Annex to Final Declaration on Confidence-building measures

At the Third Review Conference it was agreed that all States Parties present the following declaration:

1. 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
A, part 1	☐	☐
A, part 2 (i)	☐	☐
A, part 2 (ii)	☐	☐
A, part 2 (iii)	☐	☐
B (I)	☐	☐
B (ii)	☐	☐
C	☐	☐
D	☐	☐
E	☐	☐
F	☐	☐
G	☐	☐

(Please mark the appropriate box(es) for each measure, with a tick.)

Date: _____

State Party to the Convention: _____

2. 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 that 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 1983 WHO Laboratory Biosafety Manual such as those designated as biosafety level 4 (BL4) or P4 or equivalent standards.

Form A, part 1

Exchange of data on research centres and laboratories[1]

1. Name(s) of facility[2] _____

2. Responsible public or private organization or company _____

3. Location and postal address _____

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

_____

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)

_____

6. If no maximum containment unit, indicate highest level of protection

_____

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

_____

[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 1983 WHO Laboratory Biosafety Manual, or equivalent.

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 programme Declaration

Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme 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 the programme.

Form A, part 2 (ii)

National biological defence research and development programme

Description

1. State the objectives and funding of the 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.

DETECTION AND DECONTAMINATION

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

100 000 EUROS

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

NO

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

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

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

The organization includes the Head of programme, the scientific staff, and support staff

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 the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

The internal organization includes the head of the programme, the scientific staff and the support staff.
The research programme Acivities are reported to the ministry of defence through the command of the army.

National biological defence research and development programme

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?
   Laboratorio de Bromatologia e de Defesa Biologica
2. Where is it located (include both address and geographical location)?
   Avenida Doutor Alfredo Bensaude, edificio do Laboratorio Militar, 4 piso. Lisboa
3. Floor area of laboratory areas by containment level:

   BL2 _30_____ (sqM)

   BL3 _51_____ (sqM)

   BL4 _____ (sqM)

   Total laboratory floor area 81_____ (sqM)

4. The organizational structure of each facility.

   (i) Total number of personnel _____7_____

   (ii) Division of personnel:

   Military _____7_____

   Civilian _____

   (iii) Division of personnel by category:

   Scientists _____5_____

   Engineers _____

   Technicians _____1_____

   Administrative and support staff _____1_____

   (iv) List the scientific disciplines represented in the scientific/ engineering staff.
   Molecular Biology; Immunology; Parasitology; Infecciology; Food Science

(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?

MINISTRY OF DEFENCE and European Defence Aency

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

Research 50%

Development _____

Test and evaluation 50%

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

NONE

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)

NONE

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[4] and/or toxins studied, as well as outdoor studies of biological aerosols.

The facility is in the third year of operation.
The work carried out relates to implemetation of biosafety procedures and testing of molecular methodology of detection.

[4] Including viruses and prions.

3. 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.

Modalities

The Third Review Conference agreed the following definition:

> An outbreak or epidemic is the occurrence of an unusually large or unexpected number of cases of an illness or health-related event in a given place at a given time. The number of cases considered as unusual will vary according to the illness or event and the community concerned.

Furthermore, reference was made to the following definitions:

> An epidemic of infectious disease is defined as the occurrence of an unusually large or unexpected number of cases of a disease known or suspected to be of infectious origin, for a given place and time. It is usually a rapidly evolving situation, requiring a rapid response (WHO internal document CDS/Mtg/82.1).
>
> The occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy. The community or region, and the time period in which the cases occur, are specified precisely. The number of cases indicating the presence of an epidemic will vary according to the agent, size and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence: epidemicity is thus relative to usual frequency of the disease in the same area, among the specified population, at the same season of the year. A single case of a communicable disease long absent from a population or first invasion by a disease not previously recognized in that area requires immediate reporting and full field investigation: two cases of such a disease associated in time and place may be sufficient evidence to be considered an epidemic. (J.M. Last, A Dictionary of Epidemiology, Oxford University Press, New York, Oxford, Toronto, 1983.)

The Third Review Conference agreed on the following:

1. In determining what constitutes an outbreak States Parties are recommended to take guidance from the above.

2. Since no universal standards exist for what might constitute a deviation from the normal pattern, States Parties agreed to utilize fully existing national reporting systems on human diseases as well as animal and plant diseases, where possible, and systems within the WHO to provide annual update of background information on diseases caused by organisms which meet the criteria for risk groups II, III and IV according to the classification in the 1983 WHO Laboratory Biosafety Manual, the occurrence of which, in their respective areas, does not necessarily constitute a deviation from normal patterns.[5]

3. 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[6] 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 1983 WHO Laboratory Biosafety Manual,

- When the causative agent is exotic to a given 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.

4. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that 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 (ii) should be used, to the extent information is known and/or applicable, for the exchange of initial as well as annual information.

5. 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.

---

[5] This information should be provided in accordance with Form B (I).

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

Form B (I)

Background information on outbreaks of reportable infectious diseases

Disease		Number of cases per year			
	1988	1989	1990	1991	1992

Form B (ii)

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 .....

4. 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.

5. CONFIDENCE-BUILDING MEASURE "D"

Active promotion of contacts

At the Third Review Conference it was 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."

Modalities

The Third Review Conference agreed on the following:

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, States parties are encouraged to provide information, to the extent possible:

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention,

- 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.

To enable States parties to follow a standardized procedure, the Third Review Conference has agreed that Form D should be used for exchange of information under this item.

Form D

Active promotion of contacts

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

For each such event, the following information should be provided:

- name of the conference, etc. .....
- arranging organization(s), etc. .....
- time .....
- place .....
- main subject(s) for the conference, etc. .....

.....

- conditions for participation .....

.....

- point of contact for further information, registration, etc. .....

.....

.....

2. Information regarding other opportunities

.....

.....

.....

6. CONFIDENCE-BUILDING MEASURE "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following:

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 the development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery, specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or control;

(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;

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 United Nations Department 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	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[7] and toxins	Yes/No	Yes/No	Yes/No	Yes/No
(c)	Imports of micro-organisms[7] and toxins	Yes/No	Yes/No	Yes/No	Yes/No

[7] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

7. 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.

2. Past offensive biological research and development programmes:

   - Yes - 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:

   - Yes - 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.

8. 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:

2. Location (mailing address):

3. General description of the types of diseases covered:

8. 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):

GenIbet BioPharmaceuticals
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:

Thypoid Fever (Phase I and Phase II Clinical Trials)