R E P U B L I C O F B U L G A R I A

DECLARATION

ON THE CONFIDENCE-BUILDING MEASURES AS AGREED AT THE THIRD REVIEW CONFERENCE OF THE PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

(covering data for 2015)

BWC/CONF.III/23

Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

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	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)	X		
A, part 2 (ii)	X		
A, part 2 (iii)	X		
B	X		
C	X		
E			
F	X		
G		X	2015

(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: **30.09.2016**

State Party to the Convention: **Republic of Bulgaria**

Date of ratification/accession to the Convention: **2 August 1972**

National point of contact:

National Centre of Infectious and Parasitic Diseases
Director: Prof. Todor Kantardjiev, DSci, MHM
26 Yanko Sakazov Blvd
Sofia 1504, Bulgaria
Tel.: +359 2 944 28 75
E-mail: director@ncipd.org

Active promotion of contacts

The Third Review Conference 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."

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, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- 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,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

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 on the following, later amended by the Seventh Review Conference:

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 latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE[2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

BL4 units – NO

Facility 1

1. Name(s) of facility[4] ***Department of Microbiology and Centre for Virology***
Military Medical Academy
3 St. Georgi Sofiiski Str.
Sofia 1606, Bulgaria
2. Responsible public or private organization or company

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

[1] World Health Organization
[2] World Organization for Animal Health
[3] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[4] 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)".

5. Number of maximum containment units[5] within the research centre and/or laboratory, with an indication of their respective size (m^2)

Microbiology – 12 containment rooms (boxes) at app. 200 m^2
Virology – 4 containment rooms (boxes) at app. 100 m^2

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

Microbiology – Isolation, identification, molecular diagnosis, antibiotic sensitivity, serology of microorganisms, identification of C. difficile toxins;
Virology – serology and molecular diagnosis of viruses and atypical bacteriae.

Facility 2

1.	Name(s) of facility[6]	***National Diagnostic Research Veterinary Medicine Institute,***
2.	Responsible public or private organization or company	***Bulgarian Food Safety Agency, Ministry of Agriculture and Food***
3.	Location and postal address	***15, Pencho Slaveikov Blvd., Sofia 1606, Bulgaria***

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence – ***state budget funding, no financing 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 (m^2)

BL3_27 (sqM)

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

Examination and analysis on bacterial /tularaemia, tuberculosis,anthrax, brucellosis, leptospirosis, salmonellosis /, virosplogical / TSE, rabies, blue tongue, MDF, Lumpy skin desease/ in animals are conducted by the National Research Diagnostic Veterinary Unstitute under the Bulgarian Food Safety Agency. and

Laboratories in NDRVMI works accordance Ch.1.1.4 Standart for managing biorisk in the veterinary laboratories and animal facilities/ Manual of Diagnostic Tests, OIE/.

BSL3 laboratories are a part of the Departments of Microbiology of the National Diagnostic Research veterinary Institute. BSL3 works with the following main strain: anthrax, tuberculosis.

BSL2 used serological tests .

[5] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.
[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 latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

Facility 3

1. Name(s) of facility[8] ***National Centre of Infectious and Parasitic Diseases***

2. Responsible public or private organization or company ***Ministry of Health***

3. Location and postal address ***26, Yanko Sakazov Blvd., Sofia 1504, Bulgaria***

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence **– *state budget funding, no financing by the Ministry of Defence.***

5. Number of maximum containment units[9] within the research centre and/or laboratory, with an indication of their respective size (m^2)

BSL3- 1 laboratory - NRL''Tuberculosis and Anthrax"

BL3 80 sqM

BSL2 – 11 laboratories - NRL"Brucelosis", NRL "Leptospirosis", NRL"Salmonella" , NRL "Rabies and Laboratory "Chlamidia and ricketsia", NRL"Classical and African swine fever and Sheep Goat pox", NRL"Bluetongue",African horse sickness",NRL"Avian influenza and Newcastle disease",NRL"FMD and swine vesicular disease", NRL "TSE"

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

National Reference Laboratory for diagnosis of tetanus, tularaemia, plague, brucellosis, cholera, anthrax, botulism

[8] 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)".

[9] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

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[10] on a State Party's territory:

Biosafety level 3[11]	**yes**
Biosafety level 2[12] (if applicable)	**yes**

Any additional relevant information as appropriate:

BSL3- 1 laboratory

NRL''Tuberculosis and Anthrax"

BSL2 – 11 laboratories

NRL"Brucelosis", NRL "Leptospirosis", NRL"Salmonella" , NRL "Rabies and

Laboratory "Chlamidia and ricketsia", NRL"Classical and African swine fever and Sheep Goat pox", NRL"Bluetongue",African horse sickness",NRL"Avian influenza and Newcastle disease",NRL"FMD and swine vesicular disease", NRL "TSE"

[10] Microorganisms pathogenic to humans and/or animals

[11] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

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

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.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

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

NO

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

Form A, part 2 (ii)

National biological defence research and development programmes

Description

1. State the objectives and funding of 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 each programme and its source.

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

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

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

6. Provide a diagram of the organizational structure of each 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 each 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 programmes

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 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.

[13] Including viruses and prions.

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.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. 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[14] 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 latest edition 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.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to 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 should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by

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

toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. 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, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[15]

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 _____

[15] See paragraph 2 of the chapeau to Confidence-Building Measure B.

Confidence-Building Measure "C"

Nothing to declare

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.

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

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 and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of

delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

Bulgarian Criminal Code, Chapter 11, section I "Crimes Commited in Generally Dangerous Manner or by the use of Generally Dangerous Means", articles 337 and 339 (last amended SG No.19/2014)

(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;

Regulation (EU) No.388/2012 of the European Parliament and of the Council of 19 April 2012 amending Council Regulation (EC) No.428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items which is directly applicable to the national legislation.

Bulgarian Defence-Related Products and Dual-Use Items and Technologies Export Control Act (last amended SG No.9/2014)

Decree of the Bulgarian Council of Ministers No.158 of 24 July 2012 on the adoption of a list of Defence-Related Products and a list of Dual-Use Items and Technologies subject to control at import.

(c) In relation to biosafety and biosecurity.

Order No.4 from 14.10.2002 of the Ministry of Labor and Social Policy and the Ministry of Health on the protection of workers from risks related to exposure to biological agents at work (SG No.105/08.11.2002)

Instruction No.5 from19.11.2003 of the Ministry of Health on the work with causative agents of bacterial, fungal and viral infections with a high medical and epidemic risk (SG No.105/14.03.2004)

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 Implementation Support Unit (ISU) within the United Nations 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.

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[16]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological	Yes/No	Yes/No	Yes/No	Yes/No

[16] Including guidelines.

agents, or toxins, weapons, equipment and means of delivery specified in Article I				
(b) Exports of micro-organisms[17] and toxins	Yes	Yes	Yes	Yes
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	Yes	Yes
(d) Biosafety[18] and biosecurity[19]	Yes	Yes	Yes	Yes

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

[18] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

[19] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

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.

   26 March 1975

2. Past offensive biological research and development programmes:

- ***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:

- **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.

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.

Form G ***Nothing new to declare***

Declaration of vaccine production facilities

1. Name of facility: **BulBio – NCIPD Ltd**

2. Location (mailing address): **26, Yanko Sakazov Blvd., Sofia 1504, Bulgaria**

3. General description of the types of diseases covered:

The company is manufacturing bacterial vaccines for immunoprophylaxis of tuberculosis, diphtheria, pertussis, tetanus, Crimean haemorrhagic fever, immunosera, blood derivatives, immunodiagnostics, allergens, polybacterial immunostimulants, culture media. BB-NCIPD Ltd. is approved to ISO 9001:2000 and ISO 9001:2008. The company is certified by the WHO as an exporter of bacterial vaccines for UN agencies.