

European Task Force on Bioterrorism

Contributions of the European Task Force on Bioterrorism To the Green Paper on Bio-Preparedness

The Commission of the European Communities Green Paper on Bio-Preparedness is a substantial progressive step toward policies for reducing the likelihood of a bio-threat and the harmful consequences should a deliberate or non intentional release of pathogen agents occur. Indeed, this paper is the most forward-thinking authoritative statement on Bio-Preparedness anywhere in the world at this time.

In the support of the European Commission Directorate General Justice, Freedom & Security (JLS), and Directorate General Health & Consumer Protection (Sanco), EuropaBio – The European Association for Bio-Industries has organized a European Workshop on Bio-Preparedness on the 20th of September 2007 in Brussels with companies, research institutes, and public bodies. Discussions mainly focused on Bio-safety, Biosecurity, Bio-defense, Bio-Preparedness, strategies and technologies in the fight against Bioterrorism.

The following comments start by commending the Green Paper's extremely significant attributes, moving increasingly to assess some of the paper's less fully developed assertions. The final two comments highlight the Green Paper's most substantial omission: the need for capacity to identify future challenges, and the need for strong policies designed to prevent terrorists from having capabilities to commit a bio-threat.

The conclusions of the workshop organised by EuropaBio with the support of STACCATO partners – Stakeholders Platform for Supply Chain Mapping Market Conditions Analysis Technologies Opportunities – are the basis of this contribution.

This contribution for the Green Paper on Bio-Preparedness is based on input from Academic, Industry, Research Institutes, EU & International Organisations experts.

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The Green Paper deserves commendation for recognizing two essential principles that should be beyond controversy.

- a. Bio-preparedness measures must be built on more generic measures that engage more stakeholders involved in public health, food safety, disease detection, military, law enforcement, customs, environmental and agricultural authorities.
- b. Bio-preparedness entails both cross-cutting commitments and multilateral consensus. There is a compelling need, therefore, for approaches that integrate multiple perspectives that transcend national boundaries.

QUESTION: Is a comprehensive approach to European biological risk reduction and preparedness required?

Answer: A risk in one nation state quickly becomes a risk to all. This was highlighted by the spread of Avian Flu but would become much more of an issues in the case of an airborne Bo agent terrorist attack. The approach should include a review of the capabilities across Europe and look at enablers and barriers to the implementation of new technologies for prevention, monitoring and decontamination. This may include a review of testing and associated legislation.

QUESTION: How could the EU bridge the gap perceived between non proliferation and international cooperation in dual use field such as biology?

Answer: Legislation in the areas of dual use technologies are often in practice over cautious and can hamper progress, information sharing and have a negative economic impact. A centralised coordination could be formed to interface the requirements of public and Biosecurity with industry and academia. This would allow requirements and capability development to be made visible to those that are assesses to be appropriate stakeholders in the field. However this would have to be implemented in a pragmatic way.

QUESTION: 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 situation?

Answer: Dangerous pathogens and toxins are colourless, odourless and tasteless and they know no borders.

In case of an attack:

- *It will come without a warning an known location*
- *The exposed population can be very large and hard to identify*
- *Its magnitude will not be clear immediately*
- *The identity of the agent of use will no be clear right away*

We need to learn the response from the natural crisis (e.g. H5N1 and foot and mouth) and use this to better prepare for the worst case scenarios.

There is currently no tangible link up between the equipment that is being designed and developed for CBRNE protection in a military scenario and the similar requirements faced by the emergency response and planning communities. By working together to promote and mature new technologies we can greatly improve the response time and situation awareness. To do this we need to begin by ensuring that each member states, industry, medical, security and intelligence stakeholders agree common aims and have means by which they can communicate and share best practices.

QUESTION: 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?

Answer: *Inter State cooperation would be preferred, however, making equipment and communication networks of the same standard between states during a cross border emergency may be more challenging. For example sharing results, common recording methods, common equipment interfaces, common radio communication system...*

It may be more practical to address common requirements and best practice in the short term as well as reviewing the capabilities across Europe and looking at enablers and barriers implementation of new technologies for prevention, monitoring and decontamination. This may include a review of testing and associated legislation.

QUESTION: 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?

Answer: *Publication of a clear guide to roles and responsibilities in this field would be a help in the short term. Mapping of involved stakeholders could be very helpful to set up a European Bio-Preparedness Directory.*

QUESTION: Should cooperation among relevant authorities and agencies at Member State and EU level be improved?

Answer: *A regular forum for Biosecurity communication needs to be established.*

There is a need to develop and test ALL the communication strategies (in page 16 – bullet 4 the focus is limited to RISK communication strategies only). When the accident occurs, the first need is to be able to exchange information to have the best possible situation awareness. There are many important decisions to take, different alternatives and several factors to take into account (in a time critical context). This means that there is a need to develop interacting decision support tools.

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

Answer: *Protection, prevention and countermeasures (medical and non-medical) need to be considered holistically. The cost of mass vaccination needs to be weighed up against the cost of developing early warning systems.*

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

Answer: *On the subject of stockpiling there are issues to be tackled if it was decided to create regional stockpiles. It would be necessary to agree on:*

- *the location of the host country and the responsible body for coordination*
- *custom clearance and transportation issues*
- *treatment of the stockpiled products*
- *the delivery of the product in an emergency*
- *financial matters (cost, reimbursement)*
- *the security and the safety of the stockpile*

EuropaBio agrees on the creation of a limited EU solidarity socks, as already exist for animal health, supported by Community funding.

2. The Green Paper laudably asserts the principle that free scientific thinking and research is a fundamental principle that should be respected. “Research and access to biological material by authorized and legitimate personnel is a highly valuable and necessary endeavour and should not be hindered.” The Green Paper recommends four critical policy initiatives that deserve great attention. These recommendations have long been discussed but have not been made mandatory. They should be the highest priority. If the European Commission goes forward with these recommendations which go beyond current policies in other advanced nations, it should set the standard for global implementation.
 - a. Physical security measures at facilities housing dangerous pathogens are critical, including national certification of critical facilities and credentialing of researchers.

Recommendation: *Certification of facilities is an essential and primary requirement for Bio-Preparedness. European initiative in this area would likely spur other scientifically advanced societies to move in a similar direction.*

Credentialing of researchers is far more controversial. Initiatives in this regard need to be carefully considered in view of the potential implications for personal privacy and non-discrimination against researchers.

- b. There should be a list of “identified bio-agents” with a specific focus on potential terrorist misuse.

Recommendations: *Lists of dangerous pathogens are simultaneously essential and extremely difficult to produce. It is essential that multiple jurisdictions employ the same lists lest confusion among different lists undermine their purpose. Moreover, such lists need to be capable of being continuously revised as new pathogens are created or discovered.*

Recommendation: *Money is well spent on combating smallpox and anthrax because those two agents pose exceptionally serious threats, but the list of additional agents that might be used in an attack is endless and even the US can not afford to develop expensive countermeasures against very many of them. Europe and US are facing a major challenge: “the need for a flexible responsive adaptive program”.*

- c. A procedure for publishing sensitive dual-use research in two different 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.”

Recommendation: *Pre-publication review of scientific research and possibly classification of its release raises profound questions for scientific freedom – questions that have been addressed in the nuclear field but not substantially in the life sciences. As an example, in the United States, these issues continue to resonate with controversy and have not, as yet, been satisfactorily addressed.*

- d. Compulsory academic courses in life sciences could focus on dual-use consequences of bioresearch and on ethics of bioresearch.

Recommendation: *Much attention in recent years has been devoted to Codes of Ethics and similar commitments to engage in bioresearch to promote life and to eschew research that is designed for malevolent purposes. While these Codes have value for raising awareness of potential risks among bio scientists, they have profound limitations for addressing intentionally hostile conduct. It is critical to consider, therefore, how Codes of Conduct can be enforceable.*

Code of Conduct:

- the code should be considered as an essential element of scientific deontology, addressed to the individual conscience of the scientist, with no automatic juridical implications;
- the main focus should be on the individual responsibility of scientists and on the principle that ethical values shall overcome hierarchy;
- the code should not contain a definition of permissible or forbidden experiments, but consider the concept of acceptable or unacceptable intents of research programmes: it should therefore take into account the frame within which a certain experiment is performed;
- the code should become an integral part of education curricula and, through its universal adoption, its adherence become compulsory for any advanced scientific training in life sciences;
- the code should not aim at establishing principles of self-censorship, but represent a tangible example of self-governance by the scientific community;
- it should also include the recognition of responsible principles of safe laboratory practice

- e. Research grants should be conditioned upon an applicant's ability to comply with existing Biosecurity standards.

Recommendation: *This is critical. Yet, standards must be consistent (at least throughout the EU; someday globally), and enforcement must be both uniform and rigorous.*

- f. There should be a system for reporting life science work with hazardous pathogens and to facilitate safe and secure exchange of samples and sensitive research results.

Recommendation: *Safeguards must be developed to ensure protection of sensitive information as well as information having proprietary value. Legal mechanisms for redressing loss of confidentiality need to be emplaced.*

- g. The international exchange of researchers and experts should be encouraged.

Recommendation: *The Green Paper is absolutely correct in asserting the imperative of encouraging international exchange of researchers.*

- h. There should be a "European Bio-Network (EBN)" as an advisory structure to recommend guidelines and codes of conduct about effective and secure bio-standards and best practices.

Recommendation: *Common minimum bio-standards and the exchange of best practices should be developed globally. The EBN could usefully contribute to that process, especially by working with international organizations that are already engaged in developing such standards. However, security standards and best practices for European laboratories should not be an end in and of itself. A central coordinator role is required – but its remit needs to be further determined beyond the policy, guidelines and codes of conduct for the researcher's role described in the Green Paper.*

- 3. The Green Paper's most profound contribution is in regard to management of a bio attack's consequences. In this context, the Green Paper appropriately calls for:

- a. Development of detection/testing tools for early warning of hazardous pathogen releases, especially for first responders. This should include facilitating laboratory and epidemiological investigations.

Recommendation: *such tools currently have limited capabilities, and some experts question whether such tools might give a false sense of security in the face of malevolent efforts to develop undetectable pathogens.*

- b. Mutual assistance modalities among EU Member States and institutions to diagnose and manage bio attacks, including prompt notification and information

exchange procedures, enhanced surveillance of unusual disease outbreaks, and facilitating laboratory cooperation and the speed of laboratory testing.

Recommendation: *In view of rapid global movement of persons and agricultural products, assistance modalities that are exclusively regional may be merely a good start. These modalities must be globally effective. In this regard, the Green Paper's insistence that "a European-level approach is necessary and appropriate" may mis-focus the dimensions of the problem.*

Moreover, while enhancing European capacity for developing medical countermeasures including vaccines and prophylactics including stockpile creation and vaccine banks, is essential, in the absence of profound law enforcement measures for preventing terrorists from committing a bio attack, such measures are likely to be a Maginot Line of defense.

- c. Flexible and effective public health and civil protection responses to stem the possible spread of infectious diseases and environmental contamination. Organisation of cross-border training/workshops could be intensified.

Recommendation: *These responses are likely to have substantial implications for individual privacy and civil liberties. Adaptations of existing laws might be called for in order to harmonize the need to limit the consequences of a bio attack with the need to preserve democratic institutions during periods of enormous panic and stress.*

Prior training/workshops have impressively focused on the need for improving trans-sectoral communication and movement of response resources. However, these exercises have strongly avoided the profound legal crises that are likely to emerge in connection with a widespread and severe bio attack. Future exercises should be explicitly designed to confront those crises.

- d. 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).

Recommendation: *This is an extremely important assertion. However, the omission of reference to Interpol, Europol, or other national and trans-national law enforcement bodies is an unjustifiable omission.*

4. The Green Paper asserts that "The EU should define an approach combining non-proliferation and international cooperation and assistance." Following that assertion is a short list of Biosecurity priorities that intrinsically have little to do with non-proliferation. Strikingly omitted here is any mention of the challenges facing international non-proliferation of bio weapons capabilities including:

- a. Measures for characterizing and distinguishing Biodefense programs that should be allowed as legitimate efforts to prepare against bio-attacks from bio-offensive programs that should be disallowed as violations of global norms against bio weapons.

- b. Measures for characterizing as allowed or disallowed under existing non-proliferation regimes the products of emerging technology, including *inter alia* non-lethal agents, nanotechnology-created delivery systems, and bio-regulators.
 - c. Measures for ensuring the prompt, comprehensive, and verifiable destruction of all bio weapons stockpiles pursuant to confidence-building oversight mechanisms and without hindrance by national security officials.
5. The Green Paper significantly asserts that “The challenge of today's bio-threats requires advance planning and a long-term policy approach.” Despite the clarity of that assertion, the Green Paper fails to discuss the fundamental impediment to bio-preparedness: the absence of any authoritative structure that can identify approaching threats and clarify policies to meet them. More than any other strategic challenge, the malevolent use of disease produces constantly changing and expanding options. However, there is no institutional capacity for identifying tomorrow’s challenges.
6. The Green Paper entirely ignores the profound role of law enforcement detection of bio-terror preparations, *i.e.* before an actual attack is committed.

There is no discussion of:

- ↪ what information-gathering modalities might be usefully employed to help identify illicit facilities where pathogens are refined and weaponized
- ↪ what training might be appropriate to enable law enforcers to recognize such illicit facilities or movements of critical items
- ↪ what authority should law enforcers have to pursue suspicious but not-yet demonstrably illegal activities
- ↪ how modalities of international legal cooperation can be strengthened to address bioterrorism at the prevention (as contrasted to the response) stage
- ↪ how European Union efforts to promote bio-preparedness can be productively integrated with the Interpol Program on Preventing Bio-Crimes

As a consequence, the Green Paper calls for a comprehensive approach to European biological risk reduction and preparedness addressing more questions on the above topics which could be discussed within the framework of a Forum such as the EBN – European Bio-Preparedness Network made of Experts from Academia, Industry, Research Institutes, EU & International Organisations. The EBN could work very closely with ESRIF – The European Security Research Innovation Forum headed by Gijs De Vries, former EU Counter Terrorism Coordinator.



The NATO Science for Peace and Security Programme

2. Workshop on Bio-Preparedness and Defence

A workshop on Bio-Preparedness will be held in Bucharest, Romania on the 25 and 26 of October. It will be co-hosted by Romania and Serbia and supported by NATO (Science for Peace and Security Programme).

The workshop on Building cooperative and Regional Approaches to Bio-Preparedness and Combating the Threat of Bioterrorism will address a number of Biodefense topics under five general strands:

1. International and Regional Responses to the illicit trafficking of biological materials and bioterrorism;
2. Health community responses to and strategies for responding to outbreaks of highly infectious diseases;
3. Bio-Preparedness and responses to bio-terrorist events;
4. Regional initiatives combating bioterrorism
5. National perspective on combating bioterrorism

This Bio-Preparedness and Defence workshop aims to strengthen activities and expand communication and coordination role of the Regional Centre for Higher Studies for Preventing Bio-terrorism which was formerly established in Bucharest as NGO in 2005. A regional Centre with a multipurpose role in a much specialised area would have a number of advantages. It could provide rapidly deployable response capability, serve as a research and development laboratory for military, law enforcement and health services, play the role of communication and coordination centre in combating Bio-terrorism in the region.

This workshop will pull together knowledge of various relevant experts from the countries, organizations and institutions which are engaged in the activities of Bio-Preparedness and defence domain. It will provide excellent possibilities to share valuable experience, exchange views and what it the most important will help to outline the future development of the

Regional Centre for Higher Studies for Preventing Bioterrorism

Your participation in this workshop would be greatly appreciated.

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Please send a letter with your confirmation and your CV