

This is one of a series of complementary papers submitted by the EU Member States for the consideration of States Parties. [A reference to the outcome of third country alignment procedure will be added.]

EU Paper on Biosafety and Biosecurity

I. An Obligation to Prevent Prohibited Activities

1. Article IV of the BTWC may be considered as the core provision relating to national implementation of the Convention. It stipulates that each State Party shall “take any necessary measures to prohibit and prevent” prohibited activities within its territory, under its jurisdiction or under its control anywhere. A close reading of Article IV demonstrates that it includes several key obligations:

2. Firstly, it covers all activities prohibited under the preceding Articles I, II and III and it refers to the comprehensive definition of BW based on the general purpose criterion.

3. Secondly, since it does not specify the actor, the recipient or the beneficiary of any of the prohibited activities, national legislation must be constructed in such a way as to effectively cover all potential actors involved in such activities.

4. Thirdly, Article IV is not simply an obligation of conduct but amounts to an obligation of result. It will not be sufficient to introduce mere prohibitions into national law to meet the obligations included in Article IV since States Parties have to take “measures to prohibit *and prevent*”. One may also refer to the need to adopt “*necessary* measures”, which can also be read as an attempt not to over-burden States Parties, introducing an element of proportionality into national implementation.

5. In the light of new risks generated by scientific developments in the field of biotechnology and terrorist threats with BW, the prevention of unimpeded access to micro-organisms and toxins that can be used as biological weapons has also gained increasing political importance.

II. Measures to Prevent Unimpeded Access to Hazardous Materials

6. Article IV of the Convention refers to “*necessary* measures”. But what does “*necessary*” mean, or to put it another way, how does a State Party know if it is necessary at all to take measures? The simple answer is risk assessment; but does this alone solve the problem? Surely not, as long as a State Party has no knowledge of whether and where it possesses materials of concern within its territory, who is handling these materials, for what purpose, and under what safety/security conditions.

7. The approach to solving the problem is twofold: knowledge of possession of potential BW materials within a territory and risk assessment.

8. The working papers and statements at the BTWC Meeting of Experts in August 2003 showed that States Parties are very well aware of the need to restrict access to dangerous micro-organisms and toxins to personnel and facilities that legitimately handle such materials in science, commerce and for diagnostic purposes. Additional information on how States Parties take care to prevent unauthorised access to such materials is available from the legislative database of the UNSCR 1540 Committee, which includes national legislation describing regulations for handling and physical protection of BW-related materials. However, the reasoning behind restricting access to such types of material is based on different types of approaches.

9. In any case, knowledge of possession of micro-organisms and toxins with a potential of BW misuse is a prerequisite for any further State action. Some States follow a procedure that requires the registration of possession or handling of such materials only. The majority of States that have implemented legislation on micro-organisms and toxins allow individuals or facilities to possess and to handle such materials only if they have successfully passed a licensing process. Such a process allows States to bind licensing to different sets of conditions that have to be fulfilled as a prerequisite by the licence applicant. It usually also subjects the licensee to oversight measures by the authority issuing a licence.

10. The licensing or registration process provides a State with knowledge of where biological materials of concern are available within its territory and who has access to them. Such knowledge provides a basis for any decision on *necessary* measures to prevent risks related to such materials within a national territory.

III. Biosafety and Biosecurity

11. The *necessary* measures implemented by States Parties to prevent unimpeded access to hazardous biological materials and to minimise risks might differ in their starting points, but provide mutually complementary concepts. They usually consist of a mixture of laws, regulations and standards for safety and security. These concepts are based on the inherent risks of specific micro-organisms and toxins.

12. A majority of States which have already implemented measures to minimise risks focus their national legislation, regulations and standards on safeguarding the workforce handling biological materials and on the protection of the environment, including the population, against accidental release or loss of hazardous materials. Some States, especially those implementing legislation after 9/11, focus their approaches on the physical protection of BW-related biological materials to prevent unauthorised access by theft or diversion by non-State actors, including terrorists.

13. In general the two concepts are labelled as Biosafety and Biosecurity; names which pose some problems for countries where the words “safety” and “security” translate into the same term in their national languages.

14. An in-depth comparison of laws, regulations and standards already enacted by States Parties demonstrates that the measures implemented under both concepts are very similar, including *inter alia*

- licensing of possession and handling,
- requirement of professional knowledge,
- reliability checks of personnel,
- listing of workforce with access to biological materials,
- classification of biological materials according to inherent risks,
- physical requirements for infrastructure based on risk classification systems for biological materials,

- organisational measures for safe handling of micro-organisms according to different risk groups, including limited access to sensitive materials on a ‘need-to-work’ basis,
- secure storage of micro-organisms and toxins according to risk group classifications,
- documentation of work (lab journals),
- authorisation of transfer of biological materials between licensed facilities only,
- measures to ensure safe/secure transport of sensitive biological materials,
- oversight by licensing or other competent agencies, etc.

15. The difference between the two concepts is primarily based on two issues. Firstly, as already mentioned, both are based on the inherent risks of certain micro-organisms and toxins. While a biosafety risk classification system is based on the inherent capability of micro-organisms to cause disease, of lesser or greater severity, in humans, animals and plants, a biosecurity risk classification system is founded on the potential of a micro-organism or toxin to be used as a weapon. In practice, with respect to safety/security of sensitive biological materials, there is little difference between the risk classes; however the biosafety concept covers a far wider number of biological materials than the biosecurity concept. Secondly, while the majority of measures under both concepts are more or less the same, the biosecurity concept focuses primarily on the prevention of access to sensitive materials by theft, diversion or intentional release. For this reason biosecurity concepts usually include additional measures to harden and safeguard facilities containing sensitive biological materials with a BW potential.

IV. How to Improve the Implementation of Biosafety/Biosecurity Measures

16. Based on national statements, the report of the 1540 Committee to the UN Security Council of April 2006 on the status of implementation of national legislative and other measures for the physical protection of BW-related materials counts 48 States having legislation in place that provides for licensing or registration requirements for hazardous biological materials and indicating that they have specific laws and regulations addressing different safety and security concerns. With regard to enforcement measures, most of these States have indicated that their penal codes or specific laws contain criminal or administrative penalties against violations of safety and security requirements. Compared with the global occurrence of a wide range of micro-organisms of concern and the need for medical, veterinary or phytosanitary diagnosis relating to diseases caused by these agents, the number of States that have implemented respective legislative and other measures seems surprisingly small.

17. The 2003 Meeting of Experts discussed biosafety/biosecurity problems extensively under the topic “*national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins*”. However, the discussion resulted in only a collation of papers which cannot alone provide a systematic catalogue identifying problems and offering possible solutions to assist States Parties without national biosafety/biosecurity legislative or other measures in filling their gaps. The 2003 Meeting, as well as the legislative database of the UNSCR 1540 Committee, clearly demonstrates that abundant information is available from measures that have already been nationally implemented and approved. The European Union proposes that States Parties develop and keep up to date a systematic catalogue of biosafety/biosecurity measures based on these data in an intersessional BTWC process from 2007 to 2010, which would be a worthwhile activity to improve national awareness about biosafety/biosecurity issues as well as assisting States Parties to enact and implement appropriate legislative and other measures to control and secure domestically sensitive biological materials.

18. States Parties that are in a situation to assist other States in developing such national biosafety/biosecurity measures should offer and provide assistance, if invited to do so. In this respect reference is also made to the European Union Council Joint Action of 27 February 2006 in

support of the Biological and Toxin Weapons Convention, that aims *inter alia* at assistance to States Parties in national implementation. A catalogue of already implemented and proven practices by States Parties worked out on the basis of existing national biosafety/biosecurity measures would facilitate any assistance activity on both the provider recipient side.
