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INCREASING TRANSPARENCY IN BIODEFENCE: A 2016 VISIT TO A GERMAN MILITARY MEDICAL BIODEFENCE FACILITY

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I. INTRODUCTION

The 1972 Biological and Toxin Weapons Convention (BWC) prohibits the development, production, stockpiling and acquisition of biological weapons, while permitting work with biological agents in types and quantities appropriate for prophylactic, protective or other peaceful purposes. The line between permitted and non-permitted (i.e. illegal) activities and programmes is often blurred in the area of biodefence, where the potential is greatest for permitted activities to cross the line, inadvertently or intentionally, into prohibited activities. States with biodefence programmes, therefore, have a special responsibility to demonstrate that their programmes are not used as a cover for offensive programmes, and that their programmes are not *perceived* as such. It is particularly important to proactively counter the perception that a biodefence programme may be used to disguise an offensive programme, or elements of an offensive programme, because such a perception may provide other states with justification for initiating or continuing their own offensive biological warfare programme.

Unusually for an arms control treaty, however, the BWC was agreed without including routine on-site verification mechanisms to enhance assurance of compliance. Efforts to introduce a legally binding verification mechanism for the BWC have failed in the past, and developments in the political, security and scientific contexts are making it increasingly clear that a fully effective verification system, or absolute certainty on full compliance with the BWC, is exceptionally difficult. Yet, this does not mean that it is impossible for states to be assured other countries are abiding by their treaty obligations. There are a number of actions and activities that cumulatively may give

SUMMARY

States with biodefence programmes have a special responsibility to ensure high standards of transparency. Most submit declarations about their programmes under the confidence-building measures (CBMs) of the 1972 Biological and Toxin Weapons Convention (BWC). Some states have recently gone further in their voluntary efforts through interactive information exchanges and on-site visits.

In 2016 Germany invited BWC states parties to visit its main military medical biodefence facility to evaluate its compliance with BWC obligations. During the visit, Germany described its biodefence activities and the related laws, regulations and practices that are in place to ensure that the activities are carried out safely, securely, responsibly and in line with the requirements of the BWC. Visitors were shown the laboratories and equipment, and engaged in constructive dialogue with facility staff. The visitors concluded they had been given valuable insight into the activities of the facility. They acknowledged that the hosts' cooperation had helped to promote transparency and confidence with regards to the BWC and provided reassurance that the facility's activities are within the permitted prophylactic, protective and other peaceful purposes of Article I of the BWC.

This paper details the two-day exercise from the perspective of the author, a civil society observer invited to take part alongside the 20 state party representatives.

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a reasonable indication of a state party's intent and compliance status over time.[1]

Paramount for states with biodefence programmes is transparency. Most states with biodefence programmes recognize their special responsibility to ensure high standards of transparency. They submit information about their programmes as required under the confidence-building measures (CBMs) of the BWC to reassure other states that their activities are solely for peaceful purposes. These CBM returns describe relevant activities, facilities, unusual outbreaks of disease and the national regulatory framework implementing the BWC. Through complete, accurate and annual submissions, the CBMs enable national patterns of normal activity to be established, and this makes a significant contribution to a compliance judgement.[2]

Strengthening compliance assessments

To maximize their transparency, an increasing number of states are now also making their CBM submissions publicly available and open to civil society. Eighteen states with biodefence programmes made their CBM returns public in 2016.[3] Recently, a small number of states have voluntarily gone further in their efforts to be transparent and to allay any potential suspicions about the status of their biodefence programmes.

For example, Canada—in the lead-up to the Seventh Review Conference in 2011—proposed a BWC 'compliance assessment' initiative.[4] The initiative approached the concept of compliance verification from the broad perspective of examining national implementation programmes rather than from the more traditional and focused perspective of inspecting facilities. It sought to demonstrate that options to evaluate compliance and implementation of the treaty exist outside of a legally binding verification mechanism for the BWC. Thus, Canada put itself forward to act as a test case and made an initial compliance assessment submission in the form of a working paper to the 2012 BWC meeting.[5] The submission provided more in-depth reporting on national implementation as well as efforts to administer and enforce those implementation measures in an effort to supplement and add to the information Canada provides through its annual CBM submissions and its quinquennial review conference compliance reports. Other interested states were invited to join in the initiative, and Switzerland, the Czech Republic and France all made working paper submissions to recent BWC meetings.[6]

Another informal, but more interactive, arrangement has been put forward by France.[7] Here, participating states physically come together to make mutual assessments of national implementation standards based on common understandings reached during the intersessional process. Like the 'compliance assessment' submissions, the 'peer review' mechanism is also aimed at building confidence and providing transparency between states. However, it is additionally aimed at improving national implementation and, importantly, sharing experiences and best practices among experts. France organized the first peer review exercise in 2013.[8] National experts from nine states parties were given presentations on French biosafety and biosecurity measures, export controls, and awareness-raising policy. The

[1] See e.g. 2013 BWC, Meeting of Experts, 'We need to talk about compliance: a response to BWC/MSP/2012/WP.11', Working paper submitted by the United Kingdom, BWC/MSP 2013/MX/WP.1, 2 July 2013. For a more general introduction to BWC verification and compliance see Lentzos, F., 'Hard to prove: compliance with the Biological Weapons Convention', King's College London Policy Brief, Aug. 2013; and Lentzos, F., '3D BIO: declare, document and demonstrate', EU Non-Proliferation Consortium Non-Proliferation Paper no. 45 (2015).

[2] It should be noted, however, that the CBM mechanism can be strengthened in a number of ways, including through revising the content and format of the forms, increasing the quantity and quality of submissions, establishing a CBM-assistance network etc. For an overview, see Lentzos, F., 'Article V: confidence-building measure', eds G. Pearson, N. Sims and M. Dando, *Key Points for the Eighth Review Conference* (University of Bradford: Bradford, 2016), pp. 179–97.

[3] United Nations Office at Geneva, 'The Biological Weapons Convention', <www.unog.ch/bwc>, 18 Oct. 2016.

[4] 2010 BWC, Meeting of States Parties, 'National implementation of the BTWC: compliance assessment: a concept paper', Working paper submitted by Canada, BWC/MSP/2010/WP.3/Rev.1, 7 Dec. 2010.

[5] 2012 BWC, Meeting of Experts, 'National implementation of the BTWC: compliance assessment', Working paper submitted by Canada and Switzerland, BWC/MSP/2012/MX/WP.17, 3 Aug. 2012.

[6] 2012 BWC, Meeting of States Parties, 'National implementation of the BTWC: compliance assessment: update', Working paper submitted by Canada, the Czech Republic and Switzerland, BWC/MSP/2012/WP.6, 5 Dec. 2012; and 2013 BWC, Meeting of Experts, 'National implementation assessment report of the Biological Weapons Convention', Working paper submitted by France, BWC/MSP/2013/MX/WP.16, 12 Aug. 2013.

[7] 2011 BWC Review Conference, 'A peer review mechanism for the Biological Weapons Convention: enhancing confidence in national implementation and international cooperation', Working paper submitted by France, BWC/CONF.VII/WP.28, 13 Dec. 2011.

[8] 2014 BWC, Meeting of States Parties, 'Peer review pilot exercise held from 4 to 6 December 2013 in Paris', Working paper submitted by France, BWC/MSP/2014/WP.3, 2 Dec. 2014.

information provided in the presentations was then illustrated through on-site visits to two civilian laboratories in France. Building on this, Belgium, Luxembourg and the Netherlands conducted a Benelux peer review exercise among themselves in 2015.[9] This exercise consisted of two phases: a first phase during which written consultations took place between the three states; and a second phase during which each individual Benelux-country organized an event and hosted visiting peers from the other two states for a review through presentations and on-site visits.

A third informal arrangement, labelled 'implementation review', mixed elements from both 'compliance assessment' and 'peer review' and was carried out by Canada, Chile, Ghana, Mexico and the United States in 2016. For the 'implementation review', all parties developed an agreed format to report on key areas of national implementation, including prohibitions and their enforcement, biosafety and biosecurity, export licensing, and oversight, education and outreach efforts intended to complement these. National reports were then exchanged, followed by visits to each capital for in-depth conversations on laws, regulations and implementation in practice.

Compliance assessment focused on biodefence

To focus compliance assessment more specifically on biodefence, military activities and on-site visits, Germany organized what it described as a 'peer review compliance visit exercise' in 2016.[10] This was part of the country's long-standing efforts to pragmatically and incrementally strengthen the BWC in order to contribute to the longer-term national and European Union (EU) objective of strengthening treaty compliance and verification capacities. In May 2016, the German Federal Foreign Office (MFA) circulated messages to all designated national points of contact, to the foreign ministries of states parties that have not provided a national contact point, to permanent missions in Geneva and to the BWC Implementation Support Unit (ISU) inviting them to the exercise. The German Ministry of Defence (MOD) was to open the Bundeswehr Institute of Microbiology in Munich, Germany, on 2–4 August 2016, to 10 bio-experts and up to 10 additional participants monitoring the visit. This exercise was a joint project organized by the German MFA and the MOD (the latter being represented by the Bundeswehr Institute of Microbiology and the Federal Armed Forces Verification Centre).

The stated objective of the exercise was to demonstrate to the visiting bio-experts that the facility complies with the provisions and obligations of the BWC. The experts would be asked to evaluate the information gained during the visit and to develop a compliance assessment report. I was invited to represent civil society and to act as an independent scientific observer. This paper details my observations of the experience. It gives background on German biodefence facilities and related CBMs, details the preparation for and activities of the two-day site visit and concludes with the bio-experts' compliance assessment discussion and their report on the exercise, as well as some short observer reflections.

II. GERMAN BIODEFENCE FACILITIES AND RELATED CBMS

In advance of the visit, participants were provided with background information on the exercise. The information included an initial introduction to the site of the visit: the Institute of Microbiology. It explained that the Institute is

> a Federal research facility for medical protection against dangerous biological pathogens. Its task is to develop procedures and measures to protect members of the Bundeswehr from diseases caused by biological agents of warfare and to assist hospitals in treating those affected. For the purposes of its research, therefore, the Institute handles a large number of different infectious agents and biological toxins which could potentially be used in biological warfare. These pathogens and toxins can cause serious, in some cases fatal, diseases which can easily be passed on from person to person and/or are difficult to treat. A key goal of the research is to be able to diagnose these reliably. The testing procedures developed in this context can also be

[9] 2016 BWC Preparatory Committee, 'Strengthening the BWC: reflecting on the peer review concept', Working paper submitted by Belgium, Luxembourg and Netherlands, BWC/CONF.VIII/PC/WP.26, 9 Aug. 2016; and 2016 BWC Preparatory Committee, 'Peer review: an innovative way to strengthen the BWC', Working paper submitted by Belgium, France, Luxembourg and Netherlands, BWC/CONF.VIII/PC/WP.13, 4 May 2016.

[10] 2016 BWC Review Conference, 'Confidence in compliance: peer review visit exercise at the Bundeswehr Institute of Microbiology in Munich, Germany', Working paper submitted by Germany, BWC/CONF.VIII/WP.11, 21 Oct. 2016.

used to investigate unclear outbreaks of disease which could potentially be caused by such biological agents. The diagnostic skills resulting from this activity can be applied in many ways, including in the diagnosis of natural infections and outbreaks that could be caused by the same pathogens.

Participants were also encouraged to review Germany's most recent CBM submission. Germany has submitted regular declarations about its biodefence programme since this aspect of the CBMs was introduced in 1992. It was among the first few states to make its CBM publicly available, which it did in 2007, and it has continued to make its submissions publicly availably every year since then.

In its 2016 submission, Germany stated that its MOD spent approximately €9.1 million on chemical, biological, radiological and/or nuclear- (CBRN) related medical defence. This included prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection. The submission provides a link to a website containing further details, in German, about the various research and development projects and their objectives.

In 2016 Germany declared five biodefence facilities. The CBM submission provides their names, locations, the floor areas of the facilities' laboratories, the organizational structure of the facilities, descriptions of the biological defence work carried out at the facilities, details about their publication policies, and lists of publicly available papers and reports resulting from work carried out during the previous 12 months.

As the main centre of Germany's medical biodefence activities, the Bundeswehr Institute of Microbiology is the first facility listed. Located on Munich's Neuherbergstrasse, the facility has 20 scientists and 39 technicians working in a total lab-floor area of 1325 m², broken down into 1258 m² of biosafety level (BSL) 2 laboratories and 67 m² of a BSL3 laboratory. The scientific disciplines represented are medicine, veterinary medicine, microbiology, virology, bacteriology, immunology, molecular biology, epidemiology and laboratory medicine. There are 6 administrative staff, bringing the total number of personnel to 65 (41 of these being military and 24 civilian). The biodefence work carried out is described as:

- research, development and evaluation of approaches for the rapid detection, identification and differentiation and typing of specific pathogens using state of the art techniques;
- establishment of sequence data banks and tools for forensic typing;
- research, development and evaluation of immunodiagnostics of relevant agents and toxins; and
- studies of the epidemiology, immunopathogenesis and immune response against *Francisella tularensis*, *Bacillus spp.*, *Burkholderia spp.*, *Brucella spp.*, *Yersinia spp.* and Flaviviruses.

The CBM submission notes that the facility's current programme covers risk groups 1, 2 and 3 pathogens, and that no outdoor studies of biological aerosols have been conducted. It states that the facility's experimental results are published in scientific journals as well as in reports to the German MOD, and are presented at national and international scientific meetings. The submission lists 36 publicly available publications from work during the previous 12 months.

The CBM submission also provides some additional information about the Institute to that regularly requested. As a different way of demonstrating transparency and engaging with peers in the wider international biodefence community, the Institute has hosted a Medical Biodefence Conference every other year for the past 30 years. In 2016, this was held over four days in April and was attended by over 500 participants from more than 50 countries. The 2016 CBM submission lists the subjects covered and provides a point of contact for registration should states parties wish to send their experts, as well as a website address for more information.

III. FACILITY PROVISIONS FOR THE EXERCISE

The day before the site visit, the 20 exercise participants met as a group. We were welcomed by the hosts and briefed about the exercise and the activities of the coming two days. The emphasis was on safety and security.

We would be entering a secure military area and were to be escorted at all times (e.g. visibly wearing our name badges and following escort personnel instructions). No filming, photographing or audio recording was to be permitted. While the use of mobile phones was allowed, it was to be restricted to the main

briefing room, social areas and outside. During the lab visit we would be entering areas where restricted information is used and where no electronic devices were permitted. We would, therefore, be asked to leave our electronic devices in the secure storage provided.

We were also briefed on the Institute's health and safety regulations. There were additional health and safety regulations for the two visitors who would be entering the high-containment BSL3 lab and preliminary queries about which two visitors would like to enter the lab were made.

Few restrictions were placed on us other than those related to safety and security. We were free to view rooms, lab equipment and installations. The type and scope of access was to be determined by Institute staff on a case-by-case basis. Any access denials could derive from national security, biosafety and health regulations, data privacy issues, unpublished scientific results or ongoing lab work. If access or certain information was refused, the Institute would explain the particular considerations and offer alternatives.

We were allowed to request visual access to paper documents and to peruse classified material up to the 'restricted' level. We were allowed a cursory look at lab journals, but we would not be provided with copies or allowed to examine them in detail. We were requested to use our common sense not to abuse or overuse this privilege.

We could speak with Institute staff and interview personnel more formally. According to the German Code of Criminal Procedure, interviewees have the legal right to remain silent in certain situations. We were requested to respect this right. Records were to be kept of any interviews conducted.

While we were not allowed to bring our own cameras, we could request photographs to be taken by the escort team. The photographs would remain with the hosts, but we could attach an index describing the photographs to the visitors' summary.

GPS would be available if we wished to determine or confirm any geographic coordinates (the postal address and facility coordinates had already been provided in the background documentation).

We were provided with hard copies of the facility provisions and the safety and security regulations. We had to sign forms to acknowledge that we had received the briefing and instructions. The exercise participants were divided into groups of 10 'visitors' (i.e. the bio-experts) who were given yellow name badges, 10 'monitors' (i.e. the 'other participants') who were given green name badges and 1 scientific observer (i.e. me) who was given a pink name badge). While no participant list was distributed, the badges indicated nationality: Algeria, Austria, Belgium, Burundi, France, Georgia, Indonesia, Jordan, Lithuania, Myanmar, the Netherlands, Nigeria, Norway, Poland, Portugal, Saudi Arabia, Switzerland, Uganda, the United Kingdom, the USA and Yemen.

A general outline of the programme was as follows: A pre-visit briefing on the morning of day one. In the afternoon, the visitors would tour the facility and interact with staff, while the monitors would receive additional briefings on BWC-related legal and policy matters. During the morning of day two, the visitors would visit the BSL3 lab complex while the monitors had scheduled side events in the lab. In the afternoon, there would be a display of the Institute's bio-reconnaissance activities for both groups. Following an assessment meeting, the visitors would present their assessment of the Institute's BWC compliance in a concluding plenary.

IV. PRE-VISIT BRIEFING

We were bussed to the barracks housing the Bundeswehr Institute of Microbiology early on the morning of 3 August and taken to the briefing room on the first floor of the Institute. We numbered about 40 people in the room.

Objectives of the visit

A senior representative from the German MFA addressed the group and outlined the key objectives of the exercise:

1. To demonstrate that the Bundeswehr Institute of Microbiology is in full compliance with the provisions and obligations of the BWC by giving states parties an opportunity to see 'first hand the authenticity of the information we submit in our CBMs' and to evaluate the Institute's compliance with the treaty;
2. To show that compliance visits can be an appropriate means of increasing transparency and demonstrating a facility's compliance with the BWC; and
3. To show that increased transparency in a military facility is possible without violating necessary military security measures. While peer review exercises are neither a substitute for verification nor necessarily

a clear indication of compliance, Germany believes on-site visits can contribute to enhanced confidence in compliance.

The German official stated that the exercise was based on the useful models provided by the French and Benelux peer review exercises, and that the many applications the German authorities had received from all over the world were 'a clear signal that interest in compliance issues and biosecurity is high in all regions'. For capacity reasons, the number of participants was limited to 20, but care had been taken to ensure a good balance of participants from the Western, Eastern and Non-Aligned Movement (NAM) regional groups.

The rest of the morning we were briefed about general CBRN defence and non-proliferation policy in Germany; the mission of the Institute, its research activities, structure and cooperation with other facilities at home and abroad; and the laws and regulations implementing the BWC in Germany. We were invited to ask questions and a number of us did.

CBRN defence and non-proliferation in Germany

The CBRN tasks of the Bundeswehr are threefold: (a) to ensure protection and an ability of the armed forces to act under CBRN threats and conditions; (b) to prevent vulnerability to potential CBRN threats and CBRN weaponry through preventive measures; and (c) to limit the consequences should a CBRN-event occur. These tasks reflect Germany's revised approach to CBRN defence and non-proliferation policy, adapted to the 21st century security environment with an emphasis on armed non-state (i.e. terrorist) actors. The aim is to act before a CBRN-event occurs. Strengthened capabilities comprise CBRN reconnaissance, prevention, CBRN consultancy, CBRN protection, defence against CBRN materials, decontamination and disinfection, water purification and CBRN medical defence.

The mission and research activities of the Institute of Microbiology

The Director of the Bundeswehr Institute of Microbiology informed us in detail about the 'B', or biological, component of the Bundeswehr's CBRN defence and non-proliferation policy. He explained that an intentional bio-attack is likely to be covert, and that the first signs will be individual unexplained cases of disease, or more likely, an outbreak of multiple unexplained cases of disease. In any disease outbreak, one must ask: What is the source? Is it food, water, animals, the environment or humans? If the disease is 'unusual', one also has to ask: Is it natural or deliberate? And if it is deliberate, one must ask: Who is the perpetrator?

To determine the causative agent in an unusual *natural* outbreak, one must obtain a biomedical sample of the disease, transport the sample to a lab—which could be a fixed lab (like the Institute) or a mobile lab (e.g. in the field), and then identify the disease-causing agent (i.e. conduct 'bio-reconnaissance'). Military responses to an unusual natural outbreak include protecting personnel by vaccination, quarantine and/or restricted movement.

To determine the causative agent in an unusual *deliberate* outbreak, one follows much of the same approach as for a natural outbreak—sampling, transporting and identifying the agent. One also needs to carry out an attribution investigation (i.e. 'bio-forensics'). As with a natural outbreak there will be a military personnel protection response. There will also most likely be a political reaction such as a military intervention or international investigations and prosecutions.

The official elaborated on the key responsibilities of medical biodefense in Germany: (*a*) to rapidly and unequivocally identify pathogens, and diagnose, prevent and treat health disorders caused by biothreat agents; (*b*) bio-reconnaissance of 'unusual' outbreaks, distinguishing natural and deliberate outbreaks, confirmation of attacks with biological agents and bioforensic verification; and (*c*) to control outbreaks and prevent epidemics.

He summarized the structure of the Institute. There are 65 staff (as declared in the CBM) plus 18 externally funded fixed-term positions spread over three departments: one on 'bacteria and toxins', where the key agents cause plague, anthrax, glanders, tularemia, brucellosis and botulism; one on 'viruses and intracellular pathogens', where key agents cause haemorrhagic fevers, viral encephalitides, Q fever or infections with rickettsiae and orthopoxviruses; and a third one on 'medical biological reconnaissance and bioforensics' with separate groups on mobile medical bio-reconnaissance and verification, stationary diagnostics of health disorders caused by biothreat agents (e.g. DNA sequencing using polymerase chain reaction, PCR, cultivation for detection of host immune

response), molecular genomics and microbial forensics, and diagnostic products development.

The Institute follows the quality management system DIN/EN/ISO 15189 for its products and services, which covers around 1500 controlled documents. Diagnostic services are provided by the Institute's Central Diagnostic Lab Division (with >130 accredited parameters). Research and development as well as validation and verification of diagnostic assays, as required by the Medical Devices Act, also form part of the research groups' responsibilities.

The Institute maintains an extensive collection of 2339 BSL3 strains—all kept in freezers. It also accommodates three national reference labs for the causative agents of brucellosis (since 2010), plague (since 2014) and tick-borne encephalitis (since 2015), and it was the national reference lab for the causative agent of tularemia from 2002 to 2014.

The Institute has multiple international collaborations, including with institutes in Afghanistan, Australia, Austria, the Democratic Republic of the Congo (DRC), Denmark, Egypt, France, Georgia, Guinea, Kazakhstan, Mali, Mongolia, Poland, Romania, Russia, Slovakia, South Africa, Sweden, Tanzania, Turkey, Ukraine, the United Arab Emirates (UAE), the USA and Zambia. The Institute also participates in the 'German Partnership Program for Excellence in Biological and Health Security', which seeks to control biological security risks and to strengthen healthcare systems against the risks of highly pathogenic agents through training, workshops, common scientific projects, scientific networking and 'scientific friendship'. Partner countries for this programme are Georgia, Kazakhstan, Mali, Tanzania and Ukraine.

The Institute Director began and ended his presentation on the topic of transparency. In his introduction, he stated that 'Transparency is part and parcel of our principles and key responsibilities'. In conclusion, he outlined examples of the Institute's transparency policy in practice: a self-commitment to the rules of good scientific practice as laid down by the German Research Foundation, maintaining an informative and public website, producing annual reports that are available on request, and hosting regular international medical biodefence conferences.

National implementation

Germany implements its BWC obligations through an array of statutory instruments. On the documentation provided to exercise participants, there are listed five acts and four regulations (two national regulations, one European Council Regulation and one European Commission Delegated Regulation)—plus the German Criminal Code of 1871 and the Code of International Criminal law of 2002—that are directly linked to BWC prohibitions and obligations. There are seven acts, 14 ordinances, two European Council Directives, one list of donor and recipient organisms for genetic work, two European agreements, and one set of convention regulations that all deal with measures to safely and securely handle biological weapons-related dual-use materials. Finally, there are five technical rules for biological agents and one leaflet issued by the Employer's Liability Insurance Association of the Chemical Industry.

We were given a sense of the complexity of jurisdiction in Germany in the presentation on national implementation of the BWC. Germany is a federal republic consisting of 16 states. Legislative and administrative responsibility is shared between the states and the federal government in some areas, including internal security, public and animal health, occupational health and disaster control. Some legislative and administrative responsibility has also been transferred to the EU.

Germany requires that facilities that work with pathogens (*a*) obtain a licence from the competent public health or veterinary supervisory authority; (*b*) demonstrate that appropriate infrastructure has been put in place; and (*c*) confirm that professional knowledge exists and personnel reliability and risk assessment measures have been implemented. Biological agents are classified according to safety risks, and particular infrastructure and equipment is linked with the different biosafety levels. A priority is placed on those pathogens that pose a high individual risk of aerosol-transmitted laboratory infections that cause severe fatal disease in humans and for which no effective treatment exists. Such pathogens are to be handled in accordance with the World Health Organization's (WHO) International Health Regulations (IHRs) at facilities that implement appropriate bio-containment precautions, especially at BSL4 or equivalent.

Personnel must undergo safety training and there are particular safety requirements for protecting employees in biological facilities. Pathogen transfers are only permitted between licensees. There are special requirements for the contained use, waste treatment and disposal of genetically modified organisms (GMOs). A licence is required to establish a genetic engineering facility. All genetic engineering work must be reported, and risk assessment of the specific experiments or work must be carried out. GMOs are classified according to safety risks, and particular infrastructure and equipment is linked with the different biosafety levels.

The German Research Foundation provides recommendations for dual-use research of concern (DURC), and the Institute also has an internal committee, that can confer with civilian stakeholders if needed, to deal with risk assessments of DURC. Staff working in facilities that are classified as security sensitive or vital for public security (e.g. Bundeswehr Institute of Microbiology facilities that handle pathogens and highly toxic substances) must undergo security vetting.

V. THE FACILITY TOUR

The 'visitors' and 'monitors' had separate programmes for the first afternoon. The programme for the visitors included an overview tour of the facility, in-depth visits to select labs, conversations with staff, and presentations and discussions of research activities. The monitors (mainly diplomats or biological arms control policy staff) remained in the briefing room for presentations by the MFA on the German Partnership Program for Excellence in Biological and Health Security. Two participants who had originally been designated as 'monitors' opted to join the visitors' programme, bringing the total number of 'visitors' to 12. I also opted for the visitors' programme.

The 13 participants in the visitors' programme (myself included) gathered with half a dozen representatives from the Bundeswehr Institute of Microbiology and the Federal Armed Forces Verification Centre around the large table in the visitors' designated 'working room' located just across the hall from the briefing room. The visitors were requested to self-select into two teams of six. The result was one team with five NAM representatives (including the team leader) and one Western Group representative, and a second team with four Western Group representatives (including the team leader) and two Eastern Group representatives. I could again choose which team I wanted to observe and opted for the predominantly 'Western Group' team in the first instance.

The plan was for the two teams to spend about an hour walking through the entire facility to obtain an overview of the approximately 60 rooms. We were encouraged to ask questions. After the tour, we would regroup and then decide which rooms we wanted to spend more time seeing in detail. It was explained to us that the barracks had been built in the 1930s, and that the laboratories were, therefore, not purpose-built but were converted offices. More importantly, the building contained large amounts of asbestos that was in the process of being removed. Therefore, there would be some areas that we could not enter. The asbestos removal process also meant the ventilation system was shut off.

Each team would be led by a senior member of the Institute's staff. An interpreter was provided for each team—not for the visitors, or even for the two senior staff members who both spoke perfect English—but for any Institute staff we might want to interview and who was not comfortable speaking in English. One or two escort staff accompanied each team.

The two visitor teams began their tours in different ends of the facility. My team comprised three microbiologists from national defence labs, a virologist from a national centre for disease control, an epidemiologist from another national centre for disease control, and a veterinarian from a national defence lab. We started in the basement and walked to the farthest end of the corridor to where, our host explained, most rooms operated as storage rooms. The first two rooms were unexpectedly locked. Our escort was sent to arrange for the rooms to be unlocked, while we continued down the corridor looking into room after room, including: a storage room, an electrical operating room, a storage room, a technical operating room, a storage room for BSL3 protective suits, a storage room for office supplies and paper storage, and a storage room with cleaning equipment and recycling storage for paper/plastics.

The 13th door we came to seemed more interesting. It was also locked and we were told the room contained the filtration system for the BSL3 lab's air supply. It also contained the lab's generator and back-up battery in case of a power failure. The next room was a lab that contained standard microbiological equipment: a refrigerator, sequencers etc. The escort returned

and we were told the storage rooms at the end of the corridor that we initially could not enter had now been unlocked. We retraced our steps. Room two was a storage room similar to the others we had seen. The first room was, however, still locked. Our escort was sent to fetch the keys. Once the door was unlocked we again found a fairly ordinary looking storage room. In the meantime, room 13 had also been unlocked and we could now see for ourselves the lab pipes, the generator and emergency back-up batteries. There was a loud hum from the generator. We pressed on.

Room 15 was another lab, this one with a PCR machine. One visitor asked why there was a biohazard sign on the door if the room was just for DNA amplification and did not handle any dangerous biological material. Our host explained that sample preparation takes place in the room so such a sign is required. Another visitor asked why one of the room signs indicated a BSL2 lab when there was no biosafety cabinet in the room—a standard feature of a BSL2 lab. Our host explained that there is currently no active research in the room, but that the Institute labels such rooms as BSL2 labs to keep its options open. He also explained that all nameplates on the doors had been covered up for personal data protection reasons during the visit. I later discovered all names had also been removed from the military uniforms worn by many personnel on site.

Room 16 contained a genome sequencer and other standard-looking lab equipment. The next room was another standard-looking BSL2 lab, with a biosafety cabinet, an incubator and a refrigerator containing toxins. Room 18 hosted chemical storage and waste chemicals. It was ventilated and was normally locked because it contained harmful and irritant material; the signage for the room confirmed this. Room 19 contained infrastructure disinfection material. Particularly eye-catching were the rows of tall rubber boots. The next four rooms were sealed and marked with 'A' for asbestos. Then came a small lab, a storage room and a room with humming machines, liquid nitrogen, and high-grade purified water for autoclaves. Room 27 was temperature controlled and contained freezers with BSL2 DNA, strains and sera. We were told the room was documented access only. When asked where the BSL3 samples were stored, we were told that they were only stored inside the BSL3 lab.

Room 28 had an electron microscope. The room next door contained photography equipment for taking digital images through microscopes. There were another couple of storage rooms, and then we walked up a floor to the overhead corridor containing the lab suite.

We started at the end of the corridor and looked into lab after lab—around 20 in total, including the prep rooms—seeing standard BSL2 features and equipment: biosafety cabinets, incubators, a laser scanning microscope, autoclaves, refrigerators, freezers, Petri dishes, growth media, agar plates, pipettes, Eppendorf tubes, centrifuges and lab coats. There were also some freezers in the hallway. Some of the labs were temperature controlled and had humming machines. Many of the labs were interconnected. We saw the BSL3 lab complex, with its adjacent viewing and control room, anteroom and personnel airlock. There were a couple of offices, a storage room and a guardroom with two guards.

There were few people around. During the tour, we saw only four or five scientists/technicians working in the labs. Once we were through the diagnostics part of the lab suite, our host announced that the tour was completed, and that we would return to the working room for some refreshments, but that afterwards we would be welcome to return to any rooms or 'hot spots' for further exploration.

Our host answered all our questions and came across as knowledgeable, friendly and responsive. The mood was generally light and friendly. Most team members took notes from time to time. While everyone took their tasks seriously, and while all the formalities of an inspection were in place, this was *not* an inspection, we had been invited in as a goodwill gesture and our hosts were voluntarily opening door after door for us.

We joined the (predominantly) NAM team waiting for us in the working room and social area just outside. They were ready to continue with the more in-depth lab tour. Having conferred with her team, the Western Group team leader said her team did not need more time in the labs, but instead wanted to hear more about the oversight structures operating in the lab and the processes, procedures and documentation they had. They stayed in the working room. I switched to the NAM team, which comprised three microbiologists (two from civilian organizations and one from a national defence lab), one pharmacist from a national defence lab, and one molecular biologist and one infectious disease specialist, both of whom were from civilian laboratories.

Our first stop was the large electron microscope room in the basement—not, it seemed, because the

group had specifically asked for this, but because our host wanted to show it to us. He explained technical details about electron microscopy and showed us how it could be used to investigate the morphology of the *bacillus* strains pictured. The next stop was upstairs, in the 'lab kitchen' with its autoclaves for waste, ovens for sterilizing glassware, dishwashers etc. Our host elaborated on the autoclaves' capacities, how they were used and how they could be misused.

He walked us through the suite of labs again, pointing things out, talking about the science, explaining processes, giving concrete examples of the sorts of experiments the Institute carries out, and answering questions in a straightforward, friendly way. He showed us refrigerators with different temperatures and opened a few to show us the vials and cell cultures inside. In one lab he showed us an example of a lab book and allowed us to see the sorts of entries it contained: PCR results, other experimental findings, comments, highlights, dates of experiments and signatures. He showed us a confocal, or inverted, microscope. He explained that the Institute stores genetically modified risk group 2 agents to provide positive controls for PCR. Standing in front of a hallway poster titled 'The Dirty Dozen', he talked about the main biological agents that form the focus for military defence. He pointed out that the causative agent of anthrax is on the list and that the Institute has a fairly large collection of more than 400 anthrax strains. In the diagnostics department he explained that the Institute has its own server and computer network to ensure that the personal data of patient samples is protected. He showed us spectrum peaks and mastermixers. The group dynamic was different from that in the other team. While the mood was friendly, the interactions were more educational and less inspection-like. We rejoined the rest of the 'visitor' group and, together with the 'monitor' group, we all boarded the bus to the hotel.

The plan for the next day was to visit the BSL3 lab and learn about bio-reconnaissance in the field. We would also make an assessment of the visit and give our hosts a presentation of it.

VI. THE BSL3 LAB

Unlike biological agents in groups 1 and 2, the agents in risk group 3 can cause severe human disease and present a serious hazard to workers; the agents may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available. At the time of the visit, the Bundeswehr Institute of Microbiology was working with a number of risk group 3 pathogens: *Bacillus anthracis*, *Brucella spp.*, *Burkholderia mallei* and *pseudomallei*, *Yersinia pestis*, *Coxiella burnetii*, *Francisella tularensis*, *Rickettsia spp.* as well as arenaviruses, bunyaviruses, flaviviruses, togaviruses and othopoxviruses.

On the morning of day two, both the NAM and Western Group teams crowded into the viewing and control room of the BSL3 lab. Both senior staff members from the Institute who had served as our team hosts the day before were present. One of them, along with two other staff members, would be escorting two select visitors into the lab (the 'lab team'). The second senior member of staff would remain with the rest of the group (the 'observer group') in the viewing and control room to talk through the lab features as well as the processes and experiments carried out in the lab.

First on the agenda for the observer group was a demonstration of the personal protective equipment used in the BSL3 lab and the correct procedure for putting it on. Normally, this would be done in the anteroom to the lab, but for the benefit of our large group, which would not fit in the anteroom, the team of five heading into the lab would dress in the viewing and control room instead. The lab team members first took off their regular lab coats and shoes, and removed watches, jewellery, keys and anything else that could tear the lab clothing. They then put on white, one-piece overalls with hoods that were made of what felt like reinforced paper. They put on blue nitrile gloves and the sleeves of the overalls were taped down. The zipper on each overall was also taped down. They were given green operating theatre shoes, white overshoes, and blue disposable shoe covers. A second pair of gloves was put on and also fixed with tape. Finally, the hood with a clear plastic visor was put on and connected to the battery-powered, high-efficiency particulate arrestance (HEPA)-filtered air ventilation system which ran down the back and was attached on the lower back with a strap around the waist. The batteries and filters were checked. The lab team was ready and headed into the anteroom, the airlock and finally the lab itself. The observer group watched the lab team through the observation window and on the monitor. Normally, when lab staff first enter the lab, they go through a series of safety checks with staff in the observation room to make sure the emergency lights, glovebox, refrigerator and so on are all working properly. Once the checklist is complete and the lab

grants approval, the staff in the observation room can leave.

While the lab team examined the lab, the observer group's host explained to us that the BSL3 lab has an independent ventilation system with a dedicated air supply and exhaust system—which we had observed in 'Room 13' the day before. There is a constant negative pressure in the personnel airlock (-30 Pa) and in the BSL3 lab (-50 Pa), which guarantees a constant airstream flowing from the personnel airlock into the BSL3 lab, preventing pathogens escaping into the anteroom and the corridors of the Institute. The negative pressure is permanently monitored and the current value indicated by a pressure gauge. The air is filtered twice before it is released. No water is released from the lab; it is either treated chemically or with heat.

The airlock doors are interlocked so that only one of them can be open at a time—either the door from the anteroom to the airlock, or the one from the airlock to the lab. The doors must be opened manually, and they are self-closing. If a door is not closed properly, an alarm signal will sound. All the doors can be opened manually from both sides, making it possible to enter the lab in case of emergency or to leave the lab in the event of a power failure. Work with pathogens is carried out under Laminar airflow cabinets or in a glovebox (-100 Pa), and lab surfaces are disinfected on a regular basis.

The visitors were eager to ask questions: Is lab access electronically monitored? How long has the BSL3 lab been in operation? Can the lab be entered at night? How many people usually work in the lab? Have you ever had a serious accident in the lab? What happens in emergencies? Are incidents reported? What equipment is inside the lab? What are the freezer security procedures? Are there regular medical checks of personnel? What happens if there is a power failure?

Towards the end of the session, we were given a demonstration of the emergency call. It was loud and quickly shut off.

We joined our hosts and the 'monitor' group, which had visited the labs that morning. The focus of the facility tour and lab visits had so far been on the Institute's departments on 'bacteria and toxins' and 'viruses and intracellular pathogens'. Following lunch, both 'visitors' and 'monitors' were also invited to view a demonstration from the Institute's third department on 'medical biological reconnaissance and bioforensics'.

VII. BIO-RECONNAISSANCE IN THE FIELD

The Institute's department on 'medical biological reconnaissance and bioforensics' develops diagnostic kits, equipment and lab support to identify disease-causing agents in the field during unusual outbreaks in theatres of military operation. The field reconnaissance teams are the special field units of the Institute's microbiologists. We were given demonstrations of the protective suits and equipment they use for sampling and of the mobile lab the Institute has developed for medical surveillance and investigation of unusual outbreaks.

An important aspect of bio-reconnaissance is sampling, which is the first-hand procurement of samples of the disease-causing agent from the environment, animals, people, food or drinking water. The Institute has a three-person reconnaissance team that can be deployed within 24 hours. The team members all wear specialized, military-green all-in-one protective suits. We were shown a heavy-duty version of the suit, which protects against both chemical and biological agents. It consisted of a cooling vest, a second vest system for voice recorders and radio communications, a hood and battery-operated blower unit, and a backpack. We were also shown a lighter version of the suit, which has a hood but no blower unit and does not protect against chemical agents. The stock for the backpacks, which are designed by the Institute, is individually tailored for each mission. We were told that the backpacks can contain sterile medical equipment; syringes (e.g. for extracting fluids from fermenters); a clean surface; nose swabs (e.g. for checking bacteria on agar plates); virus transport media; plastic bottles; waterproof, decontamination-resistant paper for recording sample details; a camera and so on. The contents are organized and tied down with velcro inside the backpack, and can be adapted to the particular needs (e.g. full necropsy, brain sampling etc) of the mission at hand. Once samples are obtained, the team has some hand-held kits for checking agents in the field, but the samples are generally brought to either stationary (fixed) labs or mobile labs for analysis.

The Bundeswehr Medical Mobile Lab provides field-deployable diagnostic capabilities for medical surveillance and investigation in the form of a modular, rapidly deployable lab that can be packed in 10–15 boxes each weighing about 30 kilograms. The boxes are tropicalized and watertight and are

not only suitable for transport on military planes, but also as passenger luggage in civilian aircraft. The lab takes up just under 20 m² and can be set up anywhere, ideally inside buildings, but also inside inflatable tents. The mobile lab we were shown was laid out with a 'reception' area for receiving medical and environmental samples and the accompanying paperwork; an area for handling the sample, containing the battery-driven, hermetically sealed and foldable glovebox, which looked like a large, transparent suitcase; and an area for amplification and sequencing work that was separated from the rest of the lab by plastic sheeting.

The mobile lab, we were told, offers a range of diagnostic technologies including enzyme-linked immunosorbent assays (ELISA), real-time PCR, real-time reverse transcription PCR (RT-PCR), light microscopy, immunofluorescence assays and immunochromatographic tests; it does not cultivate, enrich or otherwise work with live organisms. All assays have to be adapted to, and be validated on, the lab equipment. To date, the lab has established more than 50 assays for 33 different pathogens and toxins that can be used under field conditions in the mobile lab. Our host explained that there are usually four people working in the lab at any one time, and that it is the human factor, in terms of both the skill and cohesion of the team, that is considered the most critical element for a successful mobile lab field mission. Recent deployments of the lab included the Q fever outbreak in Kosovo to support the local hospital in May 2016, and the Ebola outbreak in Western Africa to support the Médecins Sans Frontières treatment unit in Guéckédou, southern Guinea, where between March 2014 and May 2015, more than 5800 samples were tested in the mobile lab, all without a single accident or infection. The Bundeswehr Medical Mobile Lab was the basis of the civilian 'European Mobile Lab' project that was launched during the Ebola outbreak.

VIII. ASSESSING COMPLIANCE

It was time to make an assessment: Did the visitors consider the facility to be in compliance with the BWC? The bio-experts from all the regions gathered around the table in the working room. No hosts were present and the doors were closed. I was observing the group. An hour had been set aside for the assessment meeting.

The person who had served as the Western Group team leader led the discussion. She began by reminding everyone of the relevant BWC articles.

Relevant treaty obligations

Article I prohibits the development, production, stockpiling and acquisition of biological weapons, but permits work with biological agents of appropriate types and quantities for prophylactic, protective or other peaceful purposes. Biodefence research for protective purposes is thereby permissible under the BWC, but must be conducted in such a way that it does not cross the line, intentionally or not, into prohibited activities. The first task, then, was to assess whether the visitors thought the Institute's work with biological agents was in types and quantities consistent with defensive and protective activities.

Article III prohibits states from transferring biological weapons and from assisting or encouraging any recipient to develop biological weapons. This includes taking proactive measures to prevent the theft of dangerous pathogens and ensuring that biodefence insiders do not misuse their access, knowledge and skills. The group should, therefore, also assess how the prohibitions on transferring means, equipment and knowledge are implemented at the Institute.

Article IV requires states to take measures to ensure national implementation of the BWC. Ensuring that biodefence programmes are subject to strict biosafety, biosecurity and dual-use research oversight is integral to fulfilling this provision, and the group's task was therefore also to consider how Germany implements the BWC and how the Institute complies with the legislation and processes established for the correct handling of pathogens.

Also of relevance are Article VII, which requires states to provide assistance to states victim of a biological attack, and Article X, which requires states to provide international cooperation and assistance more generally. Did the group judge the Institute to provide assistance and cooperate with other states?

Discussion

The Western Group team leader asked the bio-experts to be mindful of the purpose of the visit—this was about transparency, it was not an inspection—and she asked for first impressions. There seemed to be general agreement that 'everything was normal', that there

was 'a high commitment to biosafety and security', and that what we had seen was 'in line with the CBM declaration'. One of the discussion participants said that while there were no problems with quantities held at the Institute, there was the possibility for misuse in terms of the types of pathogens in possession. While this was strictly speaking true, the point was countered by other participants who noted that there was no evidence at the Institute of work moving into the area of a weapon or delivery. One participant stated: 'What we saw were standard microbiological labs and a standard BSL3 lab, and while there may of course be different national variations, there is nothing indicating a weapon system or a delivery system'.

The Western Group team leader said that in the report she would stop short of using the term 'full compliance' because we had not seen everything, but that we could visit labs of our own choosing and that this indicated some transparency. In fact, no areas had seemed restricted, as one participant noted: 'Even in the tissue culture area they would have found a way to get us access if we wanted to'. There was a short discussion about access to the BSL3 lab and its strain collection. Some said this could be improved through more modern access-control technology. Others pointed out that this would not necessarily make it more secure. It was also noted that the Institute has minimized access risks through appropriate organizational means. The emphasis on trust in its people was also discussed.

There was a brief discussion about how best to organize the report. The Western Group team leader suggested looking at different areas in turn: the facility, equipment and other material (such as strains), personnel, and procedures. Having done that, a compliance assessment could then be reached. This seemed a sensible approach to the group.

Facility

Starting with the facility, it was agreed that the approximately 1400 m² declared in the CBM submission seemed consistent with the size of the Institute. It was noted that not many staff were encountered in the labs, but it was also recognized that the exercise was taking place during the vacation period and that people started early and left early. The staff members that had been encountered were friendly and open. It was agreed that adequate information had been provided by the host leaders and through the initial briefings, and that it was not necessary to call interviews. One person expressed surprised that access to the individual labs was not more restricted internally. Others countered that this was normal practice and indeed common practice in their own national biodefence labs. It was also pointed out that the facility had four levels of security: (*a*) it was a military headquarters with restricted access; (*b*) there was restricted access to the corridor; (*c*) there was restricted access to the BSL3 lab; and (*d*) a logging mechanism tracked access to the lab. It was noted that although the facility had not been built to house labs, it had been adapted for this purpose.

Equipment and material

The discussion next turned to equipment. It was agreed that the size and types of equipment was consistent with the declared purposes, and that the personal protective equipment also conformed to the declared purposes. The two visitors who had entered the BSL3 lab were asked whether there was any notable special equipment, but they said it appeared to be a standard BSL3 lab. It was noted that none of the equipment seemed unused, except for the animal cages, which it had been explained were bought many years ago for emergency response reasons, but that the Institute normally contracts out all its animal work. One participant commented that he had scanned the publications listed in the CBM submission and nothing seemed out of line. In terms of other material, it was pointed out that the database was considered suitable in terms of access control to the strains and the chemical storage was locked as it should be.

Personnel and procedures

In terms of personnel, it was noted that there was evidence of good practice and that there was an emphasis on building up trust with staff. There were efforts to train staff, to observe how they work at the BSL2 level, and to assess the psychology and character suitability of potential BSL3 lab personnel before allowing them to work at the BSL3 level. It was remarked that one of the senior Institute staff members who served as team host acted in the Institute as project leader as well as the lead on both security and safety. This was not considered an ideal situation given potential conflicts of interest.

The Western Group team said it 'asked a lot of questions about processes and staff were very transparent'. They had received the documents they had requested. Regarding the DURC documentation, it was noted that: 'We just wanted to see a blank form, but they probably would also have provided one that was filled out had we asked for it, just blanking out the names of individuals'. Others in the team agreed. The team had also asked for data sheets for new projects. The team wanted to know the process for considering issues and any checklists for completing transports and exports. It was noted that the team had also asked for the safety incident report but that this had not been provided. It was assumed that this was an oversight or that it had proved difficult to fulfil the request under the time constraints. Nonetheless, it was noted that access would have been provided had the team pressed for it. It was asked whether anyone from the NAM team had seen any lab books. They responded positively, noting that records seemed to be very well kept.

Presentation of the assessment summary

A summary of the participants' observations was presented in a plenary in the briefing room during the final session of the day. Everyone in the room was given a chance to comment. A few minor amendments were made.

The summary opened by thanking the Institute, the escort team and everyone involved for their welcome and cooperation. It then set out the visitors' assessment approach: 'Our approach to assessing the information gained was to look at aspects relating to the facilities, equipment and materials, procedures and personnel'. The information provided in the CBM submission was taken into account as was the information provided and observed during the visit. The summary generally followed the structure of the assessment meeting discussion.

In looking at the facility, the visitors found that the size of the institution was consistent with the information provided in the CBM. It was also noted that although located within an old building, the facility had been adapted to meet the purpose of its activities. It was also noted that the physical security included several layers of access control to prevent unauthorized access to sensitive areas.

In terms of equipment and infrastructure, the summary stated that everything the visitors had seen was relevant for the prophylactic, protective and other peaceful research and diagnostic purposes stated by the Institute. It continued:

> With regard to pathogen and toxin material, particularly that held in the BSL3 strain collection, the process for access control was explained in detail to us. Although not state-of-the-art access control, the database methodology was suitable for the purpose and an example of good practice. There was also evidence of a strongly developed culture of trust between the staff. The pathogens and toxins were of types and in quantities consistent with the stated purposes in the CBM and the briefings during the visit.

It was noted that in addition to the procedures explained during the initial briefing, the visitors were given further and more detailed elaborations on request. Documentation was provided to demonstrate that specific processes were in place to assess projects considered 'dual-use research of concern' both at startup and during conduct of the work. Documented procedures for the transfer and export of pathogens and toxins from the Institute were also provided. It was noted that safety incident reporting could have been made available; that access to laboratory notebooks was permitted on specific request; and that the Institute followed international standards (ISOs).

The observations continued:

> Information was provided on training programmes for staff both on initial employment and annual refresher training covering technical, safety and procedural issues. Records of staff training for specific protocols were shown. All staff underwent security vetting, and senior staff developed relationships of trust with those in their teams. Although not requested, the opportunity for interviewing additional staff members would have been available under the facility provisions. Throughout the visit, all local personnel and escorts were very helpful and provided open responses to all requests for access, documentation and information.

The visitors concluded that they had been provided with good insight into the research and diagnostic activities of the Institute, and that the hosts' cooperation had 'helped to promote transparency and confidence with regards to the BWC and reassurance

that all activities are within the permitted prophylactic, protective and other peaceful purposes in Article I'. The procedures for biosafety and biosecurity, DURC issues, transfer and export of pathogens and toxins, and other measures had demonstrated commitment to implementing the obligations under articles III and IV of the BWC, and the information provided in the CBM submission had added to this commitment. In addition, some information had been provided on international assistance and cooperation activities of relevance to articles VII and X of the BWC.

In closing, the summary of observations maintained that as well as providing an opportunity for the Institute and Germany to demonstrate consistency with their CBM submission and transparency of their implementation of the BWC, the exercise provided a useful platform for exchange of good practices among all participants.

Observer reflections

In terms of my own observations, it seemed clear that the key objectives of the exercise had been met. The visiting bio-experts judged the Institute to be in compliance with the provisions and obligations of the BWC with a high degree of confidence (objective 1). The hosts' openness and cooperative manner significantly contributed to this assessment. In addition, it seemed that most, if not all, participants came away from the exercise convinced that compliance visits can be an appropriate means of increasing transparency and demonstrating a facility's compliance with the BWC (objective 2), and that increased transparency in a military facility is possible without violating necessary military security measures (objective 3).

There is room for improvement in at least three aspects of the exercise. First, the chemical weapons inspection model that was used as the basis for the facility provisions was not a good fit. The bio-experts did not feel the more formal inspection tools made available to them—conducting interviews, taking photographs, checking geographical coordinates—were appropriate in a transparency visit context, nor did they make use of them. Moreover, while the initial lab overview tour was considered useful, it was not felt that a second, more in-depth look at the labs would necessarily add much. Of more importance than hardware, equipment and tools were the people, processes and know-how, and in future on-site visits more emphasis could be placed on dialogue with staff and consideration of a facility's documentation, structures, procedures and practices.

Second, to increase their effectiveness, the visitor teams could meet in advance of the on-site visit. During the exercise, there was no pre-visit meeting to agree on objectives, review submitted documentation, divide up tasks, run through issues requiring special attention, agree on the organization of the report and so forth. While some of the visitors knew each other, most had not met or worked together before, and the group dynamics reflected this: the participants operated to a large extent as individuals, not as teams.

Third, a major benefit of on-site transparency visits is the opportunity they provide experts to compare approaches and share experiences, perspectives and best practices. They can also provide opportunities for substantive exchanges and the construction of informal networks of international experts. While there were some occasions for these sorts of exchanges and links to be made between the hosts and visitors in the exercise, more emphasis could be placed on mutual learning and follow-on exchanges in the design of a transparency visit.

Arms control and disarmament in the biological field is not about eliminating or reducing a material- and equipment-based threat, but about the ongoing management of a knowledge-based risk. As such, on-site peer review visits—like the Institute of Microbiology exercise that focus on interactive communication and bringing experts together—form a crucial element of that mandate. Independent observers also have an important role to play in transparency visits. Not only do they greatly enhance credibility and transparency, independent observers also provide an outside perspective on the dynamic between hosts and visitors. This dynamic is particularly significant in the biological field where the emphasis is not on counting hardware and measuring quantities but almost exclusively on conveying and establishing the intent behind research, development, production and testing activities. Civil society can provide an independent perspective on the often subjective determination process of compliance assessment judgement.

The upcoming BWC Review Conference in November 2016 must build on the pioneering efforts of the small number of states that have to date carried out on-site peer reviews and pragmatically demonstrated that options to evaluate compliance and implementation of the BWC exist outside of a legally binding verification

mechanism. States parties must agree language for the final document of the Review Conference that endorses the value of interactive information exchanges like on-site peer reviews and puts in place a standing forum within the next intersessional process whereby on-site visits and other transparency efforts can be shared and discussed by states. It is this collective dialogue that can shape and channel a movement beyond the pioneering efforts towards a gradually widening multilateralism.

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ABBREVIATIONS

BSL	Biosafety level
BWC	1972 Biological and Toxin Weapons Convention
CBMs	Confidence-building measures
CBRN	Chemical, biological, radiological and/or nuclear
DNA	Deoxyribonucleic acid
DRC	Democratic Republic of the Congo
DURC	Dual-use research of concern
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
GMOs	Genetically modified organisms
GPS	Global Positioning System
HEPA	High-efficiency particulate arrestance
IHRs	International Health Regulations
ISO	International Organization for Standardization
ISU	Implementation Support Unit
MFA	German Federal Foreign Office
MOD	Ministry of Defence
NAM	Non-Aligned Movement
PCR	Polymerase chain reaction
RT-PCR	Reverse transcription polymerase chain reaction
UAE	United Arab Emirates
WHO	World Health Organization

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A EUROPEAN NETWORK

In July 2010 the Council of the European Union decided to create a network bringing together foreign policy institutions and research centres from across the EU to encourage political and security-related dialogue and the long-term discussion of measures to combat the proliferation of weapons of mass destruction (WMD) and their delivery systems.

STRUCTURE

The EU Non-Proliferation Consortium is managed jointly by four institutes entrusted with the project, in close cooperation with the representative of the High Representative of the Union for Foreign Affairs and Security Policy. The four institutes are the Fondation pour la recherche stratégique (FRS) in Paris, the Peace Research Institute in Frankfurt (PRIF), the International Institute for Strategic Studies (IISS) in London, and Stockholm International Peace Research Institute (SIPRI). The Consortium began its work in January 2011 and forms the core of a wider network of European non-proliferation think tanks and research centres which will be closely associated with the activities of the Consortium.

MISSION

The main aim of the network of independent non-proliferation think tanks is to encourage discussion of measures to combat the proliferation of weapons of mass destruction and their delivery systems within civil society, particularly among experts, researchers and academics. The scope of activities shall also cover issues related to conventional weapons. The fruits of the network discussions can be submitted in the form of reports and recommendations to the responsible officials within the European Union.

It is expected that this network will support EU action to counter proliferation. To that end, the network can also establish cooperation with specialized institutions and research centres in third countries, in particular in those with which the EU is conducting specific non-proliferation dialogues.

http://www.nonproliferation.eu

EU NON-PROLIFERATION CONSORTIUM

The European network of independent non-proliferation think tanks

FONDATION pour la RECHERCHE STRATÉGIQUE

FOUNDATION FOR STRATEGIC RESEARCH

FRS is an independent research centre and the leading French think tank on defence and security issues. Its team of experts in a variety of fields contributes to the strategic debate in France and abroad, and provides unique expertise across the board of defence and security studies.
http://www.frstrategie.org

PRIF Peace Research Institute Frankfurt — HSFK Hessische Stiftung Friedens- und Konfliktforschung

PEACE RESEARCH INSTITUTE IN FRANKFURT

PRIF is the largest as well as the oldest peace research institute in Germany. PRIF's work is directed towards carrying out research on peace and conflict, with a special emphasis on issues of arms control, non-proliferation and disarmament.
http://www.hsfk.de

IISS

INTERNATIONAL INSTITUTE FOR STRATEGIC STUDIES

IISS is an independent centre for research, information and debate on the problems of conflict, however caused, that have, or potentially have, an important military content. It aims to provide the best possible analysis on strategic trends and to facilitate contacts.
http://www.iiss.org/

sipri

STOCKHOLM INTERNATIONAL PEACE RESEARCH INSTITUTE

SIPRI is an independent international institute dedicated to research into conflict, armaments, arms control and disarmament. Established in 1966, SIPRI provides data, analysis and recommendations, based on open sources, to policymakers, researchers, media and the interested public.
http://www.sipri.org/