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GREEN PAPER

ON BIO-PREPAREDNESS

(presented by the Commission)

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1. OBJECTIVES AND BACKGROUND

This Green Paper intends to stimulate a debate and launch a process of consultation at European level on how to reduce biological risks, and to enhance preparedness and response ("bio-preparedness"). This consultation may lead to concrete actions within the ambit of the Community's and Union's competence, in the field of bio-preparedness in 2008. Concrete actions may have to be presented and developed separately in specific strands of work following the applicable decision-making procedures and, where appropriate, impact assessment.

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

The feedback from stakeholders to the policy options and deliverables outlined in this document is essential for the Commission to evaluate the mechanisms and frameworks which are already in place and how they are implemented, identify possible shortcomings and subsequently propose specific actions where needed and in accordance with the principle of subsidiarity as set out in art 5 of the EC Treaty. Stakeholders should also consider where they see existing gaps and deficits, and what should be further improved.

Europeans regard terrorism as one of the key challenges the European Union is facing today.[1] The attacks in Madrid, London, New York and elsewhere in the world made it clear that terrorism is a threat to all States and to all peoples. Terrorists target our security, the values of our democratic societies and the basic rights and freedoms of our citizens. Terrorists may resort to non-conventional means such as biological weapons or materials. Some of these materials have the capacity to infect thousands of people, contaminate soil, buildings and transport assets, destroy agriculture and infect animal populations and eventually affect food and feed at any stage in the food supply chain. The risk of "bioterrorist" attack has been statistically low,[2] but its consequences can be devastating. If a deliberate introduction of deadly pathogens or a naturally occurring disease outbreak were to occur in the European Union or be imported from a third country, it is possible that it could affect several Member States simultaneously or spread across borders and have considerable economic and social impact.

While it is clear that the benefits of scientific development in some areas may outweigh any possible security concerns, with the global development of life sciences and biotechnology,

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1 See for example the Eurobarometer survey on public opinion in the EU: http://ec.europa.eu/public_opinion/archives/eb/eb64/eb64_en.pdf.

2 After the terrorist attacks of 11 September 2001, the first 10 confirmed cases of inhalational anthrax caused by intentional release of *Bacillus anthracis* were identified in the United States. In this context, Europe also faced the challenge of numerous anthrax-related hoaxes.

some dual-use expertise and technology could become available to criminal political entities and terrorists, potentially enabling a group to carry out disruptive biological attacks. In parallel, naturally occurring diseases, laboratory accidents or other inadvertent releases of disease agents and pathogens pose a threat which can also disrupt our societies and harm our economies.

A comprehensive legal framework has been put in place in many relevant sectors (such as the food industry, safety at the workplace, etc.) to ensure an adequate level of safety. However, in some domains imperfect implementation of safety measures and the existence of security gaps may continue to pose a risk. Europe cannot wait until accidents with severe consequences happen or for these gaps to be exploited by terrorists.

2. APPROACH AND DEFINITIONS

For the reasons mentioned above, risks from dangerous biological materials and pathogens have to be reduced and preparedness enhanced in Europe through a biological all-hazards approach – generic preparedness within overall crisis management capability. Indeed, such an approach aims at taking into consideration all potential risks, from a terrorist attack, other intentional release, accident or naturally occurring disease, so as to be prepared to handle all crisis situations relating to food supply chain protection. The reason for taking a biological all-hazards approach is that appropriate security practices cannot be built without a strong safety culture. Moreover, in the early stages of an incident it is very often difficult to identify the causes and sources of a disease. In the case of an intentional release, law enforcement will have an important role to play.

The term "preparedness" is used in a generic way covering all aspects such as prevention, protection, first response capacity, prosecution of criminals/terrorists, ,surveillance, research capacity, response and recovery. The term will also cover the steps taken to minimise the threat of deliberate contamination of the food supply through biological agents[3] and to protect against biological warfare.[4]

This is distinct from food safety, which focuses on setting standards regarding the safety of food, good manufacturing practices and quality control of agricultural products at all steps of the processing chain. It is also distinct from food security, which is defined by the World Health Organisation as access to sufficient, safe and nutritious food. Nonetheless, bio-preparedness covers a broad scope of activities relating to the protection of public health. In other contexts – laboratory environments, the research community, health care as well as manufacturing facilities, field investigations and transport – bio-safety and bio-security may also be understood in a different way.[5] The aim of bio-preparedness is not to duplicate the legal framework set up to ensure food and product safety, including emergency measures in cases of accidents or of new information about the safety of a specific product, but to complement this framework to improve security and the prevention of deliberate criminal acts, accidents as well as the response to naturally-occurring outbreaks.

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[3] Including live animals and biological agents causing zoonotic diseases.

[4] Biological warfare can be defined as the deliberate use of micro-organisms or toxins derived from living organisms to induce death or disease in humans, animals or plants.

[5] For concrete definitions of the terms "bio-safety" and "bio-security" see the WHO's Laboratory Biosecurity guidance, available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf. Further information is also available at: http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf and http://www.who.int/csr/labepidemiology/projects/biosafety/en/index.html.

In 2006, the Commission held two seminars on European Bio-Preparedness and a workshop on Transport and Traceability of Bio-materials. The results and recommendations emerging from these discussions have been fed into this Green Paper. In particular, the following issues of concern were raised: awareness about the existing legislative framework, existence and application of minimal security standards, deficits in European analytical capacity for reducing biological risks, potential misuse of research, a lack of detection capabilities, need for multi-agency and multi-sectoral cooperation, etc.

3. CONSULTATION

The Green Paper will be published on:

http://ec.europa.eu/justice_home/news/consulting_public/news_consulting_public_en.htm.

Responses should be sent by 1 October 2007. Stakeholders may use the following e-mail address: Biopreparedness@ec.europa.eu or the following mailing address:

European Commission
Bio-preparedness consultation
LX-46 3/093
1049 Brussels, Belgium

Responses from both public and private sectors will be published on the Commission's internet site unless respondents explicitly state that they wish to keep particular information or the whole response confidential.

4. OVERVIEW OF RELEVANT EU POLICIES

Combating biological risks relies on cross-cutting commitments: disarmament and non-proliferation cooperation and assistance. From this point of view, a holistic biological risk reduction approach combining the 1972 Biological and Toxins Weapons Convention, the non-proliferation suppliers group, Australia Group and public health assistance tools, would offer a unique benefit, linking security and development. EU external action instrument have a concrete added-value in this regard. At multilateral and regional level, the EU aims at enhancing the collective response capability to a biological event, including bio-terror acts.

Virtually everything that is done at the different levels to anticipate a possible defence against biological risks and bioterrorism is of relevance. A number of policies could be usually strengthened to this effect: improving disease surveillance[6] and detection systems, enhancing cross-border cooperation and communication, facilitating international laboratory cooperation, and developing mechanisms for international sharing of medical countermeasures. Such actions are already in place and could be further enhanced to the benefit the EU as a whole in the event of a naturally-occurring outbreak or a bio-terror attack. Cross-border cooperation is critical to any effective preparedness strategy and response. For this reason a European-level approach is necessary and appropriate as are efforts to coordinate activities in order to reduce biological risks and enhance preparedness.

This should also be done in the spirit of broader international cooperation. The EU and its Member States should continue working with and further strengthen cooperation on bio-preparedness within various international fora such as UN structures, the Biological Toxins

[6] A practical example is the network for epidemiological surveillance and control of communicable diseases in the Community setup by Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998.

and Weapons Convention, Australia Group, G8, NATO, etc. Within the international context, particular emphasis could be placed on enhancement of early recognition and detection of diseases on the global scale and on better promotion of European approaches to biological risks.

Many specific measures exist at EU and Member State level to ensure bio-safety and civil protection, but need to be adapted to cope with deliberate attacks. Therefore, any new actions to address possible deliberate releases may be built on existing measures.

European wide exercises, training and exchange of experts dealing with the preparedness and response to terrorist scenarios were organised under the Community Mechanism for civil protection assistance [Council Decision 2001/792/EC, Euratom]. In 2007, the legal basis for the Mechanism was updated and a Civil Protection Financial Instrument was established [Council Decision 2007/162/EC, Euratom]. These developments provide a clear legal and financial framework for the continuation and reinforcement of current activities. It is also important to recall the existing crisis management and European solidarity mechanisms.[7]

The key challenge to the food supply chain and agro-industry is the introduction of a pathogen or contaminant into the animal or food supply chains. Mitigating actions are the same as for a natural outbreak e.g. early detection, sound traceability systems, rapid control and eradication measures, contingency plans and overall coordination. Nevertheless, our tools could be developed to face bio-terror attacks during which pathogens could be introduced simultaneously in a number of different locations across the EU and to cope with simultaneous outbreaks of different diseases which could overpower the established response capacities and thereby affect public health and have an important negative trade and economic impact for the Member States and the Union as a whole.

As regards contaminants in foodstuffs, the EU has already taken measures to minimise the risks. The basic principles of EU legislation on chemical contaminants in food are found in Council Regulation (EEC) No 315/93. Other legislative instruments adopted in the field of Food Safety could also be of relevance. In particular, traceability is ensured through Regulation (EC) No 178/2002, which makes it an obligation for food business operators to be able to identify any person from whom they receive food/raw materials. The operators must also be able to identify businesses to which they supply products. The same requirements apply to importers with this “one step back – one step forward” approach. Regulation (EC) No 178/2002 also provides for emergency measures and crisis management.

Other measures which are not part of either criminal or anti-terrorist mitigation measures contribute to containing, controlling and eradicating animal diseases. For instance, animals are identified either individually with ear-tags or electronic identification, or in batches. Moreover, most livestock holdings are registered and animal movements recorded within and between Member States. These practices secure a high degree of traceability (e.g. TRACES, the TRAde Control and Expert System).

Concerning possible illegal imports of animals and animal products, the control regime centres and the legislative framework requires the approval of third countries and third country establishments, through official certification of imports and mandatory checks at border inspection posts. Provisions exist also for non-animal products through the labelling of establishments and country of origin, and traceability by batches. Customs and anti-fraud

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[7] See the Solidarity Fund regulation (EC) 2012/2002. While the present Regulation is limited to "major natural disasters", the Commission proposed in 2005 to widen the scope and to also cover "*public health emergencies*" and "*acts of terrorism*" (see COM(2005) 108final).

efforts are equally important for protecting the health and safety, in particular due to their role in controlling smuggling and counterfeiting activities.

On the public health front, various actions have already been undertaken, such as the creation in 2002 of the Health Security Committee of High-Level Representatives from Member States and the Commission, a platform for co-operation between public health laboratories in all Member States, a system for the sharing of information on smallpox emergency plans between Member States and the Commission, as well as a directory of experts for advice and investigation in cases of deliberate release of harmful agents and pathogens. Moreover, lists are kept of possible biological and chemical agents and pathogens that may be used by terrorists (smallpox, anthrax, botulinum toxin, etc.), and a guidance document on the treatment of patients exposed to pathogens has been produced by the European Medicines Evaluation Agency (EMEA).

In this context it is also important to mention the Directive (EC) No 2000/54 on the protection of workers from risks related to exposure to biological agents at work. This Directive refers to biological agents rather than micro-organisms, and includes those which have been genetically modified,[8] cell cultures and human endoparasites, which may be able to provoke infection, allergy or toxicity. Although toxicity and allergenicity are included in the definition of biological agents, the four risk groups are based on the level of risk of infection.

Regarding the enhancement of security, a Commission proposal for a Council directive on the identification and designation of European Critical Infrastructure and the assessment of the need to improve their protection[9] should also be mentioned. The proposal considers the health sector to be one of the critical infrastructure sectors. On the other hand, this paper deals with much broader issues and different set of questions compared to the proposal on the European Critical Infrastructure. Nonetheless, there may be points of contact such as protection of bio-laboratories and bio-agents. Hence, appropriate coordination of the relevant actions will take place between these two initiatives.

All this is complemented by the inspections carried out by the Food and Veterinary Office (FVO), which is part of the European Commission's Directorate-General for Health and Consumer Protection, the TRACES System, as well as 11 sectoral Rapid Alert Systems (RAS), operational 24 hours/7 days a week, such as the Rapid Alert System for Food and Feed (RASFF), the RAS-BICHAT alert system for bio- and chemo-terrorism, the monitoring and information centre of the Community mechanism for civil protection, and ARGUS, the secure general rapid alert system.

Collaboration with and within the private sector should also be highlighted. The sharing of best practices is encouraged among the pharmaceutical and food industries and large catering companies, but also between corporations and SMEs involved in the food supply chain. These organisations should be able to rely on effective response and mitigating systems when intelligence and countermeasures fail.

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8 The following legislation on genetically modified organisms is also of relevance: Directive (EEC) No 90/219 as amended by Directive (EC) No 98/81 on the contained use of genetically modified micro-organisms provides for rules on the classification of installations, as well as for contingency plans, with a cross-border dimension.

9 COM (2006) 787 final.

5. POLICY OPTIONS AND DELIVERABLES FOR THE WAY FORWARD

5.1. Key principles of bio-preparedness

Tools such as peer evaluations, awareness raising campaigns and supportive financial programmes should in the first place be used rather than new legislation, bearing in mind that a large and comprehensive legal framework already exists in many cases, at either EU or national level. Existing structures and expert groups should be used for implementation. Measures should be proportionate, affordable, sustainable and reliable in terms of the threat they seek to minimise and respond to. They will also take into consideration impacts on imports of agricultural products from Developing Countries and in particular from Least Developed Countries.

The private sector and research institutes should be involved in this process through an intensive Public-Private Security Dialogue. With regard to research, this dialogue is in the process of being established within the European Security Research and Innovation Forum (ESRIF). It will cover security research and innovation issues. The European biotechnology industry and bioresearch community need to become part of the European solution to the problems posed by biological risks.[10] It is understood that activities in the field of life sciences and biotechnology are extremely diverse in their scope,[11] and not all applications represent a threat in the context of bio-preparedness. For example, the use of biotechnological methods to produce biodegradable plastics does not entail the same risks as work on pathogens. The Commission is committed to supporting the development of life sciences and biotechnology, which represent a great potential for the EU. The objective of the present Green Paper is to contribute to improving security while fostering a safety culture and building on safety rules and best practices.

Member State authorities at national level would provide leadership and coordination in developing and implementing a consistent approach within their jurisdictions, which will be for the benefit of bio-preparedness in the EU as a whole.

Implementation of the results and recommendations arising from this consultation could be enhanced by a European Bio-Network (EBN). The EBN would be an advisory structure which would pull together European expertise on bio-preparedness from different sectors – the research community, private and public sectors (including the security and intelligence community, civil protection authorities and first responders). Its role could be to recommend possible guidelines and codes of conduct for researchers concerning materials and resources for education about effective and secure bio-standards and best practices.[12] The Network would promote and support the development of bio-standards at EU level.

The European Community has already put in place tools and mechanisms, initially developed for food safety and the fight against fraud. These instruments could be built on and used for the purpose of further reducing biological risks, including bio-terrorism. In order to be

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10 The Public-Private Security Dialogue was introduced by the Commission in its Communication on prevention, preparedness and response to terrorist attacks (COM(2004)698). The work will also take into consideration the envisaged framework for Public Private Dialogue concerning issues related to security research and innovation.

11 Communication on the mid term review of the Strategy on Life Sciences and Biotechnology, COM(2007)175 of 10. 4. 2007.

12 Such codes of conduct should also take into account where relevant, the legal situation within the EU and in third countries, including rules on export controls for dual-use technologies in the biological/biotechnology area.

prepared to prevent bio-terrorism or natural outbreaks, new approaches should be considered in addition to existing tools where necessary.

Questions

1. Is a comprehensive approach to European biological risk reduction and preparedness required?

2. How could the EU bridge the perceived gap between non-proliferation and international cooperation in a dual-use field such as biology?3. Can the current defence mechanisms for facing natural and non-intentional crisis situations become more sufficient to cope with deliberately provoked mass-scale and simultaneous crisis situations?

4. How could the European Centre for Disease Prevention and Control, as well as the European Food Safety Agency contribute to this endeavour?5. Would peer evaluation methods be useful in addressing existing shortcomings across Europe?

6. What role should be played by the private sector in a public-private partnership?

7. Should an EBN (European Bio-Network) be created in order to support the implementation of the results of this consultation?

8. How could cooperation among relevant authorities and agencies at EU level be improved?

5.2. PREVENTION AND PROTECTION

Awareness

Research institutes, researchers and small-size bio-companies with limited resources may have difficulties in following the new adjustments of rules and restrictions applicable to certain activities in the field of life sciences (e.g. rules on export of dual use goods, transportation of bio-agents, safety requirements).[13] As a consequence, the level of compliance with these regulations may differ across Member States as well as between stakeholders. For this reason, Member States with the support of the Commission could consider developing national awareness campaigns based on best practices identified across Member States.

Questions

9. Should awareness among stakeholders be increased about possible risks related to biological research and commercial activities and about the rules they have to comply with? If so, how?

10. Do you experience difficulties in following new adjustments of rules and restrictions? If so, which ones?

Minimum standards and procedures

Physical security at facilities housing non-military collections of pathogens could be enhanced and improved. A peer evaluation method covering all Member States could be used to assess application levels and practices with regard to bio-standards used in research, by industry and public bio-laboratories working with dangerous pathogens. This could include the assessment and identification of obligatory common minimum-security standards for bio-laboratories and

[13] For example, lack of awareness about the EU legal framework relating to export controls on dual-use items and technology was mentioned by exporters themselves at the conference on the reform of the EU regime for exports of dual-use items held on 26 January 2007.

the pharmaceutical industry. Internationally accepted bio-standards could be enhanced in developing schemes for the accreditation and certification of laboratories. Again, in areas where such schemes exist and function well, work should not be duplicated. Relevant parts of the OECD work on Biological Resources centres could be used to this effect.

On the basis of what is already done,[14] these standards could include:

- European guidelines for the physical protection, access control and accounting of collections of dangerous pathogens and cultures (including those synthesised in laboratories) that could threaten public health or national security.
- An agreed EU list of "identified bio-agents" with a specific focus on potential terrorist misuse.[15]
- European rules for national certification and registering of facilities with regard to compliance with bio-standards and the credentials and competences required of researchers.
- Systems where stakeholders report nationally on types of life science work that is being performed involving hazardous bio-agents usable for terrorist purposes.
- Member States' procedures for security checks on scientists and technicians who wish to work or already work with hazardous bio-agents identified in an EU list. The level of clearance and the number of persons requiring this would have to be assessed in order not to impede research and access of relevant expertise from outside the EU to European research facilities.
- A European and possible future international system for certifying reliable and trusted facilities and researchers, facilitating secure and safe exchange of samples and sensitive research results. Such a system could help to avoid obstacles which would create critical bottle necks in scientific exchange and development. Common minimum standards and certification methods are required.[16] In the first stage of this process, EU best practices for defining of what is "in the public domain" and what is "basic scientific research" could be adopted, as called for by the Commission when reviewing the EC regime of export control on dual-use items and technology.[17]
- International exchanges of researchers and inflows of experts as well as students from third countries into the EU have a positive impact on the development of life sciences and on European competitiveness. Third-country nationals should be required to comply with European bio-security arrangements and, when deemed necessary, with security provisions. Security procedures should be proportionate in order not to hamper scientific progress.

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14 See for example the Commission proposal regarding the changes to the EU legal framework of export controls for dual-use items (COM 2006 829) and in particular Article 23 thereof.

15 Several lists exist. However, they are often too general, do not necessarily suite European circumstances or are not terrorism-relevant.

16 Research results concerning listed dual-use technologies (in EC Regulation 1334/2000, as amended by Regulation 394/2006) and in some cases on non- listed dual use technologies might require the Member State's authorisation prior to being shared with other researchers/industry in third countries.

17 See COM (2006) 829.

Questions

11. Should common minimum bio-standards and the exchange of best practices be developed at the EU level?

12. Would you be interested in developing rules for national certification and registering of facilities and researchers which could facilitate European and international exchange of samples and expertise?

13. What should be included in national registers – agents, facilities, activities – ensuring that there are no loopholes and that the security and oversight requirements avoid damaging health, safety, research or industrial activities?

14. Should a limited number of bio-researchers possess security clearance? If so, on what basis would you identify them?

15. Should a specific and limited number of laboratories, health institutions, production establishments, pharmaceutical and food-processing plants be accredited on the basis of compliance with minimum security standards?

5.3. ENHANCING ANALYSIS AND SECURITY ISSUES RELATED TO BIOLOGICAL RESEARCH

Developing a European analytical capacity for reducing biological risks[18]

The Commission could fund new expertise at EU level by developing a European capacity for analysis and modelling contributing to the reduction of biological risks from future bio-threats,including risk analysis and risk classifications. Where relevant, minimum standards could be considered. New knowledge and competences could contribute to improving and developing new countermeasures and to enhancing protection of the food supply chain. The number of technical experts would also increase. This would lead to adequate and effective response mechanisms through multi-sector cooperation e.g. between food, military, law enforcement, customs, health, environmental and agricultural authorities. EU funding could be made available for joint training and awareness raising.

Some lists of dangerous biological agents and pathogens have been developed, such as during the negotiation of a "verification protocol" to the 1972 Biological and Toxins Weapons Convention. Some are categorised according to infection hazard and others based on their dual use nature and potential for weapons production. In order to conduct adequate policy development discussions and secure adequate support for Member States, it would be necessary to conduct classified discussions between national experts in order to identify and agree on a list of organisms. Biological agents and pathogens which, from a security perspective, are of concern, and which would pose a particular challenge to the Union and Member States' response and recovery capabilities, should be further identified and listed.

[18] At European level, numerous relevant research activities have been developed within the 6th Research Framework Programme, Preparatory Action for Security Research, and the current call under the 7th Research Framework Programme.

Questions

16. Do you agree that an enhanced EU-level capacity for analysis of biological risks is necessary or is the present situation satisfactory?

17. Should there be EU funding for joint training and awareness raising?

18. Should EU-level lists of biological agents of special security concern be developed jointly by the Member States and the Commission?

19. If you believe that each Member State should have its own pathogen lists, do you agree that interaction with other Member States on this topic could be beneficial for your organisation?

20. Is the current level of research activities on bio-preparedness sufficient in the EU? Which research activities should be prioritised?

Security issues related to biological research

Scientific progress is assured by the free exchange of research results and the ability to verify them. Research and access to biological material by authorised and legitimate personnel, e.g. in laboratories and the scientific community is a highly valuable and necessary endeavour and should not be hindered. Today mainly national rules exist for the exchange and access to biological material. Intra-Community transfer and transnational exchange are only partially covered by these rules. The goal to render the dissemination and use of dangerous pathogens secure should not be a hindrance to scientific research. Methods could be explored in order to monitor bio-research and the dissemination of pathogens for scientific use more effectively without impairing the privacy of the citizen. Security concerns should not prejudice competitiveness within the research community or bio-industry. Close cooperation will have to be established with the ESRIF which will set up a strategic agenda for security research and innovation.

A set of bio-security and bio-safety guidelines[19] could be developed to ensure that publicly funded research is complying with common security standards. The EBN could contribute to the identification of these guidelines. For EU funded research projects, clear ethical review procedures already exist based on the principles set out in the Research Framework Programmes. Specific bio-security and bio-safety guidelines could strengthen but not supersede these review procedures.[20]

Organisations such as not-for-profit organisations, foundations and trusts which provide funding for scientific biological research could play an important role. Research grants should not only be conditioned upon the quality of a proposal, but also upon the ability of the given applicant to comply with bio-standards as well as possible future security guidelines. Scientific journals which publish research papers could be made aware of potential security risks relating to the misuse of these scientific results.

Existing Member State and Commission rules on security which lay down the process for transmitting and storing classified information and holding classified meetings with relevant actors in both the public as well as the private domain must be respected. A specific procedure could be applied by Member States and the Commission in association with the scientific community where sensitive dual-use research results could be published in two different

[19] For the definition of the terms "bio-safety" and "bio-security" see footnote 5.

[20] A detailed explanation of the ethical review process can be found on http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=73

versions: (1) a public version with no publishing restrictions (without sensitive content), and (2) a restricted version containing the sensitive parts published in a manner allowing access only for relevant and secure bio-stakeholders. The EBN could, for example, support the preparation of these measures.

The aim of the proposed actions is not censorship of biological science. Free scientific thinking and research is a fundamental principle that should be respected, and research has a huge potential to contribute to the objectives of bio-preparedness.

Questions

21. Should public and private funding for research on bio-substances be made conditional on the compliance of bio-standards?

22. Do you agree that a publication procedure should be applied where sensitive biological dual-use research should be published in two versions:

- a public version with no publishing restrictions (without sensitive content) and

- a restricted version containing the sensitive parts of the research with access only for relevant bio-stakeholders?

23. Could the EBN assist in the development of bio-security and bio-safety guidelines for publicly funded research?

Professional code of conduct

The goal is to build up a strong culture of awareness and compliance with bio-standards already for first- and second-year life sciences and biotechnology students at university level. Compulsory academic courses in life sciences could focus on dual-use consequences of bio-research and on ethics of bio-research. The courses could cover issues such as the risks of misuse of research results in relation to biological terrorism and warfare and professional responsibility as well as liability.

In this context, it is important to mention that expert groups of the Biological and Toxin Weapons Convention recommended that codes of conduct should involve all actors dealing with bio issues and be broad enough to cover any unforeseen research and results in terms of technological development and new situations. Currently, researchers in life sciences do not have a professional code of conduct. Graduate students involved in sensitive biological research could be required to sign a professional code of conduct.

The EBN could help develop a professional code of conduct at EU level. These elements should be part of all EU-funded threat reduction programs involving redirection of former weapons scientists, such as International Science and Technology Centre ISCT.

Questions

24. Should mandatory academic courses on bio-standards and best practices become part of the university curriculum in the field relevant to life sciences??

25. Should researchers in life sciences be obliged to adopt a professional code of conduct?

26. Should the above-mentioned professional code of conduct be developed at EU level? If so, by whom?

5.4. IMPROVING SURVEILLANCE CAPACITY

In the Single Market, capital, goods and persons can circulate relatively freely. For a number of security and health reasons it is crucial that appropriate mechanisms and arrangements are in place:

- To ensure prompt notification and exchange of information in case of security threats and terrorist attacks;
- To facilitate action at EU or Member State level being taken at source in order to stem the possible spread of infectious diseases and environmental contamination;
- To ensure mutual assistance between Member States and European Institutions for the diagnosis and management of bio-incidents;
- To facilitate necessary laboratory and epidemiological investigations;
- To ensure flexible and effective public health and civil protection responses.

Public and animal health surveillance could be further enhanced to ensure effective monitoring of unusual outbreaks of human and animal disease and develop practical methods of co-ordinating European and international responses to major events that may involve bio-weapons.

As regards surveillance and detection, the Member States and the Commission could further improve their monitoring, early warning and detection capabilities, e.g.:

- Comprehensive detection systems concerning the introduction of pathogens into humans, livestock or crops;
- Improving the speed of laboratory testing;
- Better means to attribute responsibility through advanced bio-forensic methods, in particular in co-operation with third countries (US Centres for Disease Control and Prevention, Russia, China, etc.) and international organisations (WHO, FAO, OIE).

Member States, with the support of the Commission and the European Centre for Disease Prevention and Control (ECDC), could carry out a European analysis of Member States' laboratory capacity to handle crisis situations, especially the European reference laboratories, which are essential in crisis situations for the identification of pathogens and diseases. Mobile bio-laboratories or pen-site tests supported by qualified expertise may be required for early intervention and identification anywhere in the European Union or internationally, in compliance with Australia Group norms and the EC Dual-use regulation 1334/2000. Mobility, versatility and flexibility are important factors in preventing disasters of a biological nature. In such a context, the EU should define an approach combining non-proliferation and international cooperation and assistance

New priorities could include technical assistance and expertise, e.g. exchange of pathogens, culture collection inventories and the security of these collections, or increasing laboratory capacity in order to identify disease and enhance disease surveillance systems.

Detection and tools for detection are essential for early warning, especially as regards first responders, in identifying a hazardous pathogen. The Member States currently lack sufficient detection tools to test live and dangerous bio-substances and pathogens. The EU could consider further supporting the development of such detection tools and own capacity in order to strengthen its preparedness, but also its bio-competitiveness. In the context of detection and surveillance, the potential of new information and communication technologies could also be further explored.

In January 2007, the Commission concluded a public consultation on a Green Paper on detection technologies in the work of law enforcement, customs and other security authorities.[21] Future action in this area may be relevant for the further enhancement of European bio-preparedness.

Questions

27. Each Member State depends on the bio-preparedness of others. In view of this, should the current early warning mechanisms within the European Union and Member States be further adapted? If so, in what respect?

28. How could the EU coordinate the different initiatives, at national, NATO, G7 and WHO level, in order to increase the overall consistency and effectiveness of an EU capability?29. Do you consider that coordination of existing warning and detection capabilities, as well as the exchange of best practices in bio-preparedness, should be enhanced at EU level?

30. Should the EU look into the possibility of developing a capacity for test detection tools on live and dangerous substances?

5.5. RESPONSE AND RECOVERY

Cooperation between civilian health, civil protection and law enforcement authorities, between Member States and at EU level should be further strengthened. Medical and law enforcement actions are needed to ensure good co-ordination and communication between Member States' national health services, law enforcement agencies, rescue services and the military in order to draw up necessary bio-preparedness contingency plans. Member States could further integrate epidemiological and law enforcement cooperation in their contingency planning. The Commission could actively participate in and support such cooperation.

Organisation of cross-border training/workshops, at EU level and between Member States, could be intensified. These training activities/workshops could include co-operation between law enforcement organisations and epidemiologists for joint initial assessments of threats, suspected items and pathogens, and of incidents of uncertain origin. The EU and the Commission could participate in these training sessions/workshops.

Regular trans-national, multi-sector training courses on preventing, preparing for, containing, and responding to bioterrorism and/or naturally occurring disease outbreaks could be developed and conducted by the Member States and the Commission.

[21] Further details can be found under: http://ec.europa.eu/justice_home/news/consulting_public/news_consulting_public_en.htm.

More regular exercises, both at EU level and in Member States, could be further developed in order to assess whether the measures in place are adequate and appropriate, as is already done with animal health contingency plans. In this way weaknesses identified can be remedied. The goals are to:

1. Strengthen national and international capabilities to identify and quickly detect outbreaks with an epidemiology profile which could indicate a bio-terrorist attack. The purpose is to share this information quickly with appropriate Member States and EU organisations. When applicable and relevant, the UN Secretary-General investigation mechanism for alleged use of biological weapons or suspicious outbreak of disease could be used.
2. Improve multi-sector interoperability between food, civil protection, military, law enforcement, health, animal health, environmental and agricultural agencies in order to prepare for and combat bio-terrorist threats and to recover a previously disease-free status for trade purposes.
3. Increase cooperation on countermeasures and development of effective national and international countermeasures to contain the spread of deliberately released pathogens.
4. Develop and test effective risk communication strategies.
5. Depending on the scope, magnitude and time pressure of the bio-attack, define responsibilities and standard operating procedures according to scenario analysis.

Questions

31. Should co-operation among relevant authorities and agencies at Member State and EU level be improved? If so, how?

32. Are regular exercises and training courses a good approach to enhance bio-preparedness or should other additional actions be pursued?

Preserving and developing a European response to biological risks and threats

It is a very expensive and lengthy procedure to develop and test a new vaccine. This kind of capacity cannot be built up within weeks or even months. Additionally, capacity building and formal approval of medicinal products is not only a Member State matter. The private sector plays an essential role in bio-research. If there is no market for a vaccine, private industry will neither develop one, nor maintain facilities in expectation of a biological crisis situation. Emphasis could therefore be put on the establishment of antigen or vaccine banks and/or antiviral stocks for the control of known highly contagious and dangerous pathogens. The EU's Foot and Mouth Disease antigen bank or the vaccine bank for classical swine fever and bluetongue could be used as examples.

The challenge of today's bio-threats requires advance planning and a long-term policy approach. Therefore, beyond efforts already undertaken by Member States, including in the military sector, the Member States and the Commission could support the development of a public-private business model for medical countermeasures for which there is no natural market in Europe. Suitability of approaches of other countries could be considered.

The discussions on the stockpiling of vaccines are ongoing. Subsidising full solidarity stocks has been proposed. However, limited and minimum-level EU solidarity stocks could be considered. Member States and the Commission could give financial support for the costs of purchasing and storing of such stocks. This is already the case in animal health through Council Decision 90/424/EEC. Thus there would be no need to build new storage capacity,

and citizens' protection levels would be enhanced. These solidarity stocks would be released in a crisis situation and shipped, respecting time limits, to the Member State or Member States affected.

Questions

33. Do you agree with the need to build up a European capacity for developing medical countermeasures including vaccines and prophylactics?

34. Do you agree that the creation of limited EU solidarity stocks, as already exist for animal health, supported by Community funding, would be a way forward?

35. Are the provisions already in place, such as antigen and vaccine banks, or reagent banks, sufficient?