

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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (i)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (ii)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (iii)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
F	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(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: **28.3.2019**

State Party to the Convention: **Slovak republic**

Date of ratification/accession to the Convention: **5/17/93**

National point of contact: **Cyril Klement, Prof., M.D., PhD.**

Head of Regional Authority of Public Health Banská Bystrica

Cesta k nemocnici 1, 975 56 Banská Bystrica, Slovak republic

Tel: +421-48-4367733

e-mail: cyril.klement@vzbb.sk

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 WHO¹ Laboratory Biosafety Manual and/or OIE² 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) Nothing to declare

Exchange of data on research centres and laboratories³

1. Name(s) of facility⁴ _____
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

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 units⁵ within the research centre and/or laboratory, with an indication of their respective size (m²)

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

Form A, part 1 (ii) Nothing to declare

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents⁶ on a State Party's territory:

Biosafety level 3 ⁷	yes / <u>no</u>
Biosafety level 2 ⁸ (if applicable)	yes / <u>no</u>

Any additional relevant information as appropriate:

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

⁶ Microorganisms pathogenic to humans and/or animals

⁷ In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

⁸ 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) Nothing to declare

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.

Yes/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) Nothing to declare

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?

Yes/No

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) Nothing to declare

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-organisms⁹ and/or toxins studied, as well as outdoor studies of biological aerosols.

⁹ 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 agent¹⁰ 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 toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

¹⁰ It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

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 Nothing to declare

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern¹¹

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 _____

¹¹ See paragraph 2 of the chapeau to Confidence-Building Measure B.

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

In 2018, the Information Centre for Bacteriological (Biological) and Toxin Weapons Bacteriological (Biological) and Toxin Weapon continued its international cooperation within the European program for the establishment of validated procedures for detection and identification of biological toxins (Project "EuroBioTox"). This project is coordinated by Robert Koch Institute in Berlin, Germany, and aims to increase the ability to diagnose selected toxins, create a network of laboratories able to diagnose them. The Regional Public Health Authority, based in Banská Bystrica, has been a member of the external circle of laboratories involved in this project since 1 June 2017.

Foreign internships:

1. 14.01.2018-19.01.2019, RNDr. Lucia Maďarová, PhD. workshop related to the diagnosing of saxitoxin, Belfast, Northern Ireland. Project EUROBIOTOX.
2. 13.03.2018-14.03.2018, RNDr. Michaela Mancoš basic training courses on Staphylococcal enterotoxin B detection by ELISA methods and LFA, Saclay, France. Project EUROBIOTOX.

Publications and Presentations:

NAME	LECTURE	HAPPENING	PLACE	DATE
Maďarová, L., Dorner, B.G., Schaade, L., Donáth, V., Avdičová, M., Fatkulínová, M., Strhársky, J., Sedliačiková, I., Klement, C., Dorner, M. B.	Reoccurrence of the extremely rare botulinum neurotoxin subtype A3 inducing food-borne botulism in Slovakia. Poster presentation.	DGHM Meeting	Bochum, Germany	19.-21.02.2018
Maďarová, L., Strhársky, J., Klement, C.	Project Eurobiotox (Projekt Eurobiotox)	Occupational presentation	Regional Authority of Public Health Banská Bystrica	15.02.2018
Maďarová, L.	Projekt Eurobiotox	III. Consulting day of National Reference Centers Established in Regional Authority of Public Health -national activity (III. Konzultačný deň NRC zriadených na RÚVZ BB)	Regional Authority of Public Health Banská Bystrica	15.11.2018

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;

Decree of the National Council of the Slovak Republic No. 217 of 28 March 2007 on Prohibition of Biological Weapon

During 2007 was amended Decree No. 644/2007 Coll. implementing the Act No. 217/2007 Coll. on Prohibition of Biological Weapon

(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;

Decree of the National Council of the Slovak Republic No. 39 of 2 February 2011 on Dual –use Items

(c) In relation to biosafety and biosecurity.

STN EN 12128:2001 Biotechnology. Laboratories for research, development and analysis. Containment levels of microbiology, areas of risk, localities and physical safety requirements (this national standards is identical with EN 12128:1998).

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 ¹²	Amended since last year
(a)	Development,	<u>Yes/No</u>	<u>Yes/No</u>	<u>Yes/No</u>	<u>Yes/No</u>

¹² Including guidelines.

production stockpiling,
acquisition or retention of
microbial or other biological
agents, or toxins, weapons,
equipment and means of
delivery specified in Article I

(b) Exports of micro-organisms ¹³ and toxins	<u>Yes</u> /No	Yes/ <u>No</u>	Yes/ <u>No</u>	Yes/ <u>No</u>
(c) Imports of micro-organisms ¹¹ and toxins	<u>Yes</u> /No	Yes/ <u>No</u>	Yes/ <u>No</u>	Yes/ <u>No</u>
(d) Biosafety ¹⁴ and biosecurity ¹⁵	Yes/ <u>No</u>	Yes/ <u>No</u>	<u>Yes</u> /No	Yes/ <u>No</u>

¹³ Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

¹⁴ In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

¹⁵ 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 Nothing to declare

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.

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 to declare

Declaration of vaccine production facilities

1. Name of facility:

 2. Location (mailing address):

 3. General description of the types of diseases covered:
-