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		✓	2018
A, part 2 (i)		✓	2018
A, part 2 (ii)			
A, part 2 (iii)			
B	✓		
C			
E		✓	2018
F		✓	2018
G		✓	2018

(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: March 8, 2019

State Party to the Convention: Japan

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

National point of contact: Yuki Ochiai, Assistant Director, Biological and Chemical Weapons Conventions Division, 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[1]

1. Name(s) of facility[2] **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[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)

Three P4 Laboratories, Seventeen P3 Laboratories and their supporting Laboratories (2,270.36 ㎡ 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).

Exchange of data on research centres and laboratories[4]

1. Name(s) of facility[5] **RIKEN Tsukuba Campus**

2. Responsible public or private **The Institute of Physical and Chemical**

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

[2] 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)".

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

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

[5] 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)".

organization or company **Research (RIKEN)**

3. Location and postal address **3-1-1, Koyadai, 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[6] within the research centre and/or laboratory, with an indication of their respective size (m^2)

2 units, 82 ㎡ × 2

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

None

[6] 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 [7] on a State Party's territory:

Biosafety level 3[8]	yes / no
Biosafety level 2[9] (if applicable)	yes / no

Any additional relevant information as appropriate:

_____

_____

_____

_____

[7] Microorganisms pathogenic to humans and/or animals

[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] 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 37,310,000 yen for the research area of "Special Health Protection, Advanced Defense Medicine" in FY2018. 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 **13 persons**

(ii) Division of personnel:

Military **4 persons**

Civilian **9 persons**

(iii) Division of personnel by category:

Scientists	**13 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	**Yes**
Development	**No**
Test and evaluation	**No**

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

Follow the rule of the Ministry of Defence

(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.)

Nishiwaki, K., Aoki, S., Kinoshita, M., Kiyosawa, T., Suematsu, Y., Takeoka, S., Fujie, T.: In situ transplantation of adipose tissue-derived stem cells organized on porous polymer nanosheets for murine skin defects. J Biomed Mater Res B Appl Biomater, 2018. doi: 10.1002/jbm.b.34228

Hagisawa, K., Kinoshita, M., Takase, B., Hashimoto, K., Saitoh, D., Seki, S., Nishida, Y., Sakai, H.: Efficacy of Resuscitative Transfusion With Hemoglobin Vesicles in the Treatment of Massive Hemorrhage in Rabbits With Thrombocytopenic Coagulopathy and Its Effect on Hemostasis by Platelet Transfusion. Shock 50: 324-330, 2018. doi: 10.1097/SHK.0000000000001042

Takajo D, Nonoyama S.: Severe pertussis in a young infant due to household transmission: the needs of pertussis vaccination boosters in Japan. Clin Case Rep. 6: 810-812, 2018. doi: 10.1002/ccr3.1472

Misawa, K., Tarumoto, N., Tamura, S., Osa, M., Hamamoto, T., Yuki, A., Kouzaki, Y., Imai, K., Ronald, R. L., Yamaguchi, T., Murakami, T., Maesaki, S., Suzuki, Y., Kawana, A., Maeda, T.: Single nucleotide polymorphisms in genes encoding penicillin-

binding proteins in beta-lactamase-negative ampicillin-resistant Haemophilus influenzae in Japan. BMC Res Notes 11: 53, 2018. doi: 10.1186/s13104-018-3169-0

Fujikura, Y., Yuki, A., Hamamoto, T., Kawana, A., Ohkusu, K., Matsumoto, T.: Blood stream infections caused by Acinetobacter baumannii group in Japan - Epidemiological and clinical investigation. J Infect Chemother 22: 366-371, 2018. doi: 10.1016/j.jiac.2016.02.006

Fujikura, Y., Yuki, A., Hamamoto, T., Ichimura, S., Kawana, A., Ohkusu, K., Matsumoto, T.: Evaluation and validity of a polymerase chain reaction-based open reading frame typing method to dissect the molecular epidemiology for Acinetobacter baumannii in an epidemiologic study of a hospital outbreak. Am J Infect Control 44: e275-e278, 2018. doi: 10.1016/j.ajic.2016.03.059

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

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

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

[10] Including viruses and prions.

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[11]

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

Yuko Uchida, Katsushi Kanehira, Nobuhiro Takemae, Hirokazu Hikono, Takehiko Saito, Susceptibility of chickens, quail, and pigeons to an H7N9 humaninfluenzavirus and subsequent egg-passaged strains. Arch. Virol. 2017 Jan; 162(1):103-116.

Hatano et al., LAMP using a disposable pocket warmer for anthrax detection, a highly mobile and reliable method for anti-bioterrorism. JJID 63: 36-40, 2010.

K. Fukai, K. Morioka, K. Yoshida. (2011) An experimental infection in pigs using a foot-and-mouth disease virus isolated from the 2010 epidemic in Japan. J. Vet. Med. Sci. 73(9),1207-1210

Tani H, Komeno T, Fukuma A, Fukushi S, Taniguchi S, Shimojima M, Uda A, Morikawa S, Nakajima N, Furuta Y, Saijo M. Therapeutic effects of favipiravir against severe fever with thrombocytopenia syndrome virus infection in a lethal mouse model: Dose-efficacy studies upon oral administration. PLoS One. 2018 Oct 26;13(10):e0206416.

Saijo M. Pathophysiology of severe fever with thrombocytopenia syndrome and development of specific antiviral therapy. J Infect Chemother. 2018 Oct;24(10):773-781.

Kimura T, Fukuma A, Shimojima M, Yamashita Y, Mizota F, Yamashita M, Otsuka Y, Kan M, Fukushi S, Tani H, Taniguchi S, Ogata M, Kurosu T, Morikawa S, Saijo M, Shinomiya H. Seroprevalence of severe fever with thrombocytopenia syndrome (SFTS) virus antibodies in humans and animals in Ehime prefecture, Japan, an endemic region of SFTS. J Infect Chemother. 2018 Oct;24(10):802-806.

Kitagawa Y, Sakai M, Shimojima M, Saijo M, Itoh M, Gotoh B. Nonstructural protein of severe fever with thrombocytopenia syndrome phlebovirus targets STAT2 and not STAT1 to inhibit type I interferon-stimulated JAK-STAT signaling. Microbes Infect. 2018 Jun - Jul;20(6):360-368.

Gokuden M, Fukushi S, Saijo M, Nakadouzono F, Iwamoto Y, Yamamoto M, Hozumi N, Nakayama K, Ishitani K, Nishi N, Ootsubo M. Low Seroprevalence of Severe Fever with Thrombocytopenia Syndrome Virus Antibodies in Individuals Living in an Endemic Area in Japan. Jpn J Infect Dis. 2018 May 24;71(3):225-228.

Suda Y, Chamberlain J, Dowall SD, Saijo M, Horimoto T, Hewson R, Shimojima M. The Development of a Novel Diagnostic Assay That Utilizes a Pseudotyped Vesicular Stomatitis Virus for the Detection of Neutralizing Activity against Crimean-Congo Hemorrhagic Fever Virus. Jpn J Infect Dis. 2018 May 24;71(3):205-208.

Saasa N, Kajihara M, Dautu G, Mori-Kajihara A, Fukushi S, Sinkala Y, Morikawa S, Mweene A, Takada A, Yoshimatsu K, Arikawa J. Expression of a Recombinant Nucleocapsid Protein of Rift Valley Fever Virus in Vero Cells as an

Immunofluorescence Antigen and Its Use for Serosurveillance in Traditional Cattle Herds in Zambia. Vector Borne Zoonotic Dis. 2018 May;18(5):273-277.

Gaowa, Wulantuya, Yin X, Guo S, Ding C, Cao M, Kawabata H, Sato K, Ando S, Fujita H, Kawamori F, Su H, Shimada Y, Masuda S, Ohashi N. Spotted fever group Rickettsia in Inner Mongolia, China. Emerging Infectious Diseases. 24(11): 2105-2107, 2018.

The followings are information on relevant scientific major journals/publications in Japan generally available to States parties.

National Institute of Infectious Disease(NIID) publishes bimonthly Japanese Journal of Infectious Diseases (JJID), the leading infectious disease journal in Japan. JJID is available at the journal site (http://www.nih.go.jp/JJID/jjid.html).

J-STAGE is an electronic journal platform for science and technology information in Japan, developed and managed by the Japan Science and Technology Agency (JST). (https://www.jstage.jst.go.jp/browse/-char/en)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[12]	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	(Yes)/No	(Yes)/No	Yes/(No)	Yes/(No)
(b) Exports of micro-organisms[13] and toxins	(Yes)/No	(Yes)/No	(Yes)/No	(Yes)/No
(c) Imports of micro-organisms[11] and toxins	(Yes)/No	(Yes)/No	Yes/(No)	Yes/(No)
(d) Biosafety[14] and biosecurity[15]	(Yes)/No	(Yes)/No	(Yes)/No	Yes/(No)

[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.

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

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.

June 8, 1982

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

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