

Countering Bio-threats

EU Instruments for Managing Biological Materials, Technology and Knowledge

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Contents

<i>Preface</i>	<i>iv</i>
<i>Abbreviations and acronyms</i>	<i>v</i>
1. Introduction	1
Figure 1.1. The relationship of the health and security sectors	2
Box 1.1. Measures to prevent or disrupt bio-threats	4
Box 1.2. Measures to prepare for or respond to bio-threats	5
2. EU internal actions: prevention, preparedness and response	7
Managing threats to health and security	7
The EU public health programme	11
The European Centre for Disease Prevention and Control	16
Civil protection: preparedness and response	19
Using developments in research and technology to counter biological and chemical terrorism	21
Combating terrorism and bioterrorism	23
Research, technological developments and ethics	23
Box 2.1. The objectives of the Health Security Programme	10
3. EU external actions: limitations and possibilities	30
Non-proliferation activities in Russia and the other former Soviet states	31
Other EU biological non-proliferation activities	31
The international dimension of health cooperation	34
4. Assessing current efforts to manage the threat of biological proliferation	37
About the author	39

Preface

Efforts to counter threats posed by non-state actors, including bioterrorism, have led to the recognition that public health professionals need to become more aware of and sensitive to counterterrorism concerns. As new and more effective instruments are sought to prevent biological proliferation threats, it is likely to become increasingly difficult to draw a sharp line between actions needed in the public health and security sectors. This lesson was reflected in the 2003 European Union (EU) Strategy against Proliferation of Weapons of Mass Destruction, which recognized that a wider range of more integrated countermeasures are needed. These range from preparedness and response to preventive and disruptive measures against specific threats and their development and implementation. Implementing a number of the measures requires the participation of the European Commission and demands effective cooperation in and between several Commission directorates as well as cooperation between the different parts of the EU.

This paper draws on research that was carried out as part of a pilot project conducted by SIPRI to investigate how the common instruments of the EU can support and reinforce actions taken by individual European governments (acting on their own or through intergovernmental cooperation) against the proliferation of nuclear, biological and chemical (NBC) weapons. That project investigated what could be done outside the EU to reduce the danger of NBC weapon proliferation. This paper mainly examines internal measures to protect Europeans from health threats caused by the deliberate use of disease.

The author, Frida Kuhlau, in 2006 carried out a survey of the Community role in the different projects, programmes and initiatives that are under way in the EU to reduce the security risks from microorganisms and toxins. The complex picture that emerges shows the changes that are taking place as various actors—some old, some new—are combining in untried and innovative ways to develop and implement common solutions to security problems very different from those that Europeans are accustomed to facing. Kuhlau suggests that the EU has not yet found a satisfactory framework for managing bio-security risks, and that further work on prevention should be a particular priority.

SIPRI will continue to work on these issues in the next few years through case studies of how specific facilities and biomedical research complexes are trying to build more effective bio-security without prejudicing the efficiency of their core task of strengthening public health. SIPRI takes this opportunity to thank Frida Kuhlau for the work that she has done to provide the Institute with such a solid platform on which to build this future work. My thanks also go to Jetta Gilligan Borg for the editing.

Alyson J. K. Bailes
Director, SIPRI
June 2007

Abbreviations and acronyms

AG	Australia Group
AIDS	Acquired Immune Deficiency Syndrome
BTWC	Biological and Toxin Weapons Convention
CBRN	Chemical, biological, radiological and nuclear
CFSP	Common Foreign and Security Policy
DG	Directorate-general
ECDC	European Centre for Disease Prevention and Control
EGE	European Group on Ethics in Science and New Technologies
EMEA	European Medicines Agency
ERA	European Research Area
ESDP	European Security and Defence Policy
EU	European Union
EWRS	Early-warning and response system
FP6	Sixth Framework Programme for Research and Technological Development
FP7	Seventh Framework Programme for Research and Technological Development
GAERC	General Affairs and External Relations Council
GHSAG	Global Health Security Action Group
GHSI	Global Health Security Initiative
HSC	Health Security Committee
INCO	Specific International Scientific Cooperation Activities
INTAS	International Association for the Promotion of Co-operation with Scientists from the New Independent States of the Former Soviet Union
ISTC	International Science and Technology Center
JLS	Justice, Freedom and Security (Justice, liberté et sécurité) Directorate-General
JRC	Joint Research Centre
MIC	Monitoring and Information Centre
NBC	Nuclear, biological and chemical
PASR	Preparatory action on the enhancement of the European industrial potential in the field of security research

PCR	Polymerase chain reaction
RAS-BICHAT	Rapid Alert System for Biological and Chemical Attacks and Threats
R&D	Research and development
RELEX	External Relations Directorate-General
SANCO	Health and Consumer Protection Directorate-General
STCU	Science and Technology Center in Ukraine
WHO	World Health Organization
WMD	Weapon(s) of mass destruction

1. Introduction

The urgency of fighting terrorism has been heightened by the 11 September 2001 attacks on the United States and subsequent attacks around the world. The use of anthrax to attack targets in the USA in September–November 2001, reinforced the need to include various potential biological threats—such as the deliberate use of disease as a weapon—on the anti-terrorism agenda. This paper identifies the instruments available to the European Community and examines how they are employed as part of the wider effort to reduce the potential threat posed by biological agents.¹ However, it is important to recognize that these instruments and their use are only one aspect of European Union (EU) activity towards that end and that Community actions are set within the wider EU context.

In the months after the attacks on the USA, European leaders asked the Council of the European Union and the European Commission to prepare a programme to enhance Europe's security in the face of the terrorist threat.² Instructions from the leaders to meetings of the European Council and the Commission had already stressed combating chemical and biological terrorism. The Commission also proposed concentrating on issues such as public health, civil protection and research, and these were incorporated into the subsequent programme.³ The heightened perception of threat from international terrorism led several European Commission directorates-general (DGs) to focus internal activities on bioterrorism, with an emphasis on preparedness and response. Such activities are discussed in chapter 2. On the relationship between the health and security sectors see figure 1.1.

By the end of 2002 a programme of action had been adopted to improve cooperation between the member states on the evaluation of risk, the organization of early

¹ The term 'European Community' refers to the mandate of the EU's 'first pillar', i.e. policies proposed on the basis of the 1957 Treaty Establishing the European Community (Treaty of Rome, as amended by the 1997 Treaty of Amsterdam) that are set in a binding legal framework and typically involve significant powers for the European Commission (and the European Parliament). The text of the current version of the Treaty of Rome is available at URL <http://europa.eu.int/eur-lex/en/treaties/dat/EC_consol.html>. The European Community should be distinguished from the European Commission, although both are often abbreviated EC. The Commission is the executive institution that administrates and implements the EU's collective policies and decisions. The EU's first pillar refers to trade and common market activities; the second pillar to the Common Foreign and Security Policy (of which the European Security and Defence Policy is a major element); and the third pillar to Justice and Home Affairs cooperation.

² These decisions were taken at European Council meetings in Ghent (19 Oct. 2001) and Laeken (14–15 Dec. 2001). They are discussed further in chapter 2 in this paper.

³ See, in particular, European Commission, 'Communication from the Commission to the Council and the European Parliament, Civil protection: progress made in implementing the programme for preparedness for possible emergencies', COM(2002) 302 final, Brussels, 11 June 2002. Many European Commission documents are available at URL <<http://ec.europa.eu/transparency/regdoc/registre.cfm?CL=en>>.

2 COUNTERING BIO-THREATS: EU INSTRUMENTS

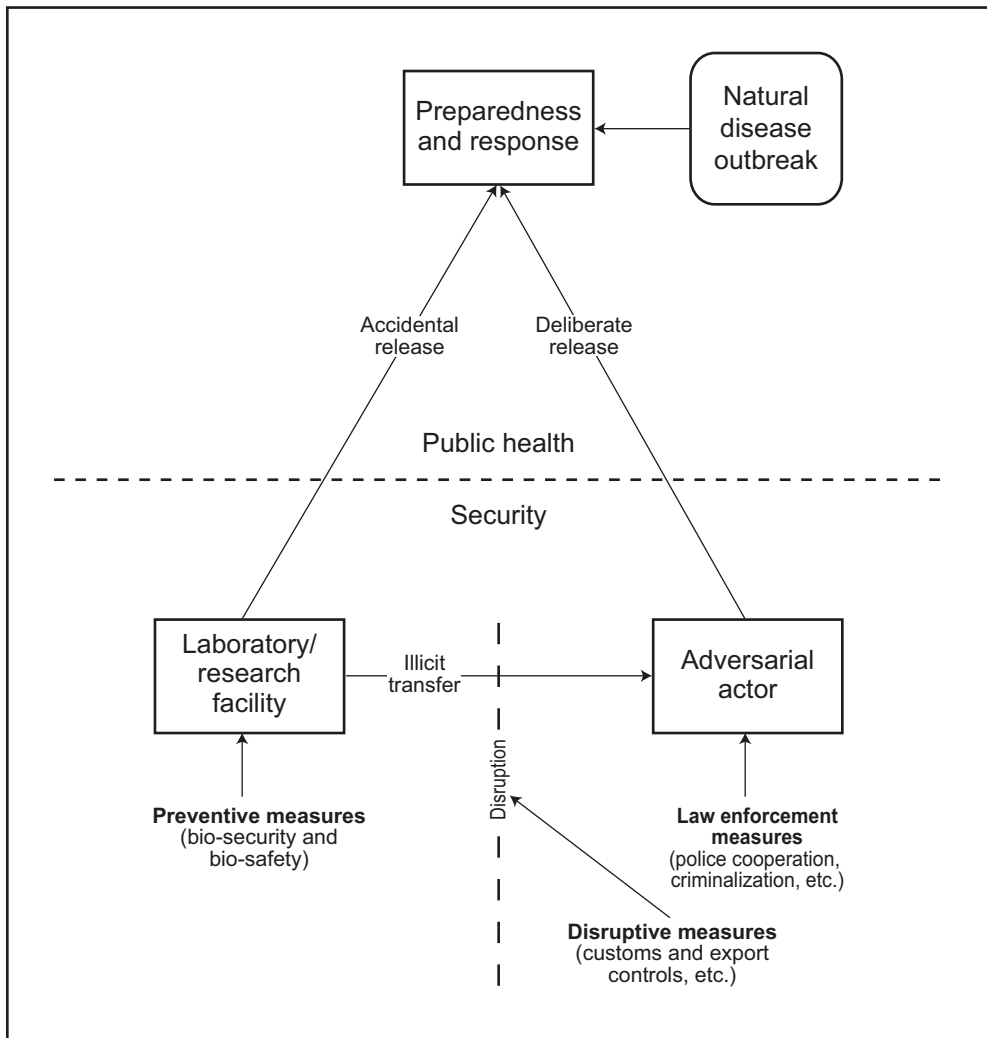


Figure 1.1. The relationship of the health and security sectors

warning and response, and on research covering infectious and toxic agents.⁴ After the terrorist attacks in Madrid on 11 March 2004, EU leaders issued a ‘declaration on combating terrorism’, and it was quickly followed by additional measures contained in an ‘EU plan of action on combating terrorism’ that was adopted in June 2004 and revised in June 2005.⁵ Reports on the progress of implementation

⁴ Council of the European Union, ‘Adoption of the programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats’, document 14627/02, Brussels, 21 Nov. 2002. Many Council of the European Union documents are available at URL <http://www.consilium.europa.eu/cms3_fo/showPage.asp?id=254&lang=EN>.

⁵ European Council, ‘Declaration on combating terrorism’, Brussels, 25 Mar. 2004, URL <http://ue.eu.int/ueDocs/cms_Data/docs/pressdata/en/ec/79637.pdf>; Council of the European Union, ‘EU

are made every six months.⁶ The plan of action includes a number of elements that are carried out in the framework of the first pillar.

In December 2005 a comprehensive EU Counter-Terrorism Strategy was approved that defines the fight against terrorism as being primarily the responsibility of the member states but that also demands close cooperation between the Council, the Commission and the European Parliament.⁷ It covers four areas: prevention, protection, disruption and response. An accompanying action plan divides the work of implementing the strategy between actors such as the Council, the Commission, the Parliament, the European Police Office (Europol), the United Nations Counter-Terrorism Committee and the member states. The strategy addresses: (a) border protection, (b) increased transport security (within and outside the EU), (c) international cooperation with partners and international organizations on the non-proliferation of chemical, biological, radiological and nuclear (CBRN) materials, (d) technical assistance on protective security to prioritized third parties as a component of wider technical assistance programmes, (e) disruption of terrorist activity, (f) pursuit of terrorists across borders, and (g) response to attacks. The response to an emergency situation will often be the same regardless of whether the emergency is of natural or deliberate origin.

Measures have also been developed through traditional non-proliferation and disarmament mechanisms. The European Security Strategy, 'A Secure Europe in a Better World' and, particularly, the EU Strategy against Proliferation of Weapons of Mass Destruction (WMD), both adopted in December 2003, demonstrated a serious will to create and maintain a united European front to combat the threats of proliferation and mass impact terrorism.⁸ Issues such as non-proliferation and disarmament have been added to the EU agenda recently as integral elements of the Common Foreign and Security Policy (CFSP) and through the new policy debates following from the December 1999 European Security and Defence Policy (ESDP). After the Madrid terrorist attacks, European leaders agreed that EU external relations should focus on countries where counterterrorist capacity needs to be enhanced and, to that end, combating terrorism was declared to be an

plan of action on combating terrorism', Brussels, 15 June 2004, document 10586/04; and Council of the European Union, 'Brussels European Council 16 and 17 June 2005: Presidency conclusions', document 10255/1/15 REV. 1, Brussels, 15 July 2005, <http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/ec/85349.pdf>.

⁶ Council of the European Union, 'Implementation of the action plan to combat terrorism', document 15704/05, Brussels, 12 Dec. 2005.

⁷ Council of the European Union, 'The European Union Counter-Terrorism Strategy', Justice and Home Affairs Council meeting, Brussels, 1 Dec. 2005, URL <http://ec.europa.eu/justice_home/fsj/terrorism/strategies/fsj_terrorism_strategies_counter_en.htm>.

⁸ Council of the European Union, 'Fight against the proliferation of weapons of mass destruction: EU Strategy against Proliferation of Weapons of Mass Destruction', document 15656/03, Brussels, 10 Dec. 2003, URL <<http://ue.eu.int/uedocs/cmsUpload/st15708.en03.pdf>>. See also Bailes, A. J. K., *The European Security Strategy: An Evolutionary History*, SIPRI Policy Paper no. 10 (SIPRI: Stockholm, Feb. 2005), URL <<http://books.sipri.org>>.

4 COUNTERING BIO-THREATS: EU INSTRUMENTS

Box 1.1. Measures to prevent or disrupt bio-threats

Adopt bio-safety measures: good laboratory practices, good manufacturing practices, etc.

Use adequate physical security measures: facility security, surveillance cameras, etc.

Redirect former weapon scientists to other work

Control, conduct background checks on and register personnel, pathogens and research in entities; and employ appropriate organizational routines

Control and conduct background checks on counterparts and visiting researchers, and employ appropriate organizational routines

Inform scientists, practitioners and students about the potential security implications (including bio-ethics) of their research and products

Educate personnel about security standards and guidelines

Require licences for the transfer of certain pathogens (i.e. export control of dual-use products)

Develop better tools for customs and licensing officers so that they can detect illicit traffic of prohibited materials

Issue certificates to individuals and entities for the handling of certain pathogens

Ensure transport security

Criminalize breaches of certificate and licence agreements and hold individuals and entities accountable

Foster police cooperation in the European Union and police and intelligence cooperation with industry and companies

objective of external assistance programmes.⁹ In November 2006 the Council decided that the Community should provide technical and financial assistance in pursuit of, among other things, risk mitigation and preparedness relating to CBRN materials or agents.¹⁰

Recent actions have demonstrated that biological threats can be managed by using a spectrum of preventive, preparatory and responsive measures (see boxes 1.1 and 1.2).¹¹ However, it is complicated to develop and implement such

⁹ This was spelled out in the Mar. 2004 'Declaration on combating terrorism' (note 5).

¹⁰ 'Regulation (EC) no. 1717/2006 of the European Parliament and of the Council of 15 November 2006 establishing an Instrument for Stability', *Official Journal of the European Union*, L327 (24 Nov. 2006), pp. 1–11.

¹¹ In Russia and the other former Soviet states cooperative programmes aim to prevent the proliferation of biological materials, technology and expertise through non-proliferation activities with facilities and individuals that possess expertise relevant to biological weapons or are believed to have been used to support the former Soviet offensive biological weapon programme. E.g. the US Department of Defense programme of Biological Weapons Proliferation Prevention in Russia focuses on the conversion of former weapon facilities and the destruction of infrastructure. International activities are also carried out to counter bioterrorism and to prevent terrorist groups from acquiring biological capabilities. For an overview of such activities worldwide see Kuhlau, F., 'Overview of ongoing international activities aimed towards preventing proliferation of biological technology, material and expertise that may be used for hostile purposes', Annex to Roffey, R., 'From bio threat reduction to

Box 1.2. Measures to prepare for or respond to bio-threats

Use early-warning and response systems to limit damage and provide adequate control, including the provision of preparedness information to medical units, veterinaries, etc.

Establish efficient and coordinated surveillance systems within and outside the European Union

Create civil protection preparedness and response systems

Ensure rapid and timely coordination of communications mechanisms, such as clear channels for communication via fax, email, telephone, and the like

Establish guidelines to enable clinical doctors to rapidly identify agents that have possible bioterrorism application

Set up preparedness and contingency plans, and make risk assessments

Build up sufficient stocks of vaccines and pharmaceuticals

Develop diagnostic capabilities, including reference laboratories, to identify and verify agents

Provide information to 'first responders' on identifying and reporting unusual outbreaks of disease

Develop appropriate detection equipment

measures because they overlap with public health concerns and because biological materials, technology and knowledge have primarily civil applications and peaceful uses. Effective work in the public health sector increasingly emphasizes international collaboration, but the public health community in the countries concerned may be reluctant to become involved in any 'securitization' (involvement of the security sector) of its work.

Security measures should be designed to complement the efforts to strengthen global public health or, at least, not to obstruct such efforts. Enhancing bio-security (i.e. improving security at facilities where such work is carried out in order to preclude unauthorized access to agents, materials and knowledge) and increasing oversight and control over proliferation-sensitive items and processes require close cooperation between the security and public health sectors. For example, the importance of cooperation in the areas of bio-security and bio-safety (enhancing safety when working with pathogens) has been recognized in the context of emerging diseases, such as avian influenza.¹² This has facilitated discussion

cooperation in biological proliferation prevention', background paper 4, Papers presented at the Conference on Strengthening European Action on WMD Non-proliferation and Disarmament: How Can Community Instruments Contribute?, Brussels, 7–8 Dec. 2005, URL <<http://www.sipri.org/contents/expcon/euppconfmaterials.html>>.

¹² 'An emerging infectious disease is either a newly recognised, clinically distinct infectious disease, or a known disease whose reported incidence within the past two decades is increasing in a given place or among a specific population.' British Health Protection Agency, *CDR Weekly: The Communicable Disease Report Weekly*, vol. 15, no. 6 (10 Feb. 2005), URL <<http://www.hpa.org.uk/cdr/archives/2005/cdr0605.pdf>>.

6 COUNTERING BIO-THREATS: EU INSTRUMENTS

between the EU and Russia of the long-term implications of emerging diseases and of the implementation of public health measures.

Efforts are concentrated on controlling threats such as those posed by scientists assisting terrorist or extremist groups, or using their knowledge for terrorist purposes. However, accidents in which infection or exposure result from research conducted in an unsafe manner or from inadequate measures against theft and unauthorized access outnumber deliberate incidents of infection or exposure.¹³ Paradoxically, although they present a greater risk to public health, such threats are discussed far less. A well-functioning, proliferation-resistant security system ought to include not only the physical security of buildings, but also all the measures necessary to raise awareness of the importance of keeping knowledge, technology and dangerous pathogens or toxins from falling into the wrong hands. Such measures should include the registration of personnel, background checks, systems of authorization for work on pathogens, licensing the trade or exchange of material and information with counterparts, and so on. If security measures fail, preparedness and response measures are important, and they must be established in any event because of threats from naturally occurring diseases. An essential element of preparedness is a system of epidemiological surveillance that can respond rapidly and operate at all levels of a state. Such a system is crucial to enable the early detection of releases of biological agents. Directly connected to this requirement is the ability to quickly identify potential disease-causing pathogens using rapid, reliable, standardized and internationally accepted diagnostic methods that enable confirmation of suspected cases of infectious disease outbreaks and characterization of the agent involved.¹⁴ Enforceable national legislation to criminalize breaches of agreed security standards, regulations that cover the relevant areas and export controls are also essential to disrupt and deter the initial process of proliferation.

In 2005 the Stockholm International Peace Research Institute examined activities in international non-proliferation and disarmament assistance carried out under EU auspices, including in the biological field. That study, which was financed by a pilot project proposed by the European Parliament and the Council of the European Union, found that the EU provides minimal funding to strengthen bio-security outside the European area and that there was, at that time, no harmonized approach or plan on how to move forward on these issues.¹⁵ This paper complements that survey by examining and evaluating activities that are carried out in the first pillar of the EU and that directly or indirectly contribute to reinforcing and managing non-proliferation in the biological field with a particular focus on Europe.

¹³ European Commission, Research Directorate-General, Directorate E: Biotechnologies, Agriculture and Food, 'Ethical implications of scientific research on bioweapons and prevention of bioterrorism', Conference report, Brussels 3–4 Feb. 2004, URL <http://europa.eu.int/comm/research/biosociety/pdf/proceedings_bioterrorism.pdf>, p. 19.

¹⁴ Roffey, R. and Kuhlau, F., 'Enhancing bio-security: the need for a global strategy', *SIPRI Yearbook 2006: Armaments, Disarmament and International Security* (Oxford University Press: Oxford, 2006), pp. 732–48.

¹⁵ See Kuhlau (note 11); and Roffey (note 11).

2. EU internal actions: prevention, preparedness and response

At an October 2001 meeting in Ghent the European heads of state and government asked the Council and the Commission ‘to prepare a programme to improve cooperation between the Member States on the evaluation of risks, alerts and intervention, the storage of such means, and in the field of research. The programme should cover the detection and identification of infectious and toxic agents as well as the prevention and treatment of chemical and biological attacks’.¹⁶ The Commission brought together various services and networks that are responsible for health protection, civil protection and research expertise to create a common platform for coordinating the EU response to all types of emergency.¹⁷ It also adopted two communications, the second of which sums up the main progress made (in terms of development and implementation) between the mechanism to facilitate cooperation in civil protection assistance interventions (the civil protection mechanism, discussed below) and the network for epidemiological surveillance and control of communicable diseases.¹⁸

Managing threats to health and security

The EU has worked to strengthen cooperation to combat infectious disease outbreaks in Europe and elsewhere. A disease outbreak can be more easily detected and contained—whether it is of natural origin or deliberately induced—through improvement of the public health system, including disease control and surveillance (human and veterinary), communications networks, diagnostic capabilities, early-warning systems, accessible medical care, medical training and vaccine programmes. Individuals cross the borders into and out of Europe every day. Managing the threats posed by communicable diseases therefore demands broad cooperation between the member states and the EU; with other organizations that are competent in the sphere of public health, such as the World Health Organization (WHO); and with other affected parties.¹⁹

¹⁶ European Council, ‘Declaration by the Heads of State or Government of the European Union and the President of the Commission: follow-up to the September 11 attacks and the fight against terrorism’, document SN 4296/2/01 REV 2, Brussels, 19 Oct. 2001, p. 5, URL <http://www.euoffice.metu.edu.tr/european_council_decisions.htm>.

¹⁷ European Commission (note 3), p. 2.

¹⁸ Council of the European Union (note 4), p. 5. See also European Commission, Health and Consumer Protection Directorate-General, ‘Communicable diseases’, URL <http://ec.europa.eu/health/ph_threats/com/comm_diseases_en.htm>.

¹⁹ ‘Decision no. 1786/2002/EC of the European Parliament and of the Council of 23 Sep. 2002 adopting a programme of Community action in the field of public health (2003–2008)—Commission Statements’, *Official Journal of the European Communities*, L271 (9 Oct. 2002), pp. 1–12, Article 1.

In the EU, among other things, the Commission's Health and Consumer Protection Directorate-General (SANCO) is mandated to coordinate EU efforts to defend against infectious diseases. However, other DGs also perform public health-related work, including those for Research and for Enterprise and Industry.

The Communicable Diseases Network and early warning

In order to meet threats to public health, since 1999 the Commission has maintained the Communicable Diseases Network, which is based on ad hoc cooperation between the EU member states.²⁰ A basic problem in the field of health protection is that bioterrorism threats are invisible. Health professionals are usually the first to recognize such threats and are in the front line when dealing with the consequences. Well-structured and well-integrated preparedness plans are therefore needed.²¹ The Communicable Diseases Network carries out its work together with the member states and consists of two pillars: surveillance and early warning.²² The surveillance systems provide information for early detection of potential outbreaks and assist in the identification of disease trends, risk factors and the need for intervention. The network was set up to detect and control communicable disease in humans regardless of the cause and manner of transmission, and its principal aim is to prevent further transmission of such disease.²³ The second pillar comprises an early-warning and response system (EWRS) to notify public health authorities in the member states and the Commission of outbreaks that have spread beyond one state. Any event that could lead to an outbreak of EU-wide significance should be reported to the EWRS whether or not a disease-specific network has been set up at the EU level, and the Commission and the member states then would agree on appropriate action. The EWRS links designated authorities in the member states and the Commission and allows for immediate exchange of views on risk assessment and management, which is crucial for timely action.²⁴ In order to increase the harmonization of the data submitted by the member states, a 2002 decision provided guidelines for reporting communicable diseases to the network.²⁵

²⁰ 'Decision no. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community', *Official Journal of the European Communities*, L268 (3 Oct. 1998), pp. 1–6.

²¹ European Commission, 'Communication from the Commission to the Council and the European Parliament, Civil protection: state of preventive alert against possible emergencies', COM(2001) 707 final, Brussels, 28 Nov. 2001, p. 5. This communication launched a series of coordinated actions across the civil protection, health, enterprise (pharmaceuticals), research, nuclear and transport and energy fields.

²² 'Decision no. 2119/98/EC of the European Parliament and of the Council' (note 20).

²³ European Commission, Health and Consumer Protection Directorate-General, 'Surveillance', URL <http://europa.eu.int/comm/health/ph_threats/com/surveillance_en.htm>.

²⁴ European Commission, Health and Consumer Protection Directorate-General, 'Early warning', URL <http://europa.eu.int/comm/health/ph_threats/com/early_warning_en.htm>.

²⁵ 'Commission Decision of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision no. 2119/98/EC of the European Parlia-

Preventing bioterrorism

SANCO created a series of networks (e.g. the EWRS) and a rapid alert system to help ensure a timely, coordinated and effective reaction to a terrorist attack. On the bases of the decisions taken at the October 2001 Ghent Council it was decided that the detection and identification of infectious and toxic agents as well as the prevention and management of the consequences of chemical and biological agent attacks were a high priority.²⁶ At the state level, the member states re-examined their preparedness plans and adapted them to the new threats. At the European level, on the initiative of SANCO, the Health Security Committee (HSC) was set up with representatives from the ministries of health of each member state. On 17 December 2001 the HSC agreed the Health Security Programme for cooperation on preparedness and response to attacks involving biological and chemical agents.²⁷ Its biological and chemical agent attack (BICHAT) programme began operation in May 2002 with an initial time frame for its work of 18 months.²⁸

The Health Security Programme (see box 2.1) comprises 25 actions grouped under four objectives: (a) to set up a mechanism for information exchange, (b) to develop the capability to detect and identify biological and chemical agents that pose a potential threat, (c) to establish stocks of medicine, a health services database and a standby facility for making medicines and health care specialists available as needed, and (d) to draw up rules, provide guidance and coordinate the EU response and links with third parties. The first objective includes the consultation and coordination of the health-related response in the event of an attack in which biological and chemical agents might be or have been used.²⁹ The projects and activities under the Health Security Programme are financed by existing funds, in particular the budget for the EU public health programmes. Other

ment and of the Council (notified under document number C(2002) 1043)', *Official Journal of the European Communities*, L86 (3 Apr. 2002), pp. 44–62.

²⁶ European Commission, '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)', COM(2003) 320 final, Brussels, 2003, pp. 1–10, URL <<http://www.sussex.ac.uk/Units/spru/hsp/2003-0602 Health Security.pdf>>.

²⁷ Tegnell, A. et al., 'The European Commission's Task Force On Bioterrorism', *Emerging Infectious Diseases*, vol. 9, no. 10 (Oct. 2003), URL <<http://www.cdc.gov/ncidod/EID/vol9no10/03-0368.htm>>.

²⁸ The rapid alert system partners in the Commission are SANCO programmes such as the Early Warning and Response System on Communicable Diseases (EWRS G/4), the Rapid Alert System for Food and Feed (RASFF D/3), the Animal Disease Notification System (ADNS E/2), the Phytosanitary Network: Organisms Harmful to Plants (EUROPHYT F/4) programme, the Rapid Information among MS and COM on Measures by Authorities and/or Producers/Distributors (RAPEX B/3) programme, the Health Controls of Imports of Veterinary Concern (ANIMO/SHIFTE/3) programme, the Environment Directorate-General's Monitoring and Information Centre of the Civil Protection Network (MIC B/4) and the RELEX DG Crisis Management Crisis Room. See Gouvras, G., 'Bioterrorism: the scourge of the 21st century?', 30 Oct. 2002, URL <http://ec.europa.eu/comm/health/ph_threats/Bioterrorisme/speech_bioterrorisme_en.htm>. On BICHAT see European Commission (note 26), p. 8.

²⁹ European Commission (note 24).

Box 2.1. The objectives of the Health Security Programme

1. An EU coordinating mechanism would be set up. A Health Security Committee (HSC) at EU level would meet regularly and, together with the Commission, would be on standby status to address and coordinate the public health response in the event of attacks using biological and chemical agents. The HSC would exchange information on preparedness and response plans and consider all aspects of public health preparedness for emergencies related to such attacks. It would also help to implement at member state level the arrangements and strategies agreed at EU level. Secure and effective links would be established to the networks for civil protection information exchange, radiological emergencies alert and food alert.
2. Action would be taken to enable the rapid detection and identification of agents and disease. A list of biological and chemical agents that are likely to be used in attacks or threats of attack would be maintained (and updated) to permit detection, identification, diagnosis and the setting up of inventories of such agents in the member states. Agreed guidelines would also be established for surveillance of such agents and for notification of their production, movement and processing.
3. An inventory of medicines and services and their use would be made as well as an evaluation of existing stocks and production capacities of preventive, prophylactic and therapeutic medicines for the identified agents. The inventory and evaluation would include the elaboration of strategies and instruments for the development of such medicines in sufficient quantity and at acceptable cost and effectiveness. An evaluation would be made of safety, the capacity of each member state to treat cases and the ability of each member state to provide assistance to other member states.
4. EU rules and guidelines would be elaborated and disseminated, and international links would be established. Health authorities and health professionals would be given advice and references to sources or standby facilities: for authoritative advice and guidance with respect to reporting, for preventing the spread of disease, for treating cases, and for dealing with persons affected or likely be affected in attacks.

Sources: Gouvras, G., 'Bioterrorism: the scourge of the 21st century?', 30 Oct. 2002, URL <http://ec.europa.eu/comm/health/ph_threats/Bioterrorisme/speech_bioterrorisme_en.htm>; and European Commission, Health and Consumer Protection Directorate-General, 'Programme of cooperation on preparedness and response to biological and chemical agent attacks (health security)', Luxembourg, 17 Dec. 2001, URL <http://forum.europa.eu.int/Public/irc/sanco/bichahsbio/library?l=/cooperation_preparedness_2/cooperation_preparedness/_EN_1.0_&a=d>.

funds, such as those provided under the EU's 2002–2006 Sixth Framework Programme for Research and Technological Development (FP6), could also be used for relevant activities.³⁰

On 1 May 2002 SANCO established the Task Force on Bio-terrorism to coordinate activities between member states and to carry out the technical work of setting up the necessary security mechanisms as defined in the Health Security Pro-

³⁰ Tegnell et al. (note 27). FP6 is a collection of the EU-level actions to fund and promote research.

gramme. The task force consists of six Commission officials and nine experts from different member states. It addresses a broad range of issues related to preparedness for and response to bioterrorist events and seeks greater collaboration between the EU and the member states.³¹

The EU public health programme

The Health Security Committee developed a mechanism to exchange and share information, created partnerships and established working groups on laboratories, biological products, chemicals, clinical guidelines, emergency plans and computer modelling of the medical consequences of the transmission and spread of infectious diseases. A related mechanism responsible for the notification of incidents involving the deliberate or threatened release of biological and chemical agents began operation in June 2002. The Rapid Alert System for Biological and Chemical Attacks and Threats (RAS-BICHAT) connects the members of the HSC and the contact points designated by its members to provide round-the-clock assistance in an emergency. It is linked to and complements the efforts of the EWRS to prevent and control communicable diseases,³² and it is also linked to the civil protection mechanism (discussed below).³³ Effective ties have been established with other health protection-related EU rapid alert systems (including those related to animals, food and plants), and the RAS-BICHAT is also connected with Commission systems that scan and summarize the information available through news agencies, the media, the Internet and the like.³⁴ All of the authorities that have been designated as contact points by the EU member states are connected through this network by email, fax and telephone. Work has continued to secure the network against technological risks and security breaches.

The detection of deliberate releases of biological agents relies primarily on the member states' surveillance systems for monitoring the occurrence of infectious diseases. New diagnostic tools for the rapid detection of such agents are being developed and are crucial to effective response.³⁵ No single state has complete preparedness or diagnostic capabilities and, in order to improve these elements collectively and make efficient use of available resources, the existing laboratory capacities are under review with the aim of making them available to all EU member states. Collaboration between laboratories has also been initiated to share

³¹ European Commission, Health and Consumer Protection Directorate-General, 'Public health: bioterrorism', URL <http://europa.eu.int/comm/health/ph_threats/Bioterrorisme/bioterrorisme_en.htm>.

³² 'Commission Decision of 22 December 1999 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 Council', *Official Journal of the European Communities*, L21 (26 Jan. 2000), pp. 32–35; and 'Decision no. 2119/98/EC of the European Parliament and of the Council' (note 20).

³³ 'Council Decision of 23 October 2001 establishing a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions (2001/792/EC, Euratom)', *Official Journal of the European Communities*, L297 (15 Nov. 2001), pp. 7–11.

³⁴ European Commission (note 26), p. 9.

³⁵ European Commission (note 26), p. 9.

techniques and to enable laboratories to participate in common quality-assurance schemes. A network to enhance research activities through common projects has also received help from the RAS-BICHAT.³⁶ Coordination of surveillance systems at the EU level is conducted under the surveillance and control of the communicable diseases framework. In the EU there are six bio-safety level 4 laboratories (laboratories equipped to study the most dangerous viruses) that are able to handle samples and specimens of high-risk agents and determine their nature. These laboratories are located in four states: one in France, two in Germany, one in Sweden and two in the United Kingdom. Additional such laboratories are expected to be set up. A network has also been formed between the laboratories to provide quality-assured diagnostic services to all member states.³⁷

In order to increase stocks of vaccines, discussions have been held between the Commission and the pharmaceutical industry about its capacity to produce vaccines, antibiotics and serums for human and animal use. As a first step the Commission established a task force with the industry to examine this issue and, in particular, to create an inventory of the availability and capacity of production, stockpiles and distribution of the serums, vaccines and antibiotics that are likely to be used in countering any biological attack.³⁸ Authorities from the member states have examined the availability of pharmaceutical products in the context of biological threats and, in cooperation with the European Medicines Agency (EMA), a list of possible pathogens and treatments has been drawn up.³⁹ On the basis of that list each member state has been asked to provide updated information to the Commission on the actions that it has taken.⁴⁰ The EU continues to examine the possible options for creating strategic stockpiles of vaccines, serums and antibiotics at the EU level. In cooperation with the European pharmaceutical industry, SANCO and the Enterprise and Industry DG will evaluate the availability and development of effective vaccines to combat communicable diseases that might be caused by a deliberate attack.⁴¹ The EU's pharmaceutical preparedness to deal with pathogens and chemicals that can be used in attacks is incomplete and insufficient. The member states have shown a preference for developing their own stockpiles of vaccines, serums and antibiotics; however, they now seem more interested and willing to invest in new biological products, such as better and safer vaccines.⁴²

The agents most likely to be used for terrorist purposes have been considered and lists of such agents have been developed, including their characteristics, the symptoms of their use, whether they cause disease and the indications of their use

³⁶ Tegnell et al. (note 27).

³⁷ European Commission (note 26), p. 11.

³⁸ European Commission (note 3), pp. 5–7.

³⁹ European Commission (note 21), p. 6. The list is available at European Medicines Agency, 'Bio-terrorism', URL <<http://www.emea.eu.int/htms/human/bioterror/bioterror.htm>>. Until 2004 EMA was known as The European Agency for the Evaluation of Medicinal Products.

⁴⁰ European Commission (note 21), p. 6.

⁴¹ European Commission (note 31).

⁴² European Commission (note 26), p. 23.

that would facilitate detection.⁴³ The list of diseases that must be reported has been expanded by adding agents that might be used by terrorists for a biological agent attack, such as tularaemia, anthrax, Q fever and smallpox. The list of pharmaceuticals authorized to be used in the event of a biological agent attack has also been updated by coordinating two existing initiatives: the EMEA and the Communicable Diseases Network. Areas have been identified where EU resources and programmes are insufficient and projects have been initiated to fill those gaps.⁴⁴

The matrix model and clinical guidelines

SANCO has published lists of agents that might be used in a biological agent attack, and a matrix model that is designed to evaluate the public health impact of a given agent has been developed for use by national authorities. The model may also be employed to identify areas where the public health response needs strengthening as regards a particular agent. The members of the HSC have approved the model, and the HSC has targeted areas of public health preparedness that need to be developed further.⁴⁵

In order to provide clinicians with guidance and generally agreed information, SANCO has produced 10 articles on 48 major agents summarizing the epidemiology of the agents and their potential use in bioterrorism. Recent data on the microbiological characteristics of the agents are also included, and the clinical features of diseases are described. The guidelines are intended to serve as useful tools for clinicians who might be called on to treat a patient infected with a bioterrorism agent. The material will be updated continuously and reports on other agents may be produced in future.⁴⁶

Emergency plans and modelling

The process of adjusting and complementing emergency plans or devising new ones is not complete, and some member states are more advanced in this work than others. Intensified work on emergency planning and computer modelling of the medical consequences of an emergency has been prioritized, and a compilation of emergency plans is being prepared to coordinate and share information.⁴⁷ International exercises, such as those conducted by the Global Health Security Action Group (GHSAG) and the Global Health Security Initiative (GHSI)—for example, Exercise Global Mercury—as well as evaluation at the EU level have demonstrated

⁴³ European Commission (note 26), p. 10.

⁴⁴ Tegnell et al. (note 27).

⁴⁵ Tegnell et al. (note 27).

⁴⁶ European Commission, Health and Consumer Protection Directorate-General, 'European clinical guidelines for bioterror agents', URL <http://europa.eu.int/comm/health/ph_threats/Bioterrorisme/clin_guidelines_en.htm>.

⁴⁷ European Commission (note 26), pp. 8, 12–13.

that the process of developing plans is not complete. The most recent exercises have focused on pandemic influenza and smallpox.⁴⁸

Directory of experts for advice and assistance

Knowledge is limited about potential bioterrorism agents, the diseases they cause, their clinical and epidemiological management, and laboratory analysis of them. In order to identify EU experts in this area and list them in a shared directory for use by the authorities of the member states, a questionnaire was sent to each member state to identify experts who are willing and able to provide advice and participate in investigations or missions conducted in response to an attack with a biological agent. The directory will be coordinated with the inventory that is maintained by the Commission's civil protection mechanism, with the roster kept by the WHO's Global Outbreak Alert and Response Network (GOARN) and with the group of experts on EU vulnerabilities to biological and chemical terrorism of the EU's Joint Research Centre (JRC).⁴⁹ A preliminary directory of experts has been set up, but more information is needed from the member states about the resources available and the individuals who are willing to participate.⁵⁰

Rapid detection and development of pharmaceuticals and vaccines

The Enterprise and Industry DG has proposed that the EU's Seventh Framework Programme for Research and Technological Development (FP7), whose budget cycle starts in 2007, should focus on security research (see the discussion below). However, before the new budget cycle begins, a security preparatory action (a pilot phase to prepare for a future security research programme) is being carried out to help reduce the risk of bioterrorism. The preparatory action is intended to help develop technologies to enable rapid detection, to provide alerts in the event of attacks using biological agents and to protect surveillance systems for critical infrastructure.⁵¹

The public health action programme for 2003–2008

On 23 September 2002 the European Parliament and the Council adopted a new Community action programme for public health for 2003–2008. It is intended to complement the policies of the member states by taking an integrated approach to

⁴⁸ European Commission, Health and Consumer Protection Directorate-General, Directorate C, Public Health and Risk Assessment, 'Communicable diseases handover of files', document D(2005) FS/SB/MCA/es/330, Luxembourg, 21 Sep. 2005, URL <http://www.ec.europa.eu/health/ph_overview/strategy/ecdc/ecdc_handover2_en.pdf>, p. 11.

⁴⁹ European Commission (note 26), p. 10. See also World Health Organization, Global Outbreak Alert and Response Network, URL <<http://www.who.int/csr/outbreaknetwork/en/>>; and the JRC's website, URL <<http://www.jrc.cec.eu.int/>>.

⁵⁰ European Commission (note 48), p. 11.

⁵¹ See European Commission, Enterprise and Industry Directorate-General, URL <http://europa.eu.int/comm/enterprise/security/faqs_en.htm#1>.

protecting and improving health and to create links with other Community programmes and actions. It aims not only to protect and improve public health and prevent disease but also to enhance the ability to respond rapidly to threats to public health.⁵²

The programme includes monitoring and rapid-reaction systems, a network to monitor public health, and access to national information and data at the level of the first pillar. It is designed to counter health threats, including major diseases; to react to unforeseen events; to investigate and coordinate response efforts; to prepare the necessary arrangements for such a response; and to coordinate, integrate and link the networks for health monitoring and for rapid-reaction to health threats—which was considered especially important.⁵³ The programme also aims to enhance the ability to respond rapidly and in a coordinated manner to health threats through the exchange of information on strategies to counter threats to health from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts. Community approaches and mechanisms are to be developed and used as appropriate.⁵⁴

Establishing a programme of Community action in the field of health and consumer protection in 2007–13

In April 2005 a communication from the Commission proposed a joint public health approach in order to promote savings and cooperation through the use of common tools, streamlined administrative and budgetary procedures, and cooperation with the recently established European Centre for Disease Prevention and Control (ECDC). The proposal urged establishing a European reference laboratory structure to develop EU diagnostic capabilities for rare or high-risk pathogens and setting criteria to evaluate laboratories. It also proposed that laboratory capacity should be increased to respond to health threats and to minimize their impact within or outside the EU.⁵⁵

The executive agency of the joint health and consumer programme would be organized in a health department and a consumer institute, managed jointly.⁵⁶ Cooperation with the health systems of the member states on health and infectious disease research is also planned for the 2007–13 budgetary period. The Enterprise

⁵² ‘Decision no. 1786/2002/EC of the European Parliament and of the Council’ (note 19).

⁵³ ‘Decision no. 1786/2002/EC of the European Parliament and of the Council’ (note 19).

⁵⁴ ‘Decision no. 1786/2002/EC of the European Parliament and of the Council’ (note 19), Annex: action and support measures, 2.4.

⁵⁵ European Commission, ‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Healthier, safer, more confident citizens: a health and consumer protection strategy’, COM(2005) 115 final, Brussels, 6 Apr. 2005, pp. 1–17.

⁵⁶ ‘Commission Decision of 15 December 2004 setting up an executive agency, the ‘Executive Agency for the Public Health Programme’, for the management of Community action in the field of public health—pursuant to Council Regulation (EC) no. 58/2003’, *Official Journal of the European Union*, L369 (16 Dec. 2004), pp. 73–75.

and Industry DG is considering a joint action on pharmaceuticals and medical devices, and cooperation with neighbouring countries is envisaged. The Justice, Freedom and Security (Justice, liberté et sécurité, JLS) DG will focus on AIDS, tuberculosis and bioterrorism and will maintain ‘appropriate’ relations with countries that do not participate in its programme. Its goal is to maximize the effectiveness of international health efforts by entities such as the WHO, the Organisation for Economic Co-operation and Development (OECD) and the Council of Europe.⁵⁷

Steps needed to enhance surveillance and control of health threats

Decision no. 2119/98/EC on ‘setting up a network for the epidemiological surveillance and control of communicable diseases in the Community’ should be further implemented, and strategies and mechanisms for preventing and responding to non-communicable disease threats should be developed.⁵⁸ Other issues of importance include a diagnostics reference laboratory (see above); the development of new and improved prevention, vaccination and immunization policies, partnerships and tools; and the monitoring of immunization status.

The response to health threats would be improved by elaborating risk management procedures for health emergencies, by enhancing the capability for coordinated responses to such emergencies, by enabling rapid and reliable communication on countermeasures, by providing guidance to health professionals and the public, and by improving awareness and interaction among the various actors. There is a need for a health infrastructure that can react rapidly and for strategies and mechanisms to improve and review the availability of and access to facilities (laboratories) and equipment (detectors etc.). In addition, a trained, permanently available core group of public health experts—who can be rapidly deployed to health crises around the globe together with mobile laboratories, protective equipment and isolation facilities—should be established and maintained.⁵⁹

The European Centre for Disease Prevention and Control

The European Centre for Disease Prevention and Control has been operational in Stockholm, Sweden, since May 2005. It is intended to strengthen defences against communicable diseases and to identify, assess and communicate information on current and emerging threats to public health.

The threat to health and well-being that communicable diseases pose to the EU member states is significant, and the ECDC was established in response to an assessment that existing arrangements were ‘simply not efficient enough to protect the EU citizens sufficiently against threats to their health posed by communicable

⁵⁷ European Commission (note 55), pp.1–20.

⁵⁸ ‘Decision no. 2119/98/EC of the European Parliament and of the Council’ (note 20).

⁵⁹ European Commission (note 55), pp. 29–30.

diseases, including the possibility of the deliberate release of infectious agents (“bio-terrorism”).⁶⁰ Notification of any outbreak of communicable disease must be made via the EWRS to the ECDC. If the source is unknown (as could be the case in a bioterrorism attack), the ECDC is empowered to take the initiative to identify, assess and communicate information about the risk posed to human health. In the event of deliberate use, the role played by the ECDC ceases at this point unless the member states or the Commission decide otherwise. In future the ECDC’s mandate may be extended beyond assessing the occurrence of disease to involvement in activities such as sending samples and having access to classified information.⁶¹

The ECDC is tasked with providing a ‘structured and systematic approach to the control of communicable diseases and other serious health threats’.⁶² It has three core functions: scientific advice, surveillance, and preparedness and response. Its scientific advice function includes collaborating with European institutions and laboratories, producing independent scientific advice and forming scientific panels to cover all communicable diseases. The ECDC will gradually assume responsibility for surveillance and for the Communicable Diseases Network. The ECDC’s responsibilities for preparedness and response include epidemic intelligence gathering, daily internal briefings on public health threats, training, outbreak response and support (including with third parties), advice to the Commission on appropriate action in response to health threats and operation of the EWRS.⁶³ The ECDC’s primary task is to coordinate activities. Initially, its budget was €5 million and it had approximately 30 staff members.

The ECDC focuses on: (a) carrying out epidemiological surveillance work, providing technical assistance to member states on surveillance issues and ‘networking’ with laboratories, (b) assisting the Commission by operating and developing the 24-hour EWRS, (c) coordinating and disseminating scientific expertise in selected areas, and (d) developing a rapid-reaction capacity for carrying out technical assistance and communications activities in the EU member states and in countries that have known or suspected human disease outbreaks. The ECDC has no laboratories but will build on the work of the laboratories of the

⁶⁰ European Commission, Health and Consumer Protection Directorate-General, ‘Preparatory actions for setting up the ECDC: handover file’, Brussels, 15 July 2005, URL <http://ec.europa.eu/health/ph_overview/strategy/ecdc/ecdc_handover1_en.pdf>. See also the European Centre for Disease Prevention and Control website, URL <<http://www.ecdc.eu>>.

⁶¹ European Centre for Disease Prevention and Control, ‘Advisory Forum meeting minutes’, Eighth meeting of the ECDC Advisory Forum, 22–23 Nov. 2006, URL <http://www.ecdc.eu.int/About_us/governance/AF/Minutes/Minutes_AF8.pdf>, pp. 8–9.

⁶² European Commission, Health and Consumer Protection Directorate-General, European Centre for Disease Control (ECDC), URL <http://ec.europa.eu/health/ph_overview/strategy/ecdc/ecdc_en.htm>.

⁶³ Jakab, Z., ‘ECDC activities in avian influenza and pandemic preparedness’, Presentation made at a SITE/SIPRI seminar, Stockholm School of Economics, Stockholm, 27 Feb. 2006.

member states and will develop a system of reference laboratories. By 2013 the ECDC is expected to have up to 300 staff and a €90 million budget.⁶⁴

An evaluation of the necessity of extending the scope of the ECDC's mission is scheduled for 2007. SANCO's Health Threat Unit has summarized the relevant documents and projects that are conducted by the Commission services relating to the fight against communicable diseases and bioterrorism in a note to the ECDC executive director.⁶⁵ All of the technical and scientific work from SANCO's communicable diseases and bioterrorism activities has also been shared with the ECDC.⁶⁶ The ECDC has a clear European focus, but the importance of working with accession states, with other neighbouring countries and with countries that are geographically distant from the EU in certain circumstances has also been realized. From a geographical perspective, the 17 countries around the periphery of the enlarged EU that are addressed by the European Neighbourhood Policy may be a particular priority. Currently, there is no work on bio-safety or bio-security in the ECDC, but this may change in future.⁶⁷

The ECDC and the Commission: distribution of responsibility

Both the Commission and the ECDC aim to avoid overlap and duplication of work, and the ECDC has assumed responsibility for some tasks previously performed by SANCO, which has provided the ECDC with an overview of SANCO's completed and ongoing work. In order to promote coherence and comprehensiveness, cooperation is needed between the EU member states, the Commission and the ECDC. In the case of a deliberately caused communicable disease outbreak, the ECDC should cooperate with the competent authority only on that authority's request.⁶⁸

The Commission retains overall supervision of the Community's Communicable Diseases Network (discussed above). It also plays the key role in proposing and adopting legislative measures in the field, although there is no reference to the ECDC in decision 2119/98/EC and thus no formal role for it.⁶⁹ However, the ECDC plays an important role in advising the Commission on scientific and technical issues and is fully associated with the work of the Communicable Diseases Network in this respect. The ECDC's role will be evaluated when decision 2119/98/EC is next reviewed.⁷⁰ Identification and assessment of health threats are key responsibilities of the ECDC, but the member states should provide relevant

⁶⁴ European Centre for Disease Prevention and Control (ECDC), 'Protecting health in Europe: the new European Centre for Disease Prevention and Control', 2005, URL <http://www.ecdc.eu.int/About_us/Key_Documents/General_presentation_of_ECDC.pdf>.

⁶⁵ European Commission (note 62).

⁶⁶ European Commission (note 48).

⁶⁷ Official of the ECDC, Communication with the author, 30 Mar. 2006.

⁶⁸ 'Regulation (EC) no. 851/2004 of the European Parliament and of the Council of 21 Apr. 2004 establishing a European Centre for disease prevention and control', *Official Journal of the European Union*, L142 (30 Apr. 2004), pp. 1–11, Article 3, paras 1–3 and Article 14.

⁶⁹ 'Decision no. 2119/98/EC of the European Parliament and of the Council' (note 20).

⁷⁰ European Commission (note 48), pp. 15–16.

information both to it and to the Commission. As soon as the ECDC has the technical capacity, it will operate the EWRS.⁷¹ Each member state is responsible for its own preparedness planning, but the ECDC assists by providing scientific and technical support. The Commission and the ECDC share responsibility for coordination at the Community level and, with the support of the ECDC, the Commission will adopt guidelines and other measures through the procedures set up in decision 2119/98/EC as needed. The ECDC has a clear mandate to support and coordinate training activities at the Community level.⁷²

In the event of a major health threat, the ECDC will play a key operational role by providing technical support (on request) to the affected member state or states to investigate and control large outbreaks. The ECDC should communicate with the Commission, the member states and others, including the general public, and relevant scientific and technical data from the ECDC's activities should be made available to them.⁷³ On the Commission's initiative, necessary measures in this regard could be adopted through an extraordinary meeting of the Communicable Diseases Network Committee.⁷⁴ The ECDC also has full responsibility for coordinating all Community level surveillance of communicable diseases. In March 2007 a handover to the ECDC was planned and 'Eurosurveillance' will be produced by the ECDC from that date. A handover of files on the surveillance networks programme was conducted in 2005–2006, and a memorandum of understanding with the Communicable Diseases Network was also drawn up.⁷⁵

To summarize, by 2008 the ECDC will have taken over a large part of the Commission's work in the areas of risk identification and assessment, operation of information networks, preparedness planning, training, response to health threats and events, communication and the formulation of scientific guidelines. The Commission will mainly be responsible for supervising, funding and implementing legislative procedures under decision 2119/98/EC and will coordinate policy making with the member states in the different areas of disease prevention and control.

Civil protection: preparedness and response

In the aftermath of the 2001 terrorist attacks in the USA, the EU established a Community 'mechanism to facilitate reinforced cooperation in civil protection

⁷¹ 'Regulation (EC) no. 851/2004 of the European Parliament and of the Council' (note 68), Article 8, para. 1.

⁷² 'Regulation (EC) no. 851/2004 of the European Parliament and of the Council' (note 68), Article 3 para. 2b, Article 9, para. 1 and Article 9, para. 6.

⁷³ European Commission (note 48), pp. 15–16; and 'Regulation (EC) no. 851/2004 of the European Parliament and of the Council' (note 68). See e.g. Article 3 paras 1 and 2e, and Article 5, para. 4.

⁷⁴ 'Commission Decision of 22 December 1999' (note 32), Annex II, paras 2.1, 3.1 and 4.

⁷⁵ European Commission (note 48), p. 25. See also ECDC Management Board, 'Minutes of the seventh meeting of the ECDC Management Board', Athens, 20–21 June 2006, URL <http://www.ecdc.eu.int/About_us/governance/MB/Minutes/Minutes_MB8.pdf>.

assistance interventions'.⁷⁶ The mechanism, which had been proposed by the Commission in 2000, was adopted by the Council in 2001 and entered into force in 2002.⁷⁷ It can be used by the member states to obtain immediate access to Community resources, thereby saving time and avoiding the need to contact multiple sources of assistance in a disaster. The member states can also contact the Commission's Communicable Diseases Network to gain access to specialized personnel and other resources.

Civil protection matters are mainly handled by Directorate A on Communication, Legal Affairs and Civil Protection of the Commission's Environment DG. Civil protection initiatives identify the threats deemed to be the most serious or likely to occur, and a communications network enables urgent information to be exchanged between member states and existing networks in response to CBRN threats. Teams of experts for coordinating interventions and an inventory of specific forms of assistance—such as serums, vaccines, training and exercises—are also included. The Monitoring and Information Centre (MIC) serves as the focal point, receives information from various networks and member states, makes available the appropriate means of intervention, and provides coordination with national authorities and other relevant networks.⁷⁸ It began operation on 29 October 2001.⁷⁹

The civil protection coordination mechanism comprises: (a) the MIC, which provides information and follows events on a 24-hour basis; (b) preliminary identification of intervention teams that are available in the civil protection or other emergency services of member states; (c) a training programme that reinforces response capacity and improves cooperation and the spread of knowledge between intervention teams; (d) assessment and coordination teams that can be deployed immediately; and (e) a common emergency communication system between the civil protection authorities of the member states and the relevant departments of the Commission.⁸⁰ An action plan was adopted to deal with the consequences of a nuclear, chemical or biological (NBC) weapon attack; it includes measures such as the MIC, information gathering on NBC expertise in the member states, and information on serum and vaccines.⁸¹ Provision has been made to link the communication systems to existing networks such as those for health (EWRS) and biological and chemical emergencies (RAS-BICHAT).⁸²

One coordination problem, connected to the EU's institutional structure, is the role that this mechanism could play in CFSP crisis management. A joint declaration by the Council and the Commission has been made on this matter that

⁷⁶ 'Council Decision of 23 October 2001' (note 33).

⁷⁷ The common platform (civil protection, health protection and research expertise) was based on the civil protection coordination mechanism in 'Council Decision of 23 October 2001' (note 33).

⁷⁸ Council of the European Union (note 4), p. 6; and European Commission (note 3), pp. 2–5.

⁷⁹ European Commission (note 21), p. 4.

⁸⁰ European Commission (note 21), p. 3.

⁸¹ European Commission (note 21), p. 4.

⁸² A Common Emergency Communication and Information System (CECIS) has been established to facilitate communication between the civil protection agencies of the member states and the Commission.

outlines the modalities for such a future role. It has been decided, for example, that the content of the military database established under the ESDP will be made available to the Community mechanism, which is considered to be important in the event of a CBRN attack.⁸³

In 2002 a Civil Protection Forum was instituted to promote exchange of information, best practice and experience on issues linked to natural and technological risks and terrorist attacks. In 2005 a proposal was made by the Commission to create a Rapid Response and Preparedness Instrument to address major emergencies. The instrument, effective as of 1 January 2007, will contribute to the development and implementation of Community civil protection measures, thereby improving the major emergency preparedness and response systems.⁸⁴

On 20 December 2002 a joint Council–Commission programme was adopted to improve EU cooperation to prevent CBRN terrorism and limit the consequences of any such attacks. The Environment DG implements and coordinates the programme. It produces working papers and annual reports, and research and technology development activities are listed in an attachment to its annual report.⁸⁵

Using developments in research and technology to counter biological and chemical terrorism

As a follow-on to the Health Security Programme, in 2001 the EU research ministers endorsed a Commission initiative to establish a research and development (R&D) expert group on ‘countering the effects of biological and chemical terrorism’. The group is part of the biotechnology, agriculture and food section of the Research DG, and representatives from the relevant government departments of each member state (e.g. the defence, health, civil protection and research departments) are members of the group.⁸⁶ Its tasks are to prepare an inventory of research activities in the member states and at the EU level to counter the effects of biological and chemical terrorism, to examine how such counterterrorism activities can be mobilized and coordinated, and to identify the additional research needed, both in the short and long term.⁸⁷ The Commission provides secretariat support to

⁸³ Ekengren, M., ‘From a European security community to a security European community: analysing EU “functional” security, the case of civil protection’, SGIR Conference, Fifth Pan-European Conference, The Hague, 9–11 Sep., 2004, URL <http://www.afes-press.de/pdf/Hague/Ekengren_functional_security_Abs.pdf>, p. 17.

⁸⁴ European Union, ‘New proposals for growth and jobs under the next financial framework 2007–13’, Press release, Brussels, 6 Apr. 2005, URL <<http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/389&format=>

⁸⁵ European Commission, ‘Compendium counter terrorism actions: contribution of the Commission services’, Commission staff working paper SEC(2004) 669, Brussels 25 May 2004, p. 57.

⁸⁶ European Commission (note 85). See also European Commission (note 26), p. 18.

⁸⁷ European Commission, ‘Report of the R&D expert group on countering the effects of biological and chemical terrorism’, Commission staff working paper SEC(2002) 698, Brussels, 3 July 2002, p. 2. On the R&D expert group see URL <<http://ec.europa.eu/transparency/regexpert/detail.cfm?ref=759&l=R>>.

the group through a restricted-access website that is used to exchange information among experts.⁸⁸

The group has contributed to identifying the topics related to bioterrorism that were covered by the ‘preparatory action on the enhancement of the European industrial potential in the field of security research’ (PASR). The PASR was launched in 2004 and remained outside the research and technology Framework Programme. It explored the conditions and mechanisms that are needed to guarantee safety and security and its work was completed in 2006. The Research DG and the Information Society and Media (INFOS) DG jointly conduct work on projects that address protection against terrorism, including biological and chemical attacks. The PASR identified and prioritized the information requirements of the efforts of governments, agencies and public authorities to combat, contain and dispose of dangerous substances and their protection activities. Its tasks also included surveillance of the EU’s borders and the development of technology to tag, track and trace goods.⁸⁹

The R&D expert group has compiled an inventory of research activities in the chemical and biological fields at the state and EU levels which lists research on the risk, prevention, detection, mitigation and management of CBRN attacks and on the scientific, social, economic and psychological vulnerabilities of society to terrorists. The Commission chaired the group, and the Research, Environment, Enterprise and Industry, and Health and Consumer Protection DGs as well as the Joint Research Centre participated. The inventory revealed that R&D programmes and capabilities vary significantly between member states, and the programmes that exist to counter the effects of biological and chemical terrorism are generally linked to defence research, publicly funded and carried out in government research institutions. The group also found that more research is taking place to counter biological terrorism than to address chemical terrorism.

Most of the EU member states have surveillance systems to monitor naturally occurring infectious diseases and, generally, the same systems could be used to monitor the deliberate release of biological agents. The member states are also developing new diagnostics for rapid detection and they possess expertise in risk analysis. The majority of the member states conduct research programmes for protection against naturally occurring infectious diseases, and relevant research is taking place in industry, specifically in pharmaceutical and biotechnology companies. Much of this research may also be relevant in the event of the deliberate release of biological and chemical agents.⁹⁰

The Commission has also set up a task force to coordinate the CBRN issues that are related to the proposed programme within its areas of competence.⁹¹ It has been

⁸⁸ European Commission (note 26), p. 19.

⁸⁹ European Commission (note 85), pp. 57–61.

⁹⁰ European Commission (note 87), pp. 3–4.

⁹¹ Council of the European Union (note 4), p. 6.

suggested that relevant research be performed on ‘genomics and biotechnology for health’ and on ‘food safety and health risks’.⁹²

Combating terrorism and bioterrorism

The Justice, Freedom and Security DG completed work on its Green Paper on bio-preparedness in 2007.⁹³ This consultation paper addresses, among other things, preventive bio-security measures (physical security, codes of conduct etc.) with the aim of creating a European bio-security strategy. Partners in the civil sector, including industry and researchers in the life sciences, are among the actors important in the efforts to strengthen bio-security.⁹⁴

The JLS DG also supports an initiative to develop international bio-safety and bio-security laboratory standards. Partners include the American Biological Safety Association, the European Biosafety Association and Det Norske Veritas.⁹⁵ This project could pave the way for activities carried out under FP7.

A Commission proposal to improve police cooperation between the member states at borders is intended to provide a framework to improve structural coordination, operational cooperation and information exchange between law enforcement authorities. Structural coordination includes the examination of the interoperability of equipment (in particular communications and surveillance technology) and joint training schemes, exchange programmes and language training. Operational cooperation encompasses joint patrols, intervention and surveillance operations, assistance to establish joint investigation teams in border regions, and assignment of police tasks to the liaison officials of the other member states. A regulatory committee to assist the Commission, composed of representatives of the member states and chaired by a representative of the Commission, reports on the measures to be taken to the regulatory committee.⁹⁶

Research, technological developments and ethics

The overall objective of the EU’s Sixth Framework Programme for Research and Technological Development was to establish a European Research Area (ERA) as

⁹² European Commission (note 21), p. 7.

⁹³ A Green Paper is a discussion paper published by the Commission on a specific policy area and addressed to interested parties who are invited to participate in a process of consultation and debate. Here bio-preparedness refers to both preventive and responsive measures, such as bio-security, preparedness and response. European Commission, ‘Green Paper on bio-preparedness’, COM(2007) 399 final, Brussels, 11 July 2007.

⁹⁴ Officials of the DG for Justice, Freedom and Security, Communication with the author, Mar. 2006.

⁹⁵ Official of the European Commission, Interview with the author, 7 Mar. 2007.

⁹⁶ European Union, ‘Schengen Area: the Commission proposes to facilitate cross border surveillance and “hot pursuit” between Member States’, document IP/05/970, Brussels, 19 July 2005, URL <<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/970&format=PDF&aged=1&language=EN&guiLanguage=en>>.

a framework for political and practical cooperation, not to focus on security issues.⁹⁷ The primary contribution to non-proliferation of the Commission's Research DG is through its activities to mobilize and coordinate the relevant European research and technological development communities. The Research DG is also involved with science- and ethics-related issues. In 2007–13 FP7 will also include the theme of security research.

The European Research Area

Since 1984 the Framework Programme has been the main financial and legal instrument to implement the European Research Area. The Framework Programmes are designed to last for a period of four years. They are drawn up and proposed by the Commission and must be adopted by the Parliament and the Council.⁹⁸

On 6 April 2005 the Commission adopted a proposal for a new EU programme for research subtitled 'building the European research area of knowledge for growth'. The 2007–13 budget of €67.8 billion proposed by the Commission for FP7 is double the budget for FP6. The main focus of FP7 will be on making research more relevant and adaptable to the needs of European industry, with an emphasis on themes rather than instruments.

Russia and the other former Soviet states have been invited to cooperate under the Framework Programme, but such cooperation has been difficult to organize. Suggestions for improving cooperation in future have been made, and international cooperation will be integrated into all programmes, thereby allowing projects to be carried out with international partners.⁹⁹

Four programmes have been proposed that focus, respectively, on cooperation, ideas, people and capacities. The cooperation programme is divided into operationally autonomous sub-programmes or themes, including health, food, agriculture, and biotechnology and the environment. Enough flexibility is ensured to accommodate new, emerging topics of scientific, industrial or policy interest. These also allow for joint, cross-thematic approaches to research subjects of common interest. The programme on capacities also addresses issues such as 'science in society'.¹⁰⁰ Research will focus on protection against terrorism, on border security and surveillance issues, and on CBRN threat awareness, including areas such as detection, prevention, identification and containment of the effects of an act of terrorism.

⁹⁷ European Commission, *The Directorate-General for Research: Building Europe's Future* (Office for Official Publications of the European Communities: Luxembourg, 2004.) URL <http://ec.europa.eu/dgs/research/pdf/corporate-brochure_en.pdf>, p. 4.

⁹⁸ EurActiv.com, '7th Research Framework Programme (FP7)', 17 Aug. 2004, URL <<http://www.euractiv.com/en/science/7th-research-framework-programme-fp7/article-117494>>.

⁹⁹ European Union, 'EU research—building knowledge Europe: the EU's new Research Framework Programme 2007–2013', Press Release, Brussels, 7 Apr. 2005.

¹⁰⁰ European Commission, 'Communication from the Commission: building the ERA of knowledge for growth', COM(2005) 118 final, Brussels, 6 Apr. 2005, pp. 5–7, URL <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0118en01.pdf>.

Life sciences and biotechnology: a strategy for Europe

The Commission attempts to develop responsible policies through a strategy of engagement in the development and application of the life sciences and biotechnology.¹⁰¹ Developments in these areas have ethical and social implications and should be viewed from a broad perspective and addressed proactively.

The action plan based on the 'strategy for Europe' aims to ensure that ethical, legal and social implications are taken into account at the earliest possible stages of Community-supported research by funding bioethics research and providing an ethical review of research proposals. Enhancement of the role of the European Group on Ethics in Science and New Technologies (EGE) has also been suggested. The Commission aims to promote collaboration between the Community and the state and local levels through networking with ethical bodies and elected representatives. Together with public and private partners the Commission plans to identify areas where consensus might be established on ethical guidelines, standards or best practice.¹⁰² In future, codes of conduct within this framework could also include ethical considerations that are relevant to biomedical dual-use research.¹⁰³

The Bureau of European Policy Advisers (BEPA) has been given the task of coordinating the Commission's action on specific policy themes involving the life sciences and biotechnology and of organizing the work of the EGE and its secretariat.¹⁰⁴ On 11 May 2005 the EGE's mandate was renewed for a four-year period. Its task is to advise the Commission on ethical questions relating to science and new technologies on its own initiative or at the request of the Commission. The Parliament and the Council may draw the Commission's attention to questions that they consider to be of major ethical importance. The EGE comprises up to 15 members, who are appointed by the president of the Commission.¹⁰⁵ The ethical issues that are discussed by the EGE are usually related to a particular case and specific technical equipment. Military applications and proliferation risks have been considered sporadically in this context. However, there is no general work on ethical norms and biological proliferation risks. The EGE and the Commission initiate projects on an equally frequent basis. The EGE also cooperates with different DGs depending on the research question under consideration.¹⁰⁶

There are generally few activities related to biological proliferation in the area of 'science and ethics', and the Commission has not considered such matters on a sys-

¹⁰¹ European Commission, 'Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: life sciences and biotechnology, a strategy for Europe', COM(2002) 27 final, 23 Jan. 2002, p. 20.

¹⁰² European Commission (note 101), p. 40.

¹⁰³ The term 'dual-use' refers to research that could have both a civil and military application.

¹⁰⁴ European Commission, Bureau of European Policy Advisers, 'Mission statement', URL <http://europa.eu.int/comm/dgs/policy_advisers/mission_statement/index_en.htm>.

¹⁰⁵ 'Commission Decision of 11 May 2005 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies', *Official Journal of the European Union*, L127 (20 May 2005), pp. 17–19, articles 1–3.

¹⁰⁶ Member of the EGE, Communication with the author, 20 Feb. 2006.

tematic basis. There is no specific code of conduct on dual-use technology and materials at the EU level, but such a code may be considered in future because FP7 addresses security issues more extensively than did FP6.¹⁰⁷ However, the Biotechnologies, Agriculture and Food Directorate of the Research DG has begun to explore the ethical implications of scientific research on biological weapons and the prevention of bioterrorism (it funded a recent conference on these issues), with a focus on the science versus security dilemma and on strengthening scientists' awareness of the possible dual-use nature of their work.¹⁰⁸

Scientific support to policies

The European Commission's scientific support to policies initiative under FP6 facilitated the decision-making process by providing information on scientific research of relevance to non-proliferation, including on improving the health, security and opportunities of EU citizens.¹⁰⁹ Several projects were carried out or were envisaged. There are strong indications that the responsibility for bio-security related research activities is being transferred from the Research DG to the Enterprise and Industry DG under FP7. However, the Research DG will continue to monitor the ongoing projects (described below) until they are completed.

1. A project for developing polymerase chain reaction (PCR) assays which can provide results more rapidly than existing diagnostic tests started in 2004 and ended in January 2006. Its aim was to develop and distribute PCR-based detection methods for viral haemorrhagic fever and variola viruses. The PCR tests will be commercially produced and are intended as a first-line diagnostic tool in laboratories that do not have bio-safety level 4 containment facilities. A different set of tests is intended to be developed for confirmation testing by laboratories with bio-safety level 4 containment facilities. This will contribute to improved laboratory detection and rapid diagnosis of viral agents that may be used as biological threats and will strengthen the laboratory infrastructure by providing enhanced preparedness against potential bioterrorism. It will also provide an earlier warning to public health authorities and will enable coordinated responses in the event of a deliberate release or accidental importation of viruses. The countries involved included France, Germany, Italy, Sweden and the UK.¹¹⁰

2. The crop bioterrorism project will establish a network of expert laboratories that will prepare lists of pathogens that pose a high risk to European crops and of crops that are most vulnerable to pathogenic attack. They will also standardize protocols for assessing the risk of epidemics once a pathogen has been introduced,

¹⁰⁷ Member of the DG for Research, Ethics unit, Communication with the author, 27 Jan. 2006.

¹⁰⁸ European Commission (note 85), pp. 57–58.

¹⁰⁹ European Commission, Directorate-General for Research, 'Scientific support to policies', URL <http://ec.europa.eu/research/fp6/ssp/index_en.htm>.

¹¹⁰ European Commission, Directorate-General for Research, 'Scientific support to policies: improving preparedness against possible use of biological agents', URL <http://ec.europa.eu/research/fp6/ssp/vhf_variola_en.htm>.

develop improved surveillance procedures and early-warning systems, prioritize fields where more research is needed, raise public awareness and encourage readiness to meet potential bio-security and bioterrorism threats related to crops. The project started in 2004 and the partners include France, Germany, Hungary, Israel, the UK and the USA.¹¹¹

3. A third project is devising a methodology to assess the impact of chemical, biological and radiological terrorism on European society. The aim is to generate an accurate intelligence estimate of the threat, analyse the actual vulnerability of society and infrastructure, produce a list of existing and planned terrorism countermeasures and suggest a mix of existing and new countermeasures. The project would inform decision making on the possible threat of chemical, biological and radiological terrorist attacks; assist in planning and assessing counterterrorism measures at the state, EU and international levels; and contribute to developing the European research policy in the area of counterterrorism. France, Spain, Sweden and the UK are involved in the project, which started in 2004 and is expected to finish in 2007.¹¹²

4. The Risk Virus Genome Database (RiViGene), also funded by the EU, will make an inventory of strains of security-relevant viruses, including their genome sequences; identify forensic markers and assess potential therapeutic and vaccine targets for viruses that are relevant to biological crime and terrorism.¹¹³

5. Biosafety-Europe was funded by FP6. It started on 1 April 2006 and is to be finalized by May 2008. It has 20 partners (including the European Biosafety Association) from 11 European countries and aims to promote harmonization and exchange of practices relating to bio-safety and bio-security management of biological-containment facilities. It will conduct an inventory that will serve as the basis for training, seminars and policymaking at the EU and state level.¹¹⁴

6. The BIOSAFE project started in 2006 and is compiling a list of select agents and studying how to strengthen the response to the deliberate release of agents by establishing a European framework to address such a threat. The study will bring together and analyse existing expertise on the virulence factors of pathogens and toxins that may be used in acts of bioterrorism.¹¹⁵

7. The Anthrax-EuroNet project was set up to bring together experts in public health, education, research and industry, and to establish a research network to accelerate the development and production of a vaccine and therapeutic countermeasures against anthrax bioterrorism. It was also intended to 'standardise and har-

¹¹¹ European Commission, Directorate-General for Research, 'Scientific support to policies: preventing epidemics among agricultural crops from deliberately introduced pathogens', URL <http://ec.europa.eu/research/fp6/ssp/crop_bioterror_en.htm>.

¹¹² European Commission, Directorate-General for Research, 'Scientific support to policies: meeting the threat of terrorist attack', URL <http://ec.europa.eu/research/fp6/ssp/assrbcvul_en.htm>.

¹¹³ See the RiViGene website, URL <<http://134.100.202.15/bni/others/rivigene/>>.

¹¹⁴ European Biosafety Association website, 'Biosafety Europe', URL <http://www.ebsaweb.eu/Biosafety_Europe.html>.

¹¹⁵ Official of the Swedish Institute for Infectious Disease Control, Communication with the author, May 2006.

monise screening and testing protocols for vaccines and therapeutic measures' and create a network to 'provide Europe with a means of addressing the current and future needs for protecting its citizens against the threats of other high-risk bio-terrorism agents and emerging diseases'.¹¹⁶ The network could eventually be integrated into the ECDC. France, Germany, Italy and the UK were involved. The project began in 2004 and ended in 2006.

The Joint Research Centre

The mission of the Joint Research Centre is to provide scientific and technical support for the development, implementation and monitoring of EU policies. It is a service of the Commission and functions as a reference centre of scientific and technical advice for the EU. The JRC serves the common interest of the member states but is independent of special interests.¹¹⁷ The JRC's scientific and technical expertise can contribute to establishing networks with the laboratories of the member states and with research centres. It works with public and private organizations—including research centres, universities, regulatory bodies, local authorities, industrial associations and companies in more than 150 major networks.

In the biological field the JRC has initiated and coordinates the Bio-response Working Group, which has access to specialist analytical capabilities and a state-of-the-art network of genetically modified organism laboratories in the EU member states. The working group's participants are international experts in the detection and fingerprinting of DNA strains, and they also deal with emergency response such as the production of smallpox vaccines and other vaccines. The JRC uses its facilities and those of the Bio-response Working Group to detect and identify relevant transgenic strains and to address biological agent attacks on the food chain (agri-terrorism).¹¹⁸ The Bio-response Working Group keeps the R&D expert group (discussed above) informed of its progress and of relevant new activities and developments.¹¹⁹

The JRC has updated its online database on biological and chemical terrorism, which is available to all authorized authorities of EU member states on request. Networks exist at the EU level for the study of many infectious diseases, but they are not specifically concerned with bio-agents and do not generally focus on research activities but rather on surveillance.¹²⁰

¹¹⁶ European Commission, Directorate-General for Research, 'Scientific support to policies: Anthrax-EuroNet scientific shield against bioterror threats', URL <http://ec.europa.eu/research/fp6/ssp/anthrax_uronet_en.htm>.

¹¹⁷ Joint Research Centre, 'Mission of the Joint Research Centre', URL <<http://www.jrc.ec.europa.eu/>>.

¹¹⁸ On GMOs see the European Network of GMO Laboratories website, URL <<http://engl.jrc.it/>>. European Commission (note 21), p. 7.

¹¹⁹ European Commission, 'Report of the R&D expert group on countering the effects of biological and chemical terrorism', Commission staff working paper, SEC(2002) 698, Brussels, 3 July, 2002, p 7.

¹²⁰ European Commission (note 87), p. 4.

The JRC's Institute for the Protection and Security of the Citizen, based in Italy, can call on the expertise of network partners and collaborating research establishments throughout the EU. Continuing instability and poverty in the former Soviet Union, which heightens the risk of proliferation of technology and material for weapons of mass destruction, is one focus of its work.

3. EU external actions: limitations and possibilities

In areas of external relations, such as aid and trade, certain measures have their legal foundation in the Treaty of Rome.¹²¹ In these areas, collectively known as the ‘first pillar’ of the EU, actions are initiated and implemented by the Commission.¹²² Under the first pillar the Commission has a more or less exclusive right to initiate proposals at the EU level in areas such as public health, research and the environment.

The EU’s foreign and security policy is decided by the governments of the member states, and the Commission is restricted in its right to submit proposals. It is not legally possible for the EU collectively to influence the actions of the individual member states on CFSP issues, which are viewed as matters of national concern. The Council of the European Union is the central decision-making institution and its secretariat helps to prepare and implement decisions. This vertical division of the EU’s separate areas of competence is potentially a major obstacle when issues span the functional boundaries of the different pillars. Issues such as non-proliferation and counterterrorism require effective inter-pillar collaboration.

The European Commission plays a key role in several areas that are relevant to addressing biological threats. The DG for External Relations (RELEX) is a central division that is responsible for the Commission’s relations with international organizations and the Council of the European Union and for its participation in the CFSP.¹²³ The work conducted by the Justice, Freedom and Security DG on counterterrorism (discussed above) is an example of how internal work within the Commission can have external dimensions, and it strengthens the argument that external contacts are vital for effectiveness in several relevant policy areas such as police and customs cooperation. The DG for External Trade drafts proposals to modify the legal basis for controlling the export of items that were not specifically designed, developed or adapted for military use but that can contribute to military programmes (i.e. dual-use items). Exports of such products have been controlled under EU law since the mid-1990s and a revised Council regulation adopted in 2000 sets up a dual-use export control regime that applies to listed biological items as agreed by the Australia Group (AG).¹²⁴

¹²¹ Treaty of Rome (note 1).

¹²² Swedish EU information website, URL <<http://www.eu-upplysningen.se/>>.

¹²³ European Commission, Directorate General for External Relations website, URL <http://ec.europa.eu/dgs/external_relations/general/mission_en.htm>.

¹²⁴ ‘Council Regulation (EC) no. 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology’, *Official Journal of the European Communities*, L159 (30 June 2000), p. 1. It was most recently amended and updated in ‘Council Regulation (EC) no. 394/2006 of 27 February 2006 amending and updating Regulation (EC) no. 1334/2000 setting up a Community regime for the control of exports of dual-use items and technology’, *Official*

The AG is an informal arrangement whose participants work to prevent the transfer of specified items from contributing to chemical or biological weapon programmes. All of the EU member states participate in the AG, and the European Commission is also a participant. The AG's common control lists and its guidelines for transfers of sensitive chemical or biological items are linked to the Council regulation and must be 'transposed onto' EU law.¹²⁵

Non-proliferation activities in Russia and the other former Soviet states

In the EU's near neighbourhood, non-proliferation of technologies and expertise is mainly supported by Community funds through the Moscow-based International Science and Technology Center (ISTC) and the Science and Technology Center in Ukraine (STCU).¹²⁶ The centres aim to redirect the efforts of WMD scientists from former Soviet military research programmes to peaceful civil research. The Commission funds projects carried out by Russia and other former Soviet states through the centres and partner projects, which are directly funded by industry and other organizations.¹²⁷ A 2005 EU pilot project conducted by SIPRI found that the ISTC and the STCU had focused minimal effort on the biological field in the past.¹²⁸ The Research DG's Inter-institutional and Legal Matters: Framework Programme Directorate is responsible for the ISTC and the STCU and also develops research projects together with former Soviet states in various scientific disciplines.¹²⁹

Other EU biological non-proliferation activities

On the ministerial level the EU addresses non-proliferation and disarmament issues in the General Affairs and External Relations Council (GAERC). Senior disarmament and non-proliferation officials from the ministries of foreign affairs of the EU member states participate in two preparatory bodies within the CFSP structure—the Working Group on Global Arms Control and Disarmament (CODUN) and the Working Group on Non-Proliferation (CONOP)—that meet once a month in Brussels. The working groups serve as a forum for discussion and for drafting statements, positions and decisions for submission to the GAERC. Biological issues are mainly covered in CODUN, which is also where overall EU policy on

Journal of the European Union, L74, (13 Mar. 2006), pp. 1–227. See also Australia Group, 'Objectives', URL <<http://www.australiagroup.net/en/agobj.htm>>.

¹²⁵ European Commission (note 26), p. 10.

¹²⁶ See the International Science and Technology Center website, URL <<http://www.istc.ru/>>; and the Science and Technology Center in Ukraine website, URL <<http://www.stcu.int/>>.

¹²⁷ See Kuhlau (note 11).

¹²⁸ Stockholm International Peace Research Institute, 'EU pilot project conference materials', URL <<http://www.sipri.org/contents/expcon/eupponconfmaterials.html>>.

¹²⁹ European Commission, 'Communication from the Commission: the international dimension of the European Research Area', COM (2001) 346 final, Brussels, 25 June 2001, p. 9; and the Specific International Scientific Cooperation Activities (INCO) portal, URL <http://cordis.europa.eu/inco/home_en.html>.

the 1972 Biological and Toxin Weapons Convention (BTWC) is discussed prior to decisions being taken by the GAERC.¹³⁰

The EU Strategy against Proliferation of WMD, which was agreed by the EU's heads of state and government in December 2003, demonstrates the high political importance attached to non-proliferation by the member states.¹³¹ The WMD Strategy aims to prevent third parties and terrorists from acquiring CBRN materials and delivery systems by deploying in a coherent manner all available EU instruments to prevent, protect, deter, disrupt and respond to proliferation.

The most recent report presented to the GAERC by the Council Secretariat on the implementation of the WMD Strategy places some emphasis on biological weapon non-proliferation issues.¹³² The EU is committed to 'take the lead in efforts to strengthen regulations on trade with material that can be used for the production of biological weapons'. The report states that 'an initiative will be taken in order to promote firstly, dialogue with EU industry with a view to raising the level of awareness of problems' related to WMD and, second, 'dialogue between the EU and US industry, in particular in the biological sector'. The list of priorities for coherent implementation of the WMD Strategy in the document includes a number of 'absolute priorities' for 2006. Among these are joint actions on physical protection of biological laboratories in Ukraine and in unspecified 'other countries'. A list of actions that the EU 'could support' in the period 2006–2008 is also included. For example, it is suggested that annual funding of €2 million should be allocated to support regional training in bio-safety and pathogen security. In late 2006 the GAERC endorsed a concept paper on monitoring and enhancing the consistent and effective implementation of the EU Strategy through a WMD Monitoring Centre (WMD-MC).¹³³ The concept paper suggests that all relevant EU actors should be involved and that the Office of the Personal Representative to the High Representative for the CFSP should serve as a focal point, with a core permanent staff from the Council Secretariat. The centre would build on the resources developed inside the Council Secretariat since the adoption of the WMD Strategy and would not increase staff or budget.

While the EU has provided funding for non-proliferation activities through joint actions adopted under the CFSP, there have been a limited number of such actions

¹³⁰ Feakes, D., 'The emerging European disarmament and non-proliferation agenda on chemical and biological weapons', *Disarmament Diplomacy*, no. 65 (July–Aug. 2002). The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction was signed on 10 Apr. 1972 and entered into force on 26 Mar. 1975. The text is reproduced on the SIPRI Chemical and Biological Warfare Programme website at URL <<http://www.sipri.org/contents/cbwarfare/>>.

¹³¹ Council of the European Union (note 8).

¹³² Council of the European Union, 'Implementation of the EU Strategy against proliferation of WMD: six-monthly progress report on the implementation of chapter III of the EU Strategy against the Proliferation of Weapons of Mass Destruction, updated list of priorities or a coherent implementation of the EU WMD Strategy', document no. 5279/06, Brussels, 12 Jan. 2006.

¹³³ Council of the European Union, 'EU Strategy against the Proliferation of WMD: monitoring and enhancing consistent implementation', Brussels, 12 Dec. 2006, URL <<http://register.consilium.europa.eu/pdf/en/06/st16/st16694.en06.pdf>>, pp. 2–10.

in the biological field. In early 2006 a Council joint action in support of the BTWC in the framework of the EU Strategy against the Proliferation of WMD was adopted to give practical application to some elements of the WMD Strategy. The support to the BTWC consists of promoting universality and supporting national implementation. The joint action will expire 18 months after its adoption.¹³⁴

The INCO and INTAS programmes

The general objective of international cooperation activities carried out under FP6 is to help open up the European Research Area globally. The Specific International Scientific Cooperation Activities (INCO) programme was adopted in 1994 by the European Council to provide Research DG Framework Programmes with a tool to react to the growing globalization of science and the economy.¹³⁵ INCO lends support to the implementation of the Community's foreign policy and its development aid policy in the scientific and technological fields.¹³⁶ In the field of multilateral cooperation, INCO is responsible for relations with Russia, Eastern Europe, the Caucasus and Central Asia. INCO also supervises non-proliferation programmes, and it managed the International Association for the Promotion of Co-operation with Scientists from the New Independent States of the Former Soviet Union (INTAS) during its existence.

In September 2006, in response to a Commission proposal, it was agreed that INTAS should be terminated as of 1 January 2007.¹³⁷ INTAS had promoted scientific cooperation between researchers in 12 former Soviet republics and researchers in the EU member states. It was an independent association formed by the European Community, the EU member states and like-minded countries, and it played an important bridging role between the former Soviet states and the European Union—especially relating to the EU Framework Programmes for Research and Technological Development. INTAS was the only pan-European, Community-funded organization dedicated to scientific cooperation with Russia and the other former Soviet states. It received significant contributions and support from the European Union, including financial support and secondment of staff.¹³⁸ During the FP6 period (2002–2006) it received €70 million in funding: the EU provided the major part (93 per cent), while 7 per cent of its budget came from member states,

¹³⁴ 'Council Joint Action 2006/184/CFSP of 27 February 2006 in support of the Biological and Toxin Weapons Convention in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction', *Official Journal of the European Union*, L65 (7 Mar. 2006), pp. 51–55, Articles 1–2. A common position was also adopted to ensure that the EU would express a coherent position at the Sixth BTWC Review Conference in Dec. 2006.

¹³⁵ European Commission, European Research Open to the World website, URL <http://ec.europa.eu/research/intco/achieve/edito_en.html>.

¹³⁶ Specific International Scientific Cooperation Activities (note 129).

¹³⁷ For INTAS documents see the INTAS website, URL <<http://www.intas.be/>>.

¹³⁸ INTAS, 'Statement adopted by the INTAS General Assembly on the preparation of the Seventh Framework Programme', Brussels, 29 Apr. 2005; and INTAS, 'INTAS and the EU framework programmes'.

partner countries and European organizations.¹³⁹ From its launch in 1992 to January 2007, INTAS funded more than 300 biotechnology and life science projects.¹⁴⁰ The bio-security projects included characterization of microorganisms, epidemiology, diagnostics and basic research as well as training in bio-security and bio-safety standards. INTAS's activities were in line with the aim of opening the ERA to the former Soviet states by supporting scientific cooperation. The European Parliament and the Council decided in 2002 that activities with Russia and the other former Soviet states would be carried out through INTAS in particular.¹⁴¹

In order to receive funding, project proposals were submitted online and, after initial checks by the INTAS Secretariat, eligible proposals underwent a two-step peer review evaluation process. First, independent experts evaluated the proposals; second, those results were consolidated by the Council of Scientists. The INTAS General Assembly approved the funding, and its Secretariat then entered into negotiation with the chosen partners.¹⁴² INTAS's 'main tools' included calls for research projects and networks, and the organization of scientific policy workshops on issues such as harmonization of the WHO standard operating procedures for ethical review of biomedical research and ethics of the life sciences.¹⁴³ INTAS also provided innovation grants.¹⁴⁴

The international dimension of health cooperation

A Community programme of action will also coordinate the EU's response to and relations with third parties and international organizations. The Global Health Security Initiative is such an organization.¹⁴⁵ It was established on 7 November 2001 (in response to a US proposal) at a meeting of the ministers of health of the Group of Seven (G7) industrialized countries and Mexico, the European Commission and the WHO.¹⁴⁶ The GHSI was set up to help the participants deal with health crises at the international level, to share protocols and standard

¹³⁹ INTAS, 'INTAS and the EU framework programmes' (note 138).

¹⁴⁰ Currently, around 20 projects are relevant to the bio-security aspects of these projects.

¹⁴¹ 'Decision no. 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006)', *Official Journal of the European Communities*, L232 (29 Aug. 2002), pp. 1–33.

¹⁴² INTAS, 'Funding mechanisms'.

¹⁴³ INTAS thematic and open calls for research proposals have grant budgets of \$1–15 million. See e.g. INTAS, 'Thematic call on genomics and proteomics applied to human health 2005', Brussels, 3 May 2005; and INTAS, 'Open call for research project proposals 2005–2006', Brussels, 20 Apr. 2005.

¹⁴⁴ INTAS, 'About INTAS'; and INTAS, 'Strategic scientific workshops'.

¹⁴⁵ See the GHSI website, URL <<http://www.ghsi.ca/english/index.asp>>.

¹⁴⁶ European Commission (note 26), p. 6. The G7 states are Canada, France, Germany, Italy, Japan, the UK and the USA. The European Commission and Mexico participate in the GHSI.

operating procedures, to exchange reagents and control material, and to promote the harmonization and standardization of diagnostic methods. The Global Health Security Action Group, consisting of senior officials, was formed to implement concrete actions agreed by the partners at ministerial level in the framework of the GHSI. The GHSAG is supported by a number of working groups, including the Global Health Security Laboratory Network. The group maintains a restricted access website where information is exchanged on: (a) health intervention plans, (b) monitoring of disease, (c) contamination of water and food chains, and (d) guidelines for care services. It functions as a rapid communication network in times of crisis, and a number of working groups have been established on areas such as smallpox and pandemic influenza. Through the Global Health Security Laboratory Network, bio-safety level 4 laboratories are able to carry out joint activities, including coordinating, standardizing and validating diagnostic capabilities. At their December 2006 meeting the GHSI health ministers agreed to review current laboratory security processes and procedures ‘with a view towards expediting interchange and movement of scientists among member countries high security laboratories, with the objective of rapid and timely knowledge exchange and research collaboration, primarily in the area of threat agents’.¹⁴⁷ A quality assurance project is also being prepared.¹⁴⁸

Several international projects on preparedness are funded under the Commission’s Health and Consumer Protection Directorate-General health programme for 2003–2008. These include a laboratory cooperation project with Russia, run by the Robert Koch Institute in Berlin, on improving smallpox diagnostic tests that began in 2004. Another project is the network for communicable diseases control in southern Europe and the Mediterranean countries.¹⁴⁹ Related activities include monitoring the Internet to provide advance warning of suspicious events or outbreaks; a system (MediSys) that has been set up with links to existing systems in the Commission’s External Relations DG and the Joint Research Centre; the Canadian Global Public Health Information Network; and the US Centers for Disease Control and Prevention (CDC) and Department of Health and Human Services. A health security bulletin is also distributed regularly to authorities of the EU member states and to the GHSI partners. A study of smallpox vaccines has been conducted, and information has been provided by the pharmaceutical industry on the development and production of vaccinia immunoglobulin (a key biological substance for smallpox immunization). The development of vaccines for other agents and vaccination strategies is also being pursued.¹⁵⁰ On 7 November 2003 the

¹⁴⁷ Global Health Security Initiative, Seventh Ministerial Meeting of the Global Health Security Initiative, ‘Ministerial statements’, Tokyo, 7 Dec. 2006, URL <http://www.ghsi.ca/english/statement_tokyoDec2006.asp>.

¹⁴⁸ European Commission (note 48), p. 11.

¹⁴⁹ European Commission, Health and Consumer Protection Directorate-General, ‘Projects, Public health programme 2003–2008’, URL <http://ec.europa.eu/health/ph_threats/com/projects_threats_en.htm>; see also European Commission (note 48), pp. 8–10.

¹⁵⁰ European Commission (note 48), p. 10.

GHSAG set up a research programme, chaired jointly by the Community and the USA, to assemble information from the GHSAG's working groups. The Research DG is directly involved with SANCO in setting up this 'research platform' and in establishing links with the EU's R&D expert group.¹⁵¹

As noted above, the Commission has been an active member of the GHSI since November 2001. In order to improve the information exchange and coordination between member states and to develop an inventory of available vaccines, an ad hoc health security committee and a joint task force comprised of national public health experts have been established.¹⁵² Additionally, there is a long-standing bilateral relation with the WHO to cooperate at different levels on key policy issues, including health. Regular meetings take place between the commissioner responsible for SANCO and the WHO director-general, and meetings have also been held at the technical level. Workshops have been organized on communicable diseases and health information, on the Community's Public Health Programme and on collaboration in the area of health information and bioterrorism.¹⁵³

The Commission is a full participant (a status somewhere between member and observer) in the OECD. Cooperation focuses on public health issues, such as monitoring and health data collection, and is to be further developed in the framework of the Community Public Health Programme.¹⁵⁴ All EU member states, the WHO, the Pan American Health Organization and the Community are interconnected and can exchange national surveillance system data and information on particular types of suspicious cases, such as contamination of food and water supply chains. The Community also works with the WHO on activities concerning bioterrorism in order to improve the WHO's Global Outbreak Alert and Response Network.¹⁵⁵

¹⁵¹ European Commission (note 85), p. 57.

¹⁵² European Commission (note 26).

¹⁵³ European Commission, Health and Consumer Protection Directorate-General, 'World Health Organization', URL <http://europa.eu.int/comm/health/ph_international/int_organisations/who_en.htm>.

¹⁵⁴ European Commission, Health and Consumer Protection Directorate-General, 'Organisation for Economic Co-operation and Development (OECD)', URL <http://europa.eu.int/comm/health/ph_international/int_organisations/oecd_en.htm>.

¹⁵⁵ European Commission (note 3), p. 6.

4. Assessing current efforts to manage the threat of biological proliferation

A comparison of Commission activities aimed at preventing, preparing and responding to biological health security threats indicates that preventive measures have received the least attention. The emphasis on preparing for and responding to a biological agent incident rather than on preventive measures is partly a consequence of the separation of areas of competence between the three pillars of the European Union. The intergovernmental nature of the second and third pillars complicates efforts to implement effective, well-integrated 'cross-pillar' programmes. Existing capacities could be more effectively utilized if a more 'horizontal' approach were adopted within the Commission. Such an approach would emphasize more substantive and effective interaction between the DGs in order to develop preventive measures that complement relevant work already being carried out under the first pillar, for example in the public health and research areas. Several projects on bio-safety (recently, also including important bio-security aspects) have been carried out under FP6 and will continue under FP7. These projects should be evaluated partly with a view towards avoiding duplication of work and instead focusing on using the existing experience and expertise to agree and further harmonize EU policies in the bio-safety and bio-security areas.

For example, instead of creating EU bio-security guidelines from scratch, the WHO's laboratory bio-security guidelines could be used as the basis for implementation of bio-security measures in European laboratories, thereby conserving resources.¹⁵⁶ The Commission already possesses a number of important instruments that could be used to strengthen preventive measures. Together with bio-security and bio-safety, the WHO approach includes a third component to reduce bio-risk: bioethics, an area to which the EU could usefully devote further attention.

Ideally, implementation of the various EU activities would result in the creation of parallel and integrated activities to strengthen security. This would occur both in terms of the traditional concept of defending borders against external military threats (by state and non-state actors) and in terms of 'human health security' (i.e. protecting individuals against disease).

Various enhanced security measures in the EU member states' laboratories and other biomedical facilities would limit the risk of a deliberately induced outbreak of disease, which would benefit not only public health but also the security and public health sectors. The standards developed and the lessons learned through these internal EU processes could be promoted through external activities, such as the cooperation between the EU and Russia and the other former Soviet states on public health matters.

¹⁵⁶ World Health Organization, *Biorisk Management: Laboratory Biosecurity Guidance* (WHO: Geneva, Sep. 2006), URL <http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf>, p. iii.

The EU is extensively committed to promoting and improving health, preventing disease and countering potential threats to public health. Mechanisms for preventing biological weapon attacks and the illicit spread of biological materials, technology and expertise should be included in the EU's public health efforts. Components of a preventive nature could also be more extensively included in the work of the Commission's public health divisions. The areas of competence of the private sector, of specialized research communities and of parts of the public health community ought to be involved in the discussion of and the efforts to prevent biological proliferation.

The European Centre for Disease Prevention and Control could play a role in supporting the EU's prevention activities, and its proposals for the ECDC could help to clarify the division of responsibility in the different phases of an intentional outbreak. The ECDC could become an important focal point for the European experts and scientists who will advise the EU on the areas that should be given the highest priority. The ECDC could also create curricula for the training of scientists and technicians, promote discussion of codes of conduct and practice in academia and industry, and conduct surveys and regular inventories of European national surveillance systems and laboratories that possess highly toxic pathogens.

The means used for coordination and to manage biological threats and for cooperation in the Commission, where related issues are being addressed, are not always apparent to the outside observer. This is particularly true for non-proliferation and bioterrorism activities and for public health mechanisms, such as disease surveillance, early warning and response. Significantly, the EU is tending to focus on 'back-end' aspects of bioterrorism (e.g. methods for detection, preparedness and response) rather than on 'front-end' activities that can help to prevent the release of infectious agents.

Within the EU framework a number of important activities are ongoing to manage bio-risks, but they are not sufficiently harmonized and coordinated to provide a satisfactory framework. The gaps are especially apparent in the area of prevention, and the above analysis points to the need to treat this as a priority area for further improvement in future.

About the author

Frida Kuhlau (Sweden) was a member of the SIPRI Chemical and Biological Warfare Project in October 2001–January 2007. She is co-author of the SIPRI fact sheet ‘Biotechnology and the future of the Biological and Toxin Weapons Convention’ (Nov. 2001), ‘Maintaining the effectiveness of the Chemical Weapons Convention’ (Nov. 2002), and *Non-Compliance with the Chemical Weapons Convention: Lessons from and for Iraq*, SIPRI Policy Paper no. 5 (Oct. 2003). She is also co-author of ‘Crucial guidance: a code of conduct for biodefense scientists’, *Arms Control Today* (Sep. 2006), and author of ‘Disease outbreaks: managing threats to health and security’ in Anders Mellbourn (ed.), *Health and Conflict Prevention* (Gidlunds Förlag, 2006). She contributed to the SIPRI Yearbook from 2002 to 2007. In 2005 she presented a report, ‘From bio threat reduction to cooperation in biological proliferation prevention: overview of ongoing international activities aimed towards preventing proliferation of biological technology, material and expertise that may be used for hostile purposes’, to the European Commission. Since 2006 she has conducted research on EU bio-safety and bio-security policy developments, and she is currently enrolled in a doctoral programme in bioethics at Uppsala University.

