

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"/>	2020
A, part 2 (i)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2020
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"/>	2020
G	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2020

(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 9, 2021**

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. Name(s) of facility **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 within the research centre and/or laboratory, with an indication of their respective size (m²)

Three P4 Laboratories, Seventeen P3 Laboratories and their supporting Laboratories (2,270.36 m² 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 laboratories¹

1. Name(s) of facility **RIKEN Tsukuba Campus**
2. Responsible public or private organization or company **The Institute of Physical and Chemical 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

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

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

2 units, 82 m²×2

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

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 on a State Party's territory:

Biosafety level 3	yes / no
Biosafety level 2 (if applicable)	yes / no

Any additional relevant information as appropriate:

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/ 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.

(1) Research Fund for Advanced Defense Medicine, Research Area: Special Health Protection

(2) Acquisition, Technology & Logistics Agency, Ministry of Defense, Japan, conducts research on rapid and easy-to-use detection of biological agents in JFY2020.

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

(1) Ministry of Defense provided 30,619,000 yen for the research area of “Special Health Protection, Advanced Defense Medicine” in FY2020. This research area consists of four major research fields; 1. Development of decontamination agent against Bio- and Chemical-threat, 2. 3D-culture of human skin for development of the technique of massive skin graft, 3. Evaluation of radiation damage, 4. Increase in the capability of medical counter measures (MCM) against CBRN threat. The fund was used partly for the research field 1 and 4. The fund includes the fee for hiring contract staff as research technicians.

(2) The total expenditure of the research program in JFY2020 is approximately 20 million Japanese yen. The research is funded by Ministry of Defense, Japan.

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?

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).

(1) 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”)

(2) Plan, Administration, Research – Acquisition, Technology & Logistics Agency (ATLA)

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 7 persons

(ii) Division of personnel:

Military 3 persons

Civilian 4 persons

(iii) Division of personnel by category:

Scientists 7 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, Microbiology

(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 Defense

Regarding the research about BiSCaO, follow as described in the MOU between ATLA (Acquisition, Technology & Logistics Agency) and NDMC (National Defense Medical College) Research Institute

(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.)

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- (1) Kinoshita M, Ito S, Ishikiriyama T, Sekiguchi K, Yamaguchi R, Tsuruhara R, Matsuda A, Koiwai K, Nakashima M, Nakashima H, Miyashita M, Seki S. The efficacy of post-treatment with synthetic C-reactive protein in murine bacterial peritonitis via activation of FcγRI-expressing Kupffer cells. J. Innate Immun. in press
- (2) Nishikawa M, Kinoshita M, Morimoto Y, Ishikiriyama T, Nakashima M, Nakashima H, Ono T, Seki S, Moriya T, Yamamoto J, Kishi Y. LPS preconditioning reduces liver metastasis of Colon26 cells by enhancing antitumor activity of NK cells and NKT cells in murine liver. J Gastro Hepatol in press
- (3) Otani N, Morimoto Y, Kinoshita M, Ogata T, Takeuchi S, Toyooka T, Wada K, Mori T. Serial changes of the serum phosphorylated neurofilament and its application for prediction of clinical outcome after traumatic brain injury. Surg Neurol Int in press
- (4) Yuki Y, Hagisawa K, Kinoshita M, Ishibashi H, Kaneko K, Ishida O, Saitoh D, Sakai H, Terui K. Efficacy of resuscitative infusion with hemoglobin vesicles in rabbits with massive obstetric hemorrhage. Am J Obstet Gynecol 2020 doi: 10.1016/j.ajog.2020.09.010
- (5) Eder S, Hermann C, Lamkowski A, Kinoshita M, Yamamoto T, Abend M, Shinomiya N, Port M, Rump A. A comparison of thyroïdal protection by stable iodine or perchlorate in the case of acute or prolonged radioiodine exposure. Arch Toxicol, 94: 3231-3247, 2020 doi: 10.1007/s00204-020-02809-z.
- (6) Ishida O, Hagisawa K, Yamanaka N, Tsutsumi K, Suzuki H, Takikawa M, Takeoka S, Kinoshita M. Therapeutic potential of fibrinogen α chain peptide-coated, ADP-encapsulated liposomes as a haemostatic adjuvant for post-cardiopulmonary bypass coagulopathy. Sci Rep 10; e11308, 2020. doi: 10.1038/s41598-020-68307-5
- (7) Saga R, Uchida T, Takino Y, Kondo Y, Kobayashi H, Kinoshita M, Saitoh D, Ishigami A, Makishima M. Radiation-induced gastrointestinal syndrome is exacerbated in vitamin C insufficient SMP30/GNL knockout mice. Nutrition 81: 1-8, 2020 doi: 10.1016/j.nut.2020.110931
- (8) Koga M, Toda, H, Kinoshita M, Asai F, Nagamine M, Shimizu K, Kabavashi Y, Morimoto Y, Yoshino A. Investigation of the impact of preconditioning with lipopolysaccharide on inflammation-induced gene expression in the brain and depression-like behavior in male mice. Prog Neuropsychopharmacol Biol Psychiatry 103: 109978, 2020 doi: 10.1016/j.pnpbp.2020.109978
- (9) Hagisawa K, Kinoshita M, Saitoh D, Morimoto Y, Sakai H. Intraosseous transfusion of hemoglobin vesicles in the treatment of hemorrhagic shock with collapsed vessels in a rabbit model. Transfusion 60; 1400-9, 2020. doi: 10.1111/trf.15915
- (10) Maekawa T, Uchida T, Nakata-Horiuchi Y, Kobayashi H, Kawauchi S, Kinoshita M, Saitoh D, Sato S. Oral ascorbic acid 2-glucoside prevents coordination disorder induced via laser-induced shock waves in rat brain PLoS ONE 15; e0230774, 2020. doi: 10.1371/journal.pone.0230774.
- (11) Ishihara M, Hata Y, Hiruma S, Takayama T, Nakamura S, Sato Y, Ando N, Fukuda K, Murakami K, Yokoe H. Safety of Concentrated Bioshell Calcium Oxide Water Application for Surface and Skin Disinfections against Pathogenic Microbes. Molecules. 2020 Oct 1;25(19):4502. doi: 10.3390/molecules25194502.
- (12) Nakamura S, Ishihara M, Sato Y, Takayama T, Hiruma S, Ando N, Fukuda K, Murakami K, Yokoe H. Concentrated Bioshell Calcium Oxide (BiSCaO) Water Kills

Pathogenic Microbes: Characterization and Activity. Molecules. 2020 Jun 30;25(13):3001. doi: 10.3390/molecules25133001.

(13) Takayama T, Ishihara M, Nakamura S, Sato Y, Hiruma S, Fukuda K, Murakami K, Yokoe H. Bioshell Calcium Oxide (BiSCaO) Ointment for the Disinfection and Healing of Pseudomonas aeruginosa-Infected Wounds in Hairless Rats. Int J Mol Sci. 2020 Jun 11;21(11):4176. doi: 10.3390/ijms21114176.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms² and/or toxins studied, as well as outdoor studies of biological aerosols.

Microorganisms: E. coli, Staphylococcus aureus (MRSA)

Toxins: Staphylococcal enterotoxin B (SEB)

Bacteria and toxins were used for testing in vitro bactericidal activity or for making mouse infection models. Outdoor studies of biological aerosols have never been performed.

² 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

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 _____

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

The Government of Japan maintains an open policy on the exchange of information on biological research, the results of such research being made freely available in all cases where the release is not prejudicial to vital national or commercial interests. This policy would apply to any research subject to the reporting in Forms A and B.

Selected relevant articles published

Ryota Tsunekuni, Taichiro Tanikawa, Takaaki Nakaya, Takehiko Saito
Improvement of a recombinant avian avulavirus serotype 10 vectored vaccine by the addition of untranslated regions. Vaccine. 2020 Jan 22;38(4):822-829.
<https://www.sciencedirect.com/science/article/pii/S0264410X19315002>

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	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 and toxins	Yes/No	Yes/No	Yes/No	Yes/No
(c) Imports of micro-organisms and toxins	Yes/No	Yes/No	Yes/No	Yes/No
(d) Biosafety and biosecurity	Yes/No	Yes/No	Yes/No	Yes/No

Name of legislation, regulations, and other measures:

Foreign exchange and Foreign Trade Law (1949)

Export Trade Control Order (1949)

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)

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)

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

Form G

Declaration of vaccine production facilities

No.	Name of Facility	Location (postal address)	General Description of the Types of Diseases Covered
1	Denka Co.,Ltd	2-1-1 Nihonbashi Muromachi, Chuo-ku, Tokyo, Japan	Influenza, Tetanus
2	Daiichi Sankyo Biotech 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, , 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	KM Biologics Co,Ltd	1-6-1 Okubo, Kita-ku, Kumamoto-shi, Kumamoto, Japan	Influenza, Rabies, Diphtheria, Tetanus, Japanese Encephalitis, Pertussis, , Hepatitis A, Hepatitis B, Poliomyelitis
6	Japan BCG Laboratory	Meikei building 5F 1-5-21 Otsuka , Bunkyo-ku, Tokyo, Japan	Tuberculosis