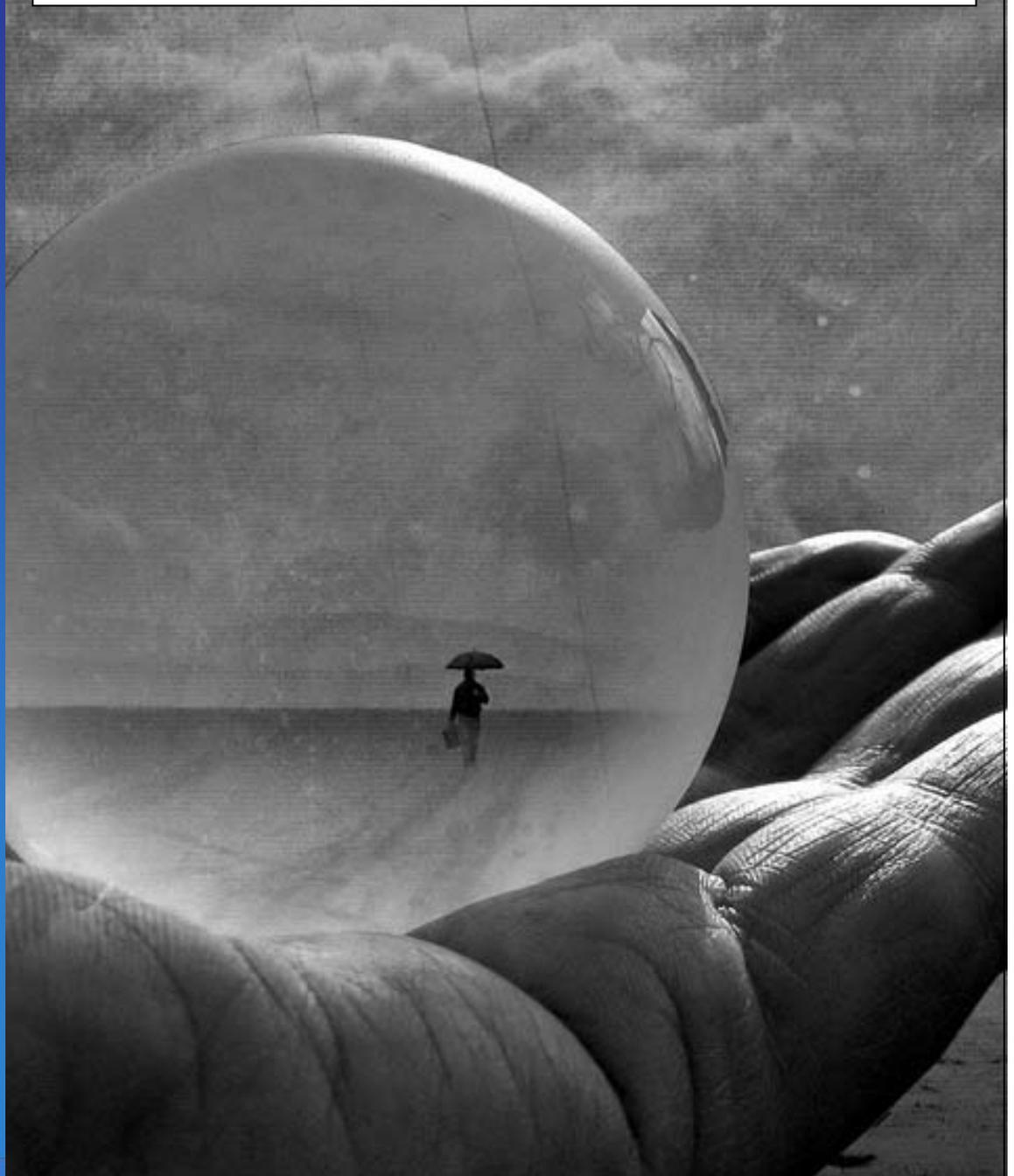




**GUIDE TO PARTICIPATING IN THE
CONFIDENCE-BUILDING MEASURES OF
THE BIOLOGICAL WEAPONS CONVENTION**



Geneva 2009

*Prepared by the United Nations Office for Disarmament
Affairs with the support of the European Union*

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Please report any errors to bwc@unog.ch

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Section I: About this Guide

This guide has been prepared by the United Nations Office for Disarmament Affairs with the support of the European Union, as part of the European Union's Joint Action in support of the Biological Weapons Convention.

The aim of the guide is to provide practical advice and guidance to officials responsible for preparing submissions for the Confidence-building Measures (CBMs) of the Biological Weapons Convention. The guide includes:

- Background information on the CBM process,
- General advice for preparing to participate in the CBMs, and
- Detailed guidance on gathering the specific information required for each form.

This guide is intended only as a practical aid and has no formal status; please refer to the decisions of the respective Review Conferences for the formal requirements of the CBMs. The guide includes some suggestions for providing information in addition to that required by the CBM forms. These are only suggestions and are not intended to imply or confer any additional obligations on States Parties.

The guide is available free to States Parties, and is published in each of the six official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish).

Section II: Introducing the Confidence-building Measures (CBMs)

The Second Review Conference (1986) of the Biological Weapons Convention agreed to introduce Confidence-building Measures "in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international co-operation in the field of peaceful biological activities". The CBMs were elaborated at a meeting of scientific and technical experts in April 1987, and were modified and considerably expanded by 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.

Although the CBMs are not derived directly from the text of the Convention itself, the Second Review Conference decided by consensus that "*the States Parties are to implement, on the basis of mutual co-operation, the following measures*". This means that participation in the CBMs is a requirement for all States Parties to the Convention.

As agreed at the Third Review Conference, the CBMs consist of seven measures or forms, A to G:

- CBM A Part 1: Exchange of data on research centres and laboratories;
 Part 2: Exchange of information on national biological defence research and development programmes.
- CBM B Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
- CBM C Encouragement of publication of results and promotion of use of knowledge.
- CBM D Active promotion of contacts
- CBM E Declaration of legislation, regulations and other measures.
- CBM F Declaration of past activities in offensive and/or defensive biological research and development programmes.
- CBM G Declaration of vaccine production facilities.

In addition to these seven forms, there is also a **cover page declaration**, sometimes referred as "Form 0". This contains a list of the CBMs with a choice of answers for each measure: "Nothing to declare" or "Nothing new to declare".

Section III: Practicalities for Submission

Deadline

The annual deadline for CBM submissions is 15 April. The information provided should cover the previous calendar year (for example, a CBM covering data for the calendar year 2001 needed to be submitted no later than 15 April 2002).

This deadline should be met whenever possible. Nevertheless, you can, if absolutely necessary, submit your CBM at any time, even after the deadline. Making a late submission is much better than failing to make a submission at all. It is easy to underestimate the time required to identify and gather the relevant information, particularly the first time it is done. In internal planning and coordination it is best to set target dates for information to be provided by relevant government departments, agencies or other bodies in good time to allow you to submit by the deadline, and if necessary check any data submitted and resolve any ambiguities.

Obtaining the forms

The blank CBM forms, in each of the six official languages, can be downloaded from the CBM section of the Implementation Support Unit website, <http://www.unog.ch/bwc/CBMs>. The forms are also reproduced in section V of this guide (page 9).

Submitting the CBM return

CBMs should be submitted to the BWC Implementation Support Unit, in the Geneva Branch of the United Nations Office for Disarmament Affairs.

You are encouraged to submit your CBM return electronically (as a Microsoft Word, RTF or PDF document) to the BWC Implementation Support Unit at bwc@unog.ch. All e-mail submissions will be acknowledged.

If you wish, you can also send a hard copy, under cover of a *note verbale* from your permanent mission in Geneva, to:

BWC Implementation Support Unit
United Nations Office for Disarmament Affairs (Geneva Branch)
Room C.115-117, Palais des Nations
1211 Geneva 10
Switzerland

Fax: +41 (0)22 917 04 83

Options for publication

CBM submissions received are published in the restricted area of the ISU website (<http://www.unog.ch/bwc/restricted> - accessible to States Parties only), unless the submitting State Party requests otherwise. Any CBMs that are not published on the website are circulated to States Parties on CD-ROM or hard copy.

Some States Parties have opted to make their CBM returns freely available on the public section of the website. These can be found on the CBM Returns page:

<http://www.unog.ch/bwc/cbms>

Section IV: Getting Started: Identifying Resources and Contacts

In order to gather the appropriate information for the CBM forms, it is helpful at the outset of the process to establish responsibilities, and identify resources and contacts within your government who have access to the relevant data. This section will provide advice on how to gather this information.

Contact Point and Focal Points

The first step in the CBM process is for your country to nominate a national contact point, if you have not already done so. The contact point will coordinate national implementation of the Convention, communicate with other States Parties and relevant international organizations, facilitate information exchange of universalization efforts, and prepare the submission of the CBMs. You may wish to nominate a specific person by name, or just an office or function (e.g. “Director, WMD Section”), which may be more convenient if staff changes occur frequently. Please provide the contact information for the national contact point to the ISU. The “National Contact Point Information Form” can be found in Annex I.

In addition to the national contact point, it is helpful to designate focal points within relevant ministries. These focal points should be in positions at their respective ministries which afford them access to information relevant to the completion of the CBM forms. Unlike contact points, these focal points should not be reported to the ISU, as their role is to assist the national contact point in the completion of the CBM forms. In order to identify possible focal points it is helpful to establish a contact list of all likely relevant government departments, agencies or other national bodies that could possibly have the data required; it is better in the first instance to look as widely as possibly.

In seeking the information for the relevant CBMs, it may be helpful to make use of draft letter formats. It is important that tailored and clear letters are sent out for each type of information category sought. Some example letter formats are provided at Annex II.

Considerations of Timing

Typically, States Parties find it helpful to hold an inter-ministerial meeting of focal points in January to bring together responsible parties from different parts of the government. These meetings help to gather data, as well as to assign responsibilities and deadlines to the relevant focal points. Be prepared to send reminders if there has been no response from relevant bodies – early February is a good time to do this. The aim here should be to have a consolidated text by mid-March for review. This enables the document to be re-examined in a timely manner so as to resolve any ambiguities or omissions.

If it becomes apparent, as the final deadlines for submission approaches, that you will be unable to furnish complete information, it is acceptable to submit forms *with all the information available at that time*, and later submit more complete information as an addendum.

Other Considerations

It is helpful to bear in mind that some of the data necessary for completing the CBMs may not be held at the national level, but instead at the provincial or local level. For this reason, some States Parties find that it is helpful to make contact at the provincial level early in the process so that information can be gathered in a timely manner.

It is important to realize that the information required for some of the forms (e.g. Form B) may already have been compiled by national authorities for reports and declarations for other international organizations and treaties. Some States Parties have found it useful to re-use this information, or to provide hyperlinks to those reports. Some organizations for which reports may have already been compiled include:

- The World Health Organization (WHO)
- United Nations Security Council Resolution 1540
- The Food and Agriculture Organization of the United Nations (FAO)
- The World Organisation for Animal Health (OIE)

Finally, information for some of the forms may be most easily gathered from non-ministerial sources on the internet. You may consider using internet search engines to find out basic information on laboratories, publications and publication policies, as well as past and future relevant academic conferences. You may also wish to contact relevant trade associations and universities directly.

Sources of advice and assistance for participating in the CBMs provided in Section VII of this document.

Section V: Detailed Guidance on Completing the Forms

This section reviews each form in turn. Information provided for each form includes any instructions on how to complete the form as agreed upon at the Third Review Conference, additional guidance developed for this document, a copy of a blank form, and an example of a completed form. Blank forms and accompanying text adopted by the Third Review Conference appear on a grey background; examples of completed forms appear in boxes.

FORM A (PART 1)

CONFIDENCE-BUILDING MEASURE "A":

Part 1: Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed that data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the 1983 WHO Laboratory Biosafety Manual such as those designated as biosafety level 4 (BL4) or P4 or equivalent standards.

Guidance for completing Form A, Part 1

In order to complete Form A Part 1, the first step is to identify any facilities having maximum containment laboratories meeting the criteria for such laboratories as specified in the WHO Laboratory Biosafety Manual*. In general, this relates to Biosafety Level 4 (BL4) laboratories which are designed for working with Risk Group 4 microorganisms, which, according to the Biosafety Manual are pathogens that usually cause "serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available."

If your country does not have a BL4 laboratory, or does not use the WHO system to categorize laboratories, we would suggest that, in the interest of transparency, you complete Form A, Part 1 for the laboratories in your country that handle pathogens that usually cause serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and where effective treatment and preventive measures are not usually available. As there is a close relationship between human and animal diseases, it is important not to overlook animal laboratories when identifying facilities to report on this form. It may also be helpful to provide information on facilities dealing with relevant plant pathogens. (Note that these are only suggestions: the strict requirement of Form A Part I is only to report BL4 or equivalent laboratories.)

* The third edition of the Biosafety Manual is available in PDF form online at <http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

In many countries, the ministry of health will hold this information; ministries of defence, science, technology or education may also be relevant. Ministries or agencies dealing with agriculture should be consulted for any maximum containment laboratories working on or storing animal or plant pathogens. Ministries dealing with safety legislation, biosecurity, genetic engineering, or any other regulatory processes relevant to containment facilities may also need to be contacted. Relevant trade associations, professional bodies, research councils and central university authorities may also be able to provide information on relevant facilities and contact points.

The responsible ministry or agency may have the required information about these facilities on file, in which case it is simply a matter of transferring the data to the CBM form. Alternatively, it may be necessary to contact each facility individually to obtain the necessary information about its activities. In this case, the national CBM contact point should keep an up-to-date list of facilities and relevant contacts at the key ministries etc and where possible at the facilities themselves.

How to fill out the form:

This form should be completed for each facility to be declared.

1. Name(s) of facility – Please list all of the common names by which the facility is known.
2. Responsible public or private organization or company – Please indicate the organization or company which owns, operates, or is otherwise responsible for this facility. If it is unclear, this information may be available on the facility's web site.
3. Location and postal address – Please include the location and postal address of the *facility*. You may also wish to consider including other contact information, such as telephone number, email address and web site.
4. Sources of financing of the reported activity, including indication if the activity is wholly or partly financed by the ministry of defence. – This information should be available from accounts departments, the public record and financial records, such as tax returns.
5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²) – This information should be available from laboratory administration, floor plans, or blueprints. If you are unable to determine their exact size, please provide an estimate, but clearly mark that it is an estimate.
6. If no maximum containment unit, indicate highest level of protection – Please describe the containment measures taken at the unit with the highest level of protection. Include the number of units at that level and indicate their respective size.
7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate – Please list all activities in the lab; this information can be gathered by reviewing the current and recent projects undertaken by the lab. It is important to note what types of micro-organisms and/or toxins are being used,

especially if they have been associated with offensive biological weapons programmes in the past.

CBM Form

Form A, part 1	
<u>Exchange of data on research centres and laboratories¹</u>	
1.	Name(s) of facility ² _____
2.	Responsible public or private organization or company _____ _____
3.	Location and postal address _____ _____ _____
4.	Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence _____
5.	Number of maximum containment units ³ within the research centre and/or laboratory, with an indication of their respective size (m ²) _____
6.	If no maximum containment unit, indicate highest level of protection _____
7.	Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate _____ _____ _____

¹ The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

² For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

³ In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

Example of Completed Form A, Part I

[Adapted from a CBM form completed by Australia]

Attachment I.1

Exchange of data on research centres and laboratories

Background Information

Australia has three maximum containment units which meet the criteria for a “maximum containment laboratory” as specified in the 1983 WHO Laboratory Biosafety Manual. They are:

- The Australian Animal Health Laboratory (**Attachment I.2**)
- The National High Security Quarantine Laboratory (**Attachment I.3**)
- The Queensland Health Scientific Services Virology Laboratory (**Attachment I.4**)

Data on these facilities relating to questions 1 to 7 of Form A, Part I are provided below. The National High Security Laboratory (NHSQL) operates under the auspices of the Victorian Infectious Diseases Reference Laboratory (VIDRL) in Melbourne. Additional maximum containment laboratory facilities are being established at VIDRL that will boost capability for responding to a terrorist attack involving bioagents. In addition, some Australian hospitals and university departments have lower level containment units where diagnostic and research work is conducted.

During April 2006, Australian Government agencies hosted briefing sessions for laboratory stakeholders on laboratory biosecurity. The briefing sessions were intended to raise awareness of issues surrounding security for laboratories handling high-risk pathogens and to facilitate communication between stakeholders and government on regulatory models that are being proposed to address gaps in Australia's current regulation on the storage, sale and handling of hazardous biological material. Two reports were provided: the ‘Laboratories Risk Context Statement’, which was developed following an Australian Security Intelligence Organisation (ASIO) sectoral threat assessment on Australian laboratories holding high-risk human pathogens. The Risk Context Statement is intended to be used by individual laboratory owners and operators to assist in identification of local risks taking into account of operational and environmental circumstances. In addition, the draft report of the ‘Council of Australian Governments’ (COAG) Review of Hazardous Biological Material’ which considers the security of biological agents that could be used as bioterrorist weapons against humans, animals and plants was provided for industry consultation.

The CSL facility declared in previous years does not meet PC4 requirements.

Exchange of data on research centres and laboratories

1. Name of facility

Australian Animal Health Laboratory

2. Responsible public or private organisation/ company

Commonwealth Scientific and Industrial Research Organisation (Federal Government) and the Department of Agriculture, Fisheries and Forestry (Federal Government). Note: Australia has a two-tiered system of Government, with the Federal Government and, to a lesser extent, the six respective State Governments all involved in the formulation and implementation of Government policy.

3. Location and postal address

Location	Postal address
5 Port Arlington Road Geelong, Victoria AUSTRALIA	PO Bag 24 Geelong VIC 3220 AUSTRALIA

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. The AAHL is funded by the Australian Government, via CSIRO and the Department of Agriculture, Fisheries and Forestry. It is also funded by industry organisations and commercial companies.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

One maximum containment system and enclosure. Total floor space 11,000m², comprising three main parts: a large-animal accommodation area, total floor area about 3,500 m² made up of 29 rooms – each of these with a floor area of about 24 m² – and with a service area, incinerator, and autopsy area.

A laboratory complex of total floor area about 3,500 m² made up of three functional laboratory suites – each of these with a floor area of about 1,100 m² – and each comprised of six laboratories and four attached small-animal rooms. The laboratory suites are for diagnosis, pathology and virology. There are attached service areas.

A common support area for glass washing, tissue culture, laundry and other services.

6. If no maximum containment unit, indicate highest level of protection

N/A

7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate.

The AAHL plays a vital role in maintaining Australia's capability to quickly diagnose exotic (foreign) and emerging animal diseases. This is achieved through ongoing research programmes to develop the most sensitive, accurate and timely diagnostic tests, which are critical to the success of any eradication campaign in the event of a disease outbreak. AAHL also undertakes research to develop new diagnostic tests, vaccines and treatments for endemic animal diseases of national importance. Major diseases of livestock, aquaculture animals, and wildlife, are studied. AAHL includes a high-biocontainment facility, to safely fulfil its major role of diagnosing emergency animal disease outbreaks. The laboratory is a World Animal Health Organisation reference laboratory for avian influenza, Newcastle disease, bluetongue disease, and epizootic haematopoietic necrosis virus (EHNV). The AAHL is also an OIE Collaborating Centre for New and Emerging Diseases, a WHO Collaborating Centre for Severe Acute Respiratory Syndrome (SARS), and a national reference laboratory for rabies and brucella.

Attachment 1.3

Exchange of data on research centres and laboratories

1. Name of facility

National High Security Quarantine Laboratory

2. Responsible public or private organisation/company:

Department of Health and Ageing (Commonwealth Government), Department of Human Services (State government).

3. Location and postal address:

Location	Postal address
Victorian Infectious Diseases Reference Laboratory 10 Wreckyn Street North Melbourne Victoria AUSTRALIA	National High Security Quarantine Laboratory c/o VIDRL Locked Bag 815 Carlton South VIC 3053 AUSTRALIA

4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. It receives funding from Commonwealth and State Departments of Health.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

One high security laboratory, containing two portable isolation units. Total area 90m².

6. If no maximum containment unit, indicate highest level of protection

N/A

7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate

The diagnosis of possible imported cases of viral haemorrhagic fever or other quarantinable viral diseases such as yellow fever. Development of laboratory tests and protocols for exotic respiratory viral diseases, including SARS. See, also, background information at Attachment 1.1.

Attachment 1.4

Exchange of data on research centres and laboratories

1. Name of facility

Queensland Health Scientific Services.

2. Responsible public or private organisation/company:

Queensland Department of Health (State Government).

3. Location and postal address:

Location	Postal address
39 Kessels Road Coopers Plains Queensland AUSTRALIA	PO Box 594 Archerfield QLD 4108 AUSTRALIA

4. Source(s) of financing, of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

This facility receives no funding from the Australian Government Department of Defence. It receives funding from Commonwealth and State Departments of Health.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

Two. Total area 150m².

6. If no maximum containment unit, indicate highest level of protection

N/A.

7. Scope and general description of activities, including type(s) of micro-organism and/or toxins as appropriate

The maximum containment facilities service a state government public health virology laboratory which has both a diagnostic and a research function. The laboratory is a WHO Centre for Arbovirus Reference and Research. The maximum containment facilities are used for the development and performance of diagnostic tests on patients with suspected exotic or endemic viral illness requiring such containment facilities, such as Hendra virus or exotic haemorrhagic fever viruses. The laboratory currently has no other PC4 pathogens but has introduced the SARS coronavirus into this facility for diagnostic purposes. The laboratory intends to introduce reagents useful for the diagnosis of a number of exotic viral diseases including Ebola, Lassa, Junin, Rift Valley fevers and Hantavirus among others. These reagents will consist of either inactivated diagnostic reagents, cloned viral subunits or live virus.

FORM A (PART 2)

Part 2: Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

- (1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;
- (2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;
- (3) The organizational structure of the programme and its reporting relationships; and
- (4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated:
 - (a) location;
 - (b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;
 - (c) the total number of staff employed, including those contracted full time for more than six months;
 - (d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;
 - (e) a list of the scientific disciplines of the scientific/engineering staff;
 - (f) the source and funding levels in the following three areas: research, development, and test and evaluation; and
 - (g) the policy regarding publication and a list of publicly-available papers and reports.

Guidance for completing Form A, Part 2

The ministry of defence will in almost all cases be responsible for any biological defence programmes or activities, if they exist. However, other ministries or departments may have responsibility for civilian defence, counter-terrorism or homeland security functions that also involve biological research and development programmes or activities. It is important to check with such entities to see whether they fund any such activities or are responsible for operating any facilities themselves.

The form requires detailed information on both the programmes and the individual facilities at which the work is conducted, and the ministries will probably need considerable time to provide it. They may need to obtain additional data from individual facilities, so it is worth designating a contact point/official at each site whose job it is to collate the data required here for a main contact point in the defence or other relevant ministry itself. Collation of the necessary data may require contacting a wide range of individuals at facilities, including for instance building managers, personnel, finance, technical and programme managers. The selection of a point of contact at facilities should ensure that such an individual is knowledgeable about the activities of the site as a whole and knows who to approach for the data in the CBM form.

CBM Form

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.	

Example of Completed Form A, Part 2

[Adapted from a CBM form completed by Germany]

Form A, Part 2 (i)
<u>National Biological Defence Research and Development Programme Declaration</u>
1) 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 programme would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.
YES
If the answer is YES, complete Form A, part 2 (ii) which will provide a description of the programme.

Form A, Part 2 (ii)
<u>National Biological Defence Research and Development Programme</u>
II: Description
I. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme:
Federal Ministry of Defence : The RD activities of the national programme include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection.

* Including viruses and prions.

Summaries and objectives of all research and development projects in the field of Medical NBC Defence are published on the Internet under www.bundeswehr.de.

Federal Ministry of Interior:

A B-Task Force pilot project is conducted with focus on the development of rapid detection systems for B agents. Within the scope of the project is the development of real time detection systems based on the polymerase chain reaction (PCR) and the evaluation of the PCR assays for high throughput screening tests. All investigations were accomplished at the Bernhard-Nocht-Institut Hamburg (BNI) and its facilities (see Form A, part I). The project was completed in November 2007.

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

Federal Ministry of Defence:

The total funding in 2007 was approx. 11,4 Mio Euro.

The programme is funded by the Federal Ministry of Defence.

Federal Ministry of Interior:

The funding in 2007 for the B-Task Force project Hamburg was approx. 44.000,00 €.

The programme is funded by the Federal Office for Civil Protection and Disaster Assistance.

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

Yes

4. What proportion of the total funds for the programme is expended in these contracted or other facilities?

Federal Ministry of Defence:

approx. 32 percent

Federal Ministry of Interior:

approx. 100 percent

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

Federal Ministry of Defence:

The objective of the contracted activities is to provide pertinent expertise and hardware to the Federal Ministry of Defence for the improvement of the B-defence capabilities. The research areas are the same as mentioned above under # 1.

The Federal Ministry of Interior:

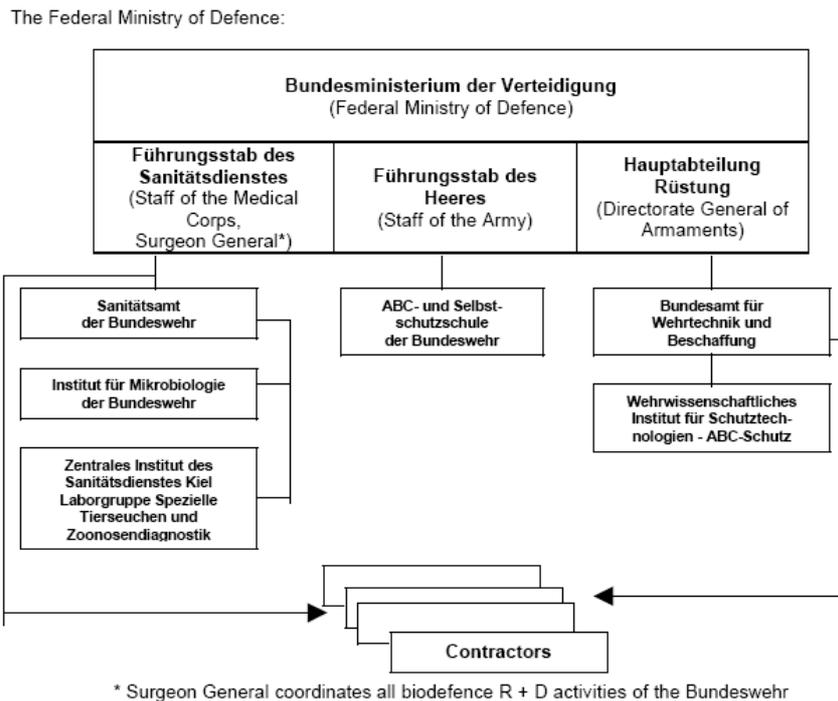
The objective of the contracted activities is the development of a rapid detection system to be able to react as fast as possible in case of a bioterrorist attack or casualty to minimise the threatening effect on human population and economy.

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

The Federal Ministry of Interior:

The Federal Office for Civil Protection and Disaster Assistance authorizes facilities like the Bernhard-Nocht-Institute in accordance with their expertise for the development of new real time detection systems for the identification of B-agents and organisms with high impact on public health.

The Federal Ministry of Defence:



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.

Forms A, part 2 (iii) is attached

Form A, part 2 (iii)

National Biological Defence Research and Development Programme

1. What is the name of the facility?

ABC- und Selbstschutzschule der Bundeswehr
(NBC-Defence and Self-protection School of the Bundeswehr)

2. Where is it located?

D-87527 Sonthofen/Allgäu, Mühlenweg 2
(47°31 north, 10°17 east)

3. Floor area of laboratory areas by containment level:

BL 2q	270
BL 3	--
BL 4	--
Total Laboratory Floor Area	270 m ²

4. The organisational structure of the facility: The workload of the Biology Section of the facility is approx. 95 percent in B-defence and 5 percent in environmental protection. The following personnel figures cover the total strength for both working areas because of the engagement of some of the personnel in both areas.

- I) Total number of personnel: 4
- II) Division of personnel:
 - Military --
 - Civilian 4
- III) Division of personnel by category:
 - Scientists 1
 - Engineers --
 - Technicians 2
 - Admin. and support staff 1
- IV) Represented scientific disciplines:
 - Parasitology, toxicology, microbiology, veterinary medicine
- V) Contractor staff: 0
- VI) Source of funding: Federal Ministry of Defence
- VII) Funding levels for the following programme areas:

The funding for the 95 percent share for personnel, consumable items and equipment in 2007 was approx. 0,2 million €

 - Development 25 %
 - Test and Evaluation 15 %
 - Education and Training 60 %
- VIII) Publication policy:

Results will be published primarily in reports to the Federal Office for Military Technology and Procurement and to the Federal Ministry of Defence and will be presented in scientific meetings.

IX) Lists of public available papers and reports resulting from the work during the previous 12 months:

none

5. Brief description of the biological defence work carried out at the facility, including types of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

- a. Conceptual development of biological defence in the Bundeswehr
- b. Initiation of and participation in the development of biological defence material and equipment; drafting of operational requirements
- c. Review and establishment of detection methods for pathogens and toxins suitable for military use
- d. Training of NBC defence personnel (theory and practice) including familiarisation with the handling of vectors, microorganisms and toxins
- e. Training support for non-military government authorities
- f. Training support for military personnel of other states
- g. Initiation and expert monitoring of studies in the field of biological defence
- h. Drafting of joint publications for biological defence

The current programme covers R I and R II organisms, inactivated material of pathogens R III and RIV, insects and ticks as well as high and low-molecular toxins; no work has been done with active viruses.

No outdoor studies of biological aerosols.

FORM B

CONFIDENCE-BUILDING MEASURE "B":

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

Modalities

The Third Review Conference agreed the following definition:

An outbreak or epidemic is the occurrence of an unusually large or unexpected number of cases of an illness or health-related event in a given place at a given time. The number of cases considered as unusual will vary according to the illness or event and the community concerned.

Furthermore, reference was made to the following definitions:

An epidemic of infectious disease is defined as the occurrence of an unusually large or unexpected number of cases of a disease known or suspected to be of infectious origin, for a given place and time. It is usually a rapidly evolving situation, requiring a rapid response (WHO internal document CDS/Mtg/82.1).

The occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy. The community or region, and the time period in which the cases occur, are specified precisely. The number of cases indicating the presence of an epidemic will vary according to the agent, size and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence: epidemicity is thus relative to usual frequency of the disease in the same area, among the specified population, at the same season of the year. A single case of a communicable disease long absent from a population or first invasion by a disease not previously recognized in that area requires immediate reporting and full field investigation: two cases of such a disease associated in time and place may be sufficient evidence to be considered an epidemic. (J.M. Last, A Dictionary of Epidemiology, Oxford University Press, New York, Oxford, Toronto, 1983.)

The Third Review Conference agreed on the following:

1. In determining what constitutes an outbreak States Parties are recommended to take guidance from the above.
2. Since no universal standards exist for what might constitute a deviation from the normal pattern, States Parties agreed to utilize fully existing national reporting systems on human diseases as well as animal and plant diseases, where possible, and systems within the WHO to provide annual update of background information on diseases caused by organisms which meet the criteria for risk groups II, III and IV according to the classification in the 1983 WHO Laboratory Biosafety Manual, the occurrence of which, in their respective areas, does not necessarily constitute a deviation from normal patterns.*
3. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:
 - When the cause of the outbreak cannot be readily determined or the causative agent** is difficult to diagnose,
 - When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the 1983 WHO Laboratory Biosafety Manual,
 - When the causative agent is exotic to a given region,
 - When the disease follows an unusual pattern of development,
 - When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
 - When suspicions arise of the possible occurrence of a new disease.
4. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports.

To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B (ii) should be used, to the extent information is known and/or applicable, for the exchange of initial as well as annual information.

5. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations.

* This information should be provided in accordance with Form B (I).

** It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

Guidance for completing Form B

This measure includes *two* quite separate requirements:

- Form B(i): background information on outbreaks of reportable infectious diseases in humans, animals and plants, which might utilize national and international reporting systems to provide an annual update; *and*
- Form B(ii): information on outbreaks of infectious diseases and similar occurrences caused by toxins, "that seem to deviate from the normal pattern". The form contains additional information on how to determine whether an outbreak meets this rather vague criterion. To enhance confidence, an initial report can be provided promptly after recognition of the relevance of an outbreak to CBM B(ii), and should be followed up by an annual report.

The ministry of health will in most cases be the source of information for diseases affecting humans, while the ministry of agriculture or equivalent agency will have data on outbreaks affecting animals and plants. For human diseases, the ministry of health may already have submitted a report or reports to the WHO, and this will become increasingly common now the WHO's revised International Health Regulations (IHR 2005) have entered into force.

It is important however not to see disease outbreaks that should be notified under the IHR as the only ones that could be relevant for this CBM. There could be others of a purely domestic nature that meet the criteria in the CBM modalities.

Similarly, the ministry of agriculture may report to the World Organisation for Animal Health (OIE) or to the Food and Agriculture Organization (FAO) on animal and plant disease outbreaks, respectively. You may include cross-reference to these reports – such as hyperlinks to the relevant pages on the WHO/OIE website as relevant. It may also be useful to provide links to any available national reports on an outbreak such as those produced or commissioned by a regulatory agency or government department.

Note that although the table in Form B(i) lists the years 1988-1992, you should substitute the most recent five years. For example, if you were completing the CBM covering 2009, you should fill in this table for the years 2005-2009. The table could be duplicated to provide separate tables for human, animal and plant diseases. The information provided in the tables provides a background that can help to identify major changes in incidence of diseases over time and, where significant increases or decreases in incidences occur, it could be helpful to include an indication of the possible reasons for these differences.

CBM Form

Form B (I)

Background information on outbreaks of reportable infectious diseases

Disease	Number of cases per year				
	1988	1989	1990	1991	1992

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. Time of cognizance of the outbreak
2. Location and approximate area affected
3. Type of disease/intoxication
4. Suspected source of disease/
intoxication
5. Possible causative agent(s)
6. Main characteristics of systems
7. Detailed symptoms, when applicable

 - respiratory
 - circulatory
 - neurological/behavioural
 - intestinal
 - dermatological
 - nephrological
 - other

8. Deviation(s) from the normal pattern as regards

 - type

-	development
-	place of occurrence
-	time of occurrence
-	symptoms
-	virulence pattern
-	drug resistance pattern
-	agent(s) difficult to diagnose
-	presence of unusual vectors
-	other
9.	Approximate number of primary cases
10.	Approximate number of total cases
11.	Number of deaths
12.	Development of the outbreak
13.	Measures taken

Example of Completed Form B

[Adapted from a CBM completed by the United Kingdom]

Form B (i)

Background information on outbreaks of reportable infectious diseases in humans –
England and Wales

Data from Statutory Notifications of Infectious Diseases (England and Wales)

Disease	Number of cases per year				
	2004	2005	2006	2007‡	2008†
Acute encephalitis	20	19	19	18	24
Acute poliomyelitis	0	0	0	0	0
Anthrax	0	0	1	0	1
Cholera	31	34	37	41	40
Diphtheria**	10	9	10	9	5
Dysentery	1,203	1,237	1,122	1,217	1,161
Food poisoning	70,311	70,407	70,603	72,382	69,111
Leptospirosis	14	31	24	37	44

Measles**	2,356	2,089	3,705	3,670	5,130
Meningitis	1,267	1,381	1,494	1,251	1,190
Meningococcal septicaemia	691	721	657	673	529
Mumps**	16,367	56,256	12,841	7,196	7,892
Ophthalmia neonatorum	85	87	100	83	76
Paratyphoid fever	134	119	185	126	168
Plague	0	0	0	0	0
Rabies	0	0	0	0	0
Relapsing fever	0	0	0	0	0
Rubella**	1,287	1,155	1,221	1,082	1,107
Scarlet fever	2,201	1,678	2,166	1,948	2,913
Smallpox	0	0	0	0	0
Tetanus	12	3	0	4	7
Tuberculosis	6,723	7,628	7,621	6,989	7,155
Typhoid fever	146	179	201	208	238
Typhus fever	1	1	6	0	5
Viral haemorrhagic fever	0	0	5	1	0
Viral hepatitis	3,932	4,109	4,007	3,857	4,780
<i>Hepatitis A</i>	784	513	433	333	381
<i>Hepatitis B</i>	1,215	1,325	1,165	1,265	1,594
<i>Hepatitis C</i>	1,851	2,120	2,194	2,040	2,545
Other and unknown	82	151	215	219	260

‡ Adjusted (confirmed) annual totals

† Provisional annual totals

** Note: In recent years a substantial proportion of notified cases of these diseases are shown subsequently not to be the implicated infection but do not get de-notified

Full information on Statutory Notifications of Infectious Diseases in England and Wales can be obtained via:

<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1191942172956?p=1191942172956>

<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListNameDesc/Page/1233906822114?p=1233906822114>

http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733756346?p=1191942172956

http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1233822588667

Background information on outbreaks of reportable infectious diseases in animals –
United Kingdom*

Disease	Number of confirmed cases per year				
	2004	2005	2006	2007	2008
African Horse Sickness					
African Swine Fever					
Anthrax			1		
Aujeszky's Disease					
Notifiable Avian Disease			3	5	2
Bat Rabies	1		1	1	1
Bovine Spongiform Encephalopathy					
Bluetongue				66	71
Brucellosis (Brucella abortus)					
Brucellosis (Brucella melitensis)					
Classical Swine Fever					
Contagious agalactia					
Contagious Bovine Pleuro-pneumonia					
Contagious Epididymitis (Brucella ovis)					
Contagious Equine Metritis Organism (CEMO)		1	1	1	2
Dourine					
Enzootic Bovine Leukosis					
Epizootic Haemorrhagic Virus Disease					
Epizootic Lymphangitis					
Equine Viral Arteritis	1				
Equine Viral Encephalomyelitis					
Equine Infectious Anaemia					
Foot and Mouth Disease				8	
Glanders and Farcy					
Goat Pox					
Lumpy Skin Disease					
Newcastle Disease		1	1		
Paramyxovirus of pigeons					
Pest des Petits Ruminants					
Rabies					1**
Rift Valley Fever					
Rinderpest (Cattle plague)					
Scrapie					
Sheep pox					
Swine Vesicular Disease					
Teschen Disease (Porcine enterovirus encephalomyelitis)					
Tuberculosis (Bovine TB)					
Vesicular Stomatitis					
Warble Fly					

* This table shows confirmed exotic notifiable disease investigations. Further information can be found at:

<http://www.defra.gov.uk/animalh/diseases/notifiable/ndi2008.htm>

Full information on all UK notifiable animal diseases can be obtained via:

<http://www.defra.gov.uk/animalh/diseases/notifiable/index.htm>

and UK reports to the World Organisation for Animal Health (OIE) can be found on the OIE website:

http://www.oie.int/wahis/public.php?page=country_reporting&this_country_code=GBR&detailed=1

** Rabies case involved one imported dog held in quarantine.

Form B (i)

Background information on outbreaks of reportable infectious diseases in Plants - United Kingdom

Disease	Number of cases per year				
	2004	2005	2006	2007*	2008
<i>Ciborinia camelliae</i> (Camelia flower blight)					
<i>Clavibacter michiganensis subsp. sepedonicus</i> (Ring rot in seed potatoes)	2				
<i>Colletotrichum acutatum</i> (Strawberry black spot) in propagating crops				1	
<i>Columnea latent viriod</i>				4	
<i>Erwinia amylovora</i> (Fireblight)					
<i>Florida passionflower virus</i>				1	3
<i>Pepino mosaic virus</i> in tomato crops			8	3	4
<i>Phytophthora kernoviae</i>	16	19	7	10	24
<i>Phytophthora ramorum</i> (Sudden Oak Death)	141	163	74	103	121
<i>Plasmopara obducens</i> (Downy mildew) of <i>Impatiens</i>					
<i>Potato spindle tuber viroid</i>					

Potato virus M (non-European isolate) in seed potato crops					1
<i>Puccinia horiana</i> (Chrysanthemum white rust)					
<i>Ralstonia solanacearum</i> (potato brown rot)		1			
<i>Ralstonia solanacearum</i> (potato brown rot) in river surveys	6	4	1	6	5
<i>Synchytricum endobioticum</i> (potato wart disease) in private gardens					2
Tobacco mild green mosaic virus					2
<i>Xanthomonas fragariae</i>	3	2			

**Confirmed figures*

The serious diseases above were all investigated, but occurrence could be explained by normal introduction means and there was no evidence of deliberate malicious introduction. There were also a number of findings of less important routine notifiable diseases, but these can also be explained by natural means of spread or by trade pathways.

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

1. Time of cognizance of the outbreak August 2007
2. Location and approximate area affected Surrey county, England
3. Type of disease/intoxication Foot and mouth disease
4. Suspected source of disease/intoxication Laboratory escape
5. Possible causative agent(s) Foot and mouth disease virus
6. Main characteristics of systems
7. Detailed symptoms, when applicable
 - respiratory
 - circulatory
 - neurological/behavioural

- intestinal
- dermatological	Vesicular condition of the feet, buccal mucosa and, in females, the mammary glands
- nephrological
- other
8. Deviation(s) from the normal pattern as regards	
- type
- development
- place of occurrence	FMDV is Exotic to the UK
- time of occurrence
- symptoms
- virulence pattern
- drug resistance pattern
- agent(s) difficult to diagnose
- presence of unusual vectors
- other
9. Approximate number of primary cases
10. Approximate number of total cases	238 animals at 8 premises
11. Number of deaths	0
12. Development of the outbreak	In late July there was laboratory escape of pathogen with subsequent local spread. Spread contained by measures taken below and last case was reported on 29 August 2007.
13. Measures taken	Stamping out, quarantine, movement control inside the country, zoning, disinfection of infected premises/ establishment(s), no vaccination and no treatment of affected animals.
Further information is available at: http://www.defra.gov.uk/animalh/diseases/fmd/investigations/index.htm	

FORM C

CONFIDENCE-BUILDING MEASURE "C":

Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

"Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research."

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.
2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, *inter alia*, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.
3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Guidance for completing Form C

Please use this form to describe your country's "policy as regards publication of results of biological research". Some states may have an explicit, single policy; many others may have a range of policies and guidelines set by different authorities or institutions. The ministry of education, ministry of science, or equivalents such as research councils, may have this information. It may also be worth enquiring with your national academy of science, professional associations connected with biology, and the association or body representing universities in your country.

The measure asks also specifically for information on the *policies* as regards publication of results of research carried out in research centres and laboratories included in Form A and on

outbreaks of disease reported in Form B. The specific points of contact for information on CBMs A and B should also be asked to provide information for Form C.

It is not necessary to provide a complete list of relevant journals and articles, but if you wish to draw attention to a particular article or journal, you can do so here.

It may well be worth collecting this information simultaneously with the information required for Form D (see below). If you are experiencing difficulties in completing this section, you may wish to use an internet search to get information that has already been posted online.

Example of Completed Form C

[Adapted from CBM completed by Denmark]

Denmark encourages publication of results of biological research directly related to the Convention, provided it is in compliance with good biosecurity practice.

In the annual report of 2007 Denmark draws the attention to the following publications:

Biosecurity in Scandinavia. Kristian H. Bork, Vibeke Halkjaer-Knudsen, John-Erik Stig Hansen, Erik D. Heegaard. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* Apr 2007, Vol. 5, No. 1: 62-71.

Biological Incident Response and Environmental Sampling – a European Guideline on Principles of Field Investigation. EU Commission DG Health and Consumer Protection, Health Threats Unit, 2006.

http://ec.europa.eu/health/ph_threats/com/preparedness/docs/biological.pdf

FORM D

CONFIDENCE-BUILDING MEASURE "D"

Active promotion of contacts

At the Third Review Conference it was agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

Modalities

The Third Review Conference agreed on the following:

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, States parties are encouraged to provide information, to the extent possible:

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention,
- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention.

To enable States parties to follow a standardized procedure, the Third Review Conference has agreed that Form D should be used for exchange of information under this item.

Guidance for completing Form D

This measure requires information on "planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention", as well as on other opportunities for scientific exchange and joint research. The primary goal of this form is to provide details of *future* conferences, especially those which recur on an annual basis. This will aid States Parties in identifying opportunities for networking and collaboration. If you wish, you can also use this form to include links to the proceedings of events mentioned in previous CBMs. You might also consider regular communication with the ISU about upcoming events outside of the CBM process.

In addition, it is possible that facilities and organisations providing information for other forms may be organizing or hosting relevant conferences in the *next year*. CBM submissions provide a useful vehicle for advertising the event and highlighting opportunities for scientists in other States Parties to engage with the international community. This measure should be

forward looking. As a guide to what constitutes “directly related”, you should take into account issues such as protective programmes and countering infectious diseases.

Information provided should include clear details and contact points for registration and information on the programme for the event to ensure that other States Parties can take full advantage of the opportunities. It is also important to provide information in a timely manner so as to allow time for States Parties to identify resources and arrange participation.

In many countries, much of this information can be easily found on the internet. As with Form C, the national academy of science, professional associations connected with biology, and the association or body representing universities may be able to provide relevant information.

Instructions for completing Form D

The first part of Form D should be completed in full for *each* relevant upcoming conference, symposium, seminar or other public forum for exchange.

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

Name of the conference, etc – Please give the official name of the conference

Arranging organization – Please list all organizations involved in organizing or sponsoring the event

Time – Please list the dates of the event

Place – Please list the city/town, and venue (if available) in which the event will take place

Main subject(s) of the conference, etc – Please list the subjects that the conference was organized to discuss. The information may be available on the official web site of the conference, or on that of one of its sponsors.

Conditions for Participation – Please indicate who is allowed to participate or attend the event, and what conditions they must meet in order to do so. The information may be available on the official web site of the conference, or on that of one of its sponsors.

Point of contact for further information, registration, etc – If possible please provide a name, telephone number, and email address. You may also consider including the web address of the official web site for the event, or the arranging organization. The information may be available on the official web site of the conference, or on that of one of its sponsors.

2. Information regarding other opportunities – Please include information about any other relevant events or opportunities for exchange. These might include partnership programmes, laboratory twinning programmes, data exchange programmes, or other relevant programmes.

CBM Form

Form D

Active promotion of contacts

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

For each such event, the following information should be provided:

- name of the conference, etc.
- arranging organization(s), etc.
- time
- place
- main subject(s) for the conference, etc.
.....
- conditions for participation
- point of contact for further information, registration, etc.
.....
.....

2. Information regarding other opportunities

.....
.....
.....

Example of Completed Form D

[Adapted from a CBM completed by Finland]

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

For each such event, the following information should be provided:

- **Name of the conference:** NBC 2006 Symposium
- **Arranging organizations:** The Association of Finnish Chemical Societies
Section for NBC protection, rescue and civil
defence
- **Time:** 18-21 June, 2006
- **Place:** TTT Theatre, Tampere, Finland
- **Main subject(s) for the conference:**
Symposium on Chemical, biological nuclear and radiological threats: A safety
& security challenge
- **Conditions for participation:**
Open conference
- **Point of contact for further, information, registration:**

www.nbc2006.com

NBC 2006 Symposium
University of Jyväskylä
Department of Chemistry
P.O. Box 35 FIN-40014
University of Jyväskylä
FINLAND

Fax: +358-14-260 2501

sktakala@cc.jyu.fi

FORM E

CONFIDENCE-BUILDING MEASURE "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

- (a) To prohibit the development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery, specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or control;
- (b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the United Nations Department for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Guidance for completing Form E

The national implementation of the BWC by all States Parties is crucial in so far as it helps ensure the effectiveness of the principles laid out by the Convention. As an indication of the way in which they have implemented the Convention, State Parties need to declare in Form E whether they already have legislation, regulations or other implementation measures.

Improving information sharing on BWC legal implementation increases confidence and transparency. Indeed, it gives an indication of the governance framework relevant to activities covered by the CBMs. It also allows you to compare existing tools in a spirit of sharing best practices.

Scope of Form E

Implementation is understood to include all measures that help to meet the aims and objectives of the Convention. Implementation measures can take numerous forms and function at various levels, such as: legislation; regulations; codes of conduct; and good practices. All of these measures contribute to the concrete implementation of the Convention and ensure compliance with it.

Form E addresses:

- 1) Legislation and regulation relevant to Article I of the Convention (development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery), for example legislation transposing BWC in national law or penal legislation;
- 2) Legislation and regulation relevant to Article III of the Convention (transfers), for example legislation on export and import of micro-organisms and/or toxins pathogenic to humans, animals and plants in accordance with the Convention.

In the interest of increased transparency, information on legislation and regulations governing security of pathogens, biosafety, licensing of personnel and anything else relating to national implementation of the Convention is also welcomed. Examples of such measures might include:

- Introducing a system authorizing the possession of specific biological agents and toxins;
- Authorizing the use of specific biological agents and toxins;
- Licensing work on the genetic modification of biological agents;
- Ensuring the traceability of biological agents and toxins;
- Introducing a system authorizing the transport of biological agents and toxins on national territory;
- Introducing national systems for the inspection of facilities possessing specific biological agents and toxins;
- Ensuring the physical protection of facilities possessing biological agents and toxins;
- Introducing a mandatory system for the notification of the loss or theft of biological agents and toxins.

The information provided by your country in the framework of the 1540 UNSCR resolution can be also of relevance under this form.

Filling in Form E

The blank form is composed of a table to be filled in with «yes» or «no» answers, but it is preferable to list the relevant legislation and regulations as well, and, if possible, to provide an internet link to the full text of the measure. It is also recommended to send the ISU a copy of the declared measures, in order to enrich its national implementation database.

Collecting Information

It is recommended for the CBM national contact point to use the network of ministerial focal points to gather information. Contacts at justice ministries and ministries of science and technology might be of particular use.

Updating Declared Data

Once you have declared implementation measures once, all you need to do is to indicate if there have been any changes or amendments in following years.

NB: Under the European Union Joint Action in Support of the Biological Weapons Convention, legal assistance for implementation is available. For more information contact the Implementation Support Unit.

CBM Form

<u>Form E</u>				
<u>Declaration of legislation, regulations and other measures</u>				
<u>Relating to</u>	<u>Legislation</u>	<u>Regulations</u>	<u>Other measures</u>	<u>Amended since last year</u>
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes/No	Yes/No	Yes/No	Yes/No
(b) Exports of micro-organisms* and toxins	Yes/No	Yes/No	Yes/No	Yes/No
(c) Imports of micro-organisms* and toxins	Yes/No	Yes/No	Yes/No	Yes/No

Example of Completed Form E

[Adapted from a CBM completed by Malaysia]

<u>Declaration of legislation, regulations and other measures</u>
The principal legislative provisions for the purposes of implementing Malaysia's obligations under the Convention are found in the Penal Code, the Corrosive and Explosive Substances and Offensive Weapons Act 1958, the Arms Act 1960, the Customs Act 1967, the Prevention and Control of Infectious Diseases Act 1988 and the Plant Quarantine Act 1976.

* Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

* Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

The **Penal Code** criminalizes among others –

- (a) Any unlawful or negligent or malignant act which is likely to spread the infection of any disease dangerous to life [sections 269 and 270].
- (b) Any act that vitiates the atmosphere in any place so as to make it noxious to the health of persons [section 278];
- (c) Murder and culpable homicide [section 302 and 304] and
- (d) Causing grievous hurt by dangerous weapons or means, including by means of any substance that is deleterious to the human body to inhale, to swallow, or to receive into the blood, or by means of any animal [sections 324 and 326]

The **Corrosive and Explosive Substances and Offensive Weapons Act 1958** criminalizes the possessions or corrosive and explosive substance and the carrying of offensive weapons.

The **Arms Act 1960** criminalizes among other the possession or use of arms and ammunition without the relevant licenses and permits. The expression “arms” is defined widely and encompasses “any weapon of whatever description designed or adapted or which can be adapted for the discharge of any noxious liquid, gas or other thing”.

The **Customs Act 1967** regulates the importation and exportation of all goods, including the prohibited materials under the Convention. The Act also enables the prohibition of the importation and exportation of the prohibited materials.

The **Prevention and Control of Infectious Diseases Act 1988** among other regulates the importation and exportation of pathogenic organisms or substance. A “pathogenic organism or substance” is defined to include any animal, noxious insect. Living germs, microbe, bacteria or virus, the culture of any germ, microbe, bacteria or virus or the product of any germ, microbe, bacteria or virus”.

The **Plant Quarantine Act 1976** amends and consolidates the law relating to the control, prevention and eradication of agricultural pests, noxious plants and plant diseases and extends cooperation in the control of the movement of pests in international trade.

In addition, the **Occupational Safety and Health Act 1994** provides for the safety of employees and the workplace including employees who handle dangerous substances.

Malaysia had also enacted the **Mutual Assistance in Criminal Matters Act** in 2002 to make provision for mutual assistance in criminal matters between Malaysia and other countries and for matters connected therewith. The object of this Act is for Malaysia to provide and obtain international assistance in criminal matters, including:

- (a) providing and obtaining of evidence;
- (b) the making or arrangements of persons to give evidence, or to assist in criminal investigations;
- (c) the recovery, forfeiture or confiscation of property in respect of a serious offence or a foreign serious offence;

- (d) the execution of requests for search and seizure;
- (e) the location and identification of witness and suspects;
- (f) the identification or tracing of proceeds of crime and property and instrumentalities derived from or used in commission of a serious offence or a foreign serious offence.

Malaysia is prepared to enact new legislation or to amend the existing legislative provisions if it is necessary to deal with developments in this area of the law. In fact, Malaysia is currently proposing amendments to the Penal Code to specifically criminalize terrorist acts. A “terrorist act” is defined by the Penal Code to include an act that involves the use of any microbial or biological agent or toxin.

Relating to	Legislation	Regulations	Other measures	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	Yes	No
(b) Exports of micro-organisms and toxins	Yes	Yes	Yes	No
(c) Imports of micro-organisms and toxins	Yes	Yes	Yes	No

FORM F

Guidance for completing Form F

If your country has conducted any offensive or defensive biological research and development programmes since 1 January 1946, they should be described here. In the interests of increasing the transparency, information regarding past offensive and defensive programmes before 1 January 1946 is also welcomed. The aim would be to provide a clear chronological account of these programmes from inception to termination as appropriate. This could include providing in a narrative form key dates or turning points in the programmes, agents and weapons produced, defence equipment and vaccines produced, major trials and facilities involved in the programme. You may wish to make use of any official histories that have been published or refer to any archival materials that are publicly available.

The term “programme” is understood to mean all activities and studies financed by a State Party and conducted with the aim of developing measures for protection against biological weapons (defensive programme) or to develop and produce biological weapons (offensive programme).

Research and development activities of offensive biological programmes include, *inter alia*, studies on pathogenicity and virulence, toxinology, environmental stability, aerobiology, evasion of detection and prophylaxis/treatment, production methodology, formulation, means of delivery, and other related research and development, irrespective of the level or sophistication of the science and technology used in that programme. In addition all activities that are listed under #2, third bullet of Form F (production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research) should be declared.

Activities of defensive biological research and development programmes include, *inter alia*, any type of activity or study listed under #3, third bullet of Form F (prophylaxis, pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research), irrespective of the level or sophistication of the science and technology used in that programme. The location where these activities were conducted should be provided where possible.

The amount of detail to be provided is at the discretion of the State Party but, in the interests of transparency, providing as much information as possible should be considered.

Where a State Party operated both past offensive and past defensive biological research and development programmes, the summaries of the offensive and the defensive activities should not be combined. #2 and #3 request separate summaries for offensive and defensive programmes.

The information required to fill Form F is most likely to be held by:

For filling #1 (Date of Entry into Force) of Form F:

- A State Party’s foreign ministry, or

- The UN website: <http://disarmament.un.org/TreatyStatus.nsf>. The website lists the date of deposit of the instrument of ratification/accession for each State Party. The date of entry into force is the first date of deposit with one of the Depositaries.

For filling #2 (Past Offensive Programmes) of Form F:

- The ministry of defence and national military or other national or private archives might be useful. In cases where responsibilities for research, development, production, and destruction of biological weapons and their means of delivery were split between different branches of the armed forces, it might be necessary to contact more than one focal point in the ministry or national archives. The final date for the “period of activities” should be that when all activities have ceased and the destruction of all biological weapons has been completed.
- Other ministries and agencies (i.e. industry, agriculture, health, etc.) might be relevant in cases where civil production facilities played a role, or were earmarked for production of biological weapons, or where civil facilities were involved in any other activities related to the offensive programme, including research and development.

For filling #3 (Past Defensive Programmes) of Form F:

- The ministry of defence should be able to help. Focal points may be divisions responsible for policy, research funding and defence or military equipment development and acquisition for defensive biological programmes, and medical services. Archival departments, both centrally and at relevant establishments and facilities would also be relevant here.
- The ministry of interior or homeland security may also be relevant, in cases where civil biological defensive programmes exist.

In cases where past defensive biological programmes have continued and are still in progress at the date of the first submission, the period of activities given on Form F should end with the date of first submission of Form A Part 2 (Exchange of information on national biological defence research and development programmes). In cases where a State Party, after submitting a first Form A Part 2 declaration, fails to submit continuous annual CBM declarations, the State Party shall submit a new Form F past programme declaration for the period for which no CBMs were submitted.

Filling Form F requires quite detailed information and the ministries and agencies involved will probably need considerable time to provide it. That should be taken into account for preparing Form F for meeting the deadline for CBM submission.

A State Party that conducted neither a past offensive biological research and development programme nor a past defensive programme must not complete Form F. In this case the State Party should tick the “nothing to declare”-box regarding Measure F of “Form 0” (Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange).

CBM Form

CONFIDENCE-BUILDING MEASURE "F":

Declaration of past activities in offensive and/or defensive biological research and development programmes

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

Declaration of past activities in offensive and/or defensive biological research and development programmes

1. Date of entry into force of the Convention for the State party.
2. Past offensive biological research and development programmes:
 - Yes - No
 - Period(s) of activities
 - Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.
3. Past defensive biological research and development programmes:
 - Yes - No
 - Period(s) of activities
 - Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

Example of Completed Form F

[Adapted from a CBM completed by the United Kingdom in 1992]

Declaration of past activities in offensive and/or defensive biological research and development program

1. Date of entry into force of the Convention for the State Party

The UK signed the Convention in April 1972, ratified it in March 1975, and the Convention became operative for the UK in December 1975, by which time national implementation had already been achieved by the Biological Weapons Act of 1974.

2. Past offensive biological R&D programs

- Yes

- Period(s) of Activities:

The UK had a modest programme to provide a capability to retaliate in kind should UK force be attacked by BW which started in 1940 and ceased in the late 1950s.

- Summary of the R&D activities indicating whether work was performed concerning production, test, and evaluation, weaponisation, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

United Kingdom concern about the possible future menace of the use of biological weapons (BW) began in the 1920s and continued through the 1930s with the establishment in 1936 of a sub-committee of the Committee for Imperial Defence, with a mandate “to report on the practicality of the introduction of bacteriological warfare and to make recommendations on the countermeasures which should be taken to deal with such an eventuality.” This led to the establishment in 1940 of the Biology Department, Porton (BDP).

From 1940 to 1946 the UK focus for BW studies was the Biology Department, Porton (BDP) which though located within the then Chemical Defence Experimental Station was a small autonomous organisation (up to about 45 people at its largest) set up to assess the feasibility of BW, to define the necessary defensive measures and to acquire the means to retaliate in kind in the event of use of BW against the UK or its allies. The latter part of this mandate involved carrying out trials using anthrax spores disseminated from bombs on Gruinard Island in 1942 and 1943. The success in demonstrating this method of release of spores was followed by the start of a conjoint United Kingdom, United States and Canadian development of a retaliatory capability based on cluster bombs with anthrax charged munitions, the so called N-bomb project. This project had not come to fruition by the end of the war, and the War Cabinet’s requirement for a retaliatory capability in World War II was fulfilled by the development of a modest anti-livestock aircraft-delivered BW capability based on anthrax spores in cattle cakes. A stockpile

of 5,000,000 cattle cakes was produced by BDP in 1942-3 and was stored at Porton. This weapon was never employed.

In the immediate post-war period the cattle cake stockpile was destroyed by autoclaving and burning; a few cardboard boxes each holding 400 cakes were retained as curiosities in the culture collection of the then Microbiological Research Establishment (MRE) at Porton until they were destroyed in 1972 at the time of the signature of the Biological Weapons Convention.

Whilst some research on offensive aspects continued for a few years after World War II, by 1957 the UK had abandoned work on an offensive capability. Subsequent work was on biological defence and included assessment of hazards should BW be used against the UK.

3. Past defensive biological R&D programmes

- Yes

- Period(s) of Activities:

1940-Present

- Summary of the R&D activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

BW defence was pursued from 1940 by BDP, notably in evaluation of respiratory protection, immunisation, anti-biotic therapy, and decontamination. By 1946 the BDP had become the Microbiological Research Department (MRD). In 1951 the MRD moved to a separate building in from within what had now become the Chemical Defence Experimental Establishment (CDEE). It was still known as MRD until 1957 when it became the Microbiological Research Establishment (MRE), under which title it continued until 1979.

Defensive studies were carried on from 1946 at MRD and then at MRE. The programme involved work on pathogenicity and virulence, aerobiology and experimental inhalation infection, detection and warning of BW aerosols, rapid identification of BW agents and rapid diagnosis of infectious diseases, prophylaxis, toxins, physical protection for individual and collective use, and decontamination. Most of this work was done at Porton but in the period 1948-1955 field trials with pathogens were performed on the high seas off the Bahamas and off the Scottish coast, initially to determine the feasibility of conducting trials at sea and latterly to acquire data on the behaviour of microbial aerosols under realistic conditions. Although such work was begun during the period when offensively motivated R&D was also being pursued, the data acquired was relevant to defence.

In the late 1960s and 1970s the proportion of MRE effort devoted to BW defence was gradually reduced as a result of reductions in defence funding offset by increase in civil research and microbiology. In the late 1970s it was decided that BW defence should be carried out at the then Chemical Defence Establishment (CDE) on a much reduced scale, resulting in defence sector economies and benefits from the wholesale commitment of MRE to public health microbiology. MRE was transferred to the Public Health Laboratory Service of the Department of Health in 1979. It is now the Centre for Applied Microbiology and Research in the Public Health Service. Accordingly, on 1 April 1979, a new Defence Microbiology Division (DMD) was set up within CDE as the focus of UK research on BW defence. The impact of genetic engineering, molecular biology, and biotechnology began to be felt in the early 1980s and has been highlighted in the UK papers submitted to all three Review Conferences of the Convention. These scientific and technological developments brought about a reassessment of the potential hazard posed by living biological and toxin weapons to the UK Armed Forces, and of continuing progress towards better detection and protection. In the latter areas it was recognised that the emerging biological technologies would make a significant contribution within the integrated research programme of CDE to counter the CBW threat. In April 1991, CDE was renamed the Chemical and Biological Defence Establishment (CBDE) to reflect more accurately the scope of the Establishment's work.

The objectives and details of the current biological defence programme at CBDE are provided in Form A Part 2.

FORM G

CONFIDENCE-BUILDING MEASURE "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Guidance for completing Form G

On this form you should list all vaccine production facilities in your country, which produce vaccines that are licensed by your government for use for the protection of humans, regardless of whether they are owned or run by the government or privately. In the interests of transparency, you may wish to include sites where vaccines are packaged, processed or distributed. You might also consider listing facilities which produce vaccines for animals or plant inoculants, although this is not required by the form. The ministry of health is usually the responsible agency for licensing vaccines for use for the protection of humans, and should be able to provide a list of facilities (the ministry of agriculture may be able to help on vaccines for animals or for plant inoculants). It may also be worth considering checking with trade associations and company internet sites.

Instructions for filling out Form G:

This form should be completed for each facility.

1. Name of the Facility – Please include all names by which the facility is commonly known.
2. Location (mailing address) – You may also want to consider including the physical address of the facility (if different from the mailing address) as well as basic contact information such as telephone number, email address and web site.
3. General description of the types of diseases covered – Please list all disease for which vaccines are produced. In the interest of transparency, you may consider including information about vaccine packaging and distribution that may go on at the facility.

CBM Form

Form G

Declaration of vaccine production facilities

1. Name of facility:
2. Location (mailing address):
3. General description of the types of diseases covered:

Example of Completed Form G

[Adapted from a CBM completed by United Kingdom]

Declaration of vaccine production facilities

1. Name of facility: MedImmune UK Ltd
2. Location (mailing address): Plot 6 Renaissance Way
Boulevard Industry Park
Speke
Liverpool L24 9JW
3. General description of the types of diseases covered:

Influenza vaccine

Declaration of vaccine production facilities

1. Name of facility: Novartis Vaccines and
Diagnostics Limited
2. Location (mailing address): Gaskill Road
Speke
Liverpool, L24 9GR
3. General description of the types of diseases covered:

During 2007, Influenza vaccines only were manufactured at this facility. Two distinct types:-

a) Northern Hemisphere Influenza vaccine - Cultivation of egg adapted influenza virus
Three strains incorporated within the vaccine (Trivalent).

b) H5N1 avian influenza vaccine (monovalent i.e. single strain) - Cultivation in eggs of
attenuated H5N1 strains produced by 'Reverse Genetics'. Designated at containment
category allocated Cat 2 (Enhanced). The enhancements refer to a requirement for additional

personal protection (use of RPE) and vaccination of operators with current Northern Hemisphere Influenza vaccine.

This agent is designated as a GMO & an appropriate manufacturing licence (GM consent) has been granted from the UK Competent Authority. IAPO (the 'Importation of Animal Pathogens Order', 1980) does not apply to these strains due to attenuation at the genetic level.

Transition to a new purpose built influenza vaccine manufacturing facility is planned at the start of the 2009 manufacturing campaign. Some laboratories in the new facility are already operational.

Declaration of vaccine production facilities

1. Name of facility: Centre for Emergency Preparedness and Response
2. Location (mailing address): Porton Down
Salisbury
Wiltshire
SP4 0JG
England
3. General description of the types of diseases covered:
Manufacturer of anthrax vaccine

COVER PAGE DECLARATION ("FORM 0")

Guidance for completing Form 0

The cover page declaration ("Form 0") should in fact be completed only at the end of the process, once you have completed forms A to G. Tick the "nothing to declare" box if you had nothing to declare on that form (and remember: please write "nothing to declare" on the form itself too - don't just leave it blank).

It is vital in the interests of clarity that "Form 0" is completed when there are responses that fit these requirements. If you have put information or made changes to previous submissions in a form, leave both the tick boxes for that form empty. You may wish to state where the changes are.

In subsequent years, if information you have previously put in a form has not changed, tick the "nothing new to declare" for that form (and please write "nothing new to declare" on the form itself).

1. Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare
A, part 1	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (i)	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (ii)	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (iii)	<input type="checkbox"/>	<input type="checkbox"/>
B (I)	<input type="checkbox"/>	<input type="checkbox"/>
B (ii)	<input type="checkbox"/>	<input type="checkbox"/>
C	<input type="checkbox"/>	<input type="checkbox"/>
D	<input type="checkbox"/>	<input type="checkbox"/>
E	<input type="checkbox"/>	<input type="checkbox"/>
F	<input type="checkbox"/>	<input type="checkbox"/>
G	<input type="checkbox"/>	<input type="checkbox"/>

(Please mark the appropriate box(es) for each measure, with a tick.)

Date: _____

State Party to the Convention: _____

Section VI: Subsequent Submissions: Maintaining and Updating Data

Once your country's initial CBM submission has been made, subsequent submission will be simpler, as much of the data will not change from year to year. It is helpful for the national contact point to maintain communication with ministerial focal points and other sources of information, so that amendments to the CBM forms can be collected through the year. This will save time and energy when filling out subsequent CBM forms.

Subsequent CBM submissions should always begin with the previous year's CBM submission. Efforts should be made to go through the submission form-by-form and update whatever information may have changed since the previous year. It may be easier to do this periodically over the course of the year than to wait until the end of the year.

In addition to this guide, prepare a detailed national guidance note for personnel involved in CBM preparation – this can be important if personnel change.

Form A, Part 1: First, ascertain if any of the declared facilities have been closed in the previous year, and if any new facilities have opened during that time. Facility closures should be noted on amended forms, and new forms should be completed for new facilities. For continuing facilities, please check all information for accuracy. Please note any changes in ownership, contact information, sources of funding, number of maximum containment units, or scope of activities, and amend the forms to reflect those changes.

Form A, Part 2: Please amend the previous year's CBM submission to reflect any changes or additions to your country's national biological defence research and development programmes. For each facility declared with Form A, Part 2 (iii), please note any facility closures, new facilities, and changes to existing facilities, as for Form A, Part 1.

Form B: Please complete with the most recent year's relevant disease outbreak data.

Form C: If there have been any changes to the publication policy or policies in your country over the previous year, please amend the previous year's submission to reflect the changes.

Form D: Please amend this form with information about that year's relevant conferences and events.

Form E: Please amend this form to indicate any additions or changes to relevant legislation, regulations or other measures taken to implement the Convention.

Form F: While the history of past programmes will not have changed since the previous year's CBMs, your understanding of that history may evolve as new documents become declassified or come out of archives. Please amend this form to reflect any changes that may be necessary.

Form G: Please amend the previous year's CBM submission to reflect any changes or additions to your country's vaccine production facilities. For each facility declared, please note any facility closures, new facilities, and changes to existing facilities, as for Form A, Part 1.

Section VII: Getting Help: Sources of Advice and Assistance

Biological Weapons Convention Implementation Support Unit

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WMD Strategy and Joint Actions in support of BWC and biosafety and biosecurity:

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Stability Instrument:

Mr Jean-Paul Joulia
European Commission - DG AIDCO - Head of Unit A4
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e-mail : Jean-paul.joulia@ec.europa.eu

Seventh Research Program:

Ms Line Matthiessen-Guyader, MD, PhD
European Commission - DG Research
Head of Unit "Horizontal aspects and Coordination"
Directorate E "Biotechnology, Agriculture and Food"

Annex I: National Contact Point Information Form

The following form can be completed and returned to the Implementation Support Unit to nominate a national contact point for your country. For more information on National Contact Points please refer to *Section IV. Getting Started: Identifying Resources and Contacts* on page 7 of this guide. An online version is available at: <http://www.unog.ch/bwc/implementation>

OFFICE DES NATIONS UNIES A GENÈVE
BUREAU DES AFFAIRES DE
DÉSARMEMENT
SERVICE DE GENÈVE



UNITED NATIONS OFFICE AT GENEVA
OFFICE FOR DISARMAMENT AFFAIRS
GENEVA BRANCH



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E-Mail: bwc@unog.ch
URL: www.unog.ch/bwc

NATIONAL CONTACT POINT INFORMATION FORM

At the Sixth Review Conference in December 2006, States Parties decided to designate a national point of contact for:

- Coordinating national implementation of the Convention and communicating with other States Parties and relevant international organizations (BWC/CONF.VI/6, Part II Final Declaration, Paragraph 18).
- Preparing the submission of CBMs (BWC/CONF.VI/6, Part III Decisions and Recommendations, Paragraph 8(vi)).
- Facilitating information exchange of universalization efforts (BWC/CONF.VI/6, Part III Decisions and Recommendations, Paragraph 11(iii)).

A decision was also taken to inform the Implementation Support Unit of the details of this national point of contact. This form provides an opportunity for States Parties to provide this information.

TITLE:		
FIRST NAME:		
LAST NAME:		
POSITION / FUNCTION:		
ADDRESS	STREET:	
	TOWN:	
	POST CODE:	
	COUNTRY:	
TELEPHONE NUMBER:		
FACSIMILE NUMBER:		
E-MAIL ADDRESS:		
URL:		

Annex II: Sample Letters for Requesting CBM Information

These templates are offered to assist you in preparing letters to other government departments, agencies, ministries or other relevant bodies. They will normally be sent by the national CBM point of contact to gather the information necessary to complete the CBM return. These templates may need to be tailored to national circumstances in terms of style and content, such as through the addition of specific addressees and requests for specific information.

The onus is on the National CBM point of contact to:

- Find out who the best contacts are elsewhere in the government and in other organisations within the State Party keeping in mind that it may be necessary to approach different sections in the *same* department or organisation;
- Keep details of points of contact up-to-date;
- Ensure that the correct templates and attachments are sent with each letter. This is especially important for subsequent years when the information previously provided is being checked for accuracy or to take account of any change in status.

Essentially the basic format is the same; the only difference is to be found in the central paragraphs where the core detail will need to vary according to the particular CBM. As will be seen from the templates, information for several individual CBMs may actually reside within a single government department or organisation. Conversely, information for a single CBM may be held by several government departments and organisations. The templates are structured accordingly. This of course may not be the case in all States Parties, so the national point of contact will need to make sure that the information requests are sent to those best placed to help.

The templates prescribe plenty of time for the information to be provided to the National Point of Contract time to ensure that he/she is able to compile and submit the national CBM - and clarify, where necessary, any ambiguities or discrepancies in departmental returns - in order to meet the annual 15 April deadline. Setting shorter internal deadlines (i.e. close to 15 April) should be avoided. Time may be needed to gather the data required, or simply check that there is nothing to declare or amend, or to resolve any ambiguities. Time must also be allowed for staff absences and other competing priorities.

CBM LETTER TEMPLATE: GENERAL

To: *[Relevant Government departments, agencies or other bodies]*

**BIOLOGICAL WEAPONS CONVENTION: INFORMATION REQUEST FOR
CONFIDENCE BUILDING MEASURES RETURNS**

[Insert State Party Name] is a party to the 1972 Biological and Toxin Weapons Convention. Following decisions taken at its Review Conferences in 1986 and 1991 the States Parties have agreed that they will submit each year information about specified activities in their countries as Confidence Building Measures (CBMs). This information must be submitted to the Convention's Implementation Support Unit in Geneva by 15 April each year. It is our national policy to meet these requirements in full.

Some of these measures require information that may be within *[insert name of Government department, agency or other body]*'s area of competence and we would appreciate your help in providing this information. In particular:

- CBM *[insert letter of relevant Measure]* *[insert text for relevant measure -see Appendix A]*
- *[...include for all Measures relevant to addressee organisation]*

I have attached the relevant forms for completion and some further information about the measures that may assist in providing the required information (Appendix B). *[attach Forms and information for the CBMs listed above]*.

A brief explanation of all the CBMs is given in Appendix A. If you think that your organisation might have some information to provide on any other CBMs not listed above, please let me know and I will send you the relevant forms and information.

I would be most grateful if you could return the completed forms by *[insert relevant mechanism, e.g. email/post...]* to *[insert address/email address as relevant]* no later than *[insert deadline date, e.g. 31 January 20XX]*. We will then compile the data into a national return. Please advise me if you are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[In recent years some States Parties have made their CBM returns available on the public section of the official UN BWC website. We intend to consider doing so with our returns. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

**APPENDIX A: BIOLOGICAL AND TOXIN WEAPONS CONVENTION
CONFIDENCE BUILDING MEASURES**

CBM A Part I: Exchange of data on research centres and laboratories that meet very high national or international biosafety standards (e.g. WHO BL4/P4 or equivalent).

CBM A Part 2 (i), (ii) & (iii): Exchange of information on national biological defence research and development (R&D) programmes, including declarations on facilities where a substantial proportion of the resources are devoted to the national biological defence R&D programme.

CBM B (i) & (ii): Exchange of information on outbreaks of infectious diseases in humans, animals and plants and similar occurrences caused by toxins, including background information on outbreaks of reportable diseases as well as details on outbreaks that seem to deviate from the normal pattern.

CBM C: Encouragement of publication of results of biological research directly related to the Convention and promotion of use of knowledge gained in this research.

CBM D: Active promotion of contact between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis, and planned conferences seminars and similar events dealing with biological research directly related to the Convention (e.g. on dangerous pathogens or toxins, etc.)

CBM E: Declaration of legislation, regulations and other measures taken to implement the Convention, including prohibition of biological weapons and related activities and exports and/or imports of pathogenic micro-organisms and toxins.

CBM F: Declaration of past activities in offensive and/or defensive biological R&D programmes since 1 January 1946.

CBM G: Declarations on facilities that produce vaccines licensed by the State Party for the protection of humans.

APPENDIX B: FURTHER INFORMATION ON CBMs

[Further information should be included for each of the Measures for which information has been requested in this letter. This should include the relevant Modalities and could also include some further information from the relevant sections of this 'Guide to Participating in the Confidence Building Measures of the Biological Weapons Convention', and/or some particular guidance prepared by the National CBM point of contact.]

CBM LETTER TEMPLATE: HEALTH

To: Ministry of Health

BIOLOGICAL WEAPONS CONVENTION: INFORMATION REQUEST FOR CONFIDENCE BUILDING MEASURES RETURNS

[Insert State Party Name] is a party to the 1972 Biological and Toxin Weapons Convention. Following decisions taken at its Review Conferences in 1986 and 1991 the States Parties have agreed that they will submit each year information about specified activities in their countries as Confidence Building Measures (CBMs). This information must be submitted to the Convention's Implementation Support Unit in Geneva by 15 April each year. It is our national policy to meet these requirements in full.

Some of these measures require information that may be within the Ministry of Health's area of competence and we would appreciate your help in providing this information. In particular:

- **CBM A Part I:** Exchange of data on research centres and laboratories that meet very high national or international biosafety standards (e.g. WHO BL4/P4 or equivalent).
- **CBM B (i) & (ii):** Exchange of information on outbreaks of infectious diseases in humans, animals and plants and similar occurrences caused by toxins, including background information on outbreaks of reportable diseases as well as details on outbreaks that seem to deviate from the normal pattern.
- **CBM C:** Encouragement of publication of results of biological research directly related to the Convention and promotion of use of knowledge gained in this research.
- **CBM D:** Active promotion of contact between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis, and planned conferences seminars and similar events dealing with biological research directly related to the Convention (e.g. on dangerous pathogens or toxins, etc.)
- **CBM E:** Declaration of legislation, regulations and other measures taken to implement the Convention, including prohibition of biological weapons and related activities and exports and/or imports of pathogenic micro-organisms and toxins.
- **CBM G:** Declarations on facilities that produce vaccines licensed by the State Party for the protection of humans.

I have attached the relevant forms for completion and some further information about the measures that may assist in providing the required information (Appendix B).

A brief explanation of all the CBMs is given in Appendix A. If you think that your organisation might have some information to provide on any other CBMs not listed above, please let me know and I will send you the relevant forms and information.

I would be most grateful if you could return the completed forms by *[insert relevant mechanism, e.g. email/post...]* to *[insert address/email address as relevant]* no later than *[insert deadline date, e.g. 31 January 20XX]*. We will then compile the data into a national return. Please advise me if you are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[In recent years some States Parties have made their CBM returns available on the public section of the official UN BWC website. We intend to consider doing so with our returns. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

[Insert Appendices A and B from general letter template, as appropriate]

CBM LETTER TEMPLATE: AGRICULTURE

To: Ministry of Agriculture

**BIOLOGICAL WEAPONS CONVENTION: INFORMATION REQUEST FOR
CONFIDENCE BUILDING MEASURES RETURNS**

[*Insert State Party Name*] is a party to the 1972 Biological and Toxin Weapons Convention. Following decisions taken at its Review Conferences in 1986 and 1991 the States Parties have agreed that they will submit each year information about specified activities in their countries as Confidence Building Measures (CBMs). This information must be submitted to the Convention's Implementation Support Unit in Geneva by 15 April each year. It is our national policy to meet these requirements in full.

Some of these measures require information that may be within the Ministry of Agriculture's area of competence and we would appreciate your help in providing this information. In particular:

- **CBM A Part I:** Exchange of data on research centres and laboratories that meet very high national or international biosafety standards (e.g. WHO BL4/P4 or equivalent).
- **CBM B (i) & (ii):** Exchange of information on outbreaks of infectious diseases in humans, animals and plants and similar occurrences caused by toxins, including background information on outbreaks of reportable diseases as well as details on outbreaks that seem to deviate from the normal pattern.
- **CBM C:** Encouragement of publication of results of biological research directly related to the Convention and promotion of use of knowledge gained in this research; and,
- **CBM D:** Active promotion of contact between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis, and planned conferences seminars and similar events dealing with biological research directly related to the Convention (e.g. on dangerous pathogens or toxins, etc.)
- **CBM E:** Declaration of legislation, regulations and other measures taken to implement the Convention, including prohibition of biological weapons and related activities and exports and/or imports of pathogenic micro-organisms and toxins.

I have attached the relevant forms for completion and some further information about the measures that may assist in providing the required information (Appendix B).

A brief explanation of all the CBMs is given in Appendix A. If you think that your organisation might have some information to provide on any other CBMs not listed above, please let me know and I will send you the relevant forms and information.

I would be most grateful if you could return the completed forms by [*insert relevant mechanism, e.g. email/post...*] to [*insert address/email address as relevant*] no later than [*insert deadline date, e.g. 31*

January 20XX]. We will then compile the data into a national return. Please advise me if you are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[In recent years some States Parties have made their CBM returns available on the public section of the official UN BWC website. We intend to consider doing so with our returns. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

[Insert Appendices A and B from general letter template, as appropriate]

CBM LETTER TEMPLATE: DEFENCE

To: Ministry of Defence

BIOLOGICAL WEAPONS CONVENTION: INFORMATION REQUEST FOR CONFIDENCE BUILDING MEASURES RETURNS

[*Insert State Party Name*] is a party to the 1972 Biological and Toxin Weapons Convention. Following decisions taken at its Review Conferences in 1986 and 1991 the States Parties have agreed that they will submit each year information about specified activities in their countries as Confidence Building Measures (CBMs). This information must be submitted to the Convention's Implementation Support Unit in Geneva by 15 April each year. It is our national policy to meet these requirements in full.

Some of these measures require information that may be within the Ministry of Defence's area of competence and we would appreciate your help in providing this information. In particular:

- **CBM A Part 1:** Exchange of data on research centres and laboratories that meet very high national or international biosafety standards (e.g. WHO BL4/P4 or equivalent).
- **CBM A Part 2 (i), (ii) & (iii):** Exchange of information on national biological defence research and development (R&D) programmes, including declarations on facilities where a substantial proportion of the resources are devoted to the national biological defence R&D programme.
- **CBM C:** Encouragement of publication of results of biological research directly related to the Convention and promotion of use of knowledge gained in this research.
- **CBM D:** Active promotion of contact between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis, and planned conferences seminars and similar events dealing with biological research directly related to the Convention (e.g. on dangerous pathogens or toxins, etc.)
- **CBM F:** Declaration of past activities in offensive and/or defensive biological R&D programmes since 1 January 1946.

I have attached the relevant forms for completion and some further information about the measures that may assist in providing the required information (Appendix B).

A brief explanation of all the CBMs is given in Appendix A. If you think that your organisation might have some information to provide on any other CBMs not listed above, please let me know and I will send you the relevant forms and information.

I would be most grateful if you could return the completed forms by [*insert relevant mechanism, e.g. email/post...*] to [*insert address/email address as relevant*] no later than [*insert deadline date, e.g. 31 January 20XX*]. We will then compile the data into a national return. Please advise me if you

are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[In recent years some States Parties have made their CBM returns available on the public section of the official UN BTWC website. We intend to consider doing so with our returns. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

[Insert Appendices A and B from general letter template, as appropriate]

CBM LETTER TEMPLATE: LEGAL AND REGULATORY AUTHORITIES

To: Ministry of Justice; Ministry of Trade/Exports

BIOLOGICAL WEAPONS CONVENTION: INFORMATION REQUEST FOR CONFIDENCE BUILDING MEASURES RETURNS

[Insert State Party Name] is a party to the 1972 Biological and Toxin Weapons Convention. Following decisions taken at its Review Conferences in 1986 and 1991 the States Parties have agreed that they will submit each year information about specified activities in their countries as Confidence Building Measures (CBMs). This information must be submitted to the Convention's Implementation Support Unit in Geneva by 15 April each year. It is our national policy to meet these requirements in full.

One of these measures requires information that may be within the Ministry of Justice's/Trade's/Exports' area of competence and we would appreciate your help in providing this information. In particular:

- **CBM E:** Declaration of legislation, regulations and other measures taken to implement the Convention, including prohibition of biological weapons and related activities and exports and/or imports of pathogenic micro-organisms and toxins.

I have attached the relevant form for completion and some further information about the measure that may assist in providing the required information (Appendix B).

A brief explanation of all the CBMs is given in Appendix A. If you think that your organisation might have some information to provide on any other CBMs not listed above, please let me know and I will send you the relevant forms and information.

I would be most grateful if you could return the completed forms by *[insert relevant mechanism, e.g. email/post...]* to *[insert address/email address as relevant]* no later than *[insert deadline date, e.g. 31 January 20XX]*. We will then compile the data into a national return. Please advise me if you are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[In recent years some States Parties have made their CBM returns available on the public section of the official UN BWC website. We intend to consider doing so with our returns. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

[Insert Appendices A and B from general letter template, as appropriate]

CBM LETTER TEMPLATE: SUBSEQUENT YEARS

*This format is to be used in subsequent years **after** the first year when the initial requests had been circulated to government departments, agencies and other organisations.*

ANNUAL INFORMATION REQUESTS FOR THE BIOLOGICAL WEAPONS CONVENTION CONFIDENCE BUILDING MEASURES

We are now collecting information for our annual submission of data for the Biological Weapons Convention Confidence Building Measures. Our national return must be submitted by 15 April 20xx. We continue to see meeting this requirement as a key policy objective and I should be most grateful for your continued assistance in this matter.

In our previous correspondence last year on this issue (see our initial request attached), we established that [*insert name of relevant government department, agency or other organisation*] had nothing to declare under CBM Measures [*insert A, B etc as required*]. Can you please confirm that this is still the case?

OR

In our previous correspondence last year on this issue (see our initial request attached), we established that [*insert name of relevant government department, agency or other organisation*] had information to declare under CBM Measures [*insert A, B etc as required*]. Can you please confirm if this is still the case, or if there are any changes (and if so the nature of any changes) that would require an up-dated CBM to be submitted? For ease of reference I attach a copy of the information on CBM [*insert A, B etc as required*] that was submitted last year.

I would be most grateful if you could respond to this request by [*insert relevant mechanism, e.g. email/post...*] no later than [*insert deadline, e.g. 31 January 20xx*]. Please advise me if you are not the most appropriate contact point for such information and pass on this request to the person in your organisation who is in a position to advise authoritatively.

[*Our previous CBM returns have been made available on the public section of the official UN BWC website and we intend that this will be the case again this year. Thus if there is any reason that any information you provide should not be made available in this way, please let me know.*]

Many thanks for your help on this matter. Please let me know if you have any questions or require any further information to help you in providing the requested information.

[*Insert Appendices A and B from general letter template, as appropriate*]