MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Diagnostic Tools and Structures for Detecting Suspicious Outbreaks of Infectious Diseases

Submitted by Germany

1. The world is facing an ongoing threat of potential attacks by terrorists with NBC weapons or respective agents. In dealing with biological threats, for the safe and rapid identification of biological agents, especially viruses, bacteria, or toxins, the focus will be on the interplay of classical and newly developed diagnostic methods.

2. For each country it is of prime importance to rapidly recognize and differentiate cases of infectious diseases that are uncommon due to the area, the time of the year or show unusually high or altered mortality and morbidity rates. Moreover, it is important to differentiate a disease as being the consequence of single travel-associated cases, a possible outbreak of periodically upcoming epidemics, like Influenza or food-borne Salmonellosis, or rather being the result of deliberate release of pathogenic agents due to a terrorist attack.

3. In addition to clinical cases suspected of being in connection with these new threats which occasionally come into focus, since the fall of 2001 ministries, organisations, and individuals in many states are facing numerous letters and other contributions with samples of food, feed, chemicals, or samples with environmental background. Frequently the letters contain a written threat by pretending to send deadly anthrax spores or poxvirus to the receiving party. In general, all material is handed over to the police or security staff, who will perform a primary risk analysis on the basis of operational evidence and intelligence information. Fortunately, the vast majority of all letters or findings have proved to be hoaxes.

4. It is an important prerequisite for microbiological diagnostics to have all incoming suspicious samples cleared as extensively as technically feasible for radioactivity, dangerous chemicals, and explosive traps. On the other hand, the letter or other contributions have to be handled carefully in order not to spoil evidence for a criminal investigation or forensics.

5. In the first place, microbial diagnostics has to rely on methods with high specificity and sensitivity to rule out false results and detect the concentration of the pathogen, if any is present. The concentration of a pathogen in a given sample can be an important hint for the

differentiation between an intentional release and a random contamination of i.e. anthrax in soil originating from an endemic area. The speed of obtaining reliable diagnostic results is equally important, since for most pathogens an early decision to initiate a therapy, i.e. by vaccination, antibiotics or neutralising agents, can be life saving. Finally, the future tests should be robust, without the need for costly diagnostic centres (lab on a chip), and should work with automation for high thru-put or for the detection of a variety of different pathogens basically in one test (chip technology).

6. The Robert Koch-Institut, which is the national reference laboratory for biological safety in Germany, has implemented logistics of handling biological samples with a pretended terrorist background. The typical microbial diagnostics of a sample with unknown contents at first aims at the rapid identification of infectious agents such as poxvirus and anthrax spores. Therefore, after receiving a suspected sample, an aliquot is inactivated and checked for pathogens in the electron microscope. This method will answer within 2 to 3 hours after arrival of the sample in the lab whether the sample contains higher concentrations of poxvirus or anthrax spores or contain biological material at all. In parallel, an aliquot of the sample is put directly on a set of pathogen-specific media and also is put in enrichment media. Either directly from the resuspended liquid sample or early in the process of enrichment, samples are prepared for a molecular investigation like a real-time Polymerase Chain Reaction. Taken together, the risk assessment for any sample follows a three-stage procedure. First, after about 3 hours after receipt a high concentration of pathogens (like the anthrax spore concentration in the letters sent in the USA in 2001) would be detected. After 6 to 12 (for some species appr. 24) hours of classical microbiology (growth and enrichment of potential pathogens) the results of nucleic acid based diagnostics or immunoassays give rise to a preliminary decision on the nature of the pathogen, if any. This is the moment where possibly contaminated persons or institutions get informed of the results and, if necessary, further action is taken. Finally, suspected samples are monitored for an additional period of time to prove if any so far unrecognised relevant growth or effect appears. Further tests are performed and in the case of a verified suspicion, animal tests are performed to prove the presence a specific pathogen or compare its virulence to standards.

7. Finally, part of the sample is kept for forensic studies and, if relevant, for research purposes. Using anthrax as an example, we will demonstrate the comparison of numerous very close relatives to anthrax that could be isolated from environmental samples and might create problems in the diagnostics.

8. Finally, new developments in diagnostic tools are presented and discussed with regard to sensitivity, specificity, rapidity, costs, and training needed for their implementation in diagnostics.

9. Just as important as the development of new technology is the control and application of safe and evidence-based methods for inactivation and disinfection of pathogens and surfaces, respectively laboratories, to work in. This is of prime importance to avoid contamination and infection of lab staff and others.

10. Further details on diagnostic tools and structures for detecting suspicious outbreaks of infectious diseases are available on the CD-ROM prepared by the Federal Foreign Office for participants at the BTWC Meeting of Experts in July 2004.

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