

## 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

<i>Measure</i>	<i>Nothing to declare</i>	<i>Nothing new to declare</i>	<i>Year of last declaration if nothing new to declare</i>
<b>A, part 1</b>	X		
<b>A, part 2 (i)</b>	X		
<b>A, part 2 (ii)</b>	X		
<b>A, part 2 (iii)</b>	X		
<b>B</b>	X		
<b>C</b>	X		
<b>E</b>	X		
<b>F</b>	X		
<b>G</b>	X		

(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: Tuesday, May 30, 2023

State Party to the Convention: Serbia

Date of ratification/accession to the Convention: Monday, April 27, 1992

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## **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<sup>1</sup> Laboratory Biosafety Manual and/or OIE<sup>2</sup> 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*<sup>3</sup>

N/A

### 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<sup>6</sup> on a State Party's territory:

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

Any additional relevant information as appropriate:

The Republic of Serbia does not currently have maximum containment Biosafety Level 3 and 4 (BL 3, BL 4) laboratories that meet the criteria for a "maximum containment laboratory" as specified in WHO Laboratory Biosafety Manual. None are envisaged for the foreseeable future.

## **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**

N/A

### **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.

N/A

## **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 [10](#) 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.

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<sup>11</sup>

#### Outbreak of COVID-19 in Serbia

1. Time of cognizance of the outbreak:

The outbreak of COVID-19 in Serbia of 2020 is still in progress.

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication:

N/A

4. Suspected source of disease/intoxication:

N/A

5. Possible causative agent(s):

N/A

6. Main characteristics of systems:

N/A

7. Detailed symptoms, when applicable

N/A

- Respiratory:

N/A

- Circulatory:

N/A

- Neurological/behavioural:

N/A

- Intestinal:

N/A

- Dermatological:

N/A

- Nephrological:

N/A

- Other:

N/A

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

- Type:

N/A

- Development:

N/A

- Place of occurrence:

N/A

- Time of occurrence:

- Symptoms:

N/A

- Virulence pattern:

N/A

- Drug resistance pattern:

N/A

- Agent(s) difficult to diagnose:

N/A

- Presence of unusual vectors:

N/A

- Other:

N/A

9. Approximate number of primary cases:

N/A

10. Approximate number of total cases:

N/A

11. Number of deaths:

12. Development of the outbreak:

Reportable infectious diseases by year:

2018: 11,960

2019: 46,081

2020: 268,998

2021: 407,342

2022: 403,000 (preliminary data)

13. Measures taken:

N/A

Notes:

Data regarding human diseases and zoonoses have been collected and coordinated methodically since 2005 under the auspices of the State Institute for Public Health. This is reported to the WHO, via the Ministry of Health.

The State Veterinary Services/Department of Agriculture reports animal diseases to the OIE. Plant diseases are monitored nationally, but are not systematically reported in the same way.

Attachments:  
N/A

# **Confidence-Building Measure "C"**

## **Encouragement of publication of results and promotion of use of knowledge**

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

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

### **Modalities**

The Third Review Conference agreed on the following:

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

### **Comments:**

As no active programs of research directly related to the Biological and Toxin Weapons Convention exist in the Republic of Serbia, there is no publication in this area.

All non-commercial research regarding biological science and infectious diseases is published in national and international journals. In the Republic of Serbia, the Government policy is to promote transparency and dissemination of knowledge in the biological sciences, especially in the field of human epidemiology.

## **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;
- (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;
- (c) In relation to biosafety and biosecurity.

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

<i>Relating to</i>	<i>Legislation</i>	<i>Regulations</i>	<i>Other measures<sup>12</sup></i>	<i>Amended since last year</i>
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	yes	yes	no	no
(b) Exports of micro-organisms <sup>13</sup> and toxins	-	no	yes	no
(c) Imports of micro-organisms <sup>13</sup> and toxins	-	no	yes	no
(d) Biosafety <sup>14</sup> and biosecurity <sup>15</sup>	-	-	-	-

Additional information to Form E:

The Republic of Serbia is currently conducting a review of its national legislation to identify where further legislation may be required to fulfill all of the State's obligations, as set out in the Convention.

Note: there is a draft legislation for b) and c)

## **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.

Wednesday, February 7, 1973

2. Past offensive biological research and development programmes:

- no

- Period(s) of activities

N/A

- 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.

N/A

3. Past defensive biological research and development programmes:

- no

- Period(s) of activities

N/A

- 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.

N/A

# **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**

#### **Declaration of vaccine production facilities**

1. Name of facility:

**Institute of Immunology and Virology "Torlak"**

2. Location (mailing address):

Vojvode Stepe Street, No. 458, 11152 Belgrade, Serbia

3. General description of the types of diseases covered:

- Diphtheria

- Tetanus

- Pertussis

- Tuberculosis

- Influenza

- Covid 19

## Notes

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. 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.
9. Including viruses and prions.
10. It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.
11. See paragraph 2 of the chapeau to Confidence-Building Measure B.
12. Including guidelines.
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.