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		X	2014
A, part 2 (i)	X		
A, part 2 (ii)	X		
A, part 2 (iii)	X		
B	X		
C	X		
E		X	2014
F		X	2014
G		X	2014

(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: 29-04-2015

State Party to the Convention: **PORTUGAL**

Date of ratification/accession to the Convention: 15-05-1975

National point of contact: **André Sobral Cordeiro** (Head, Disarmament and Non-Proliferation Division, Ministry of Foreign Affairs), Mauro Alexandre Martins (Non-Proliferation Division), Phone: +351 21 394 63 39, Fax: +351 21 394 60 3,7 E-mail: andre.cordeiro@mne.pt, mauro.martins@mne.pt.

Part 1 Exchange of data on research centres and laboratories

1. Instituto Nacional de Saúde Doutor Ricardo Jorge, I.P. (Portuguese National Health Institute) - INSA

2. Instituto Nacional de Investigação Agrária e Veterinária, I.P. (Portuguese Institute for Animal Health Research)

3. Life and Health Sciences Research Institute – University of Minho/School of Health Sciences

4. Departamento de Farmácia Galénica e Tecnologia Farmacêutica (DFGTF), Faculdade de Farmácia da Universidade de Lisboa (Department of Galenic Pharmacy and Pharmaceutical Technology (DFGTF), Faculty of Pharmacy, University of Lisbon)

5. Departamento de Microbiologia e Imunologia (DMI), Faculdade de Farmácia da Universidade de Lisboa (Department of Microbiology and Immunology, Faculty of Pharmacy, University of Lisbon)

6. Laboratório de Bromatologia e Defesa Biológica [Defence research - Form A, part 2 (i)]

1. INSTITUTO NACIONAL DE SAÚDE DOUTOR RICARDO JORGE, I.P. (PORTUGUESE NATIONAL HEALTH INSTITUTE) - INSA

Form A, part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility **Departamento de Doenças Infecciosas**
2. Responsible public or private organization or company **Instituto Nacional de Saúde Doutor Ricardo Jorge, I.P. (INSA)** - public
3. Location and postal address **Avenida Padre Cruz, 1649-016 Lisboa, PT**
4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Funding comes from the Ministry of Health.

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

No (none) BSL-4 Laboratories

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

Detection, characterization and diagnostic testing of infectious microorganisms of risk group 1, 2, and 3. At present time, INSA has 5 BSL-3 laboratories, one of which exclusively dedicated to the early detection of potential biological war agents, namely Class A and Class B microorganisms, according to CDC definition. In addition, INSA has several BSL-2 and BSL-1 laboratories dedicated to the study and diagnosis of human pathogens. During 2013 the participation in EQUATOX project contributes to the increase capacity to detect toxins of biologic origin.

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**
Biosafety level 2 (if applicable)	**YES**

Any additional relevant information as appropriate:

Detection, characterization and diagnostic testing of infectious microorganisms of risk group 1, 2 and 3. Detection At present moment INSA has 5 BSL3. 2 BLS3 dedicated to the study of TB (1 in Lisbon and 1 in Oporto); 2 BSL 3 dedicated to detection of highly pathogenic group 3 or group 4 microorganisms in inactivated samples (1 in Lisbon and 1 in Águas de Moura); 1 BSL3 with capacity for animal experimentation (arthropods and mice).

2. INSTITUTO NACIONAL DE INVESTIGAÇÃO AGRÁRIA E VETERINÁRIA, I.P. (R&D STATE LABORATORY OF THE MINISTRY OF AGRICULTURE)

Form A, part 1 (i)

Exchange of data on research centres and laboratories

1.	**Name(s) of facility**	**Unit of Animal Health**
2.	Responsible public or private Organization or company	**Instituto Nacional de Investigação Agrária e Veterinária, I.P**. - public
3.	Location and postal address	**A) Rua General Morais Sarmento, 1500-301Lisboa;** **B) Rua dos Lagidos 4485-655 Vila do Conde – Vairão**

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

All activities are supported by the Ministry of Agriculture and by Ministry of Finance. Some R & D activities are supported by the Foundation for Science and Technology (Ministry of Education and Science).

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

No (none) BSL-4 Laboratories

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

The Instituto Nacional de Investigação Agrária e Veterinária, I.P. is a R&D State Laboratory of Ministry of Agriculture, situ in Benfica (Lisbon) and Vairão (Vila do Conde). The Laboratory's main activities are:

- **Laboratory diagnosis of animal diseases, including zoonoses.**
- **Performing R & D projects on diagnosis and epidemiology of animal diseases, including zoonoses.**

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**
Biosafety level 2 (if applicable)	**YES**

Any additional relevant information as appropriate:

- **1 Unit (125 m2) BSL 3 facility for TSE diseases, in Lisbon**
- **1 Unit (40 m2) BSL 3 Brucella, Lisbon**
- **1 Unit (100m2) BSL 3 Brucella, Vila do Conde**
- **1 Unit (30 m2) Micobacterium, Lisbon**
- **Total of 6500 m2 BSL2 for veterinary Pathology, Parasitology, Virology and Bacteriology**

3. LIFE AND HEALTH SCIENCES RESEARCH INSTITUTE – UNIVERSITY OF MINHO/SCHOOL OF HEALTH SCIENCES

Form A, part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility **Life and Health Sciences Research Institute**
2. Responsible public or private organization or company **University of Minho** - public
3. Location and postal address **School of Health Sciences, Campus de Gualtar University of Minho, 4710-057 Braga Portugal**

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

All R&D activities are supported by the Foundation for Science and Technology (Ministry of Education and Science), Calouste Gulbenkian Foundation and the EU Seventh Framework Programme.

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

No (none) BSL-4 Laboratories

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

R&D projects on microbiological and immunological aspects of infectious diseases (risk group 1, 2, and 3), namely tuberculosis, buruli ulcer, and paracoccidioidomycosis

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**
Biosafety level 2 (if applicable)	**YES**

Any additional relevant information as appropriate:

BSL2: 38.4 m^2

BSL3 (facility 1): 38.8 m^2

BSL3 (facility 2): 76.8 m^2

4. DEPARTAMENTO DE FARMÁCIA GALÉNICA E TECNOLOGIA FARMACÊUTICA (DFGTF), FACULDADE DE FARMÁCIA DA UNIVERSIDADE DE LISBOA (DEPARTMENT OF GALENIC PHARMACY AND PHARMACEUTICAL TECHNOLOGY, FACULTY OF PHARMACY, UNIVERSITY OF LISBON)

Form A, part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility — **Departamento de Farmácia Galénica e Tecnologia Farmacêutica (DFGTF)**
2. Responsible public or private organization or company — **Faculdade de Farmácia da Universidade de Lisboa** – public
3. Location and postal address — **Avenida Professor Gama Pinto, 1649-003 Lisboa, PT**

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Funding comes from the Ministry of Education and Science, private entities and industry,

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

No (none) BSL-4 Laboratories

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

Qualification of microorganisms of risk group 2 used *in vitro* and *in vivo* assays.

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**
Biosafety level 2 (if applicable)	**YES**

Any additional relevant information as appropriate: **One BSL-2 Laboratory with 20 m^2**

5. DEPARTAMENTO DE MICROBIOLOGIA E IMUNOLOGIA (DMI), FACULDADE DE FARMÁCIA DA UNIVERSIDADE DE LISBOA (DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY, FACULTY OF PHARMACY, UNIVERSITY OF LISBON)

Form A, part 1 (i)

Exchange of data on research centres and laboratories

1.	Name(s) of facility	**Departamento de Microbiologia e Imunologia (DMI)**
2.	Responsible public or private organization or company	**Faculdade de Farmácia da Universidade de Lisboa** – public
3.	Location and postal address	**Avenida Professor Gama Pinto, 1649-003 Lisboa, PT**

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Funding comes from the Ministry of Education and Science, private entities and industry,

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

No (none) BSL-4 Laboratories

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

Isolation and characterisation of microorganisms of risk group 1, 2 and 3. In addition DMI has a few laboratories BSL-1 dedicated to teaching and diagnosis of human microbial pathogens.

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**
Biosafety level 2 (if applicable)	**NO**

Any additional relevant information as appropriate: **One BSL-3 Laboratory with 25 m^2**

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.

LBDB only performs research in detection and decontamination of biological agents. No development programmes of national biological defence are being conducted.

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

Detection: 212000 €

Decontamination: 50000€

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?

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)

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?

Laboratório de Bromatologia e Defesa Biológica do Exército (LBDB)/ Portuguese Army Biological Defence Laboratory

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

Avenida Doutor Alfredo Bensaúde, Edifício do Laboratório Militar, 4ºPiso, 1849-012 Lisboa, Portugal

3. Floor area of laboratory areas by containment level:

BL2 **30** (sqM)

BL3 **51** (sqM)

BL4 **none** (sqM)

Total laboratory floor area **81** (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel **14**

(ii) Division of personnel:

Military **14**

Civilian **0**

(iii) Division of personnel by category:

Scientists **10**

Engineers **0**

Technicians **3**

Administrative and support staff **1**

(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.

No

(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?

The funding is provided by the Ministry of Defence and some research projects by European Defence Agency and European Union.

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

Research	**75%**
Development	
Test and evaluation	**25%**

(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-organisms[1] and/or toxins studied, as well as outdoor studies of biological aerosols.

The wok Carried out is related to the implementation of biosafety procedures, biodecontamination procedures and also with detection of biological agents.

[1] 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 agent[2] 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] It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

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[3]

1. Time of cognizance of the outbreak

NOTHING TO DECLARE

[3] 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

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.

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

Relating to	Legislation	Regulations	Other measures[4]	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**	**YES**	**YES**	**NO**
(b) Exports of micro-organisms[5] and toxins	**YES**	**YES**	**YES**	**NO**
(c) Imports of micro-organisms[11] and toxins	**YES**	**YES**	**YES**	**NO**
(d) Biosafety[6] and biosecurity[7]	**YES**	**YES**	**YES**	**NO**

[4] Including guidelines.
[5] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[6] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national

Confidence-Building Measure "F"

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:

29-06-1972

2. Past offensive biological research and development programmes:

- **No**

- Period(s) of activities

2009-2014

3. Past defensive biological research and development programmes:

- **Yes**

- Period(s) of activities

2009-2014

- 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.

Research in development of new technologies for detection of biological agents and in decontamination of biological agents.

or international guidance.

[7] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

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:

GenIbet Biopharmaceuticals

2. Location (mailing address):

Edifício da Unidade Piloto do IBET

Estação Agronómica Nacional

Avenida da República

2780-157 Oeiras

Portugal

3. General description of the types of diseases covered:

GenIbet is a cGMP biopharmaceutical CMO (Contract Manufacturing Organization) offering specialized microbial, cell culture and viral process development and cGMP manufacturing services to research groups, biotech and pharma companies. GenIbet's activity is the manufacture and supply of materials for use in early stage drug development, pre-clinical studies and cGMP manufacturing for Phase I and II clinical trials, comprising:

A Bacterial Unit (BL2 fermentation room),

A Viral Unit for gene therapies and vaccines (BL2 bioreaction and downstream rooms),

An Animal Cell Culture Unit, (BL2 room)

On going Projects:

Development and scale up of process for the production of a cGMP oncolytic virus