratom of 6 December 1999 on the application of Article 37 of the Euratom Treaty (OJ L 324, 16.12.1999, p. 23).

## 2) International monitoring arrangements

227. The following *Community* managed/coordinated measures would be activated in the event of a major release of radioactivity, regardless of whether the release was accidental or intentional and malicious:

- ***ECURIE (European Community Urgent Radiological Information Exchange)***

ECURIE is a 24-hour emergency notification and information exchange system. The system notifies the competent authorities of the participating States (currently EU Member States, Croatia and Switzerland) and the Commission in the event of a major nuclear accident or a radiological emergency. Information concerns the current and foreseeable status of the accident, meteorological conditions, national countermeasures taken etc.

The legal basis for participation in ECURIE by the EU Member States is *Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency* (OJ L 191, 27.7.2000, p. 37) and the *Agreement of 29.1.2003 between Euratom and non-member States of the European Union on the participation of the latter in the Community arrangements for the early exchange of information in the event of radiological emergency (ECURIE)* (OJ C 102, 29.4.2003, p. 2).



- ***EURDEP (European Radiological Data Exchange Platform)***

EURDEP is both a standard data format and a network for the exchange of environmental radiation monitoring data between European countries in real-time.

Participation of the EU Member States is based on *Commission Recommendation 2000/473/Euratom of 8 June 2000 on the application of Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole* (OJ L 191, 27.7.2000, p. 37);

- ***ENSEMBLE***

ENSEMBLE is software that integrates the different weather forecasts (with the possibility of selecting preferred ones and also looking at specific national forecasts) and thus, with the input of radioactive release data, provides a relatively reliable prediction of the atmospheric dispersion of radioactive substances over time.

- ***IACRNA (Inter-Agency Committee on Response to Nuclear Accidents)***

The European Commission participates in the IACRNA and has concluded bilateral agreements with other international organisations on arrangements in the area of radiological emergency preparedness.

## **D. Consequence management**

### **1) Informing the public**

228. Council Directive 89/618/Euratom of 27 November 1989 *on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency* (OJ L 357, 7.12.1989 p. 31);

Commission Communication 91/C103/03 on the implementation of Council Directive 89/618/Euratom (OJ C 103, 19.4.1991, p. 12).

### **2) Control of contamination of foodstuffs and feedingstuffs**

229. Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down *maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency* (OJ L 371, 30.12.1987, p. 11), amended by Council Regulation No 2218/89/Euratom of 18 July 1989 (OJ L 211, 27.7.1989, p. 1).

Commission Regulation (Euratom) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency (OJ L 101, 13.4.1989, p. 17);

Commission Regulation (Euratom) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ L 83, 30.3.1990, p. 78);

230. Council Regulation (EEC) No 2219/89 of 18 July 1989 on the *special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency* (OJ L 211, 22.7.1989, p. 4);

### **3) Contamination of agricultural products – Post-Chernobyl**

231. Council Regulation (EEC) No 737/90 of 22 March 1990 on *the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station* (OJ L 82, 29.3.1990, p. 1), amended by Council Regulation (EC) No 616/2000 of 20 March 2000 (OJ L 75, 24.3.2000, p. 1).

Commission Regulation (EC) No 1609/2000 of 24 July 2000 establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 185, 25.7.2000, p. 27);

Commission Recommendation 2003/274/EC of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station (OJ L 99, 17.4.2003, p. 55 + Corrigendum in OJ L 109, 1.5.2003, p. 27);

Commission Regulation (EC) No 1635/2006 of 6 November 2006 laying down detailed rules for the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station (OJ L 306, 7.11.2006, p. 3);

### **E. International relations**

232. The Community is party to a number of relevant international conventions (*Convention on Nuclear Safety, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, Convention on Early Notification of a Nuclear Accident, Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency, Convention on the Physical Protection of Nuclear Material*). These conventions form part of the international regime for ensuring proper control of nuclear facilities and hazardous radioactive materials, providing mutual assistance in the event of incidents, and warning international partners of potential occurrences with nuclear or radioactive materials.
233. At the international level, the provisions of international Agreements such as *the Convention on the Physical Protection of Nuclear Material* should be implemented to the fullest extent. Member States should do their utmost to achieve early entry into force of the amended CPPNM for the Community and the Member States together.

## 1) IAEA International Conventions

234. Council Decision 80/565/Euratom of 9 June 1980 approving the conclusion by the Commission of the *International Convention on the Physical Protection of Nuclear Material* (OJ L 149, 17.6.1980, p. 41).

Council Decision 2007/513/Euratom of 10 July 2007 approving the accession of the European Atomic Energy Community to the *amended Convention on the Physical Protection of Nuclear Material and Nuclear Facilities* – Declaration by the European Atomic Energy Community according to Articles 18(4) and 17(3) of the CPPNM (OJ L 190, 21.7.2007, p. 12).

235. Council Decision 2005/84/Euratom of 24 January 2005 approving the accession of the European Atomic Energy Community to the *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management* (OJ L 30, 3.2.2005 p. 10)
236. Following the Council Decision approving the conclusion of the Convention on Early Notification of a Nuclear Accident (Council doc. 8284/05), the Commission adopted Decision 2005/844/Euratom of 25 November 2005 concerning the accession of the European Atomic Energy Community to the *Convention on Early Notification of a Nuclear Accident* (OJ L 314, 30.11.2005, p. 21)
237. Following the Council Decision approving the conclusion of the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency (Council doc. 8284/05), the Commission adopted Decision 2005/845/Euratom of 25 November 2005 concerning the accession of the European Atomic Energy Community to the *Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency* (OJ L 314, 30.11.2005, p. 27)

## 2) IAEA – EU – MS Additional Protocols to the Safeguards Agreements

238. INFCIRC/193 (additional) – Protocol Additional to the Agreement between the Republic of Austria, the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland, the Federal Republic of Germany, the Hellenic Republic, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Portuguese Republic, the Kingdom of Spain, the Kingdom of Sweden, the European Atomic Energy Community and the IAEA in implementation of Article III (1) and (4) of the Treaty on the Non-Proliferation of Nuclear Weapons.
239. INFCIRC/263 (additional) – Protocol Additional to the Agreement between the United Kingdom of Great Britain and Northern Ireland, the European Atomic Energy Community and the International Atomic Energy Agency for the application of safeguards in the United Kingdom of Great Britain and Northern Ireland in connection with the Treaty on the Non-Proliferation of Nuclear Weapons.
240. INFCIRC/290 (additional) – Protocol Additional to the Agreement between France, the European Atomic Energy Community and the International Atomic Energy Agency for the application of safeguards in France.

### 3) International cooperation agreements on peaceful uses of nuclear energy

241. The Community has signed cooperation agreements on peaceful uses of nuclear energy with a large number of third countries, including the main suppliers in this field: the United States of America, Canada, Australia, Argentina, Uzbekistan, Ukraine<sup>136</sup>, Japan<sup>137</sup> and Kazakhstan<sup>138</sup>. Preparations are being made for negotiations with Russia.
242. The Council adopted, on 21 January 2008, a Decision approving the conclusion of an agreement between the European Atomic Energy Community (EURATOM) and *China* for research and development cooperation in the peaceful uses of nuclear energy.<sup>139</sup> The Agreement was signed on 8 December 2004 (EU-China summit, The Hague), but since the signed text was not fully in line with the negotiation directives agreed by the Council<sup>140</sup>, the Commission had to return to the negotiating table.
243. It is recommended to explore the feasibility and added value of setting up a European network of experts responsible in the Member States for evaluating, managing and communicating nuclear and radiological risks. Both at the preparatory and operational stages, it must be ensured that the issue of confidentiality requirements is properly addressed and that no immediate duplication of work with other relevant international agencies takes place.

## XI. CRITICAL INFRASTRUCTURE PROTECTION

### A. General information

244. In addition to the special protection of facilities handling the specific infrastructures mentioned above (e.g. nuclear industries), it is important to provide a more general protection in favour of certain infrastructure that could be, on the passive side, the target of CBRN threats or risks or, on the active side, the originator of CBRN disasters.

---

<sup>136</sup> Council Decision of 29 September 2004 approving the conclusion by the Commission of an agreement for cooperation in the peaceful uses of nuclear energy between EURATOM and the Cabinet of Ministers of Ukraine (12033/04); Commission Decision of 4 April 2006 on the conclusion of the Agreement (OJ L 261, 22.9.2006, p. 26).

<sup>137</sup> Signed on 27 February 2006 (OJ L 32, 6.2.2007).

<sup>138</sup> Council Decision of 4 December 2006 approving the conclusion by the Commission of an agreement for cooperation in the peaceful uses of nuclear energy between EURATOM and the Government of the Republic of Kazakhstan (15495/06). The Commission has not yet concluded the Agreement.

<sup>139</sup> 14423/07.

<sup>140</sup> 14998/04.

245. An EPCIP ("European Programme for Critical Infrastructure Protection") policy package was put forward by the Commission in December 2006 <sup>141</sup>. 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 an 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).

246. 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.

Following informal exchanges of views at the JHA Council on 18 April 2008 and further work in the Civil Protection Working Party, the Council is very soon expected to reach political agreement on a "step by step" approach that covers *inter alia* the transport and energy sectors only, combined with a review clause after three years.

247. Work is 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 has been underway 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 not be available before the end of 2007.

---

<sup>141</sup> 16933/08 (COM (2006) 787 final) + ADD 1 + ADD 2.

## **B. Vulnerability analysis**

248. 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.

### **c) RESPONSE AND PREPAREDNESS**

## **XII. CIVIL PROTECTION**

### **A. General information**

249. The main civil protection instruments are Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument (the "*Financial Instrument*")<sup>142</sup> and Council Decision 2007/779/EC, Euratom of 8 November 2007 establishing a Community Civil Protection Mechanism (Recast) (the "*Mechanism*")<sup>143</sup>, which supersedes Council Decision No 2001/792/EC Euratom<sup>144</sup> and Commission Decision (2004/277)<sup>145</sup>. Taken together, those two acts aim at contributing to an enhancement of resources available for the response to and prevention of disasters.

250. The Financial Instrument provides the legal basis for the financing of civil protection activities including :

- the further development and establishment of forecasting, detection and early warning systems,
- training, networking, exercises and exchanges of experts and expertise,
- education, disaster awareness and self-protection of populations,
- contribution to the financing of transport of civil protection assistance when requested by a Participating State.

251. The Civil Protection Mechanism contributes inter alia 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 that are intended to be trained and interoperable,

---

<sup>142</sup> OJ L 71, 10.3.2007, p. 9.

<sup>143</sup> 11163/1/07 REV 1.

<sup>144</sup> OJ L 297, 15.11.2001, p. 7.

<sup>145</sup> OJ L 87, 25.3.2004, p. 20.

- 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.

Thirty countries – the EU-27, and the EEA countries (Liechtenstein, Norway and Iceland) – participate in the Civil Protection Mechanism.

The recast of the Mechanism by Council Decision 2007/779/EC, Euratom includes more explicitly acts of terrorism and man-made disasters in the list of possible emergencies that can trigger civil protection assistance through the Mechanism.

252. The EU Civil Protection Mechanism constitutes an efficient tool which can support Member States – at their request – for the preparedness and the effective coordinated response to terrorist threats. Its present limits are linked to the available assets (teams and means) that Member States have and are willing to share in a given emergency since the Financial Instrument does not provide for financing of additional and complementary civil protection equipments at European level.

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

253. The experts from the Member States and from the Commission have, within the framework of the Civil Protection Action Programme (now superseded by the Financial Instrument) and the Mechanism, considered several CBRN threats and the most appropriate response and identified in particular where mutual help may be possible.

254. Within the framework of the *Civil Protection Action Programme*, the call for proposal 2003-2004 identified a major project on the comparison of risk assessment and/or risk management methodologies in the sector of NBC threats. The project led to the establishment of an inventory of existing methodologies, the elaboration of best practise and draft common recommendations to be addressed to the Member States, taking into account scientific knowledge.

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

### **– Public information**

255. A major project on self-protection was undertaken within the framework of the section on "information to the public" of the *Civil Protection Action Programme 1998-2006 now superseded by the Civil Protection Financial Instrument 2007-2013*). The project focussed on accident prevention and preparedness, including CBRN risks, in private households. The project led to best practices for the appropriate behaviour in the case of an accident and major emergency. Moreover, the project led to recommendations for a basic life support kit for the European citizen at home. The support kit should encompass the necessary physical first-aid equipment for daily risks, disasters and CBRN threats.

256. The Commission recommended guidelines and techniques for public information which paid special attention to CBRN threats.

## **D. Monitoring**

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

257. *Council Decision 91/396/EEC of 29 July 1991 on the introduction of a single European emergency call number*<sup>146</sup> and *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>147</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 (MIC)**

258. *The Monitoring and Information Centre (MIC) set up under the Civil Protection Mechanism* and operated by the Commission may, with the support of CECIS (see 5 below), serve as the central hub of the Mechanism as it is here that information is received from the various networks and the Member States. The role of the MIC is to facilitate and support the mobilisation and coordination of Member States civil protection assistance during emergencies.

259. The MIC 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).

260. The MIC cooperates with appropriate international organisations in accordance with the operative rules of the Civil Protection Mechanism as set out in Decision 2007/779/EC, Euratom.

### **3) Linking the MIC to detection and early warning systems**

261. Decision 2007/779 asks the Commission to contribute to the development of detection and early warning systems for disasters which may affect the territory of the Member States, as well as to their establishment through studies and assessments on the need for and feasibility of those systems and through actions to promote their interlinkage and their linkage to the MIC and the CECIS. Those systems will take into account and build upon existing information, monitoring and detection sources.

### **4) 24h Contact points**

262. The Monitoring and Information Centre's work is based on the round-the-clock network of contacts set up 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.

---

<sup>146</sup> OJ L 217, 6.8.1991, p. 31.

<sup>147</sup> OJ L 108, 24.4.2002, p. 51.



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

263. The Member States have the possibility of exchanging urgent messages through the Common Emergency Communication and Information System (CECIS) of the Mechanism which is a secure dedicated communication network.
264. Provision has been made by the Commission for inter-linking this communication system with other Commission networks, in particular for radiological and health emergencies. The interconnections are tested and validated through exercises.
265. 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.

## **E. Preparedness**

### **1) Scenario approach**

266. In response to the request put forward by the European Council of 16-17 June 2005,<sup>148</sup> and after consultation with the EU Counter-Terrorism Coordinator, the Commission initiated a 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 focused 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 took 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.

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

267. CBRN experts may be mobilised through the civil protection Mechanism.

---

<sup>148</sup> " The European Council wishes the following points to be addressed as a priority during the second half of 2005: .... the strengthening of civil protection capabilities, particularly the medical resources available to deal with a bioterrorist attack, and the development of a rapid reaction capability based on the civil protection modules of the Member States;" (10255/1/05, p. 6).

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

268. 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 in identifying the capacities that are needed but are not sufficiently covered.
269. The Commission has conducted an analysis of data provided by Member States concerning potential assistance that could be available (shared for intervention in another Member State in the event of a terrorist attack).

### **4) Civil protection CBRN modules**

270. The Recast also reaffirms the goal of establishing an EU rapid reaction capability composed of civil protection modules consisting of the resources of one or more Member States which could be dispatched at very short notice (generally within 12 hours of a request for assistance); work self-sufficiently and autonomously; and be interoperable. Following the adoption of implementing rules by the Commission, implementation work has started including for the CBRN module; tasks, capacities, components deployment features are being defined.
271. The Commission implementing Decision of 20 December 2007<sup>149</sup> provides for civil protection modules, in particular for CBRN detection and sampling and for Search and Rescue in CBRN conditions.

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

272. The added value of the Mechanism also largely derives from the availability of experts capable of assessing needs and of coordinating intervention teams made available by the Member States.
273. 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.

### **6) Training and exercises for intervention and assessment/coordination teams**

274. 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 work together in a European context.

---

<sup>149</sup> Decision C(2007) 6464 amending Decision 2004/779/EC, Euratom as regards rules for the implementation of Council Decision 779/EC, Euratom establishing a Community Civil Protection Mechanism (OJ L 20, 24.1.2008, p. 23).

This training concerns all levels, from the head of a national intervention team up to the senior official responsible for coordinating the action of different national teams. Over 500 experts have been trained.

275. Several activities supporting preparedness against CBRN threats were organised in the past by the Community Mechanism and will continue to be organised under Council Decision 2007/162/EC, Euratom establishing a Civil Protection Financial Instrument involving training, large scale exercises and specialised exchange of experts.

The Commission organised with the relevant services of the Member States full-scale simulation exercises in the field of chemical, biological, radiological and nuclear terrorist attacks such as EURATOX (France, October 2002), COMMON CAUSE (Denmark, October 2002), EU Response/FLORIVAL II (Belgium, February 2003), EUDREX (Austria, October 2004), EURATECH (France, June 2005), EUROSOT (Italy, October 2005), NEW WATCHMANN (SANCO, EU-wide, October 2005), EULUX (Luxembourg, June 2007) and, most recently, CCAEX07 (EU Council September 2007). The Commission will finance a specific large scale exercise on CBRN involving several Member States in 2008.

## **7) Provision of pharmaceuticals**

276. The Recast provides that vaccines and related medical assistance can be part of the overall ad hoc emergency assistance channelled through the Civil Protection Mechanism in case of major terrorist attacks. The recast also provides that the Member States share general information on resources that can be made available and that the Commission should compile, in readiness for a major emergency, information on the capabilities of the Member States for maintaining a production of serums and vaccines or other necessary medical resources and on the stocks thereof which might be available for intervention.
277. 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.

## **F. Consequence management**

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

278. The Member States may seek assistance from each other 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 within the framework of the Mechanism.
279. The means and tools for coordination and information exchange among Member States and between the Member States and the Commission have been improved significantly over the seven years of the operation of the Mechanism.

280. 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 to any natural disaster or major technological accident in and outside the Union and the quality of such response.

## 2) **Provision of transport**

281. Decision 2007/779 EC, Euratom enables the Commission:

- to assist Member States in identifying transport resources and equipment that may be available from sources other than those of the Member States, such as the commercial market,
- to finance up to 50% of the cost of additional transport resources used by Member States for response under the Mechanism. This is however subject to strict criteria regarding the necessity of both the assistance and the transport needed for the delivery of that assistance. There are also strict conditions of economy, efficiency and effectiveness of the transport as laid down in the Financial Regulation. Finally, Community financing does not release the Member States from their duty to create sufficient civil protection capabilities.

On 8 August 2007, the Commission issued a Decision implementing this provision <sup>150</sup>.

## G. **International cooperation**

282. 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.

283. In 2003, the Commission and UNOCHA concluded an exchange of letters for the mutual exchange of information and cooperation in cases both the Mechanism and the UNOCHA were activated for a disaster in a third country. <sup>151</sup>.

284. In 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.

285. In 2007, a similar Administrative Arrangement was signed by the Commission with the Ministry for Emergency Services of Ukraine.

---

<sup>150</sup> Commission Decision 2007/606/EC, Euratom, of 8 August 2007 laying down rules for the implementation of the provisions on transport in Council Decision 2007/162/EC, Euratom, establishing a Civil Protection Financial Instrument (OJ L 241, 14.9.2007, p. 17).

<sup>151</sup> Exchange of letters between UNOCHA and the Commission concerning their cooperation in the framework of disaster response (in case of simultaneous interventions in a country affected by a disaster) signed, on 28 October 2004, by Commissioners Wallström and Nielson and by Under-Secretary-General of the UN Jan Egeland (16339/04).

### **XIII. PHARMACEUTICALS FOR HUMAN USE**

286. On pharmaceuticals, the starting points are the priorities set out in the Presidency conclusions on bioterrorism at the Health Council of 15 November 2001 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; and to  
(5) Promote the development of vaccines, medicines and treatments".<sup>152</sup>

#### **A. Preparedness**

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

287. 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.

288. Storage of medicines is dealt with under the third objective of the Health Security Programme agreed by the Health Security Committee on 17 December 2001<sup>153</sup>, namely creating a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available.

289. 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 have carried out an assessment of stockpiles in the Member States.

290. The ongoing work in that Task Force has given rise to a number of as yet unresolved questions and sensitive issues, in particular, drawing up an inventory of the availability and capacities of manufacture, stockpiling 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.

291. Similarly, the examination by Council bodies of the Commission communication of 2005 on "Building Solidarity through mutual assistance" led the Chairman of the Council's Health Working Party to conclude that "*Member States are ready to consider the provision of vaccines and related medical assistance as identified in the Commission's Communication on an ad hoc basis, i.e. in case of actual major terrorist attacks. Consequently, effective coordination between the civil protection and health sectors should be ensured at national and EU level, inter alia, by establishing clear channels of communication.*".<sup>154</sup>

---

<sup>152</sup> See above, paragraph 87.

<sup>153</sup> See above, paragraph 87.

<sup>154</sup> 8473/06 (partially accessible to the public).

## 2) Regulatory aspects : authorization of pharmaceuticals and recommendation for their use

292. Parliament and Council adopted on 31 March 2004:

- *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*<sup>155</sup>; Article 57(1)(q) of the Regulation 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*<sup>156</sup> *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*<sup>157</sup>. Article 5 of the Directive 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.

293. At the request of the Commission, the *European Medicines Evaluation Agency (EMEA)* 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 the use of 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 Committee for Proprietary Medicinal Products (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. 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.

---

<sup>155</sup> OJ L 136, 30.4.2004, p. 1.

<sup>156</sup> OJ L 136, 30.4.2004, p. 34.

<sup>157</sup> OJ L 311, 28.11.2001, p. 1.

- For antibiotics, production capabilities are sufficient to meet demand in the event of an emergency, and careful consideration is being given to increasing production and ensuring effective distribution to meet demand in case of crisis situations. 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 have been discussions on a common effort to be undertaken for research into and development of medicines in short supply such as vaccinia immunoglobulins and anthrax vaccines.

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

A study was completed on the dilution of existing smallpox vaccines and on vaccine immunoglobulin development. The study shows that dilution of first generation vaccines will be difficult in case of urgent need.

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

295. The EMEA *expert* group has prepared and published guidance on the development of new smallpox vaccines.

296. *The Council conclusions of 6 December 2004 on a European response to emerging zoonotic diseases*<sup>158</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.

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

297. Clinical guidelines for the recognition and case management of diseases related to 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 have been published on anthrax, smallpox, botulism, plague, tularaemia, haemorrhagic fever viruses, brucella, Q fever, encephalitis viruses, glanders and melioidosis.

## **B. Consequence Management**

298. It is recalled that an appeal for pharmaceuticals can be made through the Civil Protection Mechanism.

---

<sup>158</sup> 16051/04.

## **XIV. MILITARY SUPPORT TO EU CONSEQUENCE MANAGEMENT**

### **A. Consequence management**

#### **1) Complementarity**

299. When used outside the scope of Article 17(2) TEU, the possible use of military assets and capabilities, based on Member States' voluntary contributions, should be complementary to the civilian efforts. The arrangements developed in 2006 took into account the role and the tasks of the respective Commission services.

#### **2) "The Military Database"**

300. *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 the Council conclusions of 8 December 2003. 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>159</sup>. Since its establishment, the Military Database has been regularly updated. The latest update was finalized in April 2008. The Military Database remains a compilation of voluntary contributions from the Member States.

#### **3) "Getting assistance quickly where needed"**

301. Having considered transport as one of the critical military asset to potentially support consequence management and disaster response, a general framework document was developed for the rapid identification and coordination of Member States' voluntary contributions of transport in support of EU disaster response, if so requested and decided upon<sup>160</sup>. The arrangements allow for the coordination of sea/air transport capabilities, when offered by the Member States. The EU Movement Planning Cell, located within the EU Military Staff, will undertake the necessary coordination with military contact points in the Member States and Multinational Movement Coordination Centres.

#### **4) Coordination of other military support**

302. In 2006, the Council took note of the document entitled "Military support to EU disaster relief – Identification and coordination of available assets and capabilities"<sup>161</sup> as being a living text and agreed on the way forward described therein. The arrangements set out therein are designed to enhance the rapidity and effectiveness of the EU's response to disasters with military support. They cover the possible provision of other military support, such as medical, logistic and/or engineering support. They will be subject to review, as necessary, in the light of experience gained.

---

<sup>159</sup> 15564/03.

<sup>160</sup> 8976/06.

<sup>161</sup> 9462/3/06 REV 3.



## **B. International cooperation**

303. At informal meetings between EU and NATO staff on civil emergency planning in crisis management, there were exchanges of information on four main areas including non-binding standards for the protection of civilian populations against CBRN risks.
304. The EU and NATO have additionally increased transparency on their respective activities for the protection of civilian populations against CBRN terrorist attacks.

### **d) CROSS CUTTING**

## **XV. RESEARCH**

### **A. General information**

305. The Commission set up a group of national experts to compile an inventory of research efforts in the field of BC-terrorism within Framework Programme 5 to determine gaps and define needs and opportunities. Its report was submitted to the Council on 8 July 2002<sup>162</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 Government research institutions.*

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

306. 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.<sup>163</sup>
307. 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.

---

<sup>162</sup> 10842/02 RECH 128 PROCIV 49 SEC(2002) 698.

<sup>163</sup> 14782/03.

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

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

308. 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.
- 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**

309. 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.

310. In the context of "Scientific Support for Policies", six coordination 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.

311. 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

312. 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 EUR 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>164</sup> have been funded.

The Preparatory action on security research (PASR) (2004-2006) led to 6 projects related to CBRNE:

1. AEROBACTICS (Assessment of the quantity, identity, viability, origin and dispersion of airborne micro-organisms for application in crisis management tools);
2. BIO3R (Bioterrorism Resilience, Research, Reaction);
3. BODE (Biological Optical Detection Experiment);
4. IMPACT (Innovative measures for protection against CBRN terrorism). The objective of IMPACT was to lay the foundations for an integrated European CBRN counter terrorism research and acquisition programme and to validate, assess and demonstrate innovative technological capabilities, operational concepts and procedures to assist in developing preventive and suppressive crisis management;
5. TIARA (Treatment initiatives after radiological accidents);
6. WATERSAFE (On-Line Monitoring of Drinking Water for Public Security from Deliberate or Accidental Contamination).

313. Building on PASR, the 7<sup>th</sup> RTD Framework Programme (FP7, 2007-2013) saw a substantial increase in the budget for Security Research to EUR 1,4 billion. The protection against CBRN terrorism is addressed through the 4 missions and 3 cross cutting activities of the security research programme.

314. In parallel, DG JLS and DG ENTR jointly set up the consultative European Research and Innovation **Forum** (ESRIF), whose task is to contribute to supporting civil security policy-making with the appropriate technology and knowledge base.

---

<sup>164</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)

ESRIF built on the work already done by the Group of Personalities<sup>165</sup> and the European Security Research Advisory Board (ESRAB)<sup>166</sup>. The work of ESRIF started in December 2007. ESRIF has a mandate expiring in 2009.

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.

ESRIF will establish and carry forward a mid and long term Joint Security Research and Innovation Agenda involving all European stakeholders (both on the supply and the demand sides):

- strengthening and highlighting the importance of a public-private dialogue;
- providing a continuous analysis of capability needs in the light of threats, also leading to the definition of common user needs;
- promoting a Europe-wide single market for security equipment, systems and services, while supporting interoperability, integration, and cross-border cooperation;
- with due consideration of ethical issues, impacts on citizens' rights, and social perceptions of technological developments.

ESRIF is structured in a number of working groups: the scope of ESRIF WG6 includes *prevention, preparedness and response* through civilian means to threats involving chemical, biological, radiological or nuclear weapons (CBRN). Countering the unconventional use of high-yield explosives is also part of the scope of WG 6. Military responses are, however, not part of its scope.

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

---

<sup>165</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 EUR 1 billion per annum as well as the creation of the 'European Security Research Advisory Board' (ESRAB).

<sup>166</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. End-users and suppliers should be involved 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 (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 agenda and act as a possible reference body for the implementation of existing programmes and initiatives'.

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

316. The activities of the Joint Research Centre (JRC) 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.

317. 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**

318. 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 the EU's borders.

In addition to INSPIRE (Infrastructure for Spatial Information In Europe), a specific support action has been incorporated into 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**

319. The Commission services have started an initiative on exploring the ethical implications of scientific research into 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**

320. 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**

321. 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.
322. Coordination of European defence research is primarily through the 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 also has its own science programme which provides support for international cooperation between scientists from countries of the Euro-Atlantic Partnership Council (EAPC).

## **XVI. OVERALL COORDINATION**

### 1) **ARGUS**

323. 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 the event of a major multisectoral crisis. Thus, Commission services can improve their coordination and ensure a coherent and efficient response. However, the response to crises in specific fields remains under the responsibility of the sectoral RASs. Each RAS manages crises 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 spheres of competence and in cooperation with the other institutions.

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

324. Following the remits given by the Hague Programme and the Council Declaration on the EU response to the London bombings, the Council endorsed, on 13 June 2007, the operational EU emergency and crisis coordination manual<sup>167</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:

---

<sup>167</sup> <http://register.consilium.europa.eu/pdf/en/07/st10/st10011-re01.en07.pdf>

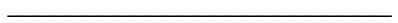
- First, the manual contains internal arrangements for political coordination in Brussels for major emergencies inside or outside the European Union by providing input for coordinated action or decisions by COREPER or the Council.
- Second, the manual pre-identifies a list of default contact points of 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

325. On 7 and 8 July 2004, the Presidency organised a seminar in The Hague on cooperation between services on the civil preparedness for possible attacks against the civilian population with CBRN agents <sup>168</sup>.

Several of its recommendations found their way into the Solidarity Programme of the Council and the Commission of 3 December 2004 on the consequences of terrorist threats and attacks <sup>169</sup>, which has superseded the 2002 CBRN Programme.




---

<sup>168</sup> 11919/04.

<sup>169</sup> 15480/04.

## PART C.

### LIST OF INSTRUMENTS

*In the alphabetical / chronological order:*

Animal protection  
Chemicals and dangerous substances  
Chemical industries  
Civil Protection  
Customs  
Environment protection  
Food protection  
Genetically Modified Organisms (GMOs)  
Human health protection  
Horizontal actions and overall coordination  
Military support  
Non-proliferation, Global disarmament and arms control  
Pharmaceuticals for human use  
Plant Protection and Plant Health Police  
Radiological and nuclear protection  
Research  
Transport

Animal protection (see p. 45)

1. Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine.
2. Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58). Directive last amended by Commission Directive 2004/21/EC of 1 March 2004 (OJ L 67, 5.3.2004, p. 27).
3. 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.
4. Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines, as amended by Decision 2001/181.
5. Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness.
6. Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease.
7. Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals.



8. 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.
9. Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing.
10. Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 024 , 30.1.1998, p. 9).
11. Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes.
12. 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.
13. Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue.
14. Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001 on a Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), as amended by Directive 2004/28/EC of 31 March 2004 (OJ L 136, 30.4.2004, p. 58).
15. Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever.
16. Commission Regulation (EC) 466/2001 setting maximum levels for certain contaminants in food.
17. Directive of the European Parliament and the Council 2002/32/EC of 7 May 2002 on undesirable substances in animal feed.
18. Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease.
19. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).
20. Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).
21. Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza.

22. 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.

Chemicals and dangerous substances (see p. 55) (*for transport, see at the end*)

23. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1). Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
24. Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on marketing and use of certain dangerous substances and preparations (OJ L 262, 27.9.1976 p. 201). Directive as last amended by Commission Decision 2006/139/EC (OJ L 384, 29.12.2006, p. 94).
25. Council Directive 96/82/EC of 9 December 1996 on the control of major accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13), as amended by Council Directive 2003/105/EC of 12 December 2003 ("Seveso II Directive") (OJ L 345, 31.12.2003, p. 97).
26. Council Decision 98/685/EC of 23 March 1998 concerning the conclusion of the Convention on the Transboundary Effects of Industrial Accidents (OJ L 326, 3.12.1998, p. 1).
27. **Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).**
28. Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1). Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).
29. Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (OJ L 63, 6.3.2003, p. 1). Regulation as last amended by Commission Regulation (EC) No 1376/2007 (OJ L 304, 24.11.2007, p. 14).
30. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 136, 29.5.2007, p. 1).

Civil Protection (see p. 70)

31. Council Decision 91/396/EEC of 29 July 1991 on the introduction of a single European emergency call number OJ L 217, 6.8.1991, p. 31.
32. Exchange of letters between UNOCHA and the Commission concerning their cooperation in the framework of disaster response (in case of simultaneous interventions in a country affected by a disaster) signed, on 28 October 2004, by Commissioners Wallström and Nielson and by Under-Secretary-General of the UN Jan Egeland (16339/04)
33. Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument (OJ L 71, 10.3.2007, p. 9).
34. Commission Decision 2007/606/EC, Euratom of 8 August 2007 laying down rules for the implementation of the provisions on transport in Council Decision 2007/162/EC, Euratom, establishing a Civil Protection Financial Instrument (OJ L 241, 14.9.2007, p. 17).
35. Council Decision 779/162/EC, Euratom of 6 December 2007 establishing a Community Civil Protection Mechanism (Recast),(OJ L 314, 1.12.2007, p. 9; declarations for the minutes: 13459/07).
36. Commission Decision 2008/73, EC, Euratom, of 20 December 2007 amending Decision 2004/779/EC, Euratom as regards rules for the implementation of Council Decision 779/EC, Euratom establishing a Community Civil Protection Mechanism (OJ L 20, 24.1.2008, p. 23).

Critical infrastructure protection (see p. 68)

37. p.m.

Environment protection (see p. 54)

38. Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (OJ L 194, 25.7.1975, p. 26).
39. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).
40. Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41 , 14/02/2003, p. 26.)
41. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1).

Feed and Food protection (see p. 38)

42. 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
43. 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 (OJ L 31 of 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4) and by Commission Regulation (EC) No 575/2006 of 7 April 2006 (OJ L 100, 8.4.2006, p. 3).
44. Regulation (EC) No 852/2004 of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).
45. Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).
46. 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 (OJ L 139, 30.4.2004, p. 206).
47. 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 (OJ L 191, 28.5.2004, p. 1).
48. Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002/EC with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64).
49. Regulation (EC) No 183/2005 of 8 February 2005 laying down requirements for feed hygiene (3677/04).
50. Regulation EC No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).
51. Commission Regulation (EC) No 776/2006 of 23 May 2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards Community reference laboratories (OJ L 136, 24.5.2006, p. 3).
52. Commission Regulation (EC) 1881/2006 setting maximum levels for certain contaminants in food.

Genetically Modified Organisms (GMOs) and biological agents (see p. 51)

53. Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, p. 1). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

54. **Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from the risks related to exposure to biological agents at work (OJ L 262, 17.10.2000, p. 21).**
55. Directive 2001/18/EC of the European Parliament and of the Council on the Deliberate Release into the Environment of Genetically Modified Organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
56. Council Decision 2002/628/EC of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety (OJ L 201, 31.7.2002, p. 48).
57. Regulation(EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).
58. Regulation (EC) No 1830/2003 of the European Parliament and of the Council, of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.32003, p. 24).
59. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
60. Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

Human health protection (see p. 23)  
**(including occupational health and safety)**

61. **Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).**
62. **Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).**
63. Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1988, p. 1). Decision at last amended by Commission Decision 2007/875/EC (OJ L 344, 28.12.2007, p. 48)
64. 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, OJ L 21 (26.1.2000, p. 32). Decision as amended by Commission Decision 2008/351/EC of 28 April 2008 (OJ L 117, 1.5.2008, p. 40).

65. 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 (OJ L 28, 3.2.2000, p. 50). Decision as last amended by Commission Decision 2007/875/EC (OJ L 344, 28.12.2007, p. 48).
66. **Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from the risks related to exposure to biological agents at work (OJ L 262, 17.10.2000, p. 21).**
67. Council conclusions of 15 November 2001 on bioterrorism (13826/01, p. 12).
68. Programme of the Health Security Committee (HSC) of 17 December 2001 on cooperation on preparedness and response to biological and chemical agent attacks (health security).
69. Commission Decision 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC (OJ L 86, 3.4.2002, p 44). Decision as last amended by Commission Decision 2003/534/EC of 17 July 2003, OJ L 184, 23.7.2003, p. 35 and Commission Decision 2008/.../EC of 28 April 2008 (OJ L ..., .... p. ...).
70. Decision 1786/2002/EC of the European Parliament and of the Council, of 23 September 2002, establishing a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p. 1).
71. 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 diseases (OJ L 184, 23.07.2003, p. 35).
72. 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 (OJ L 142, 30.4.2004, p. 1).
73. Council conclusions of 2 and 3 June 2004 on Community Influenza Pandemic Preparedness Planning (9507/04).
74. World Health Assembly Resolution WHA 58.3 of 23 May 2005 on the Revised International Health Regulations.
75. 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).
76. Decision 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of public health (2008-2013) (OJ L 301, 20.11.2007, p. 3).

Overall coordination (see p. 86)

77. Commission Decision 2006/25/EC, Euratom of 23.12.2005 amending its internal Rules of Procedure( OJ L 19, 24.1.2006, p. 20). (Introduction of ARGUS).
78. EU Emergency and Crisis Coordination Manual (CCA) (10011/1/07).

Military support (see p. 80)

79. p.m.

Non-proliferation, Global disarmament and Arms control (see p. 21)

80. Treaty on the Non-Proliferation of Nuclear Weapons.
81. Chemical Weapons Convention.
82. Biological Weapons Convention.
83. Council Regulation 1334/2000/EC setting up a Community regime for the control of exports of dual-use items and technology.
84. Joint Actions on the International Atomic Energy Agency : OJ L 165, 17.6.2006, p. 20; OJ L 193, 23.7.2005, p. 44; OJ L 182, 19.5.2004, p. 46.
85. Joint Actions on the Comprehensive Nuclear Test Ban Treaty Organisation : OJ L 176, 6.7.2007, p. 31; OJ L 88, 25.3.2006, p. 68.
86. Joint Actions on the Organisation for the Prohibition of Chemical Weapons : OJ L 85, 27.3.2007, p. 10, OJ L 331, 17.12.2005, p. 34, OJ L 349, 25.11.2004, p. 63.
87. Council Joint Action 2006/184/CFSP of February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction (OJ L 65, 7.3.2006, p. 51).
88. EU Action Plan on biological and toxin weapons, complementary to the EU Action Plan in support of BTWC (OJ C 57, 9.3.2006, p. 1).
89. Council Joint Action 2006/419/CFSP in support of the implementation of United Nations Security Council Resolution 1540 (2004) and in the framework of the implementation of the EU Strategy against the proliferation of Weapons of Mass Destruction, OJ L 165, 17.6.2006, p. 30.
90. Joint Action on the Security Proliferation Initiative : see 9211/04 and 10052/04.
91. Council Joint Action 2008/307/CFSP of 14 April 2008 in support of World Health Organisation activities in the area of laboratory bio-safety and bio-security in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction (OJ L106, 16.4.2008, p. 17).

92. Common Positions :  
OJ 176, 6.7.2007, p. 39, (CWC)  
OJ L 61, 28.2.2007, p. 49, (Iran)  
OJ L 88, 25.3.2006, p. 65, (BTW)  
OJ L **106**, 27.4.2005, p. 32, (NPT)  
OJ L 302, 20.11.2003, p. 34 (universalisation).

Pharmaceuticals for human use (see p. 77)

93. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 1).
94. Council 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.
95. Commission Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
96. Council conclusions of 6 December 2004 on a European response to emerging zoonotic diseases (16051/04).

Plant Protection and Plant Health (see p. 49)

97. International Plant Protection Convention **signed at Rome on 6 December 1951**.
98. Council Directive 91/414/EEC of 15 July 1997 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
99. 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 (OJ L 169, 10.7.2000, p. 1). Directive as last amended by Commission Directive **2007/41/EC of 28 June 2007 (OJ L 169, 26.9.2007, p. 51)**.
100. Regulation (EC) 396/2005 of the European Parliament and the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

Police, security and intelligence (see p. 17)

101. Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism (OJ L 344, 28.12.2001, p. 93).
102. Council Framework Decision 2002/465/JHA of 13 June 2002 on Joint Investigation Teams (OJ L 162, 20.6.2002, p. 1)
103. Council Agreement 2003/C 1212/01 of 8 May 2003 on a model agreement for setting up joint investigation teams (JIT) (OJ C 121, 25.3.2003, p. 1).



Radiological and nuclear protection (see p. 61)

104. Council Decision 80/565/Euratom of 9 June 1980 approving the conclusion by the Commission of the International Convention on the Physical Protection of Nuclear Material (OJ L 149, 17.06.1980, p. 41).
105. Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency (ECURIE (OJ L 191, 27.7.2000, p. 37).
106. Council Regulation No 3954/87/Euratom of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency (OJ L 371, 30.12.1987, p. 11). Regulation as amended by Council Regulation No 2218/89/Euratom of 18 July 1989 (OJ L 211, 27.7.1989, p. 1).
107. Commission Regulation No 944/89/Euratom of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency (OJ L 101, 13.4.1989, p. 17).
108. Council Regulation No 2219/89/EEC of 18 July 1989 on the special conditions for exporting foodstuffs and feeding stuffs following a nuclear accident or any other case of radiological emergency (OJ L 211, 22.7.1989, p. 4).
109. Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (OJ L 357, 7.12.1989 p. 31).
110. Council Regulation No 737/90/EEC of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station (OJ L 82, 30.3.1990, p. 1). Regulation as amended by Council Regulation No 616/2000 of 20 March 2000 (OJ L 75, 24.3.2000, p. 1).
111. Commission Regulation No 770/90/Euratom of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feeding stuffs following a nuclear accident or any other case of radiological emergency (OJ L 83, 29.03.90, p. 78).
112. Council Directive 90/641/Euratom of 4 December 1990 on *the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas* (OJ L 349, 13.12.1990 p. 21).
113. Commission Communication 91/C103/03 on the implementation of Council Directive 89/618/Euratom (OJ C 103, 19.4.1991, p. 12).
114. Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community (OJ L 35, 12.2.1992, p. 24).
115. Council Regulation No 1493/93/Euratom of 8 June 1993 on *shipments of radioactive substances between Member States* (OJ L 148, 19.6.1993, p. 1).

116. Commission Communication No 93/C335/02 concerning Council Regulation (Euratom) No 1493/93 (OJ C 335, 10.12.1993, p. 2).
117. Commission Decision 93/552/Euratom of 1 October 1993 establishing the standard document for the supervision and control of shipments of radioactive waste referred to in Council Directive 92/3/Euratom (OJ L 268, 29.10.1993, p. 83).
118. Commission Communication No 94/C224/02 concerning Council Directive 92/3/Euratom (OJ C 224, 12.8.1994, p. 2).
119. Council Directive 96/29/Euratom of 13 May 1996 laying down *basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation* (OJ L 159, 29 June 1996, p. 1) and repealing and replacing Council Directive 80/836/Euratom of 15 July 1980 (OJ L 246, 17.9.1980, p. 1) and Council Directive 84/467/Euratom of 3 September 1984 (OJ L 265, 5.10.1984 p. 4).
- Communication 98/C133/03 from the Commission concerning the implementation of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ C 133, 30.4.1998 p. 3).
120. Commission Recommendation 99/829/Euratom of 6 December 1999 on the application of Article 37 of the Euratom Treaty (OJ L 324, 16.12.1999, p. 23).
121. Commission Recommendation 2000/473/Euratom of 8 June 2000 on the application of Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole, (OJ L 191, 27.7.2000, p. 37).
122. Commission Regulation No 1609/2000/EC of 24 July 2000 establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 185, 25.7.2000, p. 27).
123. Action Plan to combat nuclear terrorism approved by the IAEA Board of Governors in March 2002.
124. Agreement of 29 January 2003 between Euratom and non-member States of the European Union on the participation of the latter in the Community arrangements for the early exchange of information in the event of radiological emergency (Ecurie) (OJ C 102, 29.4.2003, p. 2).
125. Commission Recommendation (EC) No 274/2003 of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station (OJ L 99, 17.4.2003, p. 55 + Corrigendum in OJ L 109, 1.5.2003, p. 27).
126. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation (OJ L 2, 6.1.2004, p. 36).

127. Council Directive 2003/122/EURATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.
128. Council Decision of 29 April 2004 enabling the Commission to adopt a Regulation on the *application of EURATOM safeguards* (7768/3/04 REV 3).
129. Council Decision of 29 September 2004 approving the conclusion by the Commission of an agreement for cooperation in the peaceful uses of nuclear energy between EURATOM and the Cabinet of Ministers of Ukraine (12033/04) + Commission Decision of 4 April 2006 on the conclusion of the Agreement (OJ L 261, 22.9.2006, p. 26).
130. Council Decision 2005/84/Euratom of 24 January 2005 approving the accession of the European Atomic Energy Community to the *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management* (OJ L 30, 3.2.2005 p. 10).
131. Commission Regulation (Euratom) No 302/2005 of 8 February 2005 on the application of Euratom safeguards (OJ L 54, 28.2.2005, p. 1).
132. Commission Decision 2005/844/Euratom of 25 November 2005 concerning the accession of the European Atomic Energy Community to *the Convention on Early Notification of a Nuclear Accident* (OJ L 314, 30.11.2005, p. 21).
133. Council Decision 2005/845/Euratom of 25 November 2005 concerning the accession of the European Atomic Energy Community to the *Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency* (OJ L 314, 30.11.2005, p. 27).
134. Commission Recommendation of 15 December 2005 on guidelines for the application of Regulation (Euratom) No 302/2005 on the application of Euratom safeguards (OJ L 28, 1.2.2006, p. 1).
135. Communication 2006/C/155/02 from the Commission *on verification of environmental radioactivity monitoring* facilities under the terms of Article 35 of the Euratom Treaty — Practical arrangements for the conduct of verification visits in Member States (OJ C 155, 4.7.2006, p. 2).
136. Commission Regulation (EC) No 1635/2006 of 6 November 2006 laying down detailed rules for the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 306, 7.11.2006, p. 3).
137. Council Directive No 2006/117/Euratom of 20 November 2006 *on the supervision and control of shipments of radioactive waste and spent fuel* (OJ L 337, 5.12.2006, p. 21).
138. Council Decision of 4 December 2006 approving the conclusion by the Commission of an agreement for cooperation in the peaceful uses of nuclear energy between EURATOM and the Government of the Republic of Kazakhstan (15495/06).

139. Council Decision 2007/513/Euratom of 10 July 2007 approving the accession of the European Atomic Energy Community to the *amended Convention on the Physical Protection of Nuclear Material and Nuclear Facilities* – Declaration by the European Atomic Energy Community according to Articles 18(4) and 17(3) of the CPPNM (OJ L 190, 21.7.2007, p. 12).

Research (see p. 81)

140. 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).

Transport of chemicals and dangerous substances (see p. 59)

141. Council common position for a Directive of the European Parliament and of the Council on the inland transport of dangerous goods (3658/07).
142. Directive 95/50/EC on uniform procedures for checks on the transport of dangerous goods by road, last amended by Directive 2001/26/EC.
143. Directive 98/91/EC relating to motor vehicles and their trailers intended for the transport of dangerous goods by road and amending Directive 70/156/EEC relating to the type approval of motor vehicles and their trailers.

