

## 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A, part 2 (i)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A, part 2 (ii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (iii)	<input 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 type="checkbox"/>	<input type="checkbox"/>
F	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
G	<input type="checkbox"/>	<input checked="" 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: April 13<sup>th</sup>, 2018

State Party to the Convention: Japan

Date of ratification/accession to the Convention: 8 June 1982

National point of contact: Eva Nakamura, Ministry of Foreign Affairs of Japan

## Confidence-Building Measure "A"

### Part 1 Exchange of data on research centres and laboratories

#### Form A, part 1 (i)

*Exchange of data on research centres and laboratories<sup>1</sup>*

1. Name(s) of facility<sup>2</sup> **Murayama Annex of National Institute of Infectious Diseases (former National Institute of Health)**
2. Responsible public or private organization or company **Ministry of Health, Labour and Welfare**
3. Location and postal address **Gakuen4-7-1, Musashimurayama, Tokyo, 208-0011, Japan**
4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence  
**Ministry of Health, Labour and Welfare**
5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)  
**Three P4 Laboratories, Seventeen P3 Laboratories and their supporting Laboratories (2,270.36 m<sup>2</sup> in totals)**
6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate  
**Laboratory diagnosis of viral haemorrhagic fever such as Lassa, Marburg and Ebola diseases (However, such diagnosis has never been performed in these laboratories so far).**

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

<sup>2</sup> 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)".

<sup>3</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

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*Exchange of data on research centres and laboratories<sup>4</sup>*

1. Name(s) of facility<sup>5</sup> **RIKENTsukubaCampus**
2. Responsible public or private organization or company **The Institute of Physical and Chemical Research (RIKEN)**
3. Location and postal address **3-1-1, Kovadai, Tsukuba-shi, Ibaraki, 305-0074, JAPAN**
4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

**Ministry of Education, Culture, Sports, Science and Technology**

5. Number of maximum containment units <sup>6</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

**2 units, 82 m<sup>2</sup> × 2**

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

**Risk assessment of recombinant DNA materials using Retrovirus**

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<sup>4</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>5</sup> 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)".

<sup>6</sup> 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 <sup>7</sup> on a State Party's territory:

Biosafety level 3 <sup>8</sup>	yes / no
Biosafety level 2 <sup>9</sup> (if applicable)	yes / no

Any additional relevant information as appropriate:

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<sup>7</sup> Microorganisms pathogenic to humans and/or animals

<sup>8</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

<sup>9</sup> 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

### 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.

#### Yes

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.

#### Research Fund for Advanced Defense Medicine, Research Area: Special Health Protection

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

Ministry of Defense provided 52,967,000 yen for the research area of “Special Health Protection, Advanced Defense Medicine” in FY2017. This research area consists of four major research fields, 1. Skin protection against blister agents, 2. Bio-scavengers against biological agents, 3. Evaluation of radiation damage, 4. R&D of radioprotective drugs, and the fund was used partly for the research field 2 “Bio-scavengers against biological agents”. The fund includes the fee for hiring contract staff as research technicians.

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

#### No

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

N/A

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

N/A

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

**Ministry of Defense – National Defense Medical College – Research Groups for Advanced Defense Medicine (in this case, the name of research project which has relation to CBM is “Research Group for Special Health Protection”)**

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?

**National Defense Medical College**

2. Where is it located (include both address and geographical location)?

**Department of Immunology and Microbiology, 3-2 Namiki, Tokorozawa, Saitama 359-8513, Japan**

3. Floor area of laboratory areas by containment level:

BL2 55 \_\_\_\_\_ (sqM)

BL3 N/A \_\_\_\_\_ (sqM)

BL4 N/A \_\_\_\_\_ (sqM)

Total laboratory floor area 55 \_\_\_\_\_ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel 12 persons

(ii) Division of personnel:

Military 4 persons

Civilian 8 persons

(iii) Division of personnel by category:

Scientists 12 persons

Engineers N/A

Technicians N/A

Administrative and support staff N/A

(iv) List the scientific disciplines represented in the scientific/engineering staff.

**Medicine, Immunology, Molecular Biology**

(v) Are contractor staff working in the facility? If so, provide an approximate number.

**4 persons (temporarily hired)**

(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?

Research Fund for Advanced Defense Medicine, Ministry of Defense

(vii) What are the funding levels for the following programme areas:

Research 52,967,000 yen

Development No

Test and evaluation No

(viii) Briefly describe the publication policy of the facility:

**Follow the rule of the Ministry of Defense**

(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.)

- Kinoshita M, Mivazaki H, Nakashima, H, Nakashima M, Nishikawa M, Ishikiriyama T, Kato S, Iwaya K, Hiroi S, Shinomiya N, Seki S.: In vivo LPS tolerance recruits CD11b<sup>+</sup> macrophages to the liver with enhanced bactericidal activity and low TNF-releasing capability, resulting in drastic resistance to lethal septicemia. J. Inn. Immun. 9:493-501, 2017. doi: 10.1159/000475931**
- Kinoshita M, Shinomiya N, Aoki S, Kiyosawa T, Seki S.: Basic fibroblast growth factor-loaded PLGA nanosheet promotes wound healing of refractory skin lesions. 2017 Chemical and Biological Defense Science & Technology Conference (CBD S&T 2017), November 28-30, 2017. Long Beach CA, USA.**

3. **Kinoshita M, Shinomiya N, Miyazaki H, Nakashima H, Nakashima M, Seki S.: Medical countermeasures using LPS tolerance to address lethal toxic shock and fatal bacterial sepsis. 2017 Chemical and Biological Defense Science & Technology Conference (CBD S&T 2017), November 28-30, 2017. Long Beach CA, USA.**

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms<sup>10</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.

1. **Making mouse models for the analysis of toxic shock syndrome induced by *Staphylococcal* enterotoxin B**

2. **Making mouse models for the analysis of LPS tolerance using *E. coli* LPS**

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<sup>10</sup> Including viruses and prions.



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## Confidence-Building Measure "B"

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

#### Form B

#### Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>11</sup>

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 \_\_\_\_\_

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<sup>11</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

- 11. Number of deaths \_\_\_\_\_
- 12. Development of the outbreak \_\_\_\_\_
- 13. Measures taken \_\_\_\_\_

## Confidence-Building Measure "C"

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

Akter A, Ooka T, Gotoh Y, Yamamoto S, Fujita H, Terasoma F, Kida K, Taira M, Nakadouzo F, Gokuden M, Hirano M, Miyashiro M, Inari K, Shimazu Y, Tabara K, Toyoda A, Yoshimura D, Itoh T, Kitano T, Sato MP, Katsura K, Mondal SI, Ogura Y, Ando S, Hayashi T. Extremely Low Genomic Diversity of Rickettsia japonica Distributed in Japan. Genome Biol Evol. 2017 Jan 1;9(1):124-133.

Satoh M, Akashi S, Ogawa M, Wakeyama T, Ogawa H, Fukuma A, Taniguchi S, Tani H, Kurosu T, Fukushi S, Shimojima M, Ando S, Saijo M. Retrospective survey of severe fever with thrombocytopenia syndrome in patients with suspected rickettsiosis in Japan. J Infect Chemother. 2017 Jan;23(1):45-50.

Taniguchi S, Fukuma A, Tani H, Fukushi S, Saijo M, Shimojima M. A neutralization assay with a severe fever with thrombocytopenia syndrome virus strain that makes plaques in inoculated cells. J Virol Methods. 2017 Jun;244:4-10.

Yoshikawa T, Fujii H, Okutani A, Shibamura M, Omura N, Egawa K, Kato H, Inagaki T, Harada S, Yamada S, Morikawa S, Saijo M. Construction and characterization of bacterial artificial chromosomes harboring the full-length genome of a highly attenuated vaccinia virus LC16m8. PLoS One. 2018, 13(2):e0192725.

Tian D, Uda A, Park ES, Hotta A, Fujita O, Yamada A, Hirayama K, Hotta K, Kovama Y, Azaki M, Morikawa S. Evaluation of Francisella tularensis  $\partial$  pdpC as a candidate live attenuated vaccine against respiratory challenge of Tularemia in C57BL/6J mouse model. Microbiol Immunol. 2018, 62(1):24-33.

Kimura M, Une Y, Suzuki M, Park E-S, Imaoka K and Morikawa S. Isolation of Brucella inopinata-like bacteria from White's and Denny's tree frogs. Vector Borne Zoonotic Dis. 2017, 17(5):297-302.

Iizuka I, Ami Y, Suzaki Y, Nagata N, Fukushi S, Ogata M, Morikawa S, Hasegawa H, Mizuguchi M, Kurane I, Saijo M. A Single Vaccination of Nonhuman Primates with Highly Attenuated Smallpox Vaccine, LC16m8, Provides Long-term Protection against Monkeypox. Jpn J Infect Dis. 2017, 70(4):408-415.

Matono T, Morita M, Yahara K, Lee KI, Izumiya H, Kaku M, Ohnishi M. Emergence of Resistance Mutations in Salmonella enterica Serovar Typhi Against Fluoroquinolones. Open Forum Infect Dis. 2017 Nov 2;4(4):ofx230.

Yoko HAYAMA, Takehisa YAMAMOTO, Sota KOBAYASHI, Norihiko MUROGA, and Toshiyuki TSUTSUI, Potential impact of species and livestock density on the epidemic size and effectiveness of control measures for foot-and-mouth disease in Japan. Vet Med Sci. 2016 Jan; 78(1): 13-22.

## Confidence-Building Measure "E"

### Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures <sup>12</sup>	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	Yes/ <input checked="" type="radio"/> No	Yes/ <input checked="" type="radio"/> No
(b) Exports of micro-organisms <sup>13</sup> and toxins	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No
(c) Imports of micro-organisms <sup>11</sup> and toxins	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	Yes/ <input checked="" type="radio"/> No	Yes/ <input checked="" type="radio"/> No
(d) Biosafety <sup>14</sup> and biosecurity <sup>15</sup>	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	<input checked="" type="radio"/> Yes/ <input type="radio"/> No	Yes/ <input checked="" type="radio"/> No

<sup>12</sup> Including guidelines.

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

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

<sup>15</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

**Name of legislation, regulations, and other measures:**

**Foreign exchange and Foreign Trade Law (1948)**

**Export Trade Control Order (1949)**

**Law on Implementing the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction and the Other Conventions (1982)**

**Ordinance of the Ministry Specifying Goods and Technologies Pursuant to Provisions of the Appended Table 1 of the Export Control Order and the Appended Table of the Foreign Exchange Order (1991)**

**Cabinet Order for the Enforcement of the Law on Implementing the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (1995)**

**The Law Concerning the Prevention of Infections and Medical Care for Patients of Infections (1998)**

## **Confidence-Building Measure "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.

**June 8, 1982**

2. Past offensive biological research and development programmes:

**None**

3. Past defensive biological research and development programmes:

**None**

## Confidence-Building Measure "G"

### Declaration of vaccine production facilities

No.	Name of Facility	Location (postal address)	General Description of the Types of Diseases Covered
1	Denka Seiken Co., Ltd	2-1-1 Nihonbashi Muromachi, Chuo-ku, Tokyo, Japan	Influenza, Tetanus
2	Kitasato Daiichi Sankyo Vaccine Co.,Ltd	6-111 Arai, Kitamoto-shi, Saitama, Japan	Influenza, Rubella, Diphtheria, Tetanus, Pertussis, Measles, Mumps, Poliomyelitis
3	Takeda Pharmaceutical Co.,Ltd	4-1-1 Doshomachi, Chuo-ku, Osaka, Japan	Influenza, Diphtheria, Tetanus, Pertussis, Measles, Mumps, Rubella
4	The Research Foundation for Microbial Diseases of Osaka University (BIKEN)	3-1 Yamadaoka, Suita-shi, Osaka, Japan	Influenza, Diphtheria, Tetanus, Varicella, Japanese Encephalitis, Pertussis, Measles, Rubella, Poliomyelitis
5	The Chemo-Sero- Therapeutic Research Institute (KAKETSUKEN)	1-6-1 Okubo, Kita-ku, Kumamoto-shi, Kumamoto, Japan	Influenza, Rabies, Diphtheria, Tetanus, Japanese Encephalitis, Pertussis, Mumps, Hepatitis A, Hepatitis B, Poliomyelitis
6	Japan BCG Laboratory	4-2-6 Kohinata, Bunkyo-ku, Tokyo, Japan	Tuberculosis