Biological Weapons Convention - National Implementation in Germany

Joint BWC Implementation Support Unit/
EU Joint Action CBM activity with
Republic of Moldova
Chisinau, 22 – 24 June 2011

Dr. Volker Beck
Federal Foreign Office
Germany
BWC Implementation Obligations

► Article I:  … never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain …

► Article III:  … not transfer to any recipient whatsoever, directly or indirectly, …

► Article IV:  … in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition and retaining … of agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention
Implementation of Article I Obligations

- BWC entered in force: March 1975

- Germany’s BW Arms Control Policy
  - Treaties of Rome of 25/03/1957
  - War Weapons Control Act of 20/01/1961
  - Foreign Trade and Payments Act of 28/04/1961
  - Biological Weapons Convention Implementation Act of 21/02/1983
    (Ratification of the Biological Weapons Convention)
Implementation of Article I Obligations

► War Weapons Control Act (Kriegswaffenkontrollgesetz)

Section 18 Prohibition of Biological and Chemical Weapons

(1) It is forbidden to
   1. develop, produce or trade in biological or chemical weapons, to acquire them from or transfer them to another person, to import or export them, to transport them through or otherwise bring them into or out of federal territory, or otherwise to exercise actual control over them,
   1a. induce another person to commit an act specified in item 1 above, or
   2. encourage an act specified in item 1 above.

Section 20 Penal Provisions on Biological and Chemical Weapons

Annex: War Weapons Control List
Implementation of Article III Obligations

► BWC obligation: … not to transfer to any recipient …

► Implementation area: export control

► Foreign Trade and Payments Act of 28/04/1961 (Aussenwirtschaftsgesetz) and Foreign Trade and Payments Regulation of 18/12/1986 (Aussenwirtschaftsverordnung)

► Council Regulation (EC) 428/2009 of 05/05/2009 (EU Dual-use Regulation)

► Core elements of legislation: export licensing, dual-use control lists, intangible transfers, end-use, catch all clause, transit control, brokering,
Implementation of Article IV Obligations

► BWC obligation: … to prohibit and prevent …

► 2001 – Bioterrorism: a new BWC aspect

national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins (BWC/CONF.V/17) [2001/2002]

► Focus on biosafety and biosecurity
  - biosafety: protect people and environment from agents
  - biosecurity: protect agents and toxins from people
German Biosafety and Biosecurity Legislation

- No unique biosafety or biosecurity act

- Relevant bits and pieces of regulating biosafety and biosecurity are contained in legislation addressing
  - human, animal and plant infectious diseases,
  - occupational health,
  - genetic engineering,
  - dangerous goods handling and transport,
  - import and export control,
  - war weapons and chemical weapons control,
  - security vetting of personnel,
  - technical rules for laboratories,
  - penal code, etc.

- ISU BWC Implementation Database counts more than 45 German acts, regulations, technical rules, etc.
Protection against Infection Act

Section 44
Requirement to obtain an authorization for activities involving pathogens

Any person who wishes to import or export pathogens to and from the territory covered by this Act, store, supply or work with them there requires an authorization to do so from the competent authority.

Section 45
Exceptions

(1) An authorization pursuant to section 44 shall not be required by persons who are licensed to exercise the profession of physician, dental surgeon or veterinary surgeon in their own practice, for microbiological tests for the purpose of exploratory medical or veterinary diagnosis using cultural methods that are restricted to the primary culturing and subsequent subculturing for the purpose of resistance determination and who employ methods that are not geared to detecting specific pathogens that are subject to notification, in so far as the examinations are performed for the direct treatment of their own patients for their own practice.
Security Vetting Act

  - vetting of personnel being entrusted with a security-sensitive activity in facilities vital for public security,

- Security Vetting Identification Ordinance of 30/07/2003
  - facilities vital for public security … include, *inter alia*, entities working with and transporting highly toxic substances and pathogens
Biosecurity in Context with Biosafety

► CEN (Comité Européen de Normalisation):

CEN Workshop Agreement (CWA)15793 “Laboratory Biorisk Management Standard” (Feb 2008)

Workshop consortium: ABSA, EBSA, DNV

Financing: EU GD Justice, Liberty and Security

Aim (1): Implementation of a biosafety and biosecurity management systems for laboratories (*performance oriented*)

Aim (2): Laboratory certification by third parties
<table>
<thead>
<tr>
<th>CWA 15793 Gliederung</th>
<th>CWA 15793 Überschrift</th>
<th>CWA 15793 Forderung</th>
<th>Korrespondierende deutsche Rechtsgrundlagen</th>
<th>Ergänzende Anforderungen aus den TRBAn 100, 250, 400, 500 und anderen technischen Regeln des Arbeitsschutzrecht</th>
</tr>
</thead>
</table>
| 4.4.2.4              | Training              | The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained. | ArbsG § 7, 12  
BioStoffV § 12  
GenTSV § 12, 15 | TRBA 100 (Ziffern 5.1; 5.1; 5.1)  
TRBA 250 (Ziffern 5.1; 5.1.3; 5.2; 7.4.1; 7.4.2; 7.6)  
TRBA 400 (Ziffer 5)  
BGV-A1 § 31 |
| 4.4.3                | Consultation and communication | The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be documented. Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization. | ArbsG § 3 (2);  
BioStoffV § 16  
GenG § 18, 21, 28  
GenTSV §§ 12, 14, 15, 17, 18  
GenTNottV § 4  
TierSEV §§ 5, 6  
IIIG § 49, 50 | TRBA 250 (Ziffer 4.2.4; 5.1.2) |
| 4.4.4                | Operational control   | The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The organization shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions. | BioStoffV §§ 5-8, 10-12  
GenTG §§ 8-10, 12, 25  
GenTSV § 18  
ASiG §§ 3, 6 | TRBA 250 (Ziffer 4.2.4)  
BGV-A1 § 8 |
| 4.4.4.1              | General safety        | The organization shall ensure that a formal process is in place to identify and manage risk associated with general safety. | ArbsG §§ 3, 5  
BioStoffV § 7  
GenTG § 5  
GenTSV § 8, 18  
BetSichV § 4 | TRBA 400 (Ziffer 3.2) |
|                      |                       | The organization shall ensure that an accurate and up- | BioStoffV §§ 8, 10, 13 | TRBA 250 (Ziffer 6.1; 6.2) |
Other Implementation Issues

► **Codes of Conduct**
- Deutsche Forschungsgemeinschaft (major German research-funding organisation)
- International Association of Synthetic Biology (commercial companies)
- Max Planck Gesellschaft (major German research organisation in life-sciences)
- Bio Deutschland (more than 280 German bio-companies)

► **Biopreparedness**
Thank you for your attention!

Questions?