



European Commission
Directorate-General Justice, Freedom and Security

BIO-Preparedness

The objective of combating bio-terrorism cuts across a wide range of challenges. These include: tracking shipments of lethal biological agents; enforcing international sanctions; coordinating verification and information exchanges among law enforcement agencies, customs authorities and the scientific community; reorienting research and development funds toward prevention; boosting security at virological research facilities; raising public awareness; stockpiling and harmonising sufficient quantities of vaccines and prophylactics that could be shared between nations as well as improving communications and coordination between public and private actors, including the interaction between civil and military authorities.

In the event of a bioterrorist attack the public health response is critical in identifying the nature of the attack and the appropriate response. Communicable disease outbreaks can pose a significant threat to the health and well being of the European Union's citizens.

The protection of citizens from bioterrorism requires intense efforts from our side and we cannot afford to be complacent. While focus must be maintained on a prevention strategy in the face of such serious threats, at the same time we require an immense amount of preparedness and a clear consequence management strategy to cater for any possible worst case scenarios.

Prevention must prevail over reaction to a bio-terrorist event. The consequences of such an event would be devastating, but how to prevent such an outbreak? This could only be efficiently addressed within a common framework. To think



about bio-terrorism in national terms is necessarily inadequate. It is estimated that an outbreak of contagious disease near any international airport would reach other major airports within 48 hrs.

Public health (counter) measures vary depending by the nature of the event (biological, chemical, environmental, linked to a natural disaster or complex situation, etc.) and by the context where the event is placed (resources, political background, national health systems and legal frameworks, etc.). Examples of control measures are: identification and quarantine of contacts; measures to increase social distance; measures to decrease the interval between onset of symptoms and isolation of ill patients; disinfection; limit travel; entry and exit screening; vector control; etc.

On the preparedness aspect, particularly in terms of consequence management in the event of a biological or chemical attack, it is sometimes not easy to draw the line and decide where it stops being a health issue and when it becomes a security issue or vice-versa.

As bio-defence research is a highly valuable and necessary endeavour, efforts to strengthen bio-security at high containment facilities could serve to further prevent diversion of materials and reduce the threat of potential bio-terrorists obtaining such materials. At the same time bio-defence research and access to biological material by authorized and legitimate personnel and the scientific community should not be hindered in the rush to secure dangerous pathogens or deter diversion.



Most countries have a complex set of laws and regulations that involve micro-organisms and there are guidelines for working with, handling, as well as packaging for transport of biological samples based on international guidelines. This is in line with the present set of EU regulations. Each State could review the whole set of their own regulations to see if there are loopholes. Such an exercise has been carried out in the EU where each country filled in a questionnaire so that Member States legislation with relevance for the BTWC (Biological and Toxin Weapons Convention) could be compared.

Countries need legislation to monitor the transfers, domestic and international, of dangerous diseases. A national inventory of dangerous strains and genetic material including gene libraries could be considered. The biotechnology industry could encourage self regulation on a global level to promote better bio-security measures. In many countries there is legislation governing this but industry should not wait for this. There may also be a need for the oversight of hazardous research.

Although the European Union has consistently supported efforts to increase the mechanism of public health security, gaps exist in EU preparedness. Areas of regulation standard setting, increasing facility capacity and strengthening international collaboration could be possible areas for review.

In order to swiftly halt the potential spread of disease and/or environmental contamination, mutual assistance for diagnosis and case management, access to special laboratory services and expertise for epidemiology investigations for compatible public health response could be considered. National efforts to increase public health security would serve to strengthen disease surveillance



across the Member States, the increase of laboratory capacity for diagnostics and analysis could be evaluated, and strong collaborative efforts with the World Health Organization maintained.

Prevention of bio-terrorism may require a comprehensive approach which includes not only criminalizing the possession and development of biological weapons with a malicious intent, but also increasing bio-security at high containment facilities, enforcing standards on the transportation of dangerous pathogens, creating a European level consensus on vaccine stockpiling and prophylactics, the adoption of licensed products over vaccines whose current safety and availability are largely unknown and increasing international cooperation with key agencies.

Laboratory certification and strengthening international bio-security standards could reduce the risk of illegal possession and use of biological agents in a deliberate attack. One idea could be to create a register of individuals and agencies in Europe that handle these potentially lethal bio-substances

To boost the security of bio-material it could be imagined to set-up a "fingerprint system" to tag biological agents similar to what the IAEA (International Atomic Energy Agency) does by identifying specific nuclear shipments and batches via trace samples on the special containers used to transport the hazardous material.

Facilities and personnel working with listed/selected/highly hazardous biological agents and toxins could be registered/licensed or approved as well as transfers of bio agents both nationally and internationally but the question is



how to achieve this– what should and what should not be included – ensuring that there are no loopholes-while ensuring that the security and oversight requirements avoid hampering health, safety, research or industrial activities.

All legitimate facilities, academic research institutions or companies could be required to register if they store, research, produce, handle or transfer listed pathogens. This would imply that the transfer of listed pathogens would only be possible between registered entities, nationally or internationally.

The capacity to quickly and accurately identify unusual disease outbreak is a critical feature. Identification of disease outbreak and origin requires advanced technologies and epidemiology investigation. Moreover, laboratory capacity to handle high consequence pathogens and rapidly analyze an unusual outbreak or cluster is also essential.

Identification and clinical recognition rely on high-quality laboratory diagnostic tests based on validated techniques and protocols so that deliberate releases can be rapidly confirmed or excluded. Laboratory expertise and capacity in Europe should be available to cope with high-risk agents and complex technology and methods as well as a surge in demand in case of multiple threats or attacks.

The dual-use potential of bio-science is a hotly contested topic between legitimate scientific activity and the potential danger for creating increasingly lethal technologies. The European Union has used its Dual-Use Export control regime as the main mitigating factor in preventing technology transfer on ‘dual-use’ items. Given rapid advances in bio-tech research, export control regimes may no longer be adequate as a deterrence method for proliferation.



Efforts for Bio-Security measures outside the EU could also be intensified. Implementation of confidence-building measures in the bio-safety/bio-security sphere with third countries would need to be strengthened. The initial focus could be on common challenges presented by bio-terrorism and could include a wide range of cooperative activities: consultations among civil protection authorities; expansion of current projects on bio-defence; retraining of scientists and commercialization of biotechnology projects where possible; aggressive research into vaccines, medicine, and diagnostic tests; and studies of anti-crop warfare and potential threat agents.