Seventh Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Follow-up to the recommendations and decisions of the Sixth Review Conference and the question of future review of the Convention

Review and update of the Confidence-Building Measures

Submitted by Germany, Norway and Switzerland

I. Introduction

A. Why is a CBM update necessary?

1. Over now more than twenty years, the annual number of States Parties submitting Confidence Building Measures (CBMs) has been somewhere between 30 at its lowest (1987) and 72 at its highest (2010). Annual CBM submissions are thus made on average by less than 40 percent of the States Parties to the BWC. This relative lack of participation in the CBM process is particularly unfortunate as the mechanism will only command limited transparency until more States Parties honour their commitments and submit declarations. Ignoring the mechanism weakens the concept of CBMs and may ultimately reduce, rather than build, confidence among States. The relative lack of participation in the CBM mechanism is compounded by inconsistent submissions, where states submit returns in some years but not in others, as well as by incomplete submissions, where only some of the seven forms are submitted. For these reasons the Final Document of the Sixth Review Conference states "the need for enhancing participation of States Parties in the confidence-building measures (CBM) process" and "the issue merits further and comprehensive attention at the Seventh Review Conference"[1].

2. The CBMs were developed and agreed in 1986/1987 and 1991. They have not been modified in 21 years. In addition, some of the modalities agreed need clarification for better understanding. Some CBM forms contain references to official documents of international organizations that are outdated and require update. Furthermore, some information requested under the CBMs is now available on the internet and may therefore no longer require a declaration under the CBM forms. Finally, the CBM process can be streamlined

[1] BWC/CONF.VI/6, Part III, paragraphs 8 and 9.

by making use of electronic means that were not available in the past. But, this is a final step that may take place after agreement is achieved on proposed changes of substance.

B. Preparing proposals for CBM updates for adoption at the Seventh Review Conference

3. The Governments of Switzerland, Norway and Germany together with the Geneva Forum in collaboration with the BIOS Centre of the London School of Economics organised three workshops in 2009 and 2010 to discuss the way forward for preparing the CBM discussion for the Seventh Review Conference. The workshops brought together a range of governmental and non-governmental experts to address key questions how to improve the CBM forms and the CBM process for increasing participation in the annual exchange. Discussion continued on an e-mail platform to which more than 70 experts from a wide range of States Parties, including from civil society, subscribed. The results of the workshops and the ongoing discussion were presented in the margins of the 2010 Meeting of Experts and Meeting of States Parties in Geneva.

4. The process enabled a deeper reflection and provided further proposals that go beyond the suggested changes in the attached annex. Such proposals would modify the CBM system more fundamentally in a way that would require further in depth attention, for instance in a future intersessional process. For this reason, these additional proposals are not included in the proposed changes here. Our immediate objective for the Review Conference is to reach agreement on streamlining the existing CBMs in order to increase the number of annual submissions and improve their quality.

5. At workshops in preparation for the Seventh Review Conference some participants expressed concerns that the proposed amendments of CBM forms addressing assistance and cooperation activities could be understood as an approach for avoiding an open ended Article X discussion at the Conference. This is not the intention of the respective proposals. Germany, Norway and Switzerland as proponents of the respective proposals will be fully flexible for other approaches addressing assistance and cooperation.

II. Proposals for updating the CBM forms at the Seventh Review Conference

6. The attached Annex contains a synopsis of all proposals for updating the existing Confidence Building Measures. The first column presents the original text (decisions of review conferences at adoption, modalities and forms) of the existing CBMs[2]. In the second column the proposed changes, deletions and amendments are marked in bold italics. The third column provides the rationale for the proposed changes.

[2] Originally published as the Annex to the Final Declaration of the Third Review Conference (BWC/CONF.III/23), reproduced most recently as Annex I of BWC/CONF.VII/INF.1)

Annex

A synopsis of proposals for updating the existing Confidence Building Measures

Original Text	*Proposed Changes*	*Rationale*
Confidence-Building Measure A **Part 1: Exchange of data on research centres and laboratories**	**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."	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."	Annual declaration of facilities possessing maximum containment for work with human as well as animal pathogens is meanwhile common practice. It is proposed to update the language under "modalities" and in Form A, part 1 to cover this standard.
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.	**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~~ latest version of the*** WHO[3] Laboratory Biosafety Manual ***and/or the OIE[4] Terrestrial Manual or other equivalent internationally accepted guidelines*** such as those designated as biosafety level 4 (BL4), ***BSL4*** or P4 or equivalent standards.	New WHO Laboratory Biosafety Manual version supersedes 1983 version. OIE Terrestrial Manual provides criteria for maximum containment with animal Risk Group 4 pathogens.

[3] World Health Organization
[4] World Organization for Animal Health

Original Text	*Proposed Changes*	*Rationale*
	States Parties that do not possess a facility meeting criteria for such maximum containment should continue with Form A, part 1 (ii).	See comments below.
Form A, part 1	**Form A, part 1 (i)**	Renumbering as a Form A, part 1 (ii) will be added.
Exchange of data on research centres and laboratories[5] 1. Name(s) of facility[6] 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[7] within the research centre and/or laboratory, with an indication of their respective size (m2) 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	Exchange of data on research centres and laboratories[8] 1. Name(s) of facility[9] 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[10] within the research centre and/or laboratory, with an indication of their respective size (m2) ***~~6. If no maximum containment unit, indicate highest level of protection~~*** ***~~7.~~*** 6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate ***7. Briefly describe the publication policy of the research centre and/or laboratory.*** ***8. Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)***	Old item 6 is deleted for giving reason for misinterpretation of the requirements set out in modalities. Requirement is declaration of BSL4 and not BSL3 or BSL2 laboratories. New items 7 and 8 are inserted for increasing transparency of work done at declared facilities. Insertion is in line with deletion of Form C. Inserted language is copied from item 4. (viii) of Form A, part 2 (iii) with the amendment "research centre and/or laboratory" and item 4. (ix) of Form A, part 2 (iii).

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

[6] 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)".

[7] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

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

[9] 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)".

[10] In accordance with the 1983 latest version of the WHO Laboratory Biosafety Manual, the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Original Text	*Proposed Changes*	*Rationale*
	Form A, part 1 (ii) ***If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[11] on a State Party's territory:*** ***Biosafety level 2***[12] — ***yes / no*** ***Biosafety level 3***[10] — ***yes / no***	New form in line with deletion of old item 6 of Form A, part 1. Form shall provide opportunity to declare highest biosafety level implemented in facilities handling biological agents on a State Party's territory when no BSL 4 facility is declared. No listing of facilities is required only ticking of "yes" or "no".
Confidence-Building Measure A **Part 2: Exchange of information on national biological defence research and development programmes**	**Confidence-Building Measure A** **Part 1: Exchange of information on national *~~biological defence~~* research and development programmes *(civil and military) for protection of humans, animals or plants against the hostile use of biological agents and toxins***	
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.	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 ***(civil and military) ~~on biological defence~~ for the protection of humans, animals and plants against the hostile use of biological agents and toxins***, 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 ***(civil and military) for the protection of humans, animals and plants against the hostile use of biological agents and toxins*** including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no ***~~biological defence~~ such*** research and development programme is being conducted, a null report will be provided.	When Confidence Building Measure A part 2 was agreed in 1991 "biological defence research and development programmes" were understood to be solely military activities. After 9/11 and the Anthrax letters States Parties started activating in addition civil biological defence research and development programmes. Some States Parties already now provide information on military and civil defence R+D programmes under CBM forms A part 2.

[11] Microorganisms pathogenic to humans and/or animals

[12] In accordance with the latest version of the WHO Laboratory Biosafety Manual, the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Original Text	*Proposed Changes*	*Rationale*
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.	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 ***(civil and military) for the protection of humans, animals and plants against the hostile use of biological agents and toxins*** 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.	The proposed language extends the requirement to report under this CBM not only on military but also on other R+D programmes for the protection of humans, animals and plants against the hostile use of biological agents and toxins. “Hostile use” is a clear allusion to Article I of the Convention and covers both State and non-State actors. The language change is equally applicable to CBM A, part 2 and Forms A, part 2 (i), (ii) and (iii).

Original Text	*Proposed Changes*	*Rationale*
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 (i)** **National ~~*Biological Defence*~~ Research and Development Programme *(civil and military) for Protection of Humans, Animals or Plants Against the Hostile Use of Biological Agents and Toxins* Declaration** Is there a national programme to conduct ~~***biological defence***~~ research and development ***(civil and military) for the protection of humans, animals and plants against the hostile use of biological agents and toxins*** 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	**Form A, part 2 (ii)** **National ~~*biological defence*~~ research and development programme *(civil and military) for protection of humans, animals or plants against the hostile use of biological agents and toxins*** **Description** 1. State the objectives and funding of ~~***the***~~ ***each*** 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***~~ ***each*** programme and its source. 3. Are aspects of ~~***this***~~ ***these*** programme***s*** conducted under contract with industry, academic institutions, or in other non-defence facilities? Yes/No	

Original Text	*Proposed Changes*	*Rationale*
4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?	4. If yes, what proportion of the total funds for the programme***s*** 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.	5. Summarize the objectives and research areas of the programme***s*** 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).	6. Provide a diagram of the organizational structure of ~~***the***~~ ***each*** programme ***(civil and military)*** and the reporting relationships (include individual facilities participating in the programme).	
	7. Describe the internal, i.e. within the organizational structures provided by the diagram above, and external, i.e. outside those structure, oversight mechanisms designed to compliance with the treaty obligations, as implemented nationally.	The insertion of a new item 7. is based on discussions at the intersessional process for providing information on oversight of research and development programmes for the protection of humans, animals and plants against the hostile use of biological agents and toxins.
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.	~~***7.***~~ ***8.*** 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 ***(civil and military) for the protection of humans, animals and plants against the hostile use of biological agents and toxins***, within the territory of the reporting State, or under its jurisdiction or control anywhere.	

Original Text	*Proposed Changes*	*Rationale*
Form A, part 2 (iii)	**Form A, part 2 (iii)**	
National biological defence research and development programme	**National ~~*biological defence*~~ research and development programme *(civil and military) for protection of humans, animals or plants against the hostile use of biological agents and toxins***	
Facilities	**Facilities**	
Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).	Complete a form for each facility declared in accordance with paragraph ~~*7*~~ ***8.*** in Form A, part 2 (ii).	
In shared facilities, provide the following information for the biological defence research and development portion only.	In shared facilities, provide the following information for the ~~*biological defence*~~ research and development ***for the protection of humans, animals and plants against the hostile use of biological agents and toxins*** portion only.	
1. What is the name of the facility?	1. What is the name of the facility?	
2. Where is it located (include both address and geographical location)?	2. Where is it located (include both address and geographical location)?	
3. Floor area of laboratory areas by containment level:	3. Floor area of laboratory areas by containment level:	
BL2 (sqM)	BL2 (sqM)	
BL3 (sqM)	BL3 (sqM)	
BL4 (sqM)	BL4 (sqM)	
Total laboratory floor area (sqM)	Total laboratory floor area (sqM)	
4. The organizational structure of each facility.	4. The organizational structure of each facility.	Minor amendment to clarify that listed publications should be published during the period covered by the CBM submission.
(i) Total number of personnel	(i) Total number of personnel	
(ii) Division of personnel:	(ii) Division of personnel:	
Military	Military	
Civilian	Civilian	
(iii) Division of personnel by category:	(iii) Division of personnel by category:	
Scientists	Scientists	
Engineers	Engineers	
Technicians	Technicians	
Administrative and support staff	Administrative and support staff	

Original Text	*Proposed Changes*	*Rationale*
(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.)	(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 ***published*** 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[13] and/or toxins studied, as well as outdoor studies of biological aerosols.	5. Briefly describe the ~~***biological defence***~~ work ***for the protection of humans, animals and plants against the hostile use of biological agents and toxins*** carried out at the facility, including type(s) of micro-organisms[11] and/or toxins studied, as well as ***indoor and*** outdoor studies of biological aerosols.	The insertion of "indoor and" serves the purpose clarifying that not only information on outdoor studies are requested.

[13] including viruses and prions

Original Text	*Proposed Changes*	*Rationale*
Confidence-Building Measure B **Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins**	**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.	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.	The deletion of ", and on all such events" is linked to the proposal to delete Form B(i). The original sentence connects the two requests for filling forms B (i) and B (ii). With the proposed deletion of Form B (i) the connecting language ", and on all such events" is no more required.
Modalities	**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.	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).	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	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	

Original Text	*Proposed Changes*	*Rationale*
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.)	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:	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.	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.[14]	~~***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.***~~[12]	Old item 2 sets the scope for providing annual update of background information on diseases for being provided in Form B (i). With the proposed deletion of Form B (i) old item 2. is no longer required.
3. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered	~~***3***~~ ***2***. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:	Technical change: only one footnote survives.

[14] This information should be provided in accordance with Form B (I).

Original Text	*Proposed Changes*	*Rationale*
particularly important in the following cases: - When the cause of the outbreak cannot be readily determined or the causative agent[15] 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.	- When the cause of the outbreak cannot be readily determined or the causative agent[13] 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*~~ ***latest version of the*** WHO Laboratory Biosafety Manual, - When the causative agent is exotic to a given ***geographical*** 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.	Technical change: new version superseded the 1983 edition. Clarification that region means "geographical region".
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.	~~*4*~~ ***3***. 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.	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.	Technical change: only one Form B survives.
	The declaration of electronic links to national websites or to websites of international (WHO, OIE) or other organizations (GOARN, PROMED that provide information on disease outbreaks may also satisfy the declaration requirement under Form B.	New language allowing use of information on disease outbreaks available on the Internet instead of filling the scheme provided under Form B.
5. In order to improve international	~~*5*~~ ***4***. In order to improve international cooperation in the field of	

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

Original Text	*Proposed Changes*	*Rationale*
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.	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.	
Form B (i) **Background information on outbreaks of reportable infectious diseases** *Number of cases per year* *1988 1989 1990 1991 1992* *Diseases*	**~~Form B (i)~~** **~~Background information on outbreaks of reportable infectious diseases~~** *~~Number of cases per year~~* *~~1988 1989 1990 1991 1992~~* *~~Diseases~~*	CBM declarations show that States Parties provide under B (i) more irrelevant than relevant background data. In most cases better information today is available on theInternet, therefore deletion is proposed.
Form B (ii) **Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**	**Form B *~~(ii)~~*** **Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**	Technical change: only one Form B survives.
	Use the following declaration scheme or when available notify links to national websites and/or websites of international (WHO, OIE) ~~or~~ and other organizations (GOARN, PROMED) that provide information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern	Notification of or reports on outbreaks of diseases are today publicly accessible on the Internet. The provision of weblinks on outbreaks is estimated to provide sufficient information under Form B. In cases in which no weblink is available or additional information is deemed to be necessary the old form may be filled.
1. Time of cognizance of the outbreak	1. Time of cognizance of the outbreak	
2. Location and approximate area affected	2. Location and approximate area affected	
3. Type of disease/intoxication	3. Type of disease/intoxication	
4. Suspected source of disease/intoxication	4. Suspected source of disease/intoxication	

Original Text	*Proposed Changes*	*Rationale*
5. Possible causative agent(s)	5. Possible causative agent(s)	
6. Main characteristics of systems	6. Main characteristics of systems	
7. Detailed symptoms, when applicable - respiratory - circulatory - neurological/behavioural - intestinal - dermatological - nephrological - other	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	8. Deviation(s) from the normal pattern as regards - type - development - place of occurrence - time of occurrence - symptoms - virulence pattern - ~~***drug***~~ ***antimicrobial/pesticide*** resistance pattern - agent(s) difficult to diagnose - presence of unusual vectors - other	Clarification: the terms "antimicrobial and pesticide" resistance may better reflect than "drug" resistance what is meant here.
9. Approximate number of primary cases	9. Approximate number of primary cases	
10. Approximate number of total cases	10. Approximate number of total cases	
11. Number of deaths	11. Number of deaths	
12. Development of the outbreak	12. Development of the outbreak	
13. Measures taken	13. Measures taken	
	14. Assistance requested: yes / no	Amendment meeting assistance aspects of disease outbreaks.
	15. Assistance received: yes / no	

Original Text	*Proposed Changes*	*Rationale*
Confidence Building Measure C	~~**Confidence Building Measure C**~~	
Encouragement of publication of results and promotion of use of knowledge	~~**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."	~~*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."*~~	Form C was agreed in 1991. With the development of the Internet within the last two decades research results published in scientific journals are now generally available in the world wide web. For this reason deletion of Form C is proposed.
Modalities	~~*Modalities*~~	
The Third Review Conference agreed on the following:	~~*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.	~~*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.*~~	Scientific publications and reports linked with declared facilities under Form A, part 2 (iii) will be reported under item 4. (ix) of Form A, part 2 (iii). For linking scientific publications and reports also with declared BSL 4 facilities, insertion of new items 7. and 8. in Form A, part 1 (i) is proposed. (see page 2).
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.	~~*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.	~~*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.*~~	

Original Text	*Proposed Changes*	*Rationale*
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."	**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:	**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 ***forward looking*** information, to the extent possible:	Clarification, as often historic data are declared.
- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention,	- 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.	- 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.	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.	

Original Text	*Proposed Changes*	*Rationale*
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.	**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	2. Information regarding other opportunities, ***i.e. inter alia areas in which cooperation would be welcomed/ could be offered, including indicating a point of contact or others***	Clarification

Original Text	*Proposed Changes*	*Rationale*
Confidence Building Measure E **Declaration of legislation, regulations and other measures**	**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:	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;	(a) To prohibit ***and prevent*** 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;	"to prevent" is added as insertions below focus also on prevention and not only on prohibitions.
(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;	(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; ***- biosafety and biosecurity measures;*** ***- principles, guidelines, codes , awareness raising and educational programmes addressing the "dual use" problem;***	See below
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.	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~~ Office*** 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. ***States Parties should indicate areas in which assistance to further implementation of legislation, regulations and/or other measures would be welcomed or could be offered, providing a point of contact to whom such offers might be directed.***	Delete "on request" for allowing ISU to build up a legislative database. Technical change: Former UNDDA is now UNODA

Original Text					*Proposed Changes*					*Rationale*
Form E					**Form E**					
Declaration of legislation, regulations and other measures					**Declaration of legislation, regulations and other measures**					
	Legislation	*Regulations*	*Other measures*	*Amended since last year*		*Legislation*	*Regulations*	*Other measures*	*Amended since last year*	
(a) Development, production, stockpiling, acquisition ……specified in Article I	Yes/ No	Yes/ No	Yes/ No	Yes/ No	(a) Development, production, stockpiling, acquisition specified in Article I	Yes/ No	Yes/ No	Yes/ No	Yes/ No	
(b) Exports of micro-organisms[16] and toxins	Yes/ No	Yes/ No	Yes/ No	Yes/ No	(b) Exports of micro-organisms[14] and toxins	Yes/ No	Yes/ No	Yes/ No	Yes/ No	
(c) Imports of micro-organisms[14] and toxins	Yes/ No	Yes/ No	Yes/ No	Yes/ No	(c) Imports of micro-organisms[14] and toxins	Yes/ No	Yes/ No	Yes/ No	Yes/ No	
					(d) Biosafety measures[17]	***Yes/ No o***	***Yes/ No***	***Yes/ No***	***Yes/ No***	Based on issues discussed at the intersessional process and estimated being relevant in supporting effective implementation of the Convention, the extension of Form E is proposed.
					(e) Biosecurity measures[18]	***Yes/ No***	***Yes/ No***	***Yes/ No***	***Yes/ No***	
					(f) Principles, guidelines, codes , awareness raising and educational programmes addressing the "dual use" problem			***Yes/ No***		

[16] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention

[17] ***In accordance with the latest version of the WHO Laboratory Biosafety Manual***

[18] ***In accordance with the latest version of the WHO Laboratory Biosecurity Guidance***

Original Text	*Proposed Changes*	*Rationale*
	(g) Indicate areas in which assistance for implementation of legislation, regulations and/or other measures would be welcomed, including a point of contact to whom such offers might be directed	
	(h) Indicate areas in which assistance for implementation of legislation, regulations and/or other measures could be provided, including a point of contact from whom such assistance may be requested	

Original Text	*Proposed Changes*	*Rationale*
Confidence Building Measure F **Declaration of past activities in offensive and/or defensive biological research and development programmes**	**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.	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.	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**	**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.	1. Date of entry into force of the Convention for the State party.	No change proposed. Form F should be retained as it is.
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.	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,	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	

Original Text	*Proposed Changes*	*Rationale*
diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.	protection, decontamination, and other related research, with location if possible.	

Original Text	*Proposed Changes*	*Rationale*
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.	**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 a central agency*** of the State Party for the protection of humans ***and/or animals***. Information shall be provided on Form G ***(i) and (ii)*** attached.	Annual CBM declaration of production facilities for human and animal vaccines is meanwhile common practice. It is proposed to update the language to make it a common standard. Clarification is necessary as most animal vaccines are produced in small herd/stable batches without being licensed for general marketing of animal vaccines. Only production facilities holding licenses for general marketing should be declared.
Form G **Declaration of vaccine production facilities** 1. Name of facility: 2. Location (mailing address): 3. General description of the types of diseases covered:	**Form G *(i)*** **Declaration of ~~*vaccine*~~ production facilities for *human vaccines*** 1. Name of facility: 2. Location (mailing address): 3. General description of the types of diseases covered:	Technical change caused by splitting Form G in sections for vaccines preventing human diseases and vaccines preventing animal diseases.
	Form G *(ii)* ***Declaration of production facilities for animal vaccines*** ***1. Name of facility:*** ***2. Location (mailing address):*** ***3. General description of the types of diseases covered:***	

Original Text	*Proposed Changes*	*Rationale*

Confidence Building Measure 0

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

	Nothing to declare	*Nothing new to declare*
Measure		
A, part 1		
A, part 2 (i)		
A, part 2 (ii)		
A, part 2 (iii)		
B (i)		
B (ii)		
C		
D		
E		
F		
G		

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

Date:

State Party to the Convention:

Confidence Building Measure 0

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

	Nothing to declare	*Nothing new to declare*	***Indicate year of last declaration if "Nothing new to declare"***
Measure			
A, part 1 ***(i)***			
A, part 1 ***(ii)***			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
~~***B (i)***~~			
B ~~***(ii)***~~			
~~***C***~~			
D			
E			
F			
G ***(i)***			
~~***G (ii)***~~			

(Please mark the appropriate box(es) for each measure, with a tick ***and fill in the year of last declaration in the last column where applicable***.)

Date:

State Party to the Convention:

Date of ratification/accession to the BTWC:

National point of contact :

Insertions and deletions in column "Measure" according to above proposed changes.

New column "Indicate year of last declaration if "Nothing new to declare" is proposed for improving the assessment of submitted CBMs by enabling (also electronic) links between the different annual declarations of a State Party.

Clarification