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**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE
EUROPEAN PARLIAMENT**

**ON COOPERATION IN THE EUROPEAN UNION ON PREPAREDNESS AND
RESPONSE TO BIOLOGICAL AND CHEMICAL AGENT ATTACKS
(HEALTH SECURITY)**

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TABLE OF CONTENTS

1.	INTRODUCTION	4
2.	RECENT BIOTERRORIST INCIDENTS AND REPERCUSSIONS IN THE EU	5
3.	PUBLIC HEALTH PREPAREDNESS AND RESPONSE	6
3.1.	Mechanism of alert and information exchange.....	8
3.2.	Detection and identification of biological agents	9
3.2.1.	Lists of agents	10
3.2.2.	Laboratories: inventory and cooperation	11
3.2.3.	Clinical guidelines for case recognition and management	11
3.3.	Chemical agents	12
3.4.	Emergency plans and modelling.....	12
3.5.	Directories of experts for advice and assistance	13
4.	AVAILABILITY AND STOCKPILING OF MEDICINES	14
4.1.	National stockpiles.....	15
4.2.	Options and issues regarding possible EU-level stockpiles.....	15
4.3.	Policy considerations on smallpox vaccines.....	17
4.4.	Current situation and actions foreseen.....	18
5.	RESEARCH	18
5.1.	R&D Expert Group on countering the effects of biological and chemical terrorism .	18
5.2.	The 6 th Framework Programme (FP6).....	19
6.	BUILDING A MULTI-SECTOR RESPONSE.....	19
7.	INTERNATIONAL COOPERATION.....	21
7.1.	Ottawa initiative.....	21
7.2.	Cooperation with the WHO	21
7.3.	Enlargement candidates	22
7.4.	NATO	22

8.	CONCLUSIONS AND PERSPECTIVES	22
9.	ANNEXES.....	24
9.1.	Annex 1.....	24
9.2.	Annex 2.....	26
9.3.	Annex 3 (LEGISLATIVE FINANCIAL STATEMENT).....	28

1. INTRODUCTION

1. Soon after the unprecedented terrorist attacks in the USA in September 2001, governments and international entities with responsibilities related to health protection reviewed their means across the various policies and sectors of activity to prevent and counter threats and mitigate the effects of such attacks. They immediately embarked upon reinforcing such means and devising new and adapted ones to face up to a new type of threat, that of deliberate releases of biological and chemical agents with their potential to go undetected until many individuals have become contaminated and fallen seriously ill.
2. The response of the European Union and, in particular, of the Council and the Commission, has been swift. It has been summarised in two communications issued by the Commission, the first on 28 November 2001 on “Civil protection: state of preventive alert against possible emergencies”¹ and the second on 11 June 2002 on “Civil Protection - Progress made in implementing the programme for preparedness for possible emergencies”². On 20 December 2002, the Council and the Commission adopted a joint programme to improve cooperation between Member States in the evaluation of Chemical, Biological and Radio-Nuclear (CBRN) risks, alerts and intervention, the storage of means of intervention and in the field of research as requested by the European Council at its meeting in Ghent on 19 October 2001. The programme reviews measures and actions already in place and those planned for the future and sets out the strategic objectives for fighting chemical, biological and radio-nuclear terrorism in all EU policies.
3. This communication deals with the health aspects of the EU action against bioterrorism. It describes the steps that have been taken by Health Ministers and the Commission to strengthen health defences against deliberate releases of biological and chemical agents and their co-ordination efforts at EU level. It refers to the problems and challenges on preparedness and response facing the health sector on which the onus of rapid detection of agents and early detection and treatment of exposed individuals falls. It then describes the actions that have been undertaken in the framework of the programme on health security that is currently being implemented in close collaboration between the Commission and the Member States.
4. The communication also reports on the initiative launched to address the issue of the availability and stockpiling of medicines which are indispensable for mounting an effective response to bioterrorist attacks. It describes the issues involved and presents the results of the work carried out, the current situation and perspectives for further work in this area. Brief reference is also made to actions in other policy areas and in particular food and water safety which are crucial for health protection. It finally outlines the main features of the initiatives for international cooperation in this area.
5. Work on health security at EU level is not finished by any means. It has already produced valuable and promising results. It will have to be adapted to developments and events and will be evaluated at regular intervals. Important conclusions have, nevertheless, already been drawn concerning the accomplishment of the objectives set,

¹ COM (2001) 707 final

² COM (2002) 302 final

the changing needs of the Member States and the influence of international developments. On the basis of these considerations perspectives for future EU activities and the resources and structures needed are discussed in the conclusions of the communication.

2. RECENT BIOTERRORIST INCIDENTS AND REPERCUSSIONS IN THE EU

Events

6. Shortly after the terrorist attacks of 11 September 2001, the US was hit by a spate of bioterrorist incidents involving anthrax spores. The bacillus anthrax spores released through the US postal system resulted in 23 cases of anthrax, of which eleven were inhalation cases that led to five deaths, as well as eight confirmed and four suspected cutaneous cases. Investigations suggest a single source for the deliberate releases and the strains of anthrax detected are indistinguishable. The perpetrators remain unidentified, and the risk of recurring deliberate releases remains high until they are captured.
7. The terrorist events took place in the United States but had a world-wide impact. In Europe, civil protection, security and armed forces were put on alert, and public health systems had to manage numerous items of mail containing powders suspected or claimed to be contaminated with anthrax. Neither terrorist attacks nor anthrax cases or contamination occurred in Europe, apart from a contaminated letter found in the US Embassy in Vienna, Austria, suggesting contamination within US government postal facilities. However, the pressure on European countries was high, as they quickly had to devote scarce public health resources to face a new type of threat.
8. Preparations for incidents in Europe were soon to be tested. On 7 January 2003, following raids two days earlier in premises in London, the UK authorities announced that a small amount of material found in those premises had tested positive for the presence of ricin, a toxic substance that can be fatal if ingested, inhaled or injected. The incident served as a sharp reminder to security and health authorities to intensify their efforts to plan and be ready for the deliberate dissemination of biological and chemical agents.

Health Council

9. At the Council meeting of 15 November 2001, following agreement by the Health Ministers, the Belgian Presidency issued conclusions which requested the Commission to develop an action programme of cooperation on preparedness and response to biological and chemical agent threats, which would have to address the following priorities:
 - (a) Develop a mechanism for consultation in the event of a crisis linked to the bio-terrorist risk and a capacity for the deployment of joint investigation teams;
 - (b) Set up a mechanism for information on the capacities of European laboratories with respect to the prevention of and fight against bio-terrorism;
 - (c) Set up a mechanism for information on the availability of serums, vaccines and antibiotics, including concerted strategies for developing and using those resources;

- (d) Set up a European network of experts responsible in the Member States for evaluating, managing and communicating risks;
 - (e) Promote the development of vaccines, medicines and treatments.
10. The conclusions stressed that, in developing this programme, initiatives must be closely co-ordinated with those linked to the setting up of a Community co-ordination mechanism for civil protection measures and must take account of confidentiality requirements in the case of sensitive data.

Ottawa initiative

11. On the international scene, the bioterrorist attacks were the subject of high-level contacts and meetings. Of particular importance was the meeting in Ottawa on 7 November 2001 of Health Ministers from the G7 group of countries with the participation of the Health Minister of Mexico and Mr Byrne, Member of the Commission responsible for Health and Consumer Protection. The meeting agreed a concerted global action initiative to strengthen the public health response to the threat of international biological, chemical and radio-nuclear terrorism. Progress with the implementation of this initiative is outlined in a separate section below.

Commission response

12. In response to the call by the European Council and in line with the priorities identified by Ministers in the Council, the Commission launched a series of co-ordinated actions across the civil protection, health, enterprise (pharmaceuticals), research, nuclear and transport and energy fields. These were reported in the communication on “civil protection: state of preventive alert against possible emergencies” issued on 28 November 2001. The main advances made in developing and implementing the civil protection co-ordination mechanism, the health security initiatives and activities in key complementary sectors such as research and pharmaceuticals, were summed up in the communication of 11 June 2002 on “Civil Protection - Progress made in implementing the programme for preparedness for possible emergencies”. The Commission also completed a study on the vulnerabilities of the EU from scientific and technological advances related to bioterrorism.
13. Finally, the Commission joined efforts with the Council in inventorying measures and actions across European Union policies to face up to chemical, biological and radio-nuclear terrorist threats and setting up the strategic objectives for future action. These are set out in the joint programme, agreed on 20 December 2002, to improve cooperation in the European Union for preventing and limiting the consequences of such threats.

3. PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Preparedness

14. Deliberate releases of biological and chemical agents to cause harm can be overt, with effects and victims immediately apparent, or covert, in which widespread contamination of people and the environment can occur before effects become manifest. Mitigating the effects of such releases requires early detection of the agents implicated and case recognition of those affected. Only then can a multi-sector

response be activated and its success will depend on the speed and accuracy of the agent detection and case identification. Health authorities and agencies have a crucial role in identifying agents released in various environmental compartments, including built-up environments such as dwellings, subways and transport infrastructure, and distribution chains such as for food, water, air and mail. They are responsible for the timely recognition of cases and identification of persons likely to have been affected. For this, they must establish effective surveillance, familiarise clinicians with the syndromes to look out for, disseminate case management guidelines and put in place effective arrangements for prompt notifications to 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 validated techniques and protocols so that deliberate releases can be rapidly confirmed or excluded. Laboratory expertise and capacity must, in turn, be available to cope with high-risk agents and complex technology and methods as well as a surge in demand in case of multiple threats or attacks. Proper and safe arrangements must be in place for the collection and transportation of samples, reagents and specimens. Field investigation must be rapidly available to analyse relationships between cases and to establish the extent and distribution of environmental exposures, and co-ordinate contact tracing and 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 requires combining data from human and environmental epidemiology with information from security and law enforcement services. Finally, the public health system has to be prepared for conducting at the local, regional or national level, triage, contact tracing, testing, diagnosis, treatment, and prophylaxis, for large numbers of people, and for implementing other public health measures based on accurate predictions about the propagation of releases or disease.

Response

15. For threats and overt attacks, measures for physical protection and assistance need to be taken immediately and an initial assessment be made of consequences and risks so that appropriate interventions could be initiated forthwith. Covert attacks would be picked up by ad hoc monitoring or by identification of cases by the health authorities. Health authorities would then undertake preventive, remedial and treatment action, such as decontaminating exposed persons, taking swabs for analysis or administering prophylactic treatments. Emergency plans, tested with exercises ensuring the smooth interdisciplinary working between clinicians, microbiologists, toxicologists, epidemiologists, communicable disease control physicians, and radiation biologists and physicists with the civil protection, security and law enforcement services would provide a high degree of confidence in the capacity to mount a proportional multi-sector response. First responders and all other staff engaged in activities likely to expose them to risk from the release and its sequels have to be shielded from direct or indirect effects. Health response staff need to be properly equipped and organised and have timely recourse to sufficient quantities of medicines, other medical supplies, protective and decontamination equipment, detection kits and sampling equipment, and laboratory and medical services. Their numbers, means of response, especially communication, command and control systems, and their deployment capability must be strengthened to cope with the upsurge in demand that will follow an attack with many victims and withstand the pressures from the occurrence of multiple attacks or incidents.

Co-ordination in the European Union

16. The European Union is a border-free space in which products, services and people can circulate without hindrance. It is essential in such a space that appropriate arrangements be put in place to ensure prompt notification and exchange of information in case of threats and attacks, action at source be undertaken to stem the spread of disease and environmental contamination, mutual assistance be provided for diagnosis and management of cases, access to special laboratory services and expertise for epidemiological investigations be secured, and public health responses be put into effect. This, in turn, requires sharing of knowledge and good practice, laboratory facilities, equipment and products, experts and intervention personnel across the Member States of the EU, as well as good co-ordination and interoperability of preparedness and response plans. The importance of joint action in the EU to complement national measures led to the establishment on 26 October 2001 of a Health Security Committee, comprised of high-level representatives of the Health Ministers, to serve as the main instrument for cooperation in countering deliberate releases of biological and chemical agents to cause harm and the setting up in 2002 of a Task Force of national experts and Commission officials to implement an action programme to enhance health security. To give effect to the request of the Health Ministers of 15 November 2001 the Committee agreed on 17 December 2001 a programme of cooperation on preparedness and response to biological and chemical agent attacks (health security), code-named BICHAT, comprising 25 actions grouped under four objectives:
- (a) Set up a mechanism for information exchange, consultation and co-ordination for the handling of health –related issues related to attacks;
 - (b) Create an EU-wide capability for the timely detection and identification of biological and chemical agents that might be used in attacks and for the rapid and reliable determination and diagnosis of relevant cases;
 - (c) Create a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available in cases of suspected or unfolding attacks;
 - (d) Draw-up rules and disseminate guidance on facing-up to attacks from the health point of view and co-ordinating the EU response and links with third countries and international organisations.
17. The programme is being implemented since May 2002 and results so far are presented below.

3.1. Mechanism of alert and information exchange

18. This mechanism consists of the Health Security Committee and a rapid alert system established to deliver alert notification and information necessary and appropriate for co-ordinated responses to attacks and threats. The Health Security Committee is charged with exchanging information on health-related threats, sharing information and experience on preparedness and response plans and crisis management strategies, communicating rapidly in case of health-related crises, advising on preparedness and response as well as on co-ordination of emergency planning at EU-level, sharing and co-ordinating health-related crisis responses by Member States and the Commission

and facilitating and supporting co-ordination and cooperation efforts and initiatives undertaken at EU-level.

19. The Committee has forged partnerships and collaborations to face up to the new type of threat in the health field and established thematic working groups on laboratories, biological products, chemicals, clinical guidelines, emergency plans and modelling to allow recourse to expertise and flexible deployment of resources in Member States.

Rapid Alert System

20. A dedicated rapid alert system is in operation since June 2002 for notifications of incidents involving the deliberate or threatened release of biological and chemical agents to cause harm (code-named RAS-BICHAT). The system links the members of the Health Security Committee and contact points designated by its members to provide round the clock coverage and urgent recall in an emergency. It is linked to and complements the system established by Commission Decision 2000/57/EC of 22 December 1999³ on the 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 Council⁴ and the civil protection mechanism (Council Decision 2001/792/EC, Euratom of 23 October 2001⁵ establishing a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions). RAS-BICHAT is fully operational and uses agreed notification procedures and criteria for the classification of events according to the type of the release and the severity of consequences, using an incident scale agreed also in the context of the Ottawa Global Health Security initiative. It has been used on five occasions and tested five times and is being developed and adjusted in the light of experience and the lessons learnt so far. Effective links have been established with the other health protection-related EU rapid alert systems. The system is also linked to existing Commission systems that scan and summarise information made available through news agencies, other news media and specialised sources onto the World Wide Web. This capability will be extended to involve other sources of information, the objective being to facilitate the creation of an integrated information system where data are housed and processed to detect rapidly, track and assess threats so that advance warning could be provided before official confirmation or news break out.

3.2. Detection and identification of biological agents

21. Detection of deliberate releases of biological agents relies first and foremost on Member States' surveillance systems for monitoring the occurrence of infectious diseases. Member States, but also other countries, are developing new diagnostics for rapid detection which is a key requirement for effective response. In particular, advances in environmental detection and monitoring of information related to agents and disease outbreaks would enhance the ability to identify a release early. Co-ordination of these surveillance systems at EU level, especially for notification and exchange of information on outbreaks, is conducted under the framework of Decision 2119/98/EC of 24 September 1998 on the surveillance and control of communicable diseases.

³ OJ L 21 , 26.01.2000, p. 32

⁴ OJ L 268, 03.10.1998, p. 1

⁵ OJ L297, 15.11.2001, p. 7

3.2.1. *Lists of agents*

22. Although any biological or chemical agent capable of causing harm to health may in theory be used for terrorist purposes, a number of considerations, such as ease of production and dissemination, would point to some being more likely to be used than others. It is thus crucial to develop agreed and updateable lists of biological and chemical agents that might be used in attacks or threats, together with their characteristics and associated symptoms and diseases and indications that permit their timely detection and identification with agreed levels of certainty.

Lists in the area of Public Health

23. Biological agents in relation to bioterrorism have already been prioritised on the basis of certain criteria, such as infectiousness, virulence, persistence in the environment, ease of manipulation and dissemination and existence of defences to counter their propagation and effects. The European Agency for the Evaluation of Medicinal Products (EMA) has referred to the list published by the US Centers for Disease Control and Prevention in the advice it has given concerning vaccines and treatments (Annex 1). Commission Decision 2000/96/EC⁶ of 22.12.1999, under Decision N° 2119/98/EC of the European Parliament and of the Council, concerning diseases to be progressively covered by the European Union's communicable disease surveillance network, contains many of the agents singled out by the CDC. A Commission decision has been proposed adding *Bacillus anthracis* (for anthrax), *Francisella tularensis* (for tularemia), *Coxiella burnetii* (for Q-fever), and *Variola major* (for smallpox) to the EU lists and amending Commission Decision 2002/253/EC⁷ which lays down case definitions for reporting communicable diseases to the EU network. For other pathogens that are potential candidates for attacks, various approaches are being studied, such as improved clinical alerting mechanisms and syndrome-based surveillance systems. Moreover, in order to compile the different actions needed against biological agents that might be used for deliberate releases in a single presentation, a matrix has been developed for use by national authorities. The matrix serves to identify for each agent the actions that need to be accorded priority.

Export control lists

24. Council Regulation N° 1334/2000 setting up a regime for the control of exports of dual-use items and technology⁸, as amended and updated by Regulation (EC) N° 2432/2001 of 20.11.2001⁹, lays down lists of biological and chemical agents for which strict provisions linked to international non-proliferation regimes and export control arrangements apply. The latter are agreed by international mechanisms, one of them being the so-called Australia Group¹⁰, an international informal group of countries that base their activities on the biological and chemical weapon conventions regarding the minimisation of the risk of chemical and biological weapons proliferation. The agreements are linked to the aforementioned Council Regulation and have to be transposed onto EC law. The latest meeting of the Australia Group in June 2002 decided to add new agents to the control lists. However, because of the adverse

⁶ OJ L28, 3.2.2000, p.50

⁷ OJ L86,3.4.2002, p.44

⁸ OJ L159, 30.6.2000, p.1

⁹ OJ L338, 20.12.2001, p.1

¹⁰ <http://www.australiagroup.net>

impact that controls may have on public health activities, such as delays in the transport of agents, samples, reagents and specimens for laboratory tests and comparisons, consultations are taking place with the Member States aimed at agreeing a common position at the Australia Group for the adoption of appropriate criteria for placing agents in control lists and for exemptions from the export control rules of transfers made by public health institutes, laboratories, agencies and centres.

3.2.2. *Laboratories: inventory and cooperation*

25. Capability for fast and accurate characterisation of biological agents is unevenly distributed in the EU. Remedying shortcomings in this area requires the development and use of special surveillance methods and arrangements to use limited laboratory resources efficiently. There are six safety level 4 laboratory facilities in four Member States of the EU that are suitable for the handling and confirmation in samples and specimens of high-risk agents such as haemorrhagic fever viruses. A network has been formed between these laboratories to provide quality-assured diagnostic services to all Member States, identify viral haemorrhagic fever and pox agents, establish an on-call availability of 24 hours seven days a week, communicate rapidly with national authorities and the Commission, develop a structure for sending/receiving and handling samples and organise training and skill development. For smallpox diagnostics, collaboration between safety level 3 and 4 laboratories would be necessary. To this end, Member States' experts have been convened by the Commission and developed a cooperation platform, including a quality assurance system. Collaboration of high safety level laboratories is also being pursued in the context of the Ottawa Global Health Security initiative, where a network has been set up to share protocols and standard operating procedures, exchange reagents and control material and promote the harmonisation and standardisation of diagnostic methods.
26. The anthrax attacks in the US and the spate of hoaxes using letters and packages that followed there and in Europe showed also how easily national laboratory systems can be overwhelmed by a spike in demand over a short period of time. It is thus crucial to ensure proper back up and mutual support between laboratory facilities of the EU Member States to avoid situations of saturation and inability to cope with a surge in demand for analyses. To this end, the Commission is promoting the conclusion of memoranda of understanding or cooperation agreements between the national laboratory systems of the Member States. The existing EU database IRIDE set up with help from the Commission and data collected through a questionnaire sent to the competent authorities of the Member States will be used to specify the terms of cooperation agreements.

3.2.3. *Clinical guidelines for case recognition and management*

27. Clinical guidelines for the recognition and case management of diseases related to the pathogens that may be used in deliberate releases are being prepared on the basis of a consensus process. The process involves review by a group of experts designated by the Health Security Committee and final approval by the latter prior to publication and dissemination to Member States.
28. Ten manuscripts have been drafted covering anthrax, smallpox, botulism, plague, tularemia, haemorrhagic fever viruses, brucella, Q fever, encephalitis viruses, glanders. They have been modified following comments by Member States' experts and endorsed by the Health Security Committee as a useful tool for the guidance of

clinicians and other health professionals. The intention is to publish them following peer-review in a scientific journal.

3.3. Chemical agents

29. Work on chemicals aims at providing Member States with a sound basis for planning and assisting each other for attacks and threats using these substances.
30. A matrix to aid Member States to identify priorities in this area has been drawn up by the compilation of a series of lists of chemical threats to arrive at groups of substances requiring the same public health and medical approaches. The matrix takes into account the international cooperation on the preparation of a list of chemical agents agreed within the Global Health Security Action Group. It also takes into account data on dangerous chemicals collected by the Joint Research Centre pursuant to Directive 96/82/EC on the control of major accident hazards involving dangerous substances (the Seveso Directive). The risk grading of substances in the matrix takes into account the relevant provisions of the Council Directive 98/24/EC for health and safety requirements at the workplace concerning chemical agents¹¹.
31. Work is focussing on the clinical and toxicological aspects of chemical incidents, national inventories of chemical experts who can be made available, the inventory of special treatment facilities, clinical review papers and training issues. Close working relationships have been developed with national and international organisations active in these, including the National Focus for Response to Chemical Incidents in the UK, the International Programme on Chemical Safety (IPCS) run by the World Health Organisation (WHO) and the Organisation for the Prohibition of Chemical Weapons (OPCW). Cooperation with the European Association of Poison Control Centres and Clinical Toxicologists (EAPCCT) has been initiated for the preparation of clinical review documents on syndromes and treatment of chemical agents that might be used in attacks. Data from a survey of poison centres conducted by the Commission are used to compile an inventory of clinical and laboratory-related expertise in the EU. Finally, a guidance document on the use of antidotes and pharmaceuticals has been requested from EMEA.

3.4. Emergency plans and modelling

32. Immediately after the bioterrorist attacks in the US, EU Member States were forced urgently to review their emergency plans and to adjust them to face up to a new threat, that of a covert release possibly without warning or signals of impending danger. They had to make certain key assumptions and reckon with various scenarios: discovery of unusual or suspicious objects which could not simply be taken away for destruction for fear of spreading agents; discovery of biological products in the wrong place or in the wrong product; the possibility of threat or terrorist attack with or without demands, before or after harm or damage became manifest; an abnormal outbreak of disease or unusual clustering of cases without indications of link to normal or adventitious exposure; or, worse, obvious foul play or likely foul play in incidents that resulted in prompt or delayed harm to people, environment or property. They had to amplify and refine general emergency plans to cater for specific types of agents representing

¹¹ OJ L 131, 05.05.1998, p. 11

different sets of demands, as evidenced by the anthrax releases and the possibility that a smallpox case may break out at home or abroad.

33. Consultations at the EU level and internationally showed that the process of adjusting and complementing emergency plans or devising new ones is not yet complete, with some Member States more advanced than others. Member States and other countries are keen to share knowledge and experience and compare assumptions, scenarios, criteria and principles for introducing particular counter-measures at appropriate phases. They want to have plans based on carefully considered policy options. These would include the WHO's "search and containment" policy for outbreaks of infectious diseases such as smallpox which advocates ring vaccination. Different responses to an outbreak would have to be considered, depending on whether it occurred in one's territory or abroad, as well as responses to multiple outbreaks spread widely, switching between responses, or the scaling -up of existing counter-measures. Member States are also keen to develop models to make predictions about the progress of disease under different scenarios and variable quantitative and qualitative information on movements of people, social habits, various geographical, weather and transport and utility conditions. They need sound strategies for the deployment of data capture and information flow systems, medicines, medical supplies, protective and decontamination equipment, detection and sampling/monitoring devices and about the implementation potential and impact of counter-measures, such as medical treatment, vaccination, isolation and quarantine, evacuation and interdiction of premises, taken in isolation or in combination.
34. It has now become a priority under health security programme to intensify work on emergency planning and promote modelling, so as to permit the refinement and strengthening of emergency and strategic plans for threats and attacks. To this end, a compilation of national emergency plans is in progress which will serve to share and co-ordinate specific measures and a common mathematical model and data resource is being developed. An EU- wide exercise will be carried out next year to evaluate communications and compatibility of national plans. Commission participation in the exercise this year to evaluate smallpox plans and communications involving the G7 countries and Mexico will provide lessons for the conduct of the EU exercise. A central element in both efforts is the identification of needs for further EU co-ordination across the whole spectrum of policies that would be affected by a global health emergency, such as a smallpox outbreak, and the consolidation of responses within an overall EU plan.

3.5. Directories of experts for advice and assistance

35. Knowledge about bioterror agents and corresponding diseases and their clinical and epidemiological management and associated laboratory analysis is limited. Hence the need to identify relevant experts in the EU and list them in a directory to be shared by the authorities of the Member States. An expert could be made available by one Member State to another on request to the authorities of the Member State of the expert. A questionnaire has been sent to Member States to identify experts that can be made available for advice or for missions when arrangements for this type of operation have been established. Experts will be designated by the Health Security Committee in accordance with criteria on qualifications and experience that have already been drawn up. They will have to express their interest and availability to be placed in the directory and participate in investigations, as well as readiness to respond in good time and at short notice. Other appropriate instruments such as codes of conduct, terms of

reference and procedures for the consultation of the directory in strict respect of confidentiality will also be developed.

36. The directory will be managed in collaboration between the Member States and the Commission. It will be co-ordinated with the inventory held by the Commission's civil protection mechanism and the roster kept by the WHO's Global Outbreak Alert and Response Network, as well as with the Joint Research Centre's group of experts on EU vulnerabilities to biological and chemical terrorism, and arrangements will be made to have recourse to lists held by the authorities of the Member States. Regular updates will be made of contact details of all experts and new experts will be identified and added at regular intervals.

4. AVAILABILITY AND STOCKPILING OF MEDICINES

37. Immediately after the bioterrorist attacks in the USA attention focussed on the availability of medicines in the EU and the capability of industry and Member State agencies and laboratories to make good any shortcoming in production and supply. Subsequent action served also to gather data that would be useful for obtaining the general information on medical resources in the Member States as laid down in Council Decision 2001/792/EC, Euratom (reference N°5).
38. A consultation with the pharmaceutical industry was launched in November 2001. A joint Commission services - pharmaceutical industry task force was established in December 2001 to address availability, production capability, storage and distribution capacity and development plans for vaccines and other medicines used for the treatment or prevention of disease in the event of a biological attack. In the same month, a specific network was also created via the Pharmaceutical Committee¹², comprising contact points in the 15 Member States to look at stocks and availability in the Member States. At the request of the Commission, the EMEA has established two expert groups. One expert group developed guidance on the use of medicines against potential pathogens¹³ and the other expert group produced a report¹⁴ on second generation¹⁵ smallpox vaccines, based on hearings held with six major vaccine manufacturers, and guidance on the development of vaccinia virus based vaccines against small pox¹⁶.
39. In Annex 2 an overview has been compiled of the general findings on availability, product development and production capabilities within the European Union of the different medicinal products for the treatment or prevention of diseases caused by a number of pathogens¹⁷. It is not exhaustive and will be updated as necessary. It

¹² established by Council Decision 75/320/EEC

¹³ EMEA/CPMP guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism (<http://pharmacos.eudra.org> or <http://www.emea.eu.int>). Treatment/prophylaxis recommendations are given for all pathogens in the current CDC list. All agents from the list were included (see Annex 1) Additional pathogens were also included, which were thought to pose a potential threat.

¹⁴ EMEA Vaccines expert group confidential report on small pox vaccines CPMP/493/02.

¹⁵ Vaccines against smallpox are sometimes *classified* according to their state of development into first, second or third generation vaccines. An explanation of this classification is in Annex 1.

¹⁶ EMEA /CPMP/1100/02 Note for guidance on the development of vaccinia virus based vaccines against small pox.

¹⁷ Mainly the A-category pathogens of the CDC list (see Annex 1).

incorporates the recommendations from the guidance document of the Committee for Proprietary Medicinal Products (CPMP).

40. Several options were studied as part of these parallel efforts, prominent among which was the establishment of a Community-level stockpile of authorised or to be authorised second generation smallpox vaccines, manufactured according to current quality standards. The views of the Member States on this possibility were sought in several consultations, starting with an exchange of views between Ministers at the Health Council on 23 June 2002 and continuing with the representatives of Ministers in the Health Security Committee and in technical ad hoc groups.

4.1. National stockpiles

Antibiotics

41. There is stockpiling of antibiotics at national level in many of the Member States, but not in all. Some rely on requirements placed on pharmacists, distributors or hospitals but these do not necessarily cover those most suitable for countering bioterrorist attacks. Two of the larger Member States have offered to share stocks with other Member States. However, the majority of the other Member States did not wish to take up the offers made and the sharing scheme was not discussed further.

Smallpox vaccine

42. An assessment of national smallpox stockpiles has been carried out which showed that most Member States have existing or are acquiring stockpiles of smallpox vaccines. First generation vaccines have been in storage since the 1970s. One Member State resumed production of first generation (calf lymph) vaccines in January 2002. A few countries have ordered or are planning to order new (second generation) vaccines when they become available. Some Member States are considering diluting their stock of first generation vaccines so that it can provide a greater number of doses.
43. From the information received so far, the sizes of the national stockpiles in relation to the national population range from enough to provide a dose for every citizen in the Member State to enough for one citizen in thirty. A national stockpile providing total coverage for the population does not necessarily imply a mass vaccination policy – it may reflect a political decision to provide reassurance for the population and to be able to respond to an anticipated public demand. In line with WHO guidelines, all Member States have indicated that they have a targeted vaccination policy, vaccinating only close contacts of infected cases. An important feature in some Member States' smallpox plans is the preventive (before any release) vaccination of key health and emergency services staff. The US and Canada are also carrying out vaccinations of such staff as a preventive measure. It is envisaged in the US to extend vaccinations to all health and emergency services staff in case of a smallpox outbreak and, eventually, following satisfactory results from the vaccination programme, to make the vaccine available to the public on demand.

4.2. Options and issues regarding possible EU-level stockpiles

44. The Commission services-pharmaceutical industry task force and the Member States, through the Pharmaceutical Committee network and through the Health Security

Committee, considered the need for the establishment of a Community stockpile of smallpox vaccines, antibiotics and antivirals.

45. As regards antibiotics, a Community stockpile could comprise a sufficient, versatile range of antibiotics to cover as many of the potential pathogens as possible. The stock could include generic products as in most cases the corresponding original products no longer have patent protection. Foreseeable advantages of a Community stockpile of antibiotics have been considered to be increased purchasing power and economies of scale, increased comfort level from knowing there is a reserve and industry preference to deal with a central contact and a single large contract. Problems likely to be encountered include difficulties getting agreement on the choice of antibiotics within the different therapeutic classes and on the choice of final manufactured product, the likely high cost and difficulty in managing a stockpile of a number of different products at Community level and issues relating to the language of the labelling and other product information.
46. As regards smallpox vaccines, several issues were identified in the context of setting up and administering a Community-level stockpile, including:
 - such stockpile should exist in addition to national stockpiles and any national sharing arrangements and should not replace them;
 - it should provide equivalent access to all and should ensure equity for all citizens of the EU;
 - it should take future EU enlargement into account;
 - it should be suitable for the needs of the Community for at least the next ten years, when third generation vaccines may become available;
 - it should only contain second generation vaccine(s) which are authorised or to be authorised according to the criteria of safety, quality and surrogate markers for efficacy established by the EMEA expert group on vaccines.
47. The size of a Community stockpile would be influenced by national vaccination strategies, in place or foreseen, the size and precise content of the national stockpiles and modelling data predicting likely responses to a deliberate release of smallpox.
48. Foreseeable advantages of a Community level stockpile of smallpox vaccines include equity for all EU citizens, increased purchasing power and economies of scale, reduced overall costs up front by having a proportion of stockpile as bulk product and by re-launching production as necessary in response to an emergency, increased leverage to encourage companies to develop new vaccines, industry preference for dealing with one central contact and boost to confidence from knowing that there is a reserve of vaccine.
49. However, a number of issues remain unresolved, such as the significant budgetary requirement to buy and maintain a stockpile against a low probability event such as a bioterrorist attack with appreciable impact. The pharmaceutical industry has indicated that there would be a sliding scale for costs per dose, depending on the size of the order.

50. Moreover, the issue of sharing and distribution from the stockpile in case of simultaneous Member States needs could result in several options to be studied, including allotting a predetermined amount to each Member State or requiring the operators of the stockpile to maintain national stores. Also, an alternative to a distinct Community stockpile could be a “virtual” stockpile co-ordinated and administered by the Commission and made up of dedicated proportions of national stockpiles to be pledged by the Member States.

4.3. Policy considerations on smallpox vaccines

Consultations

51. Consultations on options for a Community stockpile or virtual reserve or a strategic sharing of national stockpiles showed that most Member States would not support either the establishment of a Community level stockpile of smallpox vaccines or formal arrangements for sharing national stockpiles. The Health Security Committee, at its meeting on 22 October 2002, confirmed its interim conclusion reached at the previous meeting in June 2002. For different reasons different Member States consider that an EU-level stockpile would not provide added value over the existing and planned national stockpiles.

Dilution of existing stocks

52. As regards the current availability of first generation stocks, the aggregate total number of doses available in national stocks in the European Union is in the range of 200 million. As studies performed in the USA indicate that, under ideal conditions of storage and dilution, up to 5 times dilution would result in doses retaining adequate potency, there is a presumption that diluted EU stocks would be sufficient to contain smallpox outbreaks using the search and containment vaccination strategy. However, there are doubts over the feasibility of dilution in real conditions. Moreover, most Member States expressed concern about the safety aspects of current first generation vaccines, necessitating the need for obtaining sufficient amounts of vaccinia immunoglobulin (VIG), which is at present not available.

Second generation vaccines

53. Second generation vaccines are acknowledged to have superior production and quality control methodology compared with first generation ones but there is uncertainty about their safety profile as there are no published clinical data yet about them. The efficacy of first generation vaccines (in combination with isolation and quarantine) was established during WHO’s smallpox eradication campaign, whereas for ethical reasons it will be impossible in present times to establish the efficacy of second or third generation vaccines in clinical trials. However, protective efficacy may be inferred from animal models and from clinical trials that measure surrogate markers of efficacy such as a relevant immune response or from information to be collected from the vaccination of first responders and health emergency staff now being undertaken in certain countries.

4.4. Current situation and actions foreseen

54. With respect to prophylaxis, there are no authorised vaccines in the EU against pathogens such as smallpox or plague. The only authorised anthrax vaccine is not widely available. In addition there is an insufficient supply of vaccinia immunoglobulin (VIG), used for the treatment of serious adverse reactions to smallpox vaccine and there is a need for other medicinal products which are currently unavailable or in short supply, such as an anti-botulinum immunoglobulin.
55. New, safe, authorised products are needed, particularly for the prophylaxis and treatment of smallpox and for prophylaxis against anthrax and plague. However, vaccine manufacturers have made it clear that they are reluctant to develop new vaccines without strong commercial incentives.
56. The need to respond in an emergency following a bioterrorist attack could lead to demands for the distribution of non-authorised medicines which is currently illegal or the prescription of off-label or non-authorised medicines, which raises liability issues. Advantage has been taken of the opportunity presented by the current review of the EC pharmaceutical legislation to introduce legal amendments in order to remedy this anomaly. These amendments are now being examined by the European Parliament and the Council.
57. For the immediate future, actions are being launched under the health security programme to address the needs for cooperation on medicines that have been identified by the Commission following the advice of the Health Security Committee. These are to investigate the potential of diluting first generation vaccines, to help establish sufficient quantities of vaccinia immunoglobulin (VIG), and to foster the creation of a platform for European collaboration to develop and produce biological products such as botulinum antitoxin, an improved vaccine against anthrax and a safe (third generation) vaccine against smallpox. In addition, developments on the production and availability of smallpox vaccines will be reviewed at regular intervals.

5. RESEARCH

5.1. R&D Expert Group on countering the effects of biological and chemical terrorism

58. Further to the conclusions of the Ghent European Council of 19 October 2001, Research Ministers in the Council of 30 October 2001 endorsed the Commission initiative to establish a R&D Expert Group on countering the effects of biological and chemical terrorism.
59. The R&D Expert Group was formed by representatives from each of the Member States coming from relevant Government Departments: defence, health, research, civil protection and from research establishments. It was charged with looking at the research questions linked to the detection and identification of biological and chemical agents and the prevention and treatment of attacks from such agents.
60. The R&D Expert Group prepared a report comprising an inventory of the research activities undertaken in the Member States on the basis of which several recommendations have been formulated as regards the co-ordination of research activities and the need for further research initiatives. In its working paper (SEC(2002)698) on this report, the Commission presented the main findings and

recommendations of the Group and formulated proposals on the way forward. The Commission continues to provide secretariat support to the R&D Expert Group, namely through a restricted access website which is used as a mechanism for the exchange of information between experts.

5.2. The 6th Framework Programme (FP6)

61. The development of fundamental knowledge and basic tools towards new rapid diagnostics for identifying biological and chemical agents that might be used for terrorist purposes and new vaccines and novel therapeutics against such agents, could be addressed in the priorities “life sciences, genomics and biotechnology for health” and “food quality and safety” under the 6th Framework Programme.
62. Specific research needs related to surveillance, detection, prevention and treatment could also be addressed in the “scientific support to policy” section of the programme where a specific action line has been introduced on “issues related to civil protection (including biosecurity and protection against risks arising from terrorist attacks), and crisis management”. Scientific support is foreseen to enhance surveillance capacity, models and systems, to improve detection methods and disease and risk assessment models, to strengthen networking activities for new vaccines and therapeutics, and to assess vulnerabilities of modern societies.
63. The R&D Expert group will be reconvened in the first half of 2003 to discuss the results of the first FP6 calls for proposals, update the inventory, identify additional research needs which could be addressed through subsequent calls, and extend its membership to accession countries.

6. BUILDING A MULTI-SECTOR RESPONSE

64. Chemical, biological, radiological and nuclear terrorism has direct consequences not only for people, but also for the environment, the food chain and for property. Preventing terrorist acts and mitigating their consequences requires a mobilisation of actors and resources in many sectors other than health. The joint programme adopted by the Council and the Commission on 20 December 2002 reviews the legislative and other measures already in place and spells out future actions to improve the multi-sector response that needs to be mounted against a threat or attack in the EU. Of major importance to health security are the measures and actions in food, animal, plant and water safety.

Food safety

65. The joint Council-Commission programme notes, in this context, that the EC has a broad body of legislation which covers primary production of agricultural products and industrial production of processed food. This legislative body provides different means to respond to situations in specific sectors. The measures that would be taken in response to a terrorist act in the food sector are not fundamentally different from those adopted by the Community in response to accidents in the recent past. There is consequently a sufficiently well developed body of rules for alerts and contingency plans of action (both in health and economic terms) to face up to an epidemic of criminal origin (the only differences between a terrorist act and an accidental epidemic would be the dimension of the initial phase and the number of primary outbreaks). The

various means that have been established in order to guarantee safety throughout the whole food chain have functioned in general well and the ability to respond to crises has been tested in numerous occasions. 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.

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

Animal safety

67. Numerous regulatory measures have been adopted European Union level to keep animal diseases at bay and to combat outbreaks, including Member States contingency plans to ensure a fast and harmonised response to the most serious epidemics. These measures apply whether the origin of an epidemic is accidental or the result of terrorist action. In response to animal health crises, the Commission may also adopt urgent safeguard measures to supplement existing rules. The Commission manages a bank for the storage of about 40 million doses of various antigens of the foot-and-mouth disease virus for the formulation of vaccines that can be rapidly provided to the Member States in case of emergency. The intention is to reinforce the banks of vaccines against foot-and-mouth disease, classical swine and avian influenza. The Member States have also been provided with vaccines against bluetongue. To protect animal health, harmonised rules on intra-Community trade and imports have been defined for almost all animals and their products. Imports are subject to strict controls at the Community borders. As is the case for food safety, 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.

Plant safety

68. The use of plant protection products (including pesticides) on crops are part of the food chain management. Structures specifically intended to prevent the abuse of plant protection products are already in place in the Community (including, for example, a frequent sampling) to prevent or discover unintended contamination. Inspections for presence of harmful organisms are conducted as random checks in the field, as stratified inspections in nurseries as well as at the outer borders of EU. Nurseries are responsible for notifying the local authority if specified harmful organisms are found. Plants intended for planting and specified plant products from third countries must be inspected in the third country, have to fulfil specified phytosanitary requirements and must be accompanied by a phytosanitary certificate to be imported into the EU. Phytosanitary laboratories exist in the Member States in order to provide expert assistance in the identification of plant diseases as well as for regular inspection of certain crops (e.g. potatoes). There is also a system for temporary safeguard measures in the case of an imminent danger of introduction or spread of harmful organisms. A notification scheme operates 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. 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.

Water safety

69. As regards water safety, the joint Council-Commission programme calls on the Member States and the Community to examine whether Directives 80/778/EC and 98/83/EC on the quality of drinking water and Directive 75/440/EC on the quality of surface waters used for drinking water abstraction are sufficiently covering the requirements for constant monitoring of drinking water and other appropriate monitoring and early warning systems, and whether existing expertise on chemicals, air and water can be used in order to detect biological and chemical threats more effectively at an early stage. Multi-barrier systems, the use of appropriate markers at key points and the introduction of and adherence to the HACCP system by suppliers are being promoted in the context of the programme on health security to enhance safety and confidence in early detection of infective agents and toxicants.

7. INTERNATIONAL COOPERATION

7.1. Ottawa initiative

70. Following the meeting of the G7 group of Health Ministers in Ottawa on 7 November 2001 with the participation of the Health Minister of Mexico and Mr. Byrne, a network of high-level officials was designated for the handling of crises at international level. A Global Health Security Action Group was also formed to implement the concerted global action plan agreed at Ottawa. The plan foresees the sharing of information and experience on preparedness and response plans, collaboration of laboratories, development of risk communication and management methods, promotion of mutual assistance in means to counter attacks and training for health staff.
71. The Ministers and Commissioner met for the last time in Mexico City on 6 December 2002. They agreed to hold an exercise in 2003 to evaluate smallpox plans and communications, approved an “incident scale” for the severity of deliberate releases of biological and chemical agents, set up a network of high safety level laboratories and also approved a plan for cooperation on chemical releases. They also agreed to strengthen the smallpox vaccine reserves of the WHO from the existing 600000 to 200 million doses. The Global Health Security Action Group is organising a number of workshops to take forward these actions. The Commission fully participates in these activities and constitutes the link with the corresponding activities at EU level. The next ministerial meeting is planned for 10 October 2003 in Berlin.

7.2. Cooperation with the WHO

72. In addition to the cooperation with the WHO in the framework of the Ottawa Global Health Security Action initiative, the Commission is cooperating bilaterally with WHO on a number of subjects related to countering effects of deliberate release of biological and chemical agents. Important meetings and consultations have been organised by the WHO with direct Commission involvement on key aspects of health sector responses to biological and chemical terrorism. Joint work is focussing on the production of biological products, such as VIG, as well as on chemical agents and global health intelligence.

7.3. Enlargement candidates

73. Following the request of the authorities of the enlargement candidates, information sessions on EU action on bio-terrorism were held during the meeting of the High-level Committee on Health in Madrid on 19-20 March 2001 and the special meeting on enlargement in Luxembourg on 5 July 2002. Further information sessions will be conducted in the future. It is intended to invite the accession countries, as well as the EEA countries, to join the Health Security Committee at its next meeting and participate thereafter in the activities on health security.
74. One of the activities of the Programme of Community action in the field of public health (2003-2008) is to promote exchange of information concerning strategies to counter health threats from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts, and developing or using, when appropriate, Community approaches and mechanisms. Participation by candidate countries in the programme will allow them to benefit in particular from the development of guidelines and manuals related to preparedness and response to biological or chemical agent attacks.

7.4. NATO

75. Following requests from NATO, a number of meetings have been held between officials from the Council and the Commission, on the one hand, and NATO officials, on the other. An exchange of papers ensued on the respective frameworks, published material and current inventories of activities concerning CBRN incidents and this could serve as a basis for further exchange of information and cooperation on deliberate releases. Of particular value in this respect will be NATO guidance and protocols on environmental sampling and assessment concerning such incidents and their update.

8. CONCLUSIONS AND PERSPECTIVES

76. Since the bioterrorist attacks in the US, a series of measures have been taken by the Member States, the EU and internationally to reinforce preparedness for and response to deliberate releases of biological and chemical agents to cause harm. The extent and degree of implementation of measures varies between countries, as do their resources in expertise, materials, equipment and facilities.
77. Of utmost importance in countering bioterrorism is speedy detection of a release and immediate transmission of alert and relevant information to those charged with mounting the appropriate response. Member States are improving their epidemiological surveillance apparatus and their biological and chemical monitoring capabilities and have set up national systems of alert and information transmission. At the European Union level, the Rapid Alert System for biological and chemical attacks and threats was set up to allow prompt transmission of alerts and exchange of information between the Member States and the Commission. The system needs to evolve and expand to be able to capture and interpret public health intelligence and provide advance warning of outbreaks. Routine surveillance will also need to be strengthened and, to this end, the Commission intends to adopt a decision on surveillance of certain bioterror agents in due course.

78. It is essential that Member States are in a position to consult each other and co-ordinate their preparation and responses to the highest degree possible. The European Union has, through the Health Security Committee, a mechanism for consultation and co-ordination that can be called to advise and steer joint actions in case of emergency and provide coherence to counter-measures throughout the Union. It also provides the platform through which emergency plans and modelling are shared and assistance in expertise and other resources can be made available between Member States. A lot more needs to be done on specific plans for certain agents and the Commission is undertaking urgent work to assist Member States in this crucial area.
79. Adequate capacity in public health and health services will be crucial in deciding on counter-measures or switching to different ones. Laboratory capacity is not sufficient in many Member States. It is imperative that Member States share resources and those with advanced facilities assist those without. The Member States and the Commission are working together to bring this about. They are also working together to prepare the health services for emergencies through the issuance of guidelines, the dispatch of expertise and the provision of scientific advice.
80. Shielding people against agents and mitigating the effects of exposure to them requires recourse to suitable medicines. But the European Union's pharmaceutical armamentarium against pathogens and chemicals that can be used in attacks is incomplete and insufficient. Stockpiling at EU level or under the auspices of the EU has been considered, but Member States have shown preference for and are developing national stockpiles only. They are however, keen to undertake action at the European Union level for the development of new biological products such as vaccinia immunoglobulin, anti-toxins and better and safer vaccines.
81. The implementation of the European Union's programme on health security helped to drive action on bioterrorism forward. The programme is implemented by national experts and Commission officials that work together in the ad hoc Task Force on health security under the guidance of the Health Security Committee. From the experience gained so far, it has become apparent that more time is needed fully to accomplish the objectives of the programme and fulfil the Member States' requirements for EU cooperation than was initially foreseen. This would necessitate the continuation of the secondment of national experts and also longer-term investments to ensure that key functions in health security instituted by the Task Force, such as the operation of the rapid alert system, the maintenance of the Health Security Committee consultation and co-ordination mechanism, the updating of plans, models, guidelines and experts' directories and the organisation of training sessions, are properly discharged.

9. ANNEXES

9.1. Annex 1

EMA-CPMP guidance on medicinal products and vaccines

CPMP guidance on medicinal products

82. At the request of the European Commission and the EMA, the Committee for Proprietary Medicinal Products (CPMP) produced a guidance document on the use of medicinal products for treatment and prophylaxis of biological agents, that might be used as weapons of bioterrorism. The first version of the guidance, produced on 16th January 2002, considered those agents in the US Centre for Disease Control's (CDC) list of agents that might be used for the purposes of bioterrorism starting with Category A (smallpox (*Variola major*), anthrax (*Bacillus anthracis*), plague (*Yersinia pestis*), botulism (*Clostridium botulinum* toxin), tularemia (*Francisella tularensis*), viral haemorrhagic fevers (filoviruses e.g. Ebola, Marburg and arenaviruses e.g. Lassa, Machupo)). These high-priority agents pose the most serious risk to health security because they can be easily disseminated or transmitted from person to person, cause high mortality and have the potential for major public health impact, might cause public panic and social disruption and require special action for public health preparedness.
83. On 21 February 2002 and 21 March 2002 the document was extended to cover agents in the other two categories of CDC's list, namely category B agents that are moderately easy to disseminate, can cause moderate morbidity and low mortality and require specific enhancements of diagnostic capacity and enhanced disease surveillance (brucellosis (*Brucella* species), toxins (e.g. Ricin toxin from *Ricinus communis*, Staphylococcus enterotoxin B, Epsilon toxin of *Clostridium perfringens*), glanders (*Burkholderia mallei*), melioidosis (*Burkholderia pseudomallei*), Q fever (*Coxiella burnetii*), psittacosis (*Chlamydia psittaci*), typhus fever (*Rickettsia prowazekii*), food safety threats (*Salmonella* sp, *Escherichia coli* 0157:H7, *Shigella*), water safety threats (e.g. *Vibrio cholerae*, *Cryptosporidium parvum*), viral encephalitis (alphaviruses e.g. Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis)) and, finally category C agents that could be engineered for mass dissemination in the future because of availability, ease of production and dissemination and potential for high morbidity and mortality and major health impact (emerging infectious diseases threats (e.g. hantaviruses and Nipah virus)).
84. On 25 July 2002 the document was extended to include information on nationally authorised vaccines and immunoglobulins for the prevention or post-exposure prophylaxis of some infections.
85. This document is not intended to be a comprehensive guideline on the management of patients and the public health measures that would be necessary in the case of such an attack. It is confined to the possible drugs and regimens that might be useful in the case of an attack with each agent listed. There are differences between Member States in the content of the Summaries of Product Characteristics (SPC) for many of the drugs that have been suggested for treatment and/or prophylaxis. Few of the drugs mentioned are authorised for the treatment and/or prophylaxis of the specific diseases mentioned and the licensing status and the actual availability of some of the drugs suggested varies

between EU Member states. All these factors may well influence drugs that would actually be used in the case of an attack. Moreover some medicines, including anti-toxins, may have to be obtained through special access mechanisms in individual Member States. National prescribing information and guidance regarding each of the medicinal products suggested have to be taken into account and expertise should be consulted first. This guidance document will be updated on a regular basis as appropriate.

Smallpox vaccines

86. **First** generation vaccines were used in WHO's world wide smallpox eradication campaign. They are made according to the standards and techniques of the 1970s, mainly using animal skin as a substrate. They have proven efficacy, but the manufacturing process does not meet current quality requirements for live vaccines in terms of quality control testing and batch release. They are known to have major side effects such as encephalitis, progressive vaccinia and eczema vaccinatum.
87. The EMEA expert group on smallpox vaccines agreed on a number of points in relation to first generation vaccines, including that they could not be authorised according to modern day standards and that additional batches should not be manufactured using the old techniques. However, it was agreed that existing stocks of first generation vaccines could be used in an emergency until second generation vaccines are available and have shown positive clinical study results (safety and immunogenicity).
88. **Second** generation vaccines are manufactured using tissue culture, which results in better reproducibility and better compliance with modern production standards (GMP requirements). They are made from similar strains as used for the first generation vaccines.
89. EMEA published in July 2002 a guidance document¹⁸ for the manufacture and control of second generation vaccines, which sets the standards against which new products will be assessed. A number of second generation vaccines are in development. The EMEA will provide scientific advice on development if requested. The vaccine industry is reluctant however to develop new second generation vaccines without being certain of firm prior orders.
90. The next stage of vaccine development (**third** generation vaccines) aims at reducing side effects by attenuation or genetic engineering (gene deletions) of the vaccinia virus strain.
91. It is expected that recombinant DNA technologies will achieve an efficacious vaccine with an acceptable safety profile. However, it would be 7 to 10 years before an authorised product could be available and, due to the costs of research and development, it is unlikely that a commercial company could be persuaded to develop a biotech vaccine without a firm prior order from Member States or the Community to purchase the finished product.

¹⁸ EMEA/CPMP/1100/02 Note for Guidance on the Development of Vaccinia Virus Based Vaccines against smallpox.

9.2. Annex 2

OVERVIEW OF INFORMATION COLLECTED ON THE CURRENT EU PREPAREDNESS STATUS WITH REGARD TO MEDICINAL PRODUCTS

	Availability	Products in development	Industrial Production Capabilities
Anti-biotics	<p>Suitable authorised antibiotics available for use¹⁹ against most bacteriological pathogens listed in <u>Annex 1</u>, including <i>Bacillus anthracis</i>.</p> <p>Off-label use necessary for many products. No major problems with supplies currently anticipated.</p>	<p>No information provided in context of activity against identified biological threats</p>	<p>Probably sufficient capability to respond to an attack involving different bacterial pathogens, but response time probably not fast enough to meet emergency needs. Very few manufacturers hold significant emergency stocks. Most can step up production, without compromising other operations.</p>
Vaccines	<p>No authorised smallpox, anthrax or plague vaccines available on the EU market</p> <p>Smallpox:</p> <p>Nearly all Member States have stockpiles of unauthorised 1st generation vaccines for use in emergency</p> <p>Anthrax:</p> <p>At least one Member State has a stock of unknown quantity of an authorised vaccine</p>	<p><u>Smallpox</u>: Small number of 2nd generation vaccines in development. 3rd generation vaccines will take another 7 – 10 years</p> <p><u>Anthrax</u>: New vaccine development being considered by some companies and Member State institutes. Collaboration to pool expertise and technology necessary</p> <p><u>Plague</u>: At least 2 Member State institutions are working on a new vaccine</p>	<p>Smallpox:</p> <p>There is potential to produce enough doses of 2nd generation vaccine available for every EU citizen within 12-36 months. However there is no guarantee that the 2nd generation will be safer than and as effective as the 1st generation vaccines. However, they will meet current quality standards for vaccines.</p>

¹⁹

treatment or prophylaxis

Anti-virals	No authorised antivirals available for the agents listed in <u>Annex 1</u>	Ribavirin, cidofovir being investigated for activity against smallpox	
Anti-toxins	Very limited supply of botulic antitoxin. Only one commercial producer now re-launching production; it will then take 18 months before product is available		

9.3. Annex 3

LEGISLATIVE FINANCIAL STATEMENT

Policy area:	PUBLIC HEALTH
Activity:	HEALTH SECURITY

<p>Title of action: COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT ON COOPERATION IN THE EUROPEAN UNION ON PREPAREDNESS AND RESPONSE TO BIOLOGICAL AND CHEMICAL AGENT ATTACKS (HEALTH SECURITY)</p>
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1. BUDGET LINE(S) + HEADING(S)

- a. A-7003 National and international civil servants and private-sector staff temporarily assigned to the institution
- b. A-701 Missions
- c. A-7030 Meetings
- d. A-705 Studies and consultations

2. OVERALL FIGURES

2.1 Total allocation for action

Part A of the Budget: EUR 5 282 904

2.2 Period of application

2003–2008

2.3 Overall multiannual estimate of expenditure

Schedule of commitment appropriations/payment appropriations (financial intervention)(see point 6.1.1)

	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and subs. years	Total
Commitment appropriations							
Payment appropriations							

Technical and administrative assistance and support expenditure (*see point 6.1.2*)

CA							None
PA							None

Subtotal a+b							
CA							
PA							

Overall financial impact of human resources and other administrative expenditure
(see points 7.2 and 7.3)

CA/PA	480 264	960 528	960 528	960 528	960 528	960 528	5 282 904
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TOTAL a+b+c							
CA	480 264	960 528	960 528	960 528	960 528	960 528	5 282 904
PA	480 264	960 528	960 528	960 528	960 528	960 528	5 282 904

2.4 Compatibility with the financial programming and the financial perspective

- Proposal compatible with the existing financial programming
- This proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the Interinstitutional Agreement.

2.5 Financial impact on revenue

- No financial implications (involves technical aspects regarding implementation of a measure)

OR

- Proposal has financial impact – the effect on revenue is as follows:

Note: All details and observations pertaining to the method of calculating the effect on revenue should be included in a separate annex.

EUR million (to the first decimal place)

Budget line	Revenue	Before the action (year n-1)	Situation following action							
			Year n ³	n+1	n+2	n+3	n+4	n+5		
	a) Revenue in absolute terms ¹									
	b) Change in revenue ²	Δ								

(Please specify each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line)

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA participation	Participation applicant countries	Heading financial perspective
Comp/ Non-comp Non-compulsory expenditure	Diff/Non-diff Non-diff. appr.	YES/NO NO	YES/NO YES	YES/NO YES	N° 5

4. LEGAL BASIS

Article 152 of the Treaty

5. DESCRIPTION AND GROUNDS

5.1 Need for Community intervention²⁰

5.1.1 Objectives pursued

(Describe the problem(s)/need(s) (in measurable terms) that the intervention is designed to solve/satisfy (the baseline situation against which later progress can be measured). Describe the objectives in terms of expected outcomes (for example as a change in the above baseline situation.)

The Ministers of Health have noted that, since the events of autumn 2001, there has been a need to intensify cooperation between the Member States and the Commission to strengthen health defences against deliberate releases of biological agents. This Communication reflects the progress made in carrying out the 25 actions which form a coherent health security programme and describes the outlook for continuation of action at Community level in this field. Health security is a major component in the Commission's "stability and security" objective for 2003 et 2004.

The measures pursue the following main goals:

to set 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 in attacks;

to create a EU-wide capability for the timely detection and identification of biological and chemical agents that might be used in attacks and for the rapid and reliable determination and diagnosis of relevant cases, in particular by building on systems already available and aiming at long-term sustainability;

to create a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available in cases of suspected or unfolding attacks;

to draw up rules and disseminate guidance on facing up to attacks from the health point of view and coordinating the EU response and links with third countries and international organisations.

²⁰ For further information see separate guidance paper.

5.1.2. *Measures taken in connection with ex ante evaluation*

(This involves:

explaining how and when the ex ante evaluation was conducted (author, timing and whether the report(s) is/are available) or how the corresponding information was gathered²¹

describing briefly the findings and lessons learnt from the ex ante evaluation.)

5.1.3. *Measures taken following ex post evaluation*

(Where a programme is being renewed, the lessons to be learned from an interim or ex post evaluation should also be described briefly.)

5.2. Actions envisaged and arrangements for budget intervention

(This point should describe the logic behind the proposal. It should specify the main actions to achieve the general objective. Each action should have one or more specific objectives. These should indicate the progress expected over the proposed period. They should also look beyond immediate outputs but be sufficiently precise to allow concrete results to be identified. Specify for each main action:

- the target population(s) (specify number of beneficiaries if possible);*
- the specific objectives set for the programming period (in measurable terms);*
- the concrete measures to be taken to implement the action;*
- the immediate outputs;*
- the expected effects/impact on the achievement of the general objective.*

Information should also be given on the budget intervention arrangements (rate and form of the required financial assistance.)

Provision must be made in the Community budget for payment, during an extension phase (of at least 18 months), of the remuneration of the national experts specifically seconded to the Commission to carry out actions in connection with health security, their expenses for the missions necessary to perform these tasks, reimbursement of the travelling expenses of the members of the Health Security Committee and its working groups and costs of specific studies and consultations connected with health security issues.

5.3. Implementation arrangements

(Specify the methods to be used to implement the planned actions: direct management by the Commission using either regular or outside staff only, or by externalisation. In the latter case, give details of the arrangements envisaged for this

²¹ For the minimum information that must be presented in relation to new initiatives, see document SEC (2000)1051.

externalisation (TAO, agencies, offices, decentralised executive units, management shared with Member States – national, regional and local authorities).

Indicate the effect of the externalisation model chosen on the financial intervention, management and support resources and on human resources (seconded officials, etc.).)

The actions will be carried out by permanent and temporary civil servants, auxiliaries and national experts on detachment.

6. FINANCIAL IMPACT

Implementation of the health security actions has no other financial impact on Part B of the Community Budget.

6.1 Total financial impact on Part B (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1 Financial intervention

Commitments in EUR million (to the third decimal place)

Breakdown	Year n	n + 1	n + 2	n + 3	n+ 4	n + 5 and subs. years	Total
Action 1							
Action 2							
Etc.							
TOTAL							

6.1.2. *Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and subs. years	Total
1) Technical and administrative assistance							
Technical assistance offices:							
b) Other technical and administrative assistance: intra-muros: extra-muros: of which for construction and maintenance of computerised management systems:							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)²²

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)

Commitments in EUR million (to the third decimal place)

Breakdown	Type of outputs (projects, files, etc.)	Number of outputs (total for years 1...n)	Average unit cost	Total cost (total for years 1...n)
	1	2	3	4=(2X3)
Action 1 Measure 1 Measure 2 Action 2 Measure 1 Measure 2 Measure 3 Etc.				
TOTAL COST				

If necessary, explain the method of calculation.

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1 Impact on human resources

Types of post	Staff to be assigned to management of the action, using existing and/or additional resources		Total	Description of tasks deriving from the action
	Number of permanent posts	Number of temporary posts		
Permanent officials or temporary staff	A B C			
Other human resources		8 national experts on detachment		Implementation of actions to strengthen health security cooperation; support for actions to be carried out by the Commission.
Total		8 national experts on detachment		

²² For further information see separate guidance paper.

7.2. Overall financial impact of human resources

Type of human resources	Amounts EUR	Method of calculation *
Officials Temporary staff		
Other human resources National and international civil servants and private-sector staff temporarily assigned to the institution (budget line A-7003)	(8 x 44 316 =) 354 528	Costs incurred by the Commission for secondment of 8 national experts for the specific purpose of promoting health security cooperation: EUR 44 316 per expert per year
Total	354 528	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

None

Budget line (number and heading)	Amounts EUR	Method of calculation
Overall allocation (Title A7) A0701 – Missions A07030 – Meetings	96 000 310 000	EUR 8 000 per month 4 meetings of the Health Security Committee and 2 meetings of each of its 5 working groups per year (25 government representatives per meeting: 15 from the Member States and 10 from the acceding countries)
A07031 – Compulsory committees ⁽¹⁾ A07032 – Non-compulsory committees ⁽¹⁾ A07040 – Conferences A0705 – Studies and consultations ... Other expenditure (please specify)	200 000	Specific studies and consultations on health security: 4 x 50 000
Information systems (A-5001/A-4300)		
Other expenditure - Part A (specify)		
Total	606 000	

The amounts are total expenditure for twelve months.

(1) Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	EUR
II.	Duration of action	Years
III.	Total cost of action (I x II)	EUR

(In the estimate of human and administrative resources required for the action, DGs/Services must take into account the decisions taken by the Commission in its orientation debate and when adopting the preliminary draft budget (PDB). This means that DGs must show that human resources can be covered by the indicative pre-allocation made when the PDB was adopted.

Exceptional cases (i.e. those where the action concerned could not be foreseen when the PDB was being prepared) must be referred to the Commission for a decision on whether and how (by means of an amendment of the indicative pre-allocation, an ad hoc redeployment exercise, a supplementary/amending budget or a letter of amendment to the draft budget) implementation of the proposed action can be accepted.)

8. FOLLOW-UP AND EVALUATION

8.1 Follow-up arrangements

(Adequate follow-up information must be collected, from the start of each action, on the inputs, outputs and results of the intervention. In practice, this involves: (i) fixing indicators for inputs, outputs and results; (ii) establishing data collection methods.)

The actions carried out within the health security programme are intended to achieve concrete results within a precise timetable. The situation at the end of April 2003 is as follows:

Key deliverables and milestones set at the adoption of the programme and added in the light of developments and priorities agreed:

TASKS	Status on 30 April 2003
Biological and chemical agent threats network established and operational	Completed – improvement on-going in a second phase
List - Inventories of agents	Bioagents : Matrix+Australia Group work done Chemicals : in progress
Classification of events and investigation protocols	Classification: completed -Protocols: in progress Planning and modelling: in progress
Lab inventories, requirements and standards	P4 lab network set up-Ring test agreed National Lab network to be set up-questionnaire sent 15.January 2003-results analysed Agreements to be done
Experts' directories and investigation team rules	Questionnaire sent 31 January 2003 Team rules being drawn
Guidelines for health professionals	10 drafts prepared Peer review and publication in progress
Medicine stock inventories	Information collected: table compiled on Member State stocks Vaccine and antibiotics Stockpile question: work completed VIG, smallpox vaccine dilution project on-going Other biologicals work in progress
Health resources and services inventories	Inventory chapters defined Collection of data being coordinated with DG ENV- Agreements for assistance to be done

Rules on circulation of persons, animals and products	Safety of food, animals, plants: review completed and reported Water safety: review completed –follow-up by DG ENV to be done Persons : Review in progress with DG JAI
Guidelines on decontamination and restoration	Work initiated
Training modules	Work initiated
Smallpox emergency plans and modelling	Compilation and comparison completed Modelling priorities and data needs defined
EU Smallpox exercise	Specifications prepared – exercise to take place in 2004
Adverse event monitoring on vaccinations	System of data collection set up and data to be collected
Extension to and integration in the cooperation mechanism and the RAS-BICHAT alert system of accession and EEA countries	Negotiations are being initiated
Patient isolation techniques	Priorities defined and working group to be formed
Installation of a Web-based medical intelligence system for advance warnings and trend analysis	Collaboration has been started with the JRC and links made with existing Commission systems
Review and analysis of incidents involving claims of releases	Pilot project with several Member States has started
Free movement of people and transport rules impacted by bioterror events	Review on-going

8.2. Arrangements and schedule for the planned evaluation

(Describe the planned schedule and arrangements for interim and ex post evaluations to assess whether the intervention has achieved the objectives set. In the case of multiannual programmes, at least one thorough evaluation is needed during the life cycle of the programme. For other activities, ex post or mid-term evaluations should be carried out at intervals not exceeding six years.)

An interim evaluation is planned for May 2003. This will comprise a self-assessment report and two evaluation sessions by an external expert, who must produce recommendations and, if appropriate, a recasting of the current or prospective actions, especially in the light of developments with regard to international priorities and technical progress in the field of health security.

Conduct of the evaluation exercise

- a. Analyse the actions, results achieved, failings, reasons for missing targets (such as changing priorities, new requests or tasks, unforeseen events, imprecise definition of activities, new information, difficulties in collaboration with Member States and other services, lack of sufficient resources or timely deployment of resources etc.).
- b. Revise timetables for actions and deliverables that are propose to be maintained.

- c. Propose new actions if circumstances and events so require, giving reasons, conditions for success and risks, and providing deliverables with associated timetable, milestones and resources that will be required.
- d. Re-formulate more precisely existing actions and revise deliverables, timetables and resources if necessary.
- e. The evaluation should be concluded with the production, if appropriate, of a revised programme of action that respects the resource constraints imposed by the Commission.

9. FRAUD PREVENTION MEASURES

(Article 3(4) of the Financial Regulation: “In order to prevent risk of fraud or irregularity, the Commission shall record in the financial statement any information regarding existing and planned fraud prevention and protection measures.”)