## **Invited Articles**

## EU Approach to Bio-terrorism

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Bio-terrorism has emerged in recent years as a key challenge for European security. The Health Security Committee (HSC) is responsible for coordinating health preparedness systems and emergency response plans and raising the alert in the event of a health-related incident of EU concern. The approach to biological risks suggested by the EC in the Green Paper is an "all-hazards approach". **B**io-terrorism has emerged in recent years as a key challenge for European security. To respond to this threat, the European Union (EU) has engaged in the endeavour of preventing and protecting from possible bioterrorist attacks, fostering preparedness in its Member States through a comprehensive approach.

The nature of the bioterrorist threat for Europe is peculiar. In fact, a biological attack could likely affect several Member States of the EU simultaneously and have considerable economic and social impact. Therefore, the coordination of Member States' responses to deal with the occurrence of a biological accident emerges as vital.

The first concrete action to protect the Union from the menace of bio-terrorism was the establishment of the Health Security Committee (HSC) in November 2001. The mandate of the HSC is to ensure coordination and exchange of information among Member States in the case of the release of biological or other agents which may threaten public health. The HSC is responsible for coordinating health preparedness systems and emergency response plans and raising the alert in the event of a health-related incident of EU concern.

By means of a series of Communications (i.e. Communication 2003/320 in June 2003, Communication 2004/701 in October 2004 and Communication 2005/605 in November 2005) the European Commission (EC) has developed its strategy to enhance intracommunity cooperation against the bioterrorist threat in various respects. Although such communications are not legally binding, they outline the key policy tendencies of the EU and put forward guidelines for Member States' action. Firstly, with regard to the protection of public health, the EC requests that national authorities implement health measures (e.g. effective surveillance systems, systems for prompt notifications of information) in Member States to create the capabilities for rapid detection and identification of deliberate releases of biological agents. Since the EU is a border-free area, rapid notification and exchange of information in the event of biological threats are crucial components of an effective response. Accordingly, the creation of a Community programme of cooperation on preparedness and response to biological and chemical agent attacks (BICHAT programme) has been essential together with the establishment of a relevant rapid alert system ("RAS-BICHAT") for notifications of incidents involving the deliberate release of biological and chemical agents.

Similarly, with a view to enhancing preparedness and consequence management capabilities for civil protection, the EC has introduced the Monitoring and Information Centre (MIC), a special unit that receives requests for assistance from the countries hit by a disaster and forwards them to all Member States. Also, a number of specific community rapid alert systems (operating as information exchange networks) for a swift response to emergency situations have been established (e.g. ECURIE system for radiological emergency, EWRS for communicable diseases).

However, the turning point of the EU fight against bio-terrorism was the Green Paper on Bio-preparedness of July 11, 2007. Through this instrument the EC launched a comprehensive discussion with all relevant stakeholders (public health authorities, law enforcers, bioindustry, academia) on possible legislative measures to enhance preparedness and response capabilities to biological threats. It is to highlight that the Green Paper does not consist of legal binding provisions. Nonetheless, its principles may eventually be translated into future EU legislation.

The approach to biological risks suggested by the EC in the Green Paper is an "all-hazards approach". This means to enhance preparedness and response capabilities to biological threats regardless of the origin of the risk (which could be the naturally occurring release of biological agents or the malicious use of dual-use expertise and technology for criminal intents). The aim is to set up a European strategy for a *generic preparedness* to cope with all crisis situations. Since a large number of specific measures on bio-safety and civil protection have already been emplaced at either the European and the Member State level, the EC emphasizes that the priority is not to adopt new legislation. Rather, it is crucial to adapt existing tools to enable them to efficiently respond to deliberate biological attacks. Therefore, tools such as peer evaluations, awareness raising campaigns and supportive financial programmes should be developed first.

The Green Paper highlights the need of a close collaboration with the private sector. Accordingly, sharing information and best practices with private actors (for example, pharmaceutical industry, food industries, SMEs) should be promoted. In the view of the EC, the European biotechnology industry and the bio-research community have to become part of the European solution to the problems posed by biological risks.

The EC also underlines the necessity of developing a European analytical capacity for a multi-sector response to the bioterrorist threat bringing together expertise from different fields involved (scientific research, law enforcement, military, health, environmental authorities, etc.). Equally, the security of facilities housing collections of pathogens should be enhanced. To this aim, Member States should identify a set of obligatory common minimum-security standards for bio-laboratories and the pharmaceutical industry.

Since the EU seeks to promote scientific progress while assuring safety and security, the research on dangerous pathogens should be rendered secure without obstructing scientific bio-research. Therefore, the Green Paper recommends the adoption of bio-security and bio-safety guidelines to enable public health authorities and law enforcers to monitor bio-research and the dissemination of pathogens for scientific use and verify their compliance with security standards. With the same view, a common European professional code of conduct for researchers is envisaged to raise awareness on possible misuse of bio-research for criminal intents. Another key component of the EU biopreparedness is the improvement of European surveillance capacities. Since the EU is a single common market where capitals, goods and persons enjoy cross-border free circulation, the freedom of movement shall be ensured as well as security and health protection at the same time. Hence, Member States are required to adopt a series of measures aiming at improving public health surveillance, early warning and detection capabilities.

Finally, with regard to the development of response and recovery capabilities in the response to emergency situations, the EC proposes that Member States increase intracommunity cooperation to develop capabilities to identify and detect bioterrorist attacks and improve multi-sector interoperability between authorities involved.

In conclusion, while there remain certain issues of concern in the EU approach to bioterrorism (such as the practical implementation of minimal security standards and the potential to misuse material and/or knowledge on bioresearch), the Green Paper has given new impetus to the discussion within and between Member States on a collective action to reduce biological risks. In fact, it is crucial for an transnational community such as the EU to tackle the bioterrorist threat with a coordinated approach bringing together national efforts with the European dimension in mind and develop the effectiveness of a common crossborder response to biological risks.