ROMANIA

Confidence Building Measure Return
(covering data for 2019)

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, 10 April 1972

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

(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: **15 October 2019**

State Party to the Convention: **ROMANIA**

Date of ratification/accession to the Convention: **25 July 1979**

National point of contact: **OSCE, Non-Proliferation and Arms Control Directorate**

Ministry of Foreign Affairs

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Active promotion of contacts

The Third Review Conference 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."

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, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

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

- 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,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

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 on the following, later amended by the Seventh Review Conference:

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 latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE[2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

1. Name(s) of facility[4] _____

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

[1] World Health Organization

[2] World Organization for Animal Health

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

[4] 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)".

_____

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

_____

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

_____

_____

_____

[5] 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[6] on a State Party's territory:

Biosafety level 3[7]	**No (under construction)**
Biosafety level 2[8] (if applicable)	**yes**

Any additional relevant information as appropriate:

The facility operating the BSL 2+ containment laboratory is the **Military Medical Research Center**, located in Bucharest, Institutul Medico – Militar street, District 1. The public institution responsible for the reported activity is the Ministry of National Defence, which finances it completely. For daily activities, the specialists work in the Level 2+ laboratory.

[6] Microorganisms pathogenic to humans and/or animals

[7] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[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.

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[9] on a State Party's territory:

Biosafety level 3[10]	**yes (not fully operational, pending validation)**
Biosafety level 2[11] (if applicable)	**yes**

Any additional relevant information as appropriate:

The National Institute for Infectious Diseases "Matei Balș" Bucharest (INBI MB) is the most important Romanian medical institution in charge with the management of patients with infectious diseases and consequently with victims of incidents involving biological agents. INBI MB is currently being charged by the Ministry of Health with the management of patients in case of out of the ordinary outbreaks (major, unusual, pandemic, such as the early stages of the Ebola epidemic in West Africa in 2014, when INBI MB was charged with the management of the potential Ebola infected patients on Romanian territory). INBI MB provides scientific counselling regarding infectious diseases policies in Romania for the Ministry of Health and also performs tasks related to first response in unusual outbreaks (such as the ones triggered by SARS, MERS CoV, H7N9 or H5N1 influenza viruses etc.). INBI MB functions as the seat for the National Anti-AIDS Commission (www.cnlas.ro), managing the prevention and treatment of AIDS on national level.

INBI MB is also involved in medical research, having a very modern and state of the art equipped Centre for Biomolecular Applied Research in Infectious Diseases, **including BSL2 and BSL3 facilities**. This laboratory facility is located in a 4 floor (plus a 5th technical floor) building with over 3300 sqm and has several dedicated areas for virology, bacteriology, molecular biology, genetics, immunology, clinical biochemistry as well as imagistics (radiology, CT, MRI etc. for patient use). These laboratories are employed in diagnostic and applied research activities, including test validation, test development and microbiological surveys. The primary objectives of these facilities are to provide a capability allowing Romania to:

- Survey human health status in relation with circulating pathogenic strains (microbiological surveillance);
- Identification of strains of certain micro-organisms not usually found in this country.

[9] Microorganisms pathogenic to humans and/or animals

[10] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[11] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

The **BSL3 facilities** are located at the second floor (areas dedicated to pathogenic fungi and Mycobacterium tuberculosis) but mainly at the 4th floor (540 sqm), with separated access from the ground level, includes a HLCC (High Level of Containment Care) infected patient management area (unique in Romania, designed for managing at least 2 patients simultaneously) as well as a nearby BSL3+ laboratory (with both glove box and level A suit systems), suited for diagnostic activities involving highly dangerous pathogens, up to P4 (including some of the select agents that have the potential to pose a severe threat to public health and safety). However, this capability refers mainly to diagnostic procedures performed on human biological samples (environmental samples will need further actions toward methods and techniques validation).

INBI MB **has no operational BSL4** and is not involved in any national biological defence research and development program.

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[12] on a State Party's territory:

Biosafety level 3[13]	**no**
Biosafety level 2[14] (if applicable)	**yes**

Any additional relevant information as appropriate:

The facility operating BSL2 containment laboratories is the research department of the **National Society "Pasteur Institute" SA** (Giulesti street no. 333, sector 6, Postal Code 060269, Bucharest). The source of financing of the reported activity is the Ministry of Education, the Pasteur Institute, SC Pasteur – Filipesti Branch SRL and SC Farmavet SA.

The research regards animal viruses, bacteria and parasites: epidemiological and pathological aspects, diagnosis methods, prophylactic / therapeutic bio/medical products (*Escherichia coli, Mycoplasma meleagridis, M. iowae, M. gallisepticum, M. synoviae, M. hyorhinis, M. hyodisenteriae, M. flocularis, Actinobacillus pleuropenumoniae, Haemophillus parasuis, Erysipelothrix rhusiopathiae, Lawsonia intracellularis, Bordetella bronchiseptica, Brachispira hyodisenteriae, Brachisipira pilosicoli*, porcine circovirus 2, porcine respiratory and reproductive syndrome virus, herpes viruses – Marek, Aujeszky, avian laringotracheitis, canine parvovirus, porcine parvovirus, porcine adenovirus, porcine sapelovirus, porcine A rotavirus, porcine epidemic diarrhea virus, avian rhinotracheitis virus, *Ornithobacterium rhinotracheale*, avian adenoviruses, avian coronavirus, avian leukosis viruses, avipox virus, avian bursitis virus, avian reovirus, avian metapneumovirus, rabies virus, *Toxoplasma gondii, Chlamydophila abortus, Mycoplasma agalactiae, Clostridium perfringens, Clostridium septicum, Clostridium novyi, Clostridium chauvoei, Pasteurella multocida* indol-, *Brucella ovis, Leptospira* spp). Diagnostic services for animal breeders and livestock farms are also provided.

The laboratories activities are organized in accordance to ISO 9001:2008 and for some of their methods to ISO 17025:2005 requirements.

[12] Microorganisms pathogenic to humans and/or animals

[13] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[14] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

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[15] on a State Party's territory:

Biosafety level 3[16]	**yes (not operational)**
Biosafety level 2[17] (if applicable)	**yes**

Any additional relevant information as appropriate:

The "Cantacuzino" National Medico-Military Institute for Research and Development ("Cantacuzino" NMMIRD), located in Bucharest, operates several BSL2 containment laboratories (totalling 739.42 sqm) within the Department of Microbiology for Public Health (Viral Respiratory Infections Laboratory, Bacterial Respiratory Infections Laboratory, Viral Enteric Infections Laboratory, Vector Borne Diseases Laboratory, Sexually Transmitted Diseases Laboratory, Bacterial Enteric Infections Laboratory, Nosocomial Infections Laboratory, Anaerobical and Zoonosis Infections Laboratory, Parasitology, Molecular Epidemiology Laboratory) and the Department of Research and Development. These laboratories are employed in diagnostic and applied research activities, including test validation, test development and microbiological surveys of bacterial, viral, parasitic and mycotic diseases.

The primary objectives of these facilities are to provide a capability allowing Romania to:
- Survey human health status in relation with circulating pathogenic strains (microbiological surveillance);
- Identification of strains of certain micro-organisms not usually found in Romania.

"Cantacuzino" NMMIRD has a BSL3 facility (totalling 175 sqm) within the Department of Microbiology for Public Health, intended for diagnostic and applied research activities. Currently the BSL3 facility is not operational, as there still are several validation procedures to be performed.

"Cantacuzino" NMMIRD has no operational BSL4.

"Cantacuzino" NMMIRD is not involved in any national biological defense research and development programme.

[15] Microorganisms pathogenic to humans and/or animals
[16] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
[17] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

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[18] on a State Party's territory:

Biosafety level 3[19]	**yes**
Biosafety level 2[20] (if applicable)	**yes**

Any additional relevant information as appropriate:

Romania's National Sanitary Veterinary and Food Safety Authority (NSVFSA) operates a BSL3 containment laboratory, component of the **Institute for Diagnosis and Animal Health/ IDAH** (located in Bucharest, Dr. N. Staicovici street, no. 63, sector 5, zip code 050557; Phone: +40/374.322.013, Fax: . +40/21.411.33.94, e-mail: office@idah.ro , web: www.idah.ro/).

It is used for diagnostic in animal health and welfare; including test validation, and surveys, and participation to the international inter-comparison and proficiency tests. Primary objectives are to have a capability allowing Romania to:
- demonstrate its animal health status; and
- demonstrate strains of certain micro-organisms not found in this country.

The Institute for Diagnosis and Animal Health is a governmental institution with public financing and has no national biological defence research and development programme.

[18] Microorganisms pathogenic to humans and/or animals
[19] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
[20] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

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[21] on a State Party's territory:

Biosafety level 3[22]	**no**
Biosafety level 2[23] (if applicable)	**yes**

Any additional relevant information as appropriate:

The Institute for Hygiene and Veterinary Public Health (IHVPH), located in Bucharest, Campul Mosilor street no. 5, sector 2, postal code 021201, operates several BSL2 containment laboratories. Its source of financing comes only from the National Sanitary Veterinary and Food Safety Authority.

The Institute is the national reference laboratory in the field of animal origin products, food and animal feeding stuffs. Some of the main duties include activities of guidance, proficiency tests, technical co-ordination and control of the county Sanitary Veterinary Food Safety laboratories, sanitary veterinary expertise for animal origin foodstuffs, caring out of results confirmation for laboratory testing, participation in the development of guidelines, instructions and technical details in the field of food safety and participation in the assessment proceedings for the authorization of veterinary microbiology laboratory.

The types of the micro-organisms used in daily activities are mentioned in the following table:

No.	Micro-organism	Reference
1.	Bacillus subtilis subsp. spizizenii	ATCC 6633
2.	Clostridium perfringens	ATCC 13124
3.	Citrobacter freundii	ATCC 43864
4.	Escherichia coli	ATCC 8739
5.	Listeria monocytogenes	ATCC 19111
6.	Listeria innocua	ATCC 33090
7.	Listeria ivanovii subsp. ivanovii	ATCC 19119
8.	Pseudmonas aeruginosa	ATCC 27853
9.	Staphylococcus aureus subsp. aureus	ATCC 6538
10.	Vibrio parahaemolyticus	ATCC 17802
11.	Rhodococcus equi	ATCC 6939

[21] Microorganisms pathogenic to humans and/or animals

[22] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[23] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

12.	Salmonella enterica subsp. enterica serovar enteritidis	ATCC 13076
13.	Salmonella enterica subsp. enterica serovar typhimurium	ATCC 14028
14.	Staphylococcus epidermidis	ATCC 12228
15.	Aspergillus brasiliensis	ATCC 16404
16.	Bacillus cereus	ATCC 11778
17.	Campylobacter jejuni subsp. jejuni	ATCC 33291
18.	Cronobacter muytjensii	ATCC 51329
19.	Enterococcus faecalis	ATCC 29212
20.	Saccharomyces kudriavzevii	ATCC 2601
21.	Yersinia enterocolitica subsp. enterocolitica	ATCC 23715
22.	E. coli O103	ref. EURL VTEC B07
23.	E. coli O111	ref. EURL VTEC A07
24.	E. coli O157	ref. EURL VTEC C07
25.	E. coli O145	ref. EURL VTEC E07
26.	E. coli O26	ref. EURL VTEC D07
27.	E. coli O104:K-H12	ref. SSI H519
28.	E. coli O113:H21	ref. SSI 6182-50
29.	E. coli O55:H-	ref. SSI Su 3912-41
30.	E. coli O121:K-:H10	ref. SSI 39w
31.	E. coli O128ab:H2	ref. SSI Cigleris
32.	E. coli O146:K-:H21	ref. SSI CDC2950-54
33.	E. coli O91:K-:H-	ref. SSI H307B
34.	E. coli O104:H4	ref. SSI D4116
35.	Salmonella Braenderup	ref. SSI H9812
36.	E. coli	ref. EURL VTEC SSI-NN14
37.	E. coli	ref. EURL VTEC EA22
38.	E. coli	ref. EURL VTEC SSI-OO15
39.	E. coli	ref. SSI D2653
40.	E. coli	ref. SSI D3602
41.	E. coli	ref. SSI D3522
42.	E. coli	ref. SSI D3428
43.	E. coli	ref. SSI D3648
44.	E. coli	ref. SSI D3546
45.	E. coli	ref. SSI D3509
46.	E. coli	ref. SSI D3431
47.	E. coli	ref. SSI D4134
48.	Staphylococcus aureus	ref. EURL CPS FRI 137
49.	Staphylococcus aureus	ref. EURL CPS FRI 361
50.	Staphylococcus aureus	ref. EURL CPS A900322
51.	Staphylococcus aureus	ref. EURL CPS FRI S6
52.	Staphylococcus aureus	ref. EURL CPS FRI 326
53.	Listeria monocytogenes	ref. Anses 00EB248LM ref. collection Pasteur Institute Clip74902
54.	Listeria monocytogenes	ref. Anses EURL LM 00EB249LM ref. collection Pasteur

		Institute Clip74903
55.	Listeria monocytogenes	ref. Anses EURL LM 00EB250LM ref. collection Pasteur Institute Clip74904
56.	Listeria monocytogenes	ref. Anses EURL LM 00EB254LM ref. collection Pasteur Institute Clip74908
57.	Listeria monocytogenes	ref. Anses EURL LM 00EB256LM ref. collection Pasteur Institute Clip74910
58.	Norovirus G I	lenticule disc-Certified Reference Material from Public Health England
59.	Norovirus G II	lenticule disc-Certified Reference Material from Public Health England
60.	Hepatitis A virus	lenticule disc-Certified Reference Material from Public Health England
61.	Clostridium botulinum type B	Strain isolated by IHVPH in food
62.	Clostridium botulinum type E	Strain isolated by IHVPH in food
63.	Clostridium botulinum type B	NCTC 7273 Public Health England
64.	Clostridium botulinum type E	NCTC 7272 Public Health England
65.	Clostridium botulinum type F	NCTC 10281 Public Health England
66.	Vibrio vulnificus	NC 13647 Public Health England
67.	Vibrio cholerae	NC 11348 Public Health England
68.	Vibrio parahaemolyticus	NC 10885 Public Health England
69.	Vibrio parahaemolyticus	NC 10884 Public Health England
70.	Vibrio parahaemolyticus	NC 10903 Public Health England

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[24] on a State Party's territory:

Biosafety level 3[25]	**no**
Biosafety level 2[26] (if applicable)	**yes**

Any additional relevant information as appropriate:

The Institute for Control of Veterinary Biological Products and Medicines (ICVBPM), located in Bucharest, 39 Dudului Street, sector 6, Romania, is a unit with juridical status, functioning as a national reference institute, under the technical subordination of the National Sanitary Veterinary and Food Safety Authority. ICVBPM has competence in the field of veterinary medicinal products, biocides, feed additives, diagnosis sets, other veterinary products (vitamins, mineral supplements and cosmetics).

The main task with relevance on these issues is quality control of veterinary of live and inactivated vaccines for bacterial, viral, parasites:

- live vaccines against distemper, infectious hepatitis, infectious laryngotracheitis, parvovirosis and parainfluenza in dogs,
- inactivated vaccine for rabies,
- live and inactivated vaccines for panleucopenia, calicivirus and herpesvirus infection of cats,
- live and inactivated vaccines for IBR, BVD and SRB of bovine,
- rabies live vaccine for oral immunization in foxes,
- live vaccines against Aujeszky virus for pigs,
- live vaccine against myxomatosis and inactivated vaccines for Infectious Rabbit Hemorrhagic Disease,
- live vaccine against infectious bronchitis in poultry, infectious bursitis in poutry (Gumboro disease), Newcastle disease in poultry, inactivated vaccine against the egg drop syndrome, Inactivated vaccine against Newcastle disease and infectious bursitis in poultry,
- vaccine against porcine parvovirosis, inactivated,
- vaccine against leptospirosis in dogs and furry animals,
- inactivated vaccine against equine influenza and tetanus,
- inactivated vaccines against parvovirosis and swine erysipelas,
- live vaccine against antrax with B. Anthracis, attenuated strain 1190 R,
- live vaccines for Salmonella in poultry,
- vaccine inactivated against avian Cholerae.

[24] Microorganisms pathogenic to humans and/or animals

[25] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[26] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Quality control of veterinary pharmaceutical products (antimicrobial, anti-inflammatory, antiparasitics, etc.). To perform the quality control of pharmaceutical products is used the microorganisms test as bellow:

- Staphylococcus aureus ATCC 6538,
- Bacillus subtilis ATCC 6633, NCTC 2589,
- Pseudomonasaeruginosa ATCC 9027,
- Clostridium sporogenes ATCC 11437,
- Candida albicans ATCC 10231,
- Aspergillus Brasiliensis ATCC16404,
- Escherichia coli ATCC 8739, ATCC 10536, ATCC 1133,
- Salmonella enterica subsp. Enterica serovariant typhimurium ATCC 14028,
- Saccharomyces cerevisiae ATCC 2601,
- Micrococcus luteus ATCC 10240, ATCC 9341,
- Bordetella bronchiseptica ATCC 4617,
- Bacillus pumilus NCTC 8241, CIP 76.18,
- Staphylococcus epidermitis NCIMB 8853, CIP 68.21, ATCC 12228,
- Candida tropicalis CIP 1433-83, NCYC 1393,
- Bacillus spizizenii ATCC 4617,
- Streptococcus faecalis 8043.

Diagnostic test kits: for viral, bacterial and parasites disease by following tests: ELISA, immunodifusion test, complement bond reaction, slow and quick agglutination, immunofluorescent test, immunoperoxidase test.

The laboratory's activities are organized and performed according to ISO 17025:2005 requirements and ISO 9001:2008 requirements.

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 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.

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

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?

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?

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

3. Floor area of laboratory areas by containment level:

BL2 _____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

(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.

(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?

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

Research _____

Development _____

Test and evaluation _____

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

[27] 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[28] 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. 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

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

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[29]

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 _____

[29] 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.

Romania encourages publication of results of biological research directly related to the Convention provided it is in compliance with good biosecurity practices.

- **Scientific meetings / Scientific communications / posters**

1. **Popa M., Dinu H., Negru E., Daneș M. 2019**, Pasteur heptavalent vaccine protects against a broader spectrum of Clostridium species, Annual scientific session „Animal breeding and pathology to day", 23 – 24mai, USAMV Timisoara

2. **Mitrică Mărăcine D. C., Popa V., Herman V., Iancu I., Cătană N. 2019**, Research on the frequency of some strains of avian coronavirus in an outbreak of infectious bronchitis, Annual scientific session „Animal breeding and pathology to day", 23 – 24mai, USAMV Timisoara

3. **Mitrică Măracine D. C., Popa V., Herman V., Iancu I., Cătană N. 2019**, Research on the detection of strains belonging to the very virulent pathotypes of avian infectious bursitis, Annual scientific session „Animal breeding and pathology to day", 23 – 24mai, USAMV Timisoara

4. **Virgilia Popa, M. Culcescu, Daniela Botus, Anca Bulgaru, Mirela Popa, H. Dinu, M. Danes 2019**, Evaluation of the protection induced by the "Agavac" vaccine used in the prophylaxis of contagious agalaxy of small ruminants, Jubilee of the Academy of

Agricultural and Forestry Sciences and 92 years of institutionalized agricultural research in Romania, 3 – 4 October 2019, Bucharest

- **Published papers 2019**

1. **M. Brebi, K. Beleno, R. Ionescu, D. Turcu, M. Danes, I. Bogolin 2019**, Volatolomic analysis applied to farm animals. I. Volatile compounds in respiration of cattle, Annals of Spiru Haret University – Veterinary Medicine Series, 20 (1): 5-10

2. **Dumitru Militaru, Virgilia Popa, Beatrice Știrbu, Daniela Botuș, Mihai Daneș 2019**, Classical PCR multiplex assay for concomitant detection and discrimination of eight species and one genotype of Trichinella spp, Scientific research offer for technological transfer in agriculture, food industry and forestry, published by the Ministry Agriculture and Rural Development – Academy of Agricultural and Forestry Sciences "Gheorghe Ionescu – Sisești", Coordinator: Prof. Univ. Emeritus Dr. Ing. Dr. H.C. Valeriu Tabara, Ceres Publishing House, Bucharest, ISSN 1844-0355, 22: 189-192

3. **Popa V., Culcescu M., Botuș D., Floarea A., Popa M., Dinu H., Daneș M. 2019**, Efficacy assessment of the AGAVAC vaccine destined for contagious agalactia prophylaxis in small ruminants, on guinea pig, Short communication, Scientifical Papers: Veterinary Medicine Timisoara 52(2): 82-89, ISSN:1221-5295, USAMV Timişoara

4. **Ciucă V. 2019**, Validation studies for determination of nitrogenprotein from biological products by Kjeldahl method, Scientifical Papers: Veterinary Medicine Timisoara 52(3): 31-36, ISSN:1221-5295, USAMV Timişoara

5. **Viviana Ciuca, V. V. Safta, Romeo T. Cristina 2019**, Algorithm for the calculus of non effective predictable concentration (PNEC) for evaluation of the environmental risk of the veterinary medicinal products, Medicamentul Veterinar / Veterinary Drug 13(1): 53 – 59, P - ISSN 1843-9527, E -ISSN 2069-2463, URL:

http://www.veterinarypharmacon.com/page/vet_drug_download

6. **Viviana Ciuca, V. V. Safta, Romeo T. Cristina 2019**, Environmental risk determination algorithm for veterinary medicinal products, Medicamentul Veterinar / Veterinary Drug 13 (2): 22-27, P - ISSN 1843-9527, E -ISSN 2069-2463, URL:

http://www.veterinarypharmacon.com/page/vet_drug_download

- **International cooperation in scientific research**

Responsible from Pasteur Institute	Project	Cooperation
Dr. Mihai Danes	bTb-Test Bovine tuberculosis (bTb) caused by *Mycobacterium bovis* (*M.bovis*) and other members of the *M tuberculosis* complex	EU: Marie Sklodowska-Curie Actions, Research and Innovation Staff Exchange (RISE), Call: H2020-MSCA-RISE-2017 / USH / SC Pasteur Filiala Filipesti Srl

- **Published papers generated through research and development activities performed within "Cantacuzino" NMMIRD in 2019**

1. Popovici ED, Negru DG, Olariu T, Nagy M, Dinu S, Oprisan G, Zota L, Baditoiu LM. Application of the susceptible-infected-recovered deterministic model in a GII.P17 emergent norovirus strain outbreak in Romania in 2015. ***Infect Drug Resist.*** 2019 Aug 16;12:2543-2551. doi: 10.2147/IDR.S204175.

2. Mădălina Tudose, Elena Maria Anghel, Daniela C. Culiţa, Simona Somacescu, Jose Calderon-Moreno, Victoriţa Tecuceanu, Florea D. Dumitraşcu, Olguta Drăcea, Marcel Popa, Luminiţa Măruţescu, Coralia Bleotu, Carmen Curuţiu, Mariana C. Chifiriuc, Covalent coupling of tuberculostatic agents and graphene oxide: a promising approach for enhancing and extending their antimicrobial applications, ***Applied Surface Science (IF 4.439)*** 2019, 471:553-565, DOI: 10.1016/j.apsusc.2018.11.242

3. Daniela Cristea, Marius Trandafir, Violeta Claudia Bojincă, Adriana Simona Ciontea, Melania Mihaela Andrei, Andrei Popa, Brânduşa Elena Lixandru, Cornelia Mădălina Militaru, Alexandra Maria Năşcuţiu, Denisa Predeţeanu, Ruxandra Ionescu, Claudiu Popescu, Ani Ioana Cotar, Mircea Ioan Popa, Demetrios A. Spandidos and Irina Codiţă- „Usefulness of complex bacteriological and serological analysis in patients with spondyloarthritis" - ***Experimental and Therapeutic Medicine*** 17: 3465-3476, 2019 (DOI: 10.3892/etm.2019.7336)

4. David S, Reuter S, Harris SR, Glasner C, Feltwell T, Argimon S, Abudahab K, Goater R, Giani T, Errico G, Aspbury M, Sjunnebo S; EuSCAPE Working Group; ESGEM Study Group, Feil EJ, Rossolini GM, Aanensen DM, Grundmann H Collaborators (....., Lixandru B.....) Epidemic of carbapenem-resistant Klebsiella pneumoniae in Europe is driven by nosocomial spread. ***Nat Microbiol.*** 2019 Nov;4(11):1919-1929. doi: 10.1038/s41564-019-0492-8

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6. Mihaela Bacalum, Elena-Carmina Dragulescu, George Necula, Irina Codita & Mihai Radu. Short tryptophan- and arginine-rich peptide shows efficacy against clinical methicillin-resistant Staphylococcus aureus strains isolated from skin and soft tissue infections. 2019. ***Scientific Reports.*** 9:17176 | https://doi.org/10.1038/s41598-019-53926-4

7. Băncescu G, Dabu B, Defta C, Băncescu A. Investigation of nasal and pharingeal carriage of beta-hemolytic streptococci among dental students [abstract]. ***Rev Romana Med Lab*** 2019;27(2) suppl 1:S17. [ISI cu factor de impact]

8. Băicuș A. Monitoring Enterovirus and Norovirus circulation in sewage water using isolation on cell culture lines and GeneXpert system. ***Rom Biotechnol Lett.*** 2019; 24(5): 820-825. DOI: 10.25083/rbl/24.5/820.825

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influenza A(H3N2) among 15–64-year-olds in Europe: exploration by birth cohort. ***Euro Surveill.*** 2019;24(48):pii=1900604.

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Confidence-Building Measure "D"

(Deleted)

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[30]	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[31] and toxins	**Yes**	**Yes**	**No**	**Yes**

[30] Including guidelines.

(c) Imports of micro-organisms[11] and toxins	**Yes**	**No**	**No**	**Yes**
(d) Biosafety[32] and biosecurity[33]	**Yes**	**Yes**	**Yes**	**No**

Name of legislation, regulations and other measures

No	Specification	No	Year	Topic
1	Council Regulation (EC)	428	2009	Setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
2	Commission Delegated Regulation (EU) 2019/2199	2199	2019	Amending Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
3	Council Regulation (EU) 2015/1861	1861	2015	Modifying Council Regulation (EU) 267/2012 regarding restrictive measures against Iran
4	Government Ordinance	119	2010	Regarding the control regime of dual use operations
5	Law	197	2011	Approving Government Ordinance No 119/2010
6	Government Ordinance	12	2012	Modifying Government Ordinance No 119/2010
7	Law	35	2013	Approving Government Ordinance No 12/2012
8	Order of the Minister of Foreign Affairs	914	2012	Approving the regulation for implementing the provisions of Government Ordinance No 119/2010 regarding the control regime of dual-use operations
9	Order of the Minister of Foreign Affairs	358	2016	Approving the methodological norms for applying the provisions of Council Regulation (EU) 2015/1861 modifying Reg. (EU) 267/2012 regarding restrictive measures against Iran

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

[32] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

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

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.

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: The "Cantacuzino" National Medico-Military Institute for Research and Development, Bucharest

2. Location (mailing address): Splaiul Independentei 103 – 105, 050096, Sector 5, Bucharest, Romania

3. General description of the types of diseases covered:

While the "Cantacuzino" NMMIRD has a production facility and has, in the past, produced several vaccines, the facility is not currently operational. A Trivalent Northern Hemisphere Influenza Vaccine (egg-adapted influenza virus) was manufactured at this facility, as was a monovalent vaccine for the pandemic A/H1N1v strain. A BCG vaccine was also manufactured at the facility.

Form G

Declaration of vaccine production facilities

1. Name of facility: SC Pasteur – Filiala Filipesti Srl, working point Bucharest

2. Location (mailing address): 333 Giulesti Str., 060269 Bucharest, sector 6, Romania;

Phone: +40212209909; fax: +40212206915; email: office@pasteur.ro

3. General description of the types of diseases covered: animal diseases (viral, bacterial diseases).

Form G

Declaration of vaccine production facilities

1. Name of facility: ROMVAC COMPANY S.A.

2. Location (mailing address): 7 Centurii Drive, Voluntari, IF-077109, Romania; email: romvac@romvac.ro;

3. General description of the types of diseases covered: Carboromvac – live antrax vaccine for animals: cattle, sheep, goats, horses and swine.
