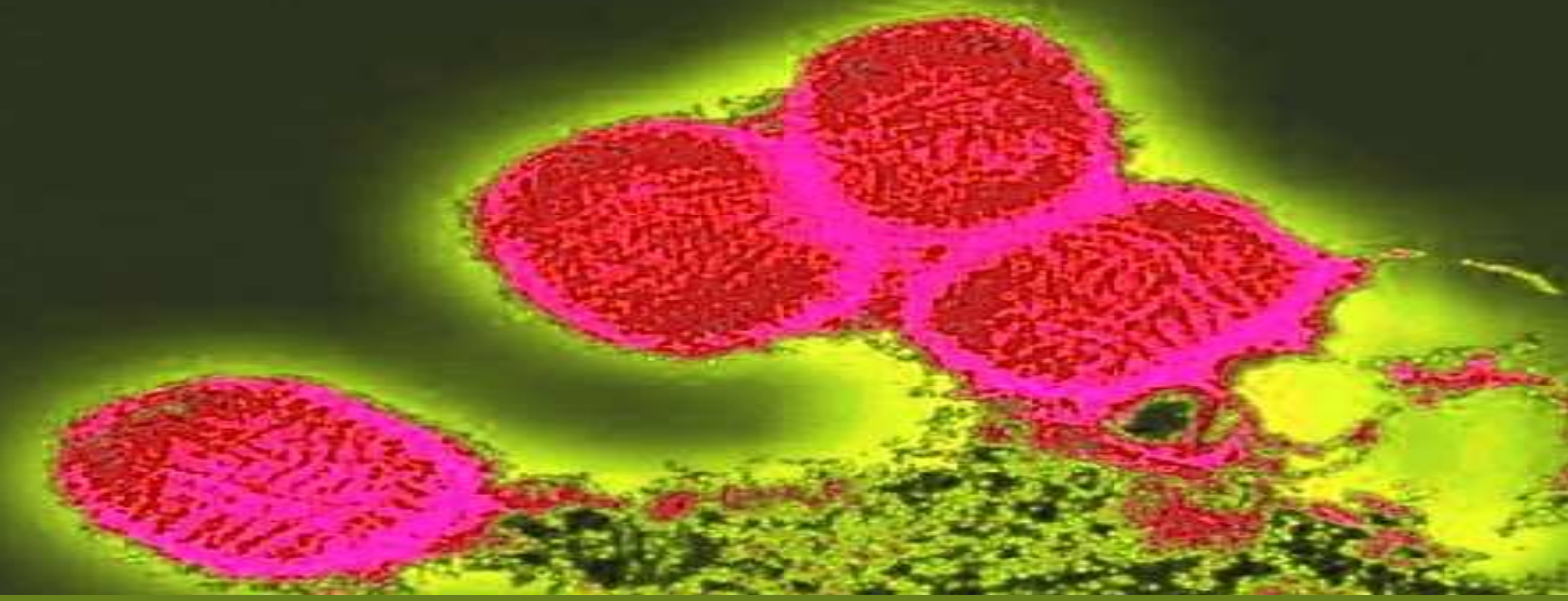

December 2008

Preparing the Ground for the CBM Content Debate

A study on the information exchange that builds confidence between States Parties to the Biological and Toxin Weapons Convention (BTWC)

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Foreword

We are now halfway through the intersessional process between the Review Conferences of the Biological Weapons Convention of 2006 and 2011. The process has led to many constructive and substantive debates between experts, members of government and representatives from NGOs and industry. Yet, despite these useful and constructive debates there is still a lot of work ahead of us. Switzerland is particularly concerned by the fact that the Convention still lacks a system to ensure compliance. In the absence of such a verification mechanism the Confidence Building Measures (CBMs) remain the only tool available to States Parties to enhance transparency and build confidence. Participation in the CBM mechanism has steadily increased until 2007, and it is crucial that this positive trend continues in the coming years.

Switzerland believes that one of the most important ways to enhance the credibility and strength of the Convention is to ensure that the CBM mechanism is effective. This is why Switzerland first funded a study on CBM data collection processes in 2007. Building on the success of the first study, and convinced that the debate on the CBM mechanism has to be continued throughout the present intersessional process, Switzerland has commissioned this follow-up study. Like its predecessor, the present study was carried out by the BIOS Centre of the London School of Economics (LSE).

This year's study aims to provide States Parties with new empirical data that addresses the quality of the data submitted. It aims to contribute to the debate on the content of the CBMs in an uncontroversial manner, and we hope that it will provide helpful guidance in the challenging discussion on CBMs ahead of us in the build-up to the Review Conference of 2011.

We would like to thank the author, Dr Filippa Lentzos, for her outstanding work. We would also like to thank Mr Richard Lennane and Dr Piers Millett from the Implementation Support Unit for lending their support to the study in spite of their ever more busy schedules. And last but not least our thank you goes to everyone who took part in one of the focus groups or the one-on-one interviews, or who contributed to this study in any other manner.

Ambassador Jacques Pitteloud
Political Affairs Secretariat
Swiss Federal Department of Foreign Affairs

Key findings

- Since the current forms were introduced in 1991, there has been an increase both in the number of States Parties declaring maximum containment facilities on CBM A Part 1 and in the number of maximum containment facilities declared. In 2007, 40 States Parties declared a total of 268 facilities, up from 26 States Parties declaring 115 facilities in 1992. Of the facilities declared only a small number are categorised as BSL4, the majority (around 80 percent) of the facilities have a lower BSL level.
- There has also been a gradual increase in the number of biodefence programmes declared on CBM A Part 2, from 13 programmes in 1992 to 25 programmes in 2007.
- National biodefence programmes can be categorised as small, medium and large as a helpful way to discuss the typical kinds of information and level of detail submitted by States Parties on their CBM returns.
- To properly interpret CBM returns, you need to be able to contextualise the information provided in terms of the particular state structures and funding sources, the organisations involved and their locations, the level of infrastructure, the institutional affiliation of the facilities, and the level of involvement of contractors and manufacturers.
- There is not one piece of information that by itself can provide confidence that programmes and activities are not in contravention of the Convention. Individual pieces of information are only “part of the puzzle.”
- Additional information does not necessarily give you more insight, but it provides more opportunities to corroborate and cross-check information.
- Key to improving transparency and strengthening confidence between States Parties is to increase the level of participation in the CBM mechanism. CBM requirements are not constraints on action but declarations of openness, and a failure to honour commitments under the mechanism indicates either a lack of interest in openness or a lack of belief in the regime of compliance.
- The regular exchange of data on current activities strengthens the regime of compliance by maximising the transparency of national patterns of normal activity. Complete, accurate and annual declarations are of the utmost importance so that deviations from the norm can be identified and information can be compared over time.
- A review of the questions asked on the CBM forms and a modernisation of the reporting process is called for.

An introduction to the study

The Confidence Building Measures (CBMs) of the Biological Weapons Convention were designed to prevent or reduce the occurrence of ambiguities, doubts and suspicions, and to improve international co-operation in the field of peaceful biological activities. Developing out of the crisis of confidence among States Parties that had resulted from the unresolved allegations of non-compliance, rapid developments in science and technology and other pressures in the early 1980s, they were agreed at the Second Review Conference in 1986, elaborated at a meeting of scientific and technical experts in 1987, and modified and considerably expanded at the Third Review Conference in 1991. They have not been modified since, although the Sixth Review Conference in 2006 agreed on various improvements to the mechanisms for submission and distribution.

One of the main functions of the CBMs is to allow and encourage States Parties to resolve compliance concerns co-operatively through exchanges of information. The experience of the past years, however, has suggested that the CBM mechanism may benefit from a substantial review to further improve it.

A central concern relates to the accuracy and comprehensiveness of the data submitted. To address this it is fundamentally important to understand the particular challenges and needs arising in different national contexts and how they impact on CBM submissions. In 2007 Switzerland sponsored a study on national data collection processes in order to draw out the experience and perspectives of those tasked with preparing the CBM return and to provide concrete examples of problems and solutions, of models, and of lessons learned in the submission process. The resulting report – *National data collection processes for CBM submissions: Revisiting the Confidence Building Measures for the Biological and Toxin Weapons Convention after twenty years of CBM submissions* – was launched and distributed during the Meeting of States Parties in December 2007. Additional copies are available from the Permanent Mission of Switzerland in Geneva (www.eda.admin.ch/geneva). It is hoped the report has been, and continues to be, constructive not only for States Parties submitting CBMs for the first time, but also for States that have consistently been submitting them for some time and for which a procedural review might be helpful.

Another key concern relates to the kind of data exchanged, and whether, in practice, the information supplied enhances transparency and builds the necessary degree of confidence between States Parties that there is no development, production, stockpiling, acquisition or retention of biological and toxin agents in contravention of the Convention. Building on the 2007 study, Switzerland has this year sponsored a second study focused on the information asked for on the CBM forms and the information submitted by States Parties.

The aim of the study is to provide novel empirical data addressing the quality of the data submitted in order to sustain the political focus on CBMs and to encourage further debate among States Parties in the lead-up to the 2011 Review Conference. It attempts to contribute to the content debate in an uncontroversial way and, as such, has used fictitious CBM returns drawn together on the basis of actual returns to provide concrete materials for discussion without directing comments at any one State Party. The “mock” CBM returns worked well in the expert discussions carried out for the study, and they can easily be adopted for use in further discussions about the information contained in CBMs. It is hoped that the findings from the expert discussions, combined with the quantitative data generated, will be helpful in the often difficult and sensitive discussion on the kind and quality of CBM information submitted for the BWC.

Design of the study

In exploring the information asked for on the CBM forms and the information submitted by States Parties, the study narrowed its focus to one of the seven forms through which information is exchanged: CBM A.

CBM A exchanges data – including name, location, scope and general description of activities – on research centres and laboratories that meet very high national and international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialise in permitted biological activities directly related to the Convention. Part 1 of CBM A concentrates on research centres and laboratories, Part 2 on national biological defence research and development programmes. Together these two parts comprise some of the most pertinent information regularly exchanged through the CBM mechanism.

The study approached the information submitted under CBM A in three ways:

1. To provide a general context and quantitative framework for the study, patterns and general trends were examined in the numbers of facilities and current biodefence programmes submitted by all States Parties over time. The data was provided by the Implementation Support Unit upon specific request from Switzerland. The questions asked were:

    - How many facilities having maximum containment laboratories were declared by each of the States Parties submitting returns at five-year intervals since the forms were modified at the Third Review conference in 1991 (i.e. in 1992, 1997, 2002 and 2007)?
    - How many States Parties submitting CBM returns since the forms were modified at the Third Review conference in 1991 (i.e. in 1992, 1997, 2002 and 2007) declared a current national biological defence research and development programme?

2. To consider the different types of information and level of detail submitted by States Parties for CBM A, the study analysed a sample of CBM returns from 23 States Parties. Over the timeframe 1992–2007 (from when the modified forms were first introduced until the most recent completed year available), the average number of annual CBM submissions has been 45, and the sample therefore equates to approximately half of the returns available in any one year.

    The sampled CBMs represented five of the six official UN languages; 74% (17/23) were in English, 9% (2/23) in Russian, 9% (2/23) in Spanish, 4% (1/23) in French and 4% (1/23) in Chinese. Every effort was made to include CBMs in Arabic, but this was regrettably not achieved. The proportion of languages included in the sample is a fair representation of the languages that CBMs have been submitted in over the 1992–2007 timeframe, where approximately 72% of CBM returns have been submitted

in English, 10% in Spanish, 8% in Russian, 6% in French, 2% in Chinese and 2% in Arabic.

Approximately half the CBM returns sampled were publicly available, either on the public section of the BWC website or on national websites. The additional CBM returns were requested bilaterally through official channels, asking whether States would agree to participate in the study and make parts of their CBMs available to an outside expert for temporary consultation.

The analysis of the sampled CBMs focused primarily on Part 2 of CBM A, on national biodefence programmes, as this is the information most relevant to the purpose of the CBM mechanism – i.e. to resolve compliance concerns with the Convention. On the basis of the sample, a set of distinct, generic answers to CBM A Part 2 were developed for small, medium and large biodefence programmes.

3. To encourage expert analysis and to provoke narrative and reflective considerations about the information contained in the CBMs, the mock CBM returns developed for small, medium and large biodefence programmes were used as a basis for moderated discussions in small groups of national experts. Three focus groups were conducted in all; two of these were with Western Group experts, the third was with NAM experts representing seven different States Parties. The groups each contained between five and ten experts with a mix of backgrounds (arms control and nonproliferation, defence, health, security, life sciences).

   In addition to the focus groups, a small number (6) of one-to-one conversations were carried out with arms control experts and ex-biological weapons inspectors.

   Questions asked during the discussions included: What could the experts conclude from the information provided? Which aspects of the information were particularly relevant? Did the information provided demonstrate transparency? Could the information engender a false sense of security? How would the experts judge when they had sufficient information to be confident that the programmes described were not offensive? What additional information would help build more confidence that the programmes described were not in contravention of the Convention?

Trends in numbers of facilities and biodefence programmes submitted

Since the forms were modified at the Third Review Conference in 1991, there has been an increase both in the number of States Parties declaring maximum containment facilities on CBM A Part 1 and in the number of maximum containment facilities declared. Figures 1 and 2 illustrate this graphically at five-year intervals starting in 1992, and Table 1 provides more detailed information in tabular form.

In obtaining these figures, each facility declared was counted. Where 'nothing new to declare' was recorded on the form, the last substantive return for the form was checked and the number of facilities in that declaration was considered to have been re-declared in the relevant year. On occasion, a State would indicate they had nothing to declare in form 0 but then proceed to make a declaration in CBM A Part 1. These declarations are accounted for in the data presented.

The most recent figures we have is that, in 2007, 40 States Parties declared a total of 268 facilities, up from 26 States Parties declaring 115 facilities in 1992.

Of the facilities declared only a small number are categorised as BSL4, the majority (around 80 percent) of the facilities have a lower BSL level. For example, in 1992, 81% (21/26) of the States that declared facilities, reported facilities with lower than a BSL4 classification; in 2002, 79% (23/29) of the States that declared facilities, reported facilities with lower than a BSL4 classification.

Figure 1: Number of SP Declaring Maximum Containment Facilities

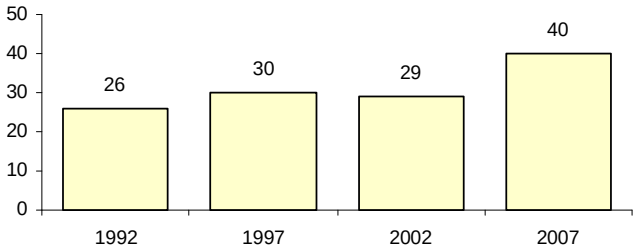
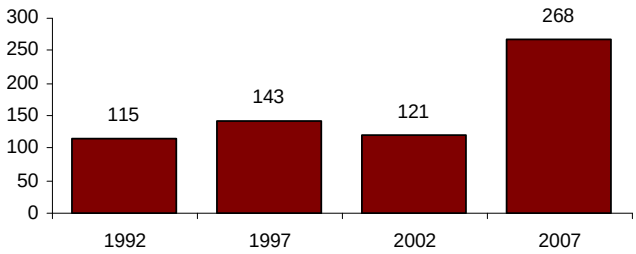


Figure 2: Total Number of Maximum Containment Facilities Declared



	1992	1997	2002	2007
Number of SP to BWC	127	140	147	159
Number of SP submitting CBMs	43	46	41	64
Number of SP submitting information on Form A1	26	30	29	40
Average number of facilities declared per SP	4.4	4.8	4.2	6.7
Total number of facilities declared	115	143	121	268

Table 1: Summary information of CBM A Part 1 on maximum containment facilities at five-yearly intervals since the current forms were introduced at the Third Review Conference.

Table 2 provides a breakdown of the number of States Parties submitting information on CBM A Part 1 (from Table 1) into those declaring 1) a single maximum containment facility, 2) between two and five facilities, 3) between six and ten facilities, and 4) more than ten facilities, at the five-yearly intervals.

As illustrated, the majority of States Parties declare less than six facilities; the number of States Parties declaring between six and ten facilities has remained similar over the years at around half a dozen; and the number of States Parties declaring more than ten facilities has gradually increased from 1 in 1992 to 5 in 2007.

The data displayed in Table 2 is graphically illustrated in Figures 3-6 on the next page.

	1992	1997	2002	2007
Number of SP declaring a single facility	5	12	10	16
Number of SP declaring between two and five facilities	13	10	10	13
Number of SP declaring between six and ten facilities	7	5	7	6
Number of SP declaring more than ten facilities	1	3	2	5

Table 2: Breakdown of number of States Parties declaring maximum containment facilities.

Figure 3: Breakdown of Number of SP Declaring Maximum Containment Facilities in 1992

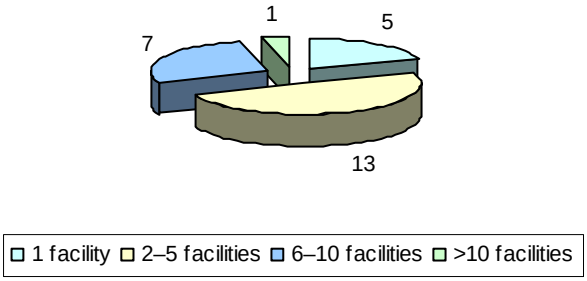


Figure 4: Breakdown of Number of SP Declaring Maximum Containment Facilities in 1997

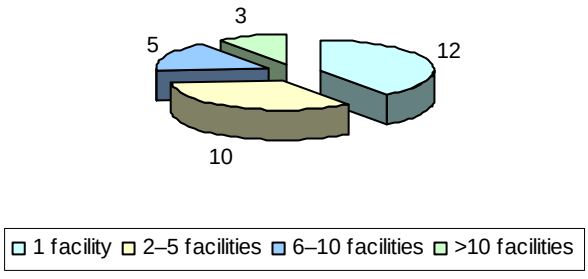


Figure 5: Breakdown of Number of SP Declaring Maximum Containment Facilities in 2002

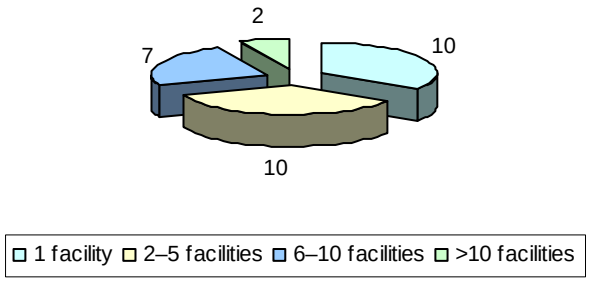


Figure 6: Breakdown of Number of SP Declaring Maximum Containment Facilities in 2007

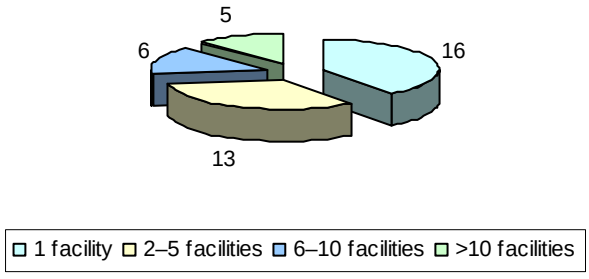


Table 3 and Figures 7-10 show that there has also been a gradual increase in the number of current biodefence programmes declared on CBM A Part 2 over the 1992–2007 timeframe, from 13 programmes in 1992 to 25 programmes in 2007.

The data is unable to tell us is whether this increase is due to newly submitting States Parties with biodefence programmes, or due to States Parties that have been submitting CBM A Part 2 for some time but which have newly acquired a biodefence programme.

Again, as with CBM A Part I, where 'nothing new to declare' was recorded on the CBM A Part 2, the last substantive return for the form was checked and the programmes in that declaration were considered to have been re-declared in the relevant year. On occasion, a State would indicate they had nothing to declare in form 0 but then proceed to make a declaration in CBM A Part 1. These declarations are accounted for in the data presented.

The remainder of this report focuses on biodefence programmes and provides a more qualitative picture of the kind of information and the level of detail submitted by States Parties on CBM A Part 2.

	1992	**1997**	**2002**	**2007**
Number of SP submitting CBMs	43	46	41	59
Number of SP providing information on biodefence programmes	13	17	18	25

Table 3: Summary information of CBM A Part 2 on biological defence programmes at five-yearly intervals since the current forms were introduced at the Third Review Conference.

Figure 7: 1992

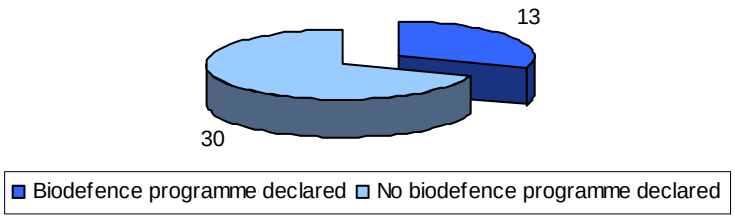


Figure 8: 1997

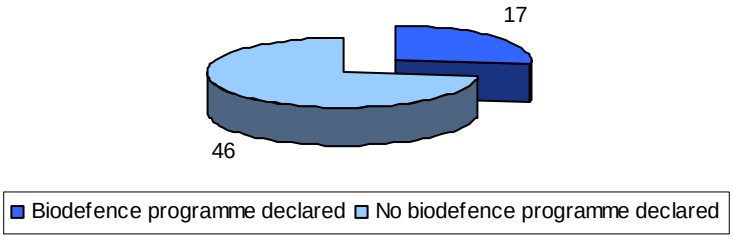


Figure 9: 2002

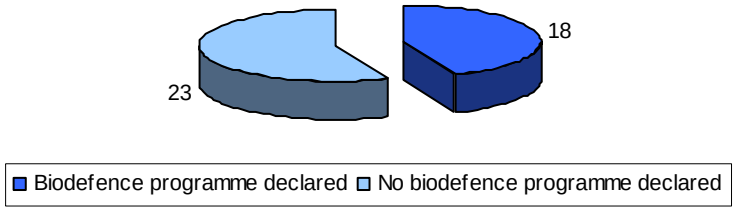
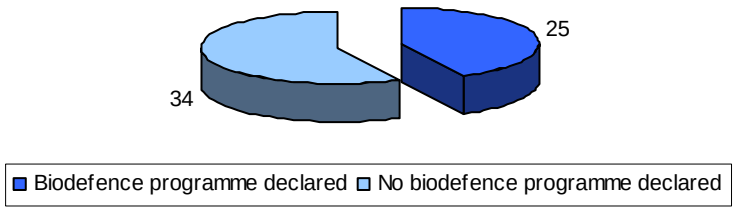


Figure 10: 2007



Information submitted on national biodefence programmes

CBM A Part 2 requires States Parties to declare whether there is a national programme to conduct biological defence research and development within their territories, or under their jurisdiction or control anywhere. The sorts of activities that are considered relevant to a biodefence programme include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection and decontamination. If a State Party does have a biodefence programme – and in 2007 25 State Parties declared that they did – CBM A Part 2 requires that the State describe the programme in terms of its objective, its funding source and amount, the contractors involved (if any), the organisational structure of the programme and the reporting relationships, and the principal research and development activities conducted. For each facility involved in the programme the State Party is also required to detail the name and location of the facility, the floor area of the laboratories, the number and kind of personnel working there, the facility's source and level of funding, its publication policy and annual list of publications, and the kind of biodefence work conducted. A copy of the CBM A Part 2 form can be found in the appendix.

In analysing the information submitted by States Parties on CBM A Part 2, the study divided the biodefence programmes described into three categories: small, medium and large. To avoid highlighting any one State Party's biodefence programme, while at the same time keeping the information as authentic as possible, the study drew on several actual returns to develop a fictitious, or "mock", CBM A Part 2 return for each of the three categories of biodefence programme.

Initially, a mock CBM A Part 2 return was developed for a medium-sized biodefence programme. This is detailed in the following three pages illustrating the typical kinds of information and level of detail submitted by States Parties. The fictitious programme is focused on detection of biological agents and toxins, on developing countermeasures, and on decontamination. The programme is wholly funded by the Ministry of Defence at an annual rate of GBP 5.5 million, with approximately 30% of the funds expended in contract or non-defence facilities. GBP 5.5 million is toward the lower end of medium-sized biodefence programme budgets, which range from GBP 5 million to GBP 50 million. However, few of what could be classified as medium-sized programmes submitted under the CBM mechanism to date have programmes at the higher end of this spectrum and a lower value was therefore chosen. The institutions involved in the fictitious programme are the Defence Science and Technology Organisation and the Biological Defence Institute, both within the Ministry of Defence. Only one facility is declared as part of the programme, containing a total laboratory floor area of 780m^2 with BSL3 as the highest containment level. The total number of personnel working at the facility is 78, approximately two fifths of which are military. 78 is again toward the low end of the personnel range at medium-sized biodefence programmes,

but in keeping with the GBP 5.5 million budget. The ratio of scientists to technicians in the fictitious programme is almost equal, in slight favour of scientists. The scientific disciplines represented cover core life science disciplines, as well as medicine and veterinary medicine. Like the biodefence programme as a whole, the facility is entirely funded by the Ministry of Defence, with half of the funding targeting research, a quarter targeting development, and a quarter targeting testing and evaluation. The facility has a policy of publishing in the open literature and references to published work are listed. Finally, a fairly comprehensive description of the biodefence work carried out at the facility is provided.

Having developed a complete mock CBM A Part 2 return for a medium-sized programme, slimmed-down versions were then developed for both a small and a large biodefence programme. As pages 19 and 20 show, these returns highlight the typical sorts of information provided on the scope and description of the programme, the source and level of funding, the facilities relevant to the programme, and the personnel involved.

Mock CBM A Part 2 for a medium-sized biodefence programme

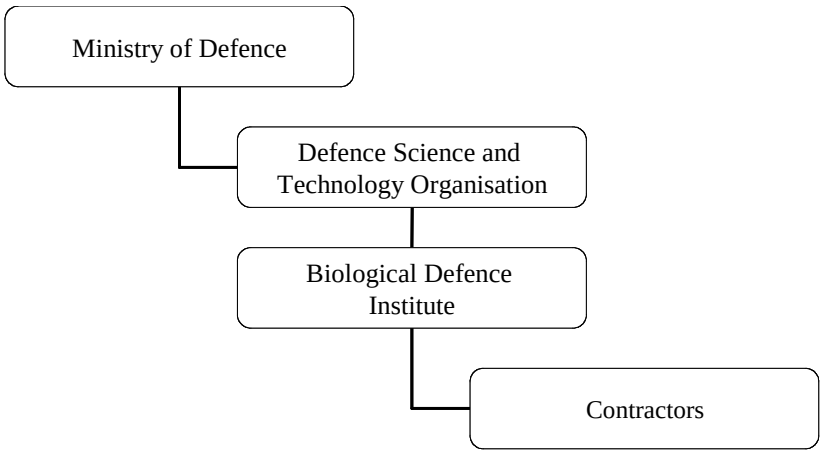
Scope and description of programme

Assessment of the hazards that may be faced by the military from biological agents and toxins. Detection of biological agents and toxins using immunological, biochemical and physical detection methods. Medical countermeasures against the infections or intoxications from biological agents and toxins. Decontamination of biological agents and toxins. Studies on the mode of action and toxicity of toxins and the mode of action and infectivity of biological agents.

Funding

Total funding for programme:	GBP 5.5M
Source(s) of funding:	Ministry of Defence
Proportion of total funds expended in contracted or other non-defence facilities:	approx. 30%
Objectives and research areas of the programme performed by contractors or in other facilities:	Contractors are used on various research topics in support of the main biodefence programme.

Organisational Structure and Reporting Relationships



Facilities relevant to the programme

Name:	Defence Science and Technology Organisation
Location:	Defence Science and Technology Organisation 4550 Place, Country (x^{o}y north x^{o}y east)

Floor area of laboratory:	
BSL 2	450m^2
BSL 3	330m^2
Total lab floor area:	780m^2

Personnel

Total number of personnel:	73
Division of personnel:	
Military	28
Civilian	45
Division of personnel by category:	
Scientists	37
Engineers	0
Technicians	31
Administrative and support staff	5
Scientific disciplines represented:	Bacteriology, biochemistry, biotechnology, chemistry, immunology, medicine, microbiology, molecular biology, parasitology, pharmacology, toxicology, veterinary medicine, virology.
Contractor staff:	2
Source(s) of funding:	Ministry of Defence
Funding levels for:	
Research	50%
Development	25%
Test and evaluation	25%
Publication policy:	All staff are encouraged to publish their research in the open literature.

List of publicly-available papers and reports resulting from work during the previous 12 months:

Jensen A, Bell R, Connors C, Singh IA, Wahlberg A, Ajana B (2004) 'Engineering antibodies for biosensor technologies' *Advances in Applied Microbiology* 54: 153-86.

Abi-Rached J, Burchell K, Amorese V, Novas C, Franklin S (2004) 'The twin arginine translocation system is essential for virulence of Yersinia pseudotuberculosis. *Journal of Bacteriology* 72:1893-1921.

Frazzetto G and Rose N (2004) 'Biotechnology for autonomous sensing systems: opportunities and challenges' *Journal of Defence Science* 8(2): 634-66.

Kaftanazi L, Kim L, Klein K, Reubi D, Schmid S, Zhang J, Kabatoff M, Clinch M (2004) 'The cytotoxic effect of anthrax lethal toxin on human lung cells in vitro and the protective action of bovine antibodies to PA and LF' *Journal of Applied oxicology* 24(3): 243-75.

Description of biodefence work

Assessment of hazards: Current work includes studying the inhalation toxicity of a wide range of materials and the aerosol survival of pathogenic bacteria and viruses. Operational analysis is also being conducted to examine the effects of BW attack on our forces, and to assess those countermeasures that might be adopted to minimise these effects.

Detection of biological agents and toxins: Immunological and gene based techniques for rapid identification of BW agents are being investigated. Recombinant and colostrum derived antibodies, and combinatorial peptides are being produced to a number of BW agents, including *B. pseudomallei*, *Bacillus anthracis*, anthrax toxins and ricin. Platforms for the amplification of antibody avidity, such as self-assembling gels, are also being investigated. Binding inhibition and cytotoxicity assays are being developed to assess the usefulness of potential therapeutic agents such as antibodies, peptides and aptamers. Research on PCR assays for the rapid detection of potential BW agents focuses on the evaluation of diagnostic tools that enable rapid detection of microbial antibiotic resistance and genetically manipulated bacteria. Assessment of particle characterisation for provision of rapid warning of a bio-aerosol are also carried out, as are studies on detection of biological material using mass spectrometry and other physico-chemical methods to determine their utility for field detection of biological toxins and BWC verification procedures – this work has included the analysis of ricin and crude extracts of ricin by MALDI and FT-ICR mass spectrometry.

Medical countermeasures: Research is carried out on new drugs and vaccines and delivery systems, for example microencapsulated antibiotics and vaccines. Microorganisms other than NDV and BG which have been used in the biological defence program are *Bacillus anthracis*, Brucella species (abortus, melitensis, neotomae, ovis and suis), Burkholderia species (mallei, pseudomallei), *F. tularensis*, *Mycobacterium tuberculosis*, *Yersinia enterocolitica*, *Yersinia pestis*, various influenza virus strains, Western Equine encephalitis, Eastern Equine Encephalitis, Venezuelan Equine Encephalitis and Chikungunya. Toxins used include botulinum toxin, staphylococcal enterotoxin B, ricin and various venoms from marine organisms, reptiles and insects. Outdoor studies have involved only NDV and BG.

Decontamination: This has included training personnel in both the theory and practice of handling vectors, microorganisms and toxins.

Mock CBM A Part 2 for a small biodefence programme

Scope and description of programme

Development of rapid detection, identification and characterisation tests for biological agents and toxins based on laser-induced Fluorescence, chip array, PCR, immunological techniques and masspectrometric methods.

Development of prophylaxis and medical countermeasures against biological agents and toxins. Model pathogens studied: *Francisella tularensis, Pseudomonas aeruginosa, Yersinia pseudotuberculosis,* mycotoxins.

Funding

Total funding for programme:	GBP 2.14M
Source(s) of funding:	Ministry of Defence

Facilities relevant to the programme

Floor area of laboratory:	
BSL 2	200m^2
BSL 3	60m^2
Total lab floor area:	260m^2

Personnel

Total number of personnel:	20
Division of personnel:	
Military	0
Civilian	20
Division of personnel by category:	
Scientists	14
Engineers	1
Technicians	4
Administrative and support staff	1
Scientific disciplines represented:	Chemistry, immunology, microbiology, molecular biology, parasitology, pharmacology, toxicology.

Source(s) of funding: Ministry of Defence

Mock CBM A Part 2 for a large biodefence programme

Scope and description of programme

Assessment of the hazards that may be faced by the military from biological agents and toxins. Characterisation of pathogenicity and dissemination characteristics of biological agents. Research is being conducted on microorganisms such as *Bacillus anthracis* and viruses such as Junin, Hantaan, Ebola, Marburg, Rift Valley fever, Venezuelan equine encephalitis and the rikettsiae *Coxiella burnetii*. Research is also conducted on protein neurotoxins such as botulinum and low molecular weight toxins such as saxitoxin. Detection, warning, identification, diagnosis and monitoring of biological and toxin agents. Development and testing in laboratories and under field conditions of vaccines, antibiotics, antivirals and antitoxins, and of protective equipment and biodecontamination capabilities.

Funding

Total funding for programme:	GBP 130M
Source(s) of funding:	Ministry of Defence

Facilities relevant to the programme

Floor area of laboratory:	
BSL 2	4380m^2
BSL 3	2550m^2
BSL 4	540m^2
Total lab floor area:	7470m^2

Personnel

Total number of personnel:	651
Division of personnel:	
Military	30
Civilian	621
Division of personnel by category:	
Scientists	466
Engineers	47
Technicians	51
Administrative and support staff	57
Scientific disciplines represented:	Aerobiology, aerosol physics, mathematics, bacteriology, biochemistry, bioinformatics, biotechnology, chemical engineering, chemistry, forensics, immunology, medicine, microbiology, molecular biology, neuropharmacology, parasitology, pharmacology, systems biology, toxicology, veterinary science, virology.
Source(s) of funding:	Ministry of Defence

Expert discussions on CBM returns and national biodefence programmes

To generate a variety of informed perspectives on the questions asked on CBM A Part 2 and the typical information provided on national biodefence programmes, the study convened small groups of experts with mixed backgrounds. The use of small groups – or focus groups – collectively discussing a given topic through the guide of an impartial moderator is a good way of exploring people's experiences, opinions, wishes and concerns, and of provoking narrative and reflective considerations. Group interaction is particularly useful for allowing people to generate their own questions, frames and concepts and to pursue their own priorities in their own vocabulary.

Employing the mock CBM returns developed for typical small, medium and large biodefence programmes, the groups discussed a number of themes related to the quality of CBM data. Some of the key points made during the discussions, as well as in conversations with individual experts, are related below.

Interpreting CBM data

The groups were first given the slimmed-down versions of the mock CBM returns, and asked what they could conclude from the information provided.

Small biodefence programme The majority of experts did not express concerns about the small biodefence programme. There were no dissemination activities or anything else in the mock CBM, they said, to suggest that the programme was on the wrong side of the offensive/ defensive boundary. There was wide agreement that if you did have any concerns these would generally be dispelled if a list of open-source publications indicating the research results was to be added.

A number of the NAM experts did, however, note that GBP 2.14M could potentially make quite a large biodefence programme in their countries. A Western Group expert made a similar point. She said it would be more helpful to know the proportion of the defence budget spent on biodefence, than the figure on its own. So rather than merely being given a figure of GBP 2.14M, it would be more helpful to know if GBP 428M is spent on defence as a whole and 0.5% is spent specifically on biodefence, or if GBP 2.14M constitutes the entire defence budget and 100% of it is spent on biodefence. Knowing these proportions would make you think differently about the GBP 2.14M figure. In essence, her point was: "You need reference points to be able to put the information in context."

This idea of reference points came up in other discussions too. With regards to personnel, it was noted that rather than just knowing the number of

personnel involved in the biodefence programme at the facility, it would be more helpful to be given this figure in proportion to the total number of personnel working at the facility. Others said they would like to know whether the 20 people are working full time or, say, only 5% of their time. Or, put differently, whether this was really 20 people or whether it represents 60 people devoting a third of their time. The distribution of scientists according to disciplines was also mentioned as more helpful information than what is currently provided in the CBMs. “Rather than being told there are 14 scientists, 1 engineer and 4 technicians and being given a list of the disciplines represented,” one expert said, “I would like to know, for example, if 10 of the scientists are working in toxicology and the remaining few in the other disciplines, because that tells you a great deal about the focus or emphasis of the programme.” Being given a breakdown of the number of personnel working in each of the BSL2 and BSL3 laboratories was felt to be another helpful reference point, to provide some coherence between the square meters of laboratory space and the personnel working there.

A slightly different concern that also came up in the discussion about BSL laboratories was that merely knowing the BSL classification of a laboratory does not tell you very much in and of itself. Many of the NAM experts, for example, said that BSL classification is not particularly indicative of the research or the biological agents that are worked with in their countries. As one expert succinctly put it: “The BSL classification might just be an indication of how much money you have.” While Junin, for example, might be classified as a risk group 4 agent to be worked with in BSL4 facilities, some countries work with Junin in BSL2 facilities simply because the virus is endemic in their country and the work necessary, but they do not have access to laboratories with a higher BSL classification. Similarly, it was also remarked that we should not assume that BSL2 or BSL3 laboratories in advanced countries necessarily equate with BSL2 or BSL3 laboratories in developing countries, as infrastructure and working practices might differ significantly. So while it is useful to know BSL classifications of facilities, it was suggested that it might be more helpful to ask for the number of facilities dealing with highly dangerous pathogens than to ask for the square-meters of BSL2, BSL3 and BSL4 laboratories.

In two of the groups, there was some disagreement on the proportion of scientists to technicians listed in the small biodefence programme. While some felt that the ratio of 14 scientists to 4 technicians was feasible, others felt it didn’t seem quite right. One commented: “This would only happen in a university! In a defence lab you’d have 14 scientists and 14 technicians because scientists are so much more expensive.”

A final point worth highlighting on the small biodefence programme was that some of the experts felt the programme’s research on detection and medical countermeasures could very well be conducted in institutes other than the Ministry of Defence, such as in Department of Health facilities or in university laboratories, and that that was actually increasingly the case. In line with this, one expert noted that with only one biological warfare agent studied (*Francisella tularensis*) it didn’t seem much of a biodefence programme at all.

Responding to this another expert said the programme was probably primarily focused on ‘proof of principle’ work, but there was some disagreement on whether ‘proof of principle’ biodefence work was feasible without pathogens.

Medium-sized biodefence programme Looking at the mock CBM of the medium-sized biodefence programme the experts did not generally express any major concerns either. Many would have wanted to see a more detailed description of the programme, but again noted that additional information in the form of a list of publications – either articles or research reports – would probably go far to allay any potential concerns. The research description “Studies on the mode of action and toxicity of toxins and the mode of action and infectivity of biological agents” was thought particularly ambiguous. Rather than just researching the infectivity of existing pathogens, it could suggest that the programme was trying to make a pathogen more infectious and testing it. Publications indicating otherwise could alleviate this concern. However, complicating the matter somewhat, it was also noted that making a pathogen more infectious and testing it to get an idea of the increased hazard this would cause could quite legitimately be done if a State had specific intelligence that this might be a threat.

In one of the groups, the question about who is counted as military and who is counted as civilian came up. Are civilian employees of the Ministry of Defence to be counted as military, or does ‘military’ just refer to uniformed personnel? Interpretation of the term was considered important because while the experts in the group generally thought of ‘military’ as uniformed armed forces and ‘civilian’ as everyone else including non-uniformed employees of the Ministry of Defence, others might think of it differently – thus inflating the number of military personnel they put down on their CBM declarations leading to misinterpretation by those analysing the forms. But what would more or less military involvement really tell you? One expert answered not too much, because some countries just have a higher military to civilian ratio in their biodefence programme than others, and this is not an indication of activities in contravention of the Convention. Another said that the breakdown within the military personnel might actually be of more interest: How many medical researchers are there? How many uniformed military, defence scientists, veterinarians? How many work on policy? “If, for example, they are all medics, that will tell you one thing,” he said, “but if a large proportion of the personnel is from artillery weapons research, that would tell you an entirely different story.” What he wanted the CBMs to tell him was whether the military was directly engaged in the programme, and, if so, in what capacity, in the policy work or in the scientific work. A related issue that came up was whether there was a way to capture the extent of non-funded military involvement in the CBMs as this too was considered useful information not currently provided on the forms.

The discussion on how to interpret the term ‘military’ led on to discussions about the importance of contextualisation. It matters who interprets the CBMs. As one expert said: “You always have a partial way of looking at the information, depending on your angle. A research scientist will have one way for example, while an intelligence officer might have a more suspicious frame

of mind." Another problem that was highlighted in interpreting the CBMs is that people are looking at them in the context of their own programme with their own definitions in mind. To properly analyse a CBM return, you need an understanding of the particular country's state structures and funding sources, of the organisations involved and their locations, of the level of infrastructure, of the institutional affiliation of the facilities, and of the level of involvement of contractors and manufacturers. "They're all important pieces of the puzzle."

Large biodefence programme More concern was generally expressed about the large biodefence programme, typically because of its sheer size and because of the types of agents used, the field-testing and aerobiology, and the number of personnel involved.

Returning to the idea of contextualisation, several of the experts highlighted that the level of concern depended a great deal on which State Party's programme this was. As one expert put it: "You don't analyse the information with a neutral frame of mind. If you know the State Party it changes how you interpret the information. It is about intent and your level of confidence in the State Party." Referring to the scope and description of the programme, another expert noted that just because the information obtained from aerosol releases could be used for offensive purposes, it would not necessarily indicate an offensive programme. "You would therefore ask yourself," he said, "whether the State Party was an ally. If it is, then it would probably share the results with you. If it is not, you would probably be much more suspicious."

The sharing of information between States through means other than the CBM mechanism also came up in the discussion around the particular agents used in the programme. Studies on viruses like Ebola, Marburg and Junin can be completely legitimate and purely defensive, but – because of the misuse potential of the information – you would not necessarily use open-source publications with detailed information on results like survivability as a way to allay concerns about the programme: "You don't want to provide a recipe book for terrorists." So, in this case, rather than asking for such studies to be published in the open literature or asking for more information to be supplied on the CBMs, you could obtain more information through bilateral consultations.

One of the experts also brought up the more formal consultation and clarification mechanism agreed at the Third Review Conference 1991. If State Party X was concerned about State Party Y's programme, and bilateral or other consultations were insufficient to allay any concerns, State Party Y could request the Depositaries to convene a consultative meeting. Specialised assistance may then be requested to clarify any ambiguities and unresolved matters through appropriate international procedures within the framework of the United Nations.

The mock CBM for the large biodefence programme also brought about discussion on the need, or not, to list the specific biological agents used in biodefence programmes. Some of the experts were concerned about listing agents for security reasons, and suggested adequate information could be

conveyed by just noting the risk groups of the organisms worked with. Instead of stating that work is carried out with "*Bacillus anthracis* and viruses such as Junin, Hantaan, Ebola, Marburg, Rift Valley fever, Venezuelan equine encephalitis and the rikettsiae *Coxiella burnetii*" as the mock CBM of the large biodefence programme does, it would, they argued, suffice to say that work is carried out with organisms from risk groups 3 and 4. One of the experts went on to say that the disciplines represented are actually of much greater interest than the organisms used, because disciplines give an indication of what can and cannot be done with the material.

Adding information

Later in the discussions, the groups were provided with the extended version of the CBM return for the medium-sized biodefence programme and asked whether the additional information provided any new insights or raised any new concerns.

One expert noted that the new information on the biodefence work carried out – particularly the work on the inhalation toxicity of a wide range of materials and the aerosol survival of pathogenic bacteria – raised some concerns in that the information gained had a large potential for misuse. While all the work could be justified as defensive, the results, especially the aerosolability results, could also be useful in the early stages of an offensive programme. Publications were once again noted as helpful in building confidence and making it more clear that the programme was carrying out bona fide defensive research.

A number of experts raised the importance of knowing the name and location of the facility, which hadn't been supplied in the slimmed-down version of the CBM. There was some disagreement on whether the coordinates were needed or not, but it was generally recognised that the name and address (and website if appropriate) were key in finding out more information and, for larger programmes, getting a sense of how different facilities were related. Ideally, you would also want information on the physical information of the facility and whether there are sub-units within a larger facility. The suggestion was made that an orientation map and facility diagram could helpfully be added to the CBMs, detailing the entire declared facility, and all relevant buildings, rooms and other structures. One expert from a less developed country said, however, that because of the low levels of security at their biodefence facility, her country was unwilling to make the physical address public, and even uncomfortable about sharing it with States Parties through the CBM mechanism.

The extended CBM also provided information on contractors, which many agreed was crucial. Subcontracting to universities or private companies was generally felt to be an indication that the research was less secretive. "It tells you something if the programme is 90% military or 90% subcontracted," one expert said. "Contracts lend a degree of transparency or at least give good

pointers as to how the programme is structured." Subcontracting also allows you to check for joint publications and can be, as another expert said, "a route to finding out more about the organisation". Adding a specific question on the percentage of subcontracting going to foreign institutions was thought to be useful as a way of indicating the level of foreign involvement. The degree of international collaboration can tell you something about the level of openness of the programme: "about the amount of money going out and the number of personnel coming in." It was also thought of interest to know which countries were working together, "and if countries decline to answer, that would be an interesting finding too."

Other experts highlighted that additional information does not necessarily give you more insight. As one expert said, "If you're trying to hide something you can just make up more things." It was generally agreed, though, that if you are trying to hide a programme, it tends to be better to omit things than to make things up. This is because the more information you have the more opportunities you have to corroborate and cross-check that information. This is especially the case if the information indicates the degree of openness of the programme, as information about subcontractors does. Closed programmes without collaborators and publications in the open-source literature "automatically make you less confident."

The discussion on the usefulness of additional information led naturally onto a discussion about whether CBMs could ever provide sufficient information to be confident that the programmes described were not offensive. In the groups it was repeatedly emphasised that there is no one piece of additional information that by itself can provide you with a definite conclusion: "There's not one thing that's the key answer." Rather, you have to ask yourself whether it all "hangs together," whether there is "an internal logic," whether "there is coherence in terms of scale, activities, scientific effort and outputs," whether there is consistency between CBM A and the information provided on the other forms, whether current submissions are consistent with past submissions, and whether CBM information matches up with information from other sources, both open and closed. These are the real questions that enable you to start interpreting the offensive/ defensive boundary, and the reason why individual bits of CBM information are characterised as only "part of the puzzle."

This is also why many of the experts agreed that CBMs would not engender a false sense of security. "CBMs are important to get more information that you can corroborate, but they don't necessarily generate a likelihood of knowing about an offensive programme." However, it was also pointed out that the utility of the CBMs is strongly influenced by the sincerity by which they are put together. Incomplete and inaccurate CBM submissions offer little assurance of compliance, and may even diminish confidence and increase suspicion. Indeed, one expert went so far as to say that since there are no checks and balances on the CBM reporting system, people can put down what they want to put down. "We all know of countries that claim that they've never had programmes, and yet facts tend to argue against that. But, in their CBMs every year, they report nothing's going on." He went on to stress, though, that

"what the CBMs do allow you to do is to obtain information from those countries who are amenable to sharing information – so while it is not a form of assurance, the CBM mechanism does encourage cooperation and the sharing of information." Another expert highlighted the value of CBMs in getting State Parties to review their own biodefence programmes on an annual basis.

Building more confidence

It was repeatedly noted in the discussions that the CBM mechanism should not be viewed as a tool to uncover offensive programmes or activities in contravention of the Biological Weapons Convention. The CBMs are first and foremost a transparency measure aimed at building confidence. The regular exchange of data on current activities strengthens the regime of compliance by maximising the transparency of national patterns of normal activity. Annual declarations are of the utmost importance so that deviations from the norm can be identified and figures can be compared over time to see if particular programmes are expanding or not. Transparency is particularly important in terms of research on topics of relevance to the BWC, as the CBM mechanism was to some extent intended to compensate for the absence of constraints on research in the Convention (which covers development but not research).

How can we increase transparency and strengthen confidence? When asked this question, the experts, almost without exception, answered that the CBM mechanism will only command limited confidence until more States Parties honour their commitments and submit declarations. Indeed, ignoring the mechanism weakens the concept of CBMs and may ultimately reduce, rather than build, confidence among States. It was emphasised that CBM requirements are not constraints on action but declarations of openness, and that a failure to honour commitments under the mechanism indicates either a lack of interest in openness or a lack of belief in the regime of compliance.

Increasing participation in the CBM mechanism was, however, not the only means expressed by which to improve transparency and strengthen confidence. It was generally recognised that a review of the questions asked on the forms and a modernisation of the reporting process was needed, but most agreed that more detailed or more intrusive questions would not be feasible. Asking for more detailed information might make States less inclined to participate, or result in less information submitted than at present. It would also increase translation costs, and, as an intelligence officer noted, "more information can actually muddle the picture by giving you more avenues for interpretation and less ability to eliminate all the possibilities." Others noted that more detailed information might mean that those States Parties who interpret transparency in a broad sense and who currently make their CBMs publicly available, might have to reappraise whether to continue doing so. The idea of two separate returns was raised – one for States Parties and one for the public – but this was not considered a particularly good solution. There

was also general agreement among the experts that the CBM questions cannot be slimmed down beyond what is currently asked. As one expert put it:

> "People tend to have very strong opinions that the CBMs are either not revealing enough or that they are revealing too much. Those that feel that they are not revealing enough would like to see a lot more detail in the CBMs. Those people who feel they reveal too much would like to see less information there. So I think we've reached a good middle ground."

Yet, while the level of detail asked for on the CBMs was generally considered appropriate, many felt that a review was needed of the questions asked. It was thought, for instance, that some of the questions could helpfully be clarified: Who is to be counted as military and who is to be counted as civilian? Is it necessary to list the specific biological agents worked with or do risk group indications suffice? Does the "total number of personnel" refer to person years or to the number of employees working at the facility? A number of the questions were also seen to require some form of modification to provide more meaningful answers. Examples raised in the discussions included asking for: the proportion of the defence budget spent on biodefence instead of the biodefence budget figure on its own, the distribution of scientists according to disciplines rather than merely the disciplines represented, the number of facilities dealing with highly dangerous pathogens and the number of personnel involved rather than the square-meters of BSL2, BSL3 and BSL4 laboratories, and the capacity in which the military is involved rather than just whether it is involved in the biodefence programme. Finally, there were also some questions not currently asked that it was thought would significantly increase the level of transparency provided by the CBMs. These included questions on: whether aerosol testing is carried out**,** the number and species of animals used in biodefence research per year, the proportion of open-source to internal/ restricted publications at a facility, non-funded military involvement in the biodefence programme, the percentage of subcontracting going to foreign institutions, the scale of clinical trials related to the biodefence programme.

The experts were also unanimously agreed that the reporting process needed modernisation. Most encouraged the development of electronic submission forms and a user-friendly, web-based information management system. It was felt that standardised forms and a simpler submission process would increase the likelihood of more States participating, and would make it easier to analyse CBMs, especially where language was a concern. Many urged the adoption of tick boxes and pull-down menus to simplify data entry and to improve the visibility of key data, as well as help functions and indicators to signal where to go next or where data still needs to be filled in.

While these examples of revisions and modifications to the forms and the CBM reporting process can only give an indication of the sort of changes experts feel would be helpful in increasing transparency and strengthening confidence, they provide a modest starting point for future discussions on the kind and quality of the information exchanged through the CBM mechanism. It

is hoped that these suggestions, together with the preceding discussion on interpreting CBM information and the quantitative data on biodefence programmes and maximum containment facilities, can input into any future revisions to the forms considered appropriate by the States Parties.

I would like to thank the States Parties that took part in the study for contributing their CBMs; the experts and officials involved for the insights they provided and for so generously giving up their time to participate in the study; my colleagues, in particular Riccarda Torriani and Reto Wollenmann, for their substantial efforts, contributions and translations; my research assistant, Caitlin Cockerton, for her excellent work and enthusiasm; and the Political Affairs Secretariat of the Swiss Federal Department of Foreign Affairs for its support of the project.

Filippa Lentzos
London, 25 November 2008

Key findings

- Since the current forms were introduced in 1991, there has been an increase both in the number of States Parties declaring maximum containment facilities on CBM A Part 1 and in the number of maximum containment facilities declared. In 2007, 40 States Parties declared a total of 268 facilities, up from 26 States Parties declaring 115 facilities in 1992. Of the facilities declared only a small number are categorised as BSL4, the majority (around 80 percent) of the facilities have a lower BSL level.
- There has also been a gradual increase in the number of biodefence programmes declared on CBM A Part 2, from 13 programmes in 1992 to 25 programmes in 2007.
- National biodefence programmes can be categorised as small, medium and large as a helpful way to discuss the typical kinds of information and level of detail submitted by States Parties on their CBM returns.
- To properly interpret CBM returns, you need to be able to contextualise the information provided in terms of the particular state structures and funding sources, the organisations involved and their locations, the level of infrastructure, the institutional affiliation of the facilities, and the level of involvement of contractors and manufacturers.
- There is not one piece of information that by itself can provide confidence that programmes and activities are not in contravention of the Convention. Individual pieces of information are only “part of the puzzle.”
- Additional information does not necessarily give you more insight, but it provides more opportunities to corroborate and cross-check information.
- Key to improving transparency and strengthening confidence between States Parties is to increase the level of participation in the CBM mechanism. CBM requirements are not constraints on action but declarations of openness, and a failure to honour commitments under the mechanism indicates either a lack of interest in openness or a lack of belief in the regime of compliance.
- The regular exchange of data on current activities strengthens the regime of compliance by maximising the transparency of national patterns of normal activity. Complete, accurate and annual declarations are of the utmost importance so that deviations from the norm can be identified and information can be compared over time.
- A review of the questions asked on the CBM forms and a modernisation of the reporting process is called for.

Form A, part 2 (i)

National biological defence research and development programme Declaration

Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes/No

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of the programme.

Form A, part 2 (ii)

National biological defence research and development programme

Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

2. State the total funding for the programme and its source.

3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes/No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Form A, part 2 (iii)

National biological defence research and development programme

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

2. Where is it located (include both address and geographical location)?

3. Floor area of laboratory areas by containment level:

BL2 _____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

(iv) List the scientific disciplines represented in the scientific/ engineering staff.

(v) Are contractor staff working in the facility? If so, provide an approximate number.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

(vii) What are the funding levels for the following programme areas:

Research _____

Development _____

Test and evaluation _____

(viii) Briefly describe the publication policy of the facility:

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms* and/or toxins studied, as well as outdoor studies of biological aerosols.