

First Meeting
Geneva, 10 – 14 November 2003
Item 6 of the agenda

Working Paper Submitted by the Federal Republic of Germany

**Core Elements of National Mechanisms to Establish and Maintain the
Security and Oversight of Dangerous Microorganisms and Toxins**

1. According to **Article IV** of the Biological and Toxin Weapons Convention *each State Party shall, in accordance with its constitutional processes, take any necessary measure to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention.* In the light of increasing dangers of **proliferation** and **terrorist threats**, it is becoming ever more important to **prevent unauthorized access** to microorganisms and toxins that can potentially be used as biological weapons.
2. The working papers and statements at the Meeting of Experts in Geneva in August 2003 showed that States Parties are very much aware of the necessity to **restrict access** to dangerous microorganisms and toxins to personnel and facilities that **legitimately** handle such materials in science and industry, or for medical and veterinary diagnosis. States Parties have implemented **national mechanisms** to establish and maintain the **security and oversight** of dangerous microorganisms and toxins, either based on respective legislation or on the basis of guidelines covering certain areas of science and industry.
3. The discussion in August demonstrated clearly that at least two schools of thought exist which are not mutually exclusive but in practice employ identical procedures to achieve the same goal. For this reason, it is not worthwhile re-opening a terminological discussion on "biosafety" and "biosecurity" or whether one is the outside and the other the inside approach to security and oversight. The following will **concentrate on the procedural level** relevant to this topic and try to identify common elements.
4. The starting point of all discussions on security and oversight of dangerous biological materials is the evaluation of the **intrinsic danger of pathogens** and toxins. The risk of diversion of a biological agent may increase in parallel with its pathogenicity/virulence or toxicity. Most of the States Parties have therefore developed lists that classify **microorganisms** according to **risk groups** or for specific purposes (United States: BWC/MSP.2003/MX/WP 6; United Kingdom: MX/WP 7; Japan: MX/WP 10 and 11; Brazil: MX/WP 20; China: MX/WP 25; Germany: MX/WP 36; Ukraine: MX/WP 42; Poland: MX/WP 44; Cuba: MX/WP 46; Bulgaria: MX/WP 58; MX/WP 62 by twelve EU member states). The classification system is based mainly on WHO recommendations and consists of

four risk groups, while other lists are designed for specific purposes such as select agent lists. Corresponding to the classification system for pathogens or to the specific-purpose lists, **facilities** in which dangerous microorganisms or toxins are handled, are classified according to the relevant **security/safety standards**.

5. The **handling of dangerous pathogens** and toxins requires **licensing** or **registration** of the **personnel** and/or of the **facility** where work is carried out with dangerous materials. With respect to licensing and/or registration, a variety of approaches can be identified. Some States Parties follow a policy under which only dangerous microorganisms and toxins that are contained on specially designed lists are controlled. Other States Parties control all activities involving microorganisms that are classified in risk group 2 and higher. Others again control activities only related to the two highest risk groups. **Specific legal procedures** for licensing/registration and control are applied to **genetic engineering work** (Sweden: WP 15; South Africa: WP 30; Germany: WP 37; Australia: WP 50; WP 62 by twelve EU member states). The licensing/registration requires the **identification of facilities** as well as the monitoring of a facility in order to assure that it meets the required security/safety standards.

6. As already mentioned, authorization to handle dangerous microorganisms and toxins might be granted in the form of licences either to personnel or to facilities. However, in both cases it should be minimum standard that **personnel** are subject to **scrutiny** concerning **professional competence** as well as **trustworthiness**. With regard to the **monitoring of facilities**, both external controls by national licensing authorities and internal controls by safety officers are required.

7. In view of the threats of bioterrorism or other criminal activities, increased attention needs to be paid to the control of transfers and especially the vulnerability of **transport systems** for dangerous materials. Though international regulations exist to secure dangerous materials during transport by air, sea and ground (Germany: WP 59), more might be done to ensure that transport systems do not become the weak link in the chain of custody which is set up to maintain security and oversight of dangerous microorganisms and toxins.

8. The working papers and statements collected in the **Chairman's collation** of the Meeting of Experts contain much valuable information to establish and maintain security and oversight of dangerous pathogens and toxins:

- access to facilities and agents by authorized personnel only,
- safety locks for areas where dangerous material is handled,
- accounting of material,
- transfers only between licensed/registered/controlled facilities or persons,
- detailed documentation of experiments,
- documentation of transfers, etc.

Not all details of information may find agreement by all States Parties. However, the information provided is an excellent source for States Parties to establish national mechanisms of security and oversight. Moreover, a number of common elements of already nationally implemented procedures can be identified.

9. **Germany proposes** that the following common elements be recommended as **core elements** of **national mechanisms** for establishing and maintaining the **security and oversight** of dangerous microorganisms and toxins in the **final document** of this Meeting of States Parties:

- **national procedures**, based on **risk assessments** of pathogens and toxins, for, among other things, the **oversight** of **facilities** and of **personnel** possessing and handling dangerous materials as well as of **transport systems**,
 - **national licensing/registration** of **facilities** and **persons**,
 - **national** internal and external **monitoring** of facilities,
 - **national penal legislation** to **limit possession** and **handling** of dangerous biological materials to licensed/registered facilities and authorized personnel only,
 - **support** for **international bodies** that have already developed **guidelines** for securing dangerous microorganisms and toxins in improving and expanding their efforts.
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