

Discussion paper Workshop 1: Bio-safety, bio-security and personnel security in Europe

Co-chaired: Mr Magnus OVILIUS, Commission
Mr Stefan SCHRECK, Commission

Subjects for discussion:

A. What substances do we want to talk about?

Should we focus on the most dangerous substances and their handling or we should look more broadly at bio-safety/bio-security? The point is that even less dangerous substances such as salmonella can bring a society to a halt, and thus there is a need for the Member States to be able to respond.

B. Laboratories

I. What is in the laboratories?

Responsible national authorities should know what is going on in the laboratories on the territory of their respective states with regard to the most dangerous substances usable for bio-terrorist purposes.

How well are the MS national registers of pathogens implemented and updated?; Is this system function well?; What other protection mechanisms are obligatory for those who handle **culture collections with high-risk pathogens or toxins?**

Is there a need to **establish a methodology for an inventory to be constantly updated and monitored of existing stocks of hazardous pathogens** in the Member States without impinging on the privacy of citizens and without prejudicing the competitiveness of business. Issues of intellectual property rights?

How can we identify in the Member States **all relevant laboratories, universities, hospitals, institutes or commercial enterprises with culture collections with high-risk pathogens or toxins** and/or that work with such agents, including their level of bio-safety/bio-security?.

II. Security and safety standards of laboratories

How are the laboratories protected and how are the dangerous substances protected within the laboratories?

The basic premise has to be that any bio-security has to be built on a robust bio-safety practice and culture. If bio-safety measures appear to be insufficient, how can we improve them?

Are we confident that access to facilities housing non-military collections of pathogens (such as those used for research) are sufficiently secure? Would common minimum-security standards applicable for facilities housing non-military collections of pathogens be a useful tool in order to prevent malicious access to dangerous pathogens? If so, what should these minimum security measures be and how can we make them proportionate to the perceived threat? Should such minimum security requirements be voluntary or obligatory?

There seems to be a need for an internationally accepted biosafety and biosecurity standard which would be suitable for accreditation and certification purposes. Therefore, it is positive to note that key stakeholders have taken an initiative to establish a new standard in the form of a CEN Workshop Agreement (CWA). The intention is to develop the standard around the WHO Laboratory Biosafety Manual (revised and re-issued last year). The interest manifested in such a project by the Biosafety-Section of the WHO Department of Communicable Disease Surveillance and Response in Geneva is an important factor in guaranteeing the impact of a new standard. Currently, the Commission is evaluating the proposed project and considering whether to provide EU funding and support from the financial decision for the “Pilot Project – Terrorism” (€7 Million).

II.1. Handling and transportation of dangerous substances

New technologies are being developed which should be able to recognise the origin of a bio-hazardous substances. In this context one can also think of **tagging** the storage containers or mark these substances in other ways. If handled by an unauthorised person, could we envisage **some system of self destruction**.

It is obvious that business would be crucial in suggesting solutions that, apart from enhancing security, can also serve a useful purpose for their own industry. An example of this would be a system whereby manufacturers of equipment for biological research (for instance equipment to manufacture synthetic viruses) are obliged to insert a microchip, which allows for the tracking of that device or programs it to shut down automatically if it has not been checked by

authorised personnel (with security clearance) after a certain period of time. This would allow us to be aware of movements of equipment that could fall into the hands of maliciously intended persons bent on launching a biological attack. It would also mean that the period of time it takes for the equipment to shut down after it was last checked would be sufficiently short so as not to allow anyone the opportunity to use that machine for any malicious intent. At the same time, the manufacturers would enjoy the benefit of knowing first-hand the precise life-span of the equipment they are producing, and gain a great deal of information on trends in the market for the purchase and re-sale of their product.

It is also obvious that not all installations and substances require the same level of security. Modern technologies can or could give us the possibility of having **different levels of security** depending on the degree of danger the substance may pose.

Similar to what is written about laboratories can be said about the **transportation of the most dangerous substances**. How can we ensure that bio-hazardous substances are handled in a secure way when being transported and how do we prevent such substances from falling into "the wrong hands"? How can we ensure that the sender of samples of hazardous material to third parties verify its use and that the receiver indeed has a "friendly intent"? Based on risk and threat assessments, maybe these samples should not event be sent to some destinations. In this context, maybe the regimes addressing transportation of the bio-hazardous substances would require attention at European, if not international level.

Questions with regard to customs should also be discussed. Is there need for an awareness raising among customs officers?; Is there already, or should there be, training for customs officers on bio-issues?; Would there exist routines for the protection of customs officers in case of a (potential) bio-related incident?

III. Laboratory capacity in Europe

Is the European laboratory capacity sufficient to deal with dangerous bio-hazardous substances?:

Do we need more mobile laboratories with intervention teams? If so, what would be the role for the ECDC. Early identification of health threats in whichever part of the world, can in fact protect lives in Europe

Is the existing EU capacity to detect and identify bio agents sufficient and can that capacity be utilised to certify bio dectors (the concept of Bio-reference laboratories)?

C. Personnel security (scientists/researchers/students)

Traceability is also important in relation to **personnel** dealing with the dangerous substances. Is it conceivable to put in place **registries that records individuals/enterprises/institutions etc. who are conducting research involving bio-hazardous agents of a particularly dangerous nature**, ensuring they possess security clearance just like any person dealing with classified material?

Can we be sure that all the persons working in laboratories across Europe possess all the credentials that one would expect to have in such a sensitive field?

Contacts with third countries' researchers

Another concern is access of third country nationals to European bio-hazardous research facilities. Third country nationals should comply with the same security criteria, as EU researchers.

A concern has been raised in regard to acceptance of security clearance across the Member States, costs and length of the procedures. This may impede research in Europe as well as competitiveness of the private sector. Scientists who do not get access to the US, due to the lengthy and complicated screening procedures may end up doing their research work elsewhere.

Spreading knowledge

Concerning the spread of knowledge in relation to bio-threats, one can argue that it is widely available on internet and publicly accessible literature. However, some results of new research should probably not be public, particularly on artificially produced new strains of viruses or accidentally produced dangerous substances. It is argued that **some form of voluntary code for scientists would be enough**.

In this context, a good and well targeted awareness raising campaign about the possible implications of research and studies used by people with malicious intents could be set-up for the scientific community to improve the situation.