

**2008 Meeting
Geneva, 1-5 December 2008**

**Meeting of Experts
Geneva, 18-22 August 2008**
Item 5 of the provisional agenda
**Consideration of national, regional and
international measures to improve biosafety
and biosecurity, including laboratory safety
and security of pathogens and toxins**

EUROPEAN UNION LEGISLATION AND RECOMMENDATIONS RELATED TO BIOSAFETY AND BIOSECURITY

Submitted by the Germany on behalf of the European Union

Biosafety and Biosecurity: a complementary system

1. While the practical and legislative implementation of biosafety measures has a long history following the development of biosciences and the growing understanding of risks linked with human, animal, and plant pathogens as well as toxins, the importance of biosecurity aspects did not emerge in scientific and public discussions until the appearance of new threats and challenges in 2001.
2. The first meeting of experts of the BTWC intersessional process 2003 to 2005 started in 2003 with some discussion about the differing definitions of the terms biosafety and biosecurity, how these are understood in different States Parties, and how their principles might address the risks and threats of dual-use biological agents and toxins. Meanwhile, the definitions developed by WHO¹ and OECD² provide a solid basis for the common understanding that biosecurity

¹ **WHO Laboratory Biosecurity Guidance**

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release

Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

² **OECD – Glossary of Terms** (<http://www.biosecuritycodes.org/gloss.htm>)

Biosafety: The safe handling practices, procedures and proper use of containment facilities to prevent accidental harm caused by living organisms either directly or indirectly to individuals within laboratories or to the environment.

measures complement biosafety measures, taking into account the special need for protection of facilities and transport systems that raise special vulnerability concerns because of the biological agents and toxins they handle, store or move.

Biosafety: prevention of risk

3. Biosafety measures are required to deal with a wide variety of human, animal and plant pathogens and toxins and are developed in accordance with science and governmental responsibilities for public, occupational, animal, plant health and environmental protection, for genetic engineering work, or for transport of dangerous goods. As a result in most countries, that legislation dealing with biosafety measures is addressed in a variety of laws rather than in a single consolidated act.

4 The primary aim of implementing biosafety measures is the prevention of risks related to unintentional exposure of humans, animals and plants to pathogens and toxins, or their accidental release to the environment. The spectrum of measures starts with preventing exposure of the workforce handling pathogens including requirements for containment to avoid release to the environment and ends with vaccination, decontamination, and other preventive measures in case of accidental or natural outbreak of infectious diseases or intoxications.

Key EU Biosafety legislation

5. Common EU legislation on biosafety focuses on the prevention of risks related to the handling of dangerous biological materials by the workforce as well as during transport. In addition to common EU directives and regulations, EU Member States have implemented many national laws, ordinances and other regulations to prevent exposure to dangerous biological materials, to protect human, animal and plant health and to regulate the safe handling of dangerous biological materials.

6. The central pieces of common EU biosafety legislation are:

- (i) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work³; and
- (ii) Council Directive 90/269/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms⁴ amended by Council Directive 98/81/EC of 26 October 1998⁵.

7. Without going into all details regulated by Directive 2000/54/EC, the key issues addressed by the Directive are:

Biosecurity: Measures to protect against the malicious use of pathogens, parts of them or their toxins in direct or indirect acts against humans, livestock or crops.

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:262:0021:0045:EN:PDF>

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0219:EN:HTML>

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0013:0031:EN:PDF>

- (i) assessment of risks linked with biological agents and classification of pathogens to four risk groups (Annex III);
- (ii) indications concerning containment measures and containment levels for laboratories (Annex V) and containment for industrial processes (Annex VI);
- (iii) prior notification to the competent authority of the use for the first time of group 2 and/or group 3 and/or group 4 biological agents,
- (iv) employers shall keep a list of workers exposed to risk group 3 and/or risk group 4 biological agents; the competent authority shall have access to the list.

8. Council Directive 90/219/EEC, as amended lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. The directive follows a similar structure to Directive 2000/54:

- (i) assessment of risks of biological activities and classification of biological activities to four containment levels (Annex III of Council Directive 98/81/EC);
- (ii) containment and other protective measures for laboratory activities, glasshouses and growth-rooms, animal units and other activities (Annex IV of Council Directive 98/81/EC);
- (iii) notification to the competent authority of any premise to be used for the first time for contained use before commencing such use;
- (iv) additional notification to the competent authority of a class 2 first contained use activity, as well as any class 3 and 4 first and subsequent contained use activity; class 3 and 4 uses require prior consent of the competent authority.

Biological facilities of concern

9. Directive 2000/54/EC and Council Directive 90/219/EEC provide for the EU Member States the legal basis to answer the key questions concerning biosafety and biosecurity matters:

- (i) do we know the facilities that handle dangerous biological materials;
- (ii) do we know who handles these materials; and
- (iii) are the facilities handling these materials controlled?

For the first question the answer is yes, as both directives require prior notification of premises to competent authorities before starting work. For the second question the answer is also yes for workers being exposed to risk group 3 and/or 4 biological agents, which are the most dangerous biological agents. Finally, the Member States' competent authorities are obliged to organise inspections and other control measures to ensure compliance with the directives.

Safe transport of dangerous biological material

10. Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road⁶ (including six amendments and adaptations) describes detailed provisions necessary for transport of infectious biological substances. Directive 95/50/EC on uniform procedures for checks on the transport of dangerous goods by road⁷, last amended by Directive 2001/26/EC refers *inter alia* to requirements set up by European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)⁸. Rail transport is regulated by Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail⁹ (as adapted) which refers *inter alia* to the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

Biosecurity – EU Green Paper on Bio-preparedness

11. In July 2007 the Commission of the European Union published a Green Paper on Bio-preparedness¹⁰. The Green Paper intends to stimulate a debate and launch a process of consultation at European level on how to reduce biological risks, and to enhance preparedness and response ("bio-preparedness"). The paper addresses existing EU legislation, decisions and recommendations to improve safety and security; it also raises questions how and by whom biosecurity and response could be improved in EU Member States. The questions raised in the paper are now under discussion in a number of expert groups. In parallel, the General Secretariat of the Council and the Commission Services started an update of the EU CBRN Inventory of 2002 and of the Bio Inventory of 2007. The inventories collate all directives, regulations, decisions, recommendations and other measures with regard to biosafety and biosecurity issued by the EU Commission and/or the EU Parliament.

12. Based on the comments to the Green Paper provided by more than 80 governmental and non-governmental organisations, the results of the ongoing discussions of the groups of experts, and the updated CBRN Inventory¹¹ the Commission and the Council will develop a policy paper to improve the Community's preparedness which shall be finalized in 2009. This policy paper will be the basis for further steps of the EU Member States to improve biosecurity.

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0055:EN:HTML>

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0050:EN:HTML>

⁸ http://www.unece.org/trans/danger/publi/adr/adr_e.html

⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0049:EN:HTML>

¹⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0399:FIN:EN:PDF>

¹¹ <http://register.consilium.europa.eu/pdf/en/08/st10/st10382.en08.pdf>