



ROMANIA

Confidence Building Measure Return (covering data for 2013)

**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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (i)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (ii)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (iii)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(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 April 2014**

State Party to the Convention: **ROMANIA**

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

National point of contact: **OSCE, Asymmetrical Risks and Non-Proliferation 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 WHO¹ Laboratory Biosafety Manual and/or OIE² 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 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents³ on a State Party's territory:

Biosafety level 3 ⁴	no (35 sqM – under construction)
Biosafety level 2 ⁵ (if applicable)	yes (52 sqM)

Any additional relevant information as appropriate:

¹ World Health Organization

² World Organization for Animal Health

³ Microorganisms pathogenic to humans and/or animals

⁴ In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

⁵ 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 facility operating the BSL 2 containment laboratory is the Military Medical Research Center, located in Bucharest, Gr. Cobalcescu street no. 24/28, 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.

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 agents⁶ on a State Party’s territory:

Biosafety level 3	no
Biosafety level 2 (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, District 6, Postal Code 060269, Bucharest). The source of financing of the reported activity is the Ministry of Education, Research, Youth and Sport and the Pasteur Institute.

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. floccularis*, porcine circovirus 2, porcine respiratory and reproductive syndrome virus, herpes viruses – Marek, Aujeszky, avian laringotracheitis, canine parvovirus, porcine parvovirus, porcine adenovirus, porcine sapelovirus, avian rhinotracheitis virus, *Ornithobacterium rhinotracheale*, avian coronavirus, avian leukosis viruses, avipox virus, avian bursitis virus, artemisinin in avian protozoal infections therapy), and to medicine residues in animals (LC-MS/MS methods).

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

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:

⁶ Microorganisms pathogenic to humans and/or animals

Biosafety level 3	yes
Biosafety level 2 (if applicable)	yes

The National Institute of Research and Development for Microbiology and Immunology (NIRDMI) “Cantacuzino”, Bucharest operates several BSL2 containment laboratories (totalling 739.42 sqm) within the Department of Microbiology for Public Health (Viral Respiratory Infections Laboratory, Vaccination Preventable Diseases Laboratory, Vector Borne Diseases Laboratory, Sexually Transmitted Diseases Laboratory, Bacterial Enteric Infections Laboratory, Nosocomial Infections Laboratory, Anaerobical, Fungal and Parazitological Infections Laboratory) and the Department of Research and Development (Innate Immunity Laboratory, Biotechnological Development Laboratory, Cellular and Molecular Immunity, Experimental Microbiology). These laboratories are used for diagnostic and applied research; including test validation, test development and surveys. Primary objectives are to have a capability allowing Romania to:

-survey of human health status in relation with circulating pathogenic strains (microbiological surveillance) ;

-identification of strains of certain micro-organisms not usually found in this country.

INCDMI “Cantacuzino”, Bucharest has an operational BSL3 facility (totalling 175 sqm) within the Department of Microbiology for Public Health, intended for diagnostic and applied research; including test validation, test development and surveys.

INCDMI “Cantacuzino”, Bucharest has no operational BSL4.

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	no
Biosafety level 2 (if applicable)	yes

The Institute for Hygiene and Veterinary Public Health, located in Bucharest, Campul Mosilor street no. 5, 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, carrying 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.

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 the publication of results of biological research directly related to the Convention, provided it is in compliance with good biosecurity practice.

NATIONAL INSTITUTE OF RESEARCH AND DEVELOPMENT FOR MICROBIOLOGY AND IMMUNOLOGY (NIRDMI) "CANTACUZINO"

- **List of 2013 ongoing international research projects**

1. Biology and control of vector borne infections in Europe (FP7 EDENext).
2. A generic framework for FAST production and evaluation of emergency VACCINES (DG SANCO/FASTVAC).
3. Development and Sustainable Manufacturing of Adjuvant Pandemic Influenza Vaccines in 4 Developing Countries (F16 SUB - 2010 BARDA 1 IDSE P 100008-01-00).
4. Combating flu in a combined action between the industry and the public sector in order to secure adequate and fast intervention in Europe (DG SANCO / FLUSECURE).
5. Therapeutic potential of modified pooled IgM and IgG preparations in experimental severe Response syndrome (SIRS) and sepsis (ACIP).
6. AquaVIR – Portable Automated Water Analyser for Viruses (FP7-NMP-2013-SMALL-7).
7. Mosquito-borne Usutu virus infection: dissecting molecular epidemiology and in vitro and ex-vivo characterization of innate immune responses (ACIP A-07-2013).

“PASTEUR” INSTITUTE

- **Scientific meetings / Scientific communications / posters (2012)**

Viviana Ciuca, Victorita Burghilea, Daniela Nita 2013: Validation studies of microbiological method for determining the antigen concentration of Antravac vaccine, Scientific Symposium of Cantacuzino Institute "Vaccine preventable diseases", Bucharest, November 21-22, 2013, published in *Romanian Archives of Microbiology and Immunology* 72 (3): 195 (ISSN 1222-3891)

Mihai Danes, Daniela Botus, Virgilia Popa, Mirela Popa, Miliana Petroff, Marian Culcescu, Alexandru Nicolae, Nicolai Poparlan, Jenica Bucur, Vlad Mihai Duma, Constatin Stirbu, Ionut Sorescu 2013: Aspects of control in vaccinated animals by PCR, immunological and histo-pathological tests, Scientific Symposium of Cantacuzino Institute "Vaccine preventable diseases", Bucharest, November 21-22, 2013, published in *Romanian Archives of Microbiology and Immunology* 72 (3): 189 (ISSN 1222-3891)

Mirela Popa, Miliana Petrof, Ionut Sorescu 2013: Molecular characterization of microbial strains for vaccine production, Scientific Symposium of Cantacuzino Institute "Vaccine preventable diseases", Bucharest, November 21-22, 2013, published in *Romanian Archives of Microbiology and Immunology* 72 (3): 188 (ISSN 1222-3891)

Eduard Marius Caplan, Daniela Lorin, Virgilia Popa, Jenica Bucur, Vlad Mihai Duma, Nicolai Poparlan 2013: Antibiotic resistance of Escherichia coli strains isolated from poultry during the period October 2012 - September 2013 in Pasteur Institute, Scientific Symposium of Cantacuzino Institute "Vaccine preventable diseases", Bucharest, November 21-22, 2013, published in *Romanian Archives of Microbiology and Immunology* 72 (3): 208 (ISSN 1222-3891)

Dumitru Militaru, Virgilia Popa, Daniela Botus, Beatrice Stirbu 2013: Studies on cytotoxicity and antibacterial effect of artemisinin, Scientific Symposium of Faculty of Veterinary Medicine, „Contribution of the scientific research to veterinary medicine progress”, Bucharest, November 21-22, 2013

- **Published papers 2013**

Virgilia Popa, Daniela Botus, Jenica Bucur, Vlad Mihai Duma, Marian Culcescu, Nicolai Poparlan 2013: Avian leukosis diagnostic and turkey specific *Mycoplasma* infections by PCR tests, Newsletter of SVMDAPSA / Avicol Magazine (ISSN 1841-0472)

/ Diagnosticul leucozelor aviare si al micoplasmozelor specifice curcilor prin teste de amplificare genetica PCR, Buletinul informativ al SMVPAAMR / Magazin Avicol (ISSN 1841-0472)

Popa Virgilia, Emilia Simion 2013, Classical PCR test based on B1 epitope gene sequence for molecular detection of Marek disease virus, Ministry of Agriculture and Rural Development, and Academy of Agricultural and Forestry. Scientific research offer for technology transfer in agriculture, food and forestry, Coordinator Gheorghe Sin, Volume 16/2013, Romanian Academy Publishing House ISSN 1844-0355, pg 186

/ Test PCR clasic pentru detectia moleculară a virusului bolii Marek prin evidentierea unei secvente din gena care codifica epitopul B1, MADR-ASAS. Oferta cercetarii stiintifice pentru transfer tehnologic in agricultura, industria alimentara si silvicultura, Coordonator Gheorghe Sin, vol. 16/2013, Ed. Academiei Romane ISSN 1844-0355, pg. 186

Popa Virgilia, Mirela Popa, Miliana Petrof, Emilia Simion 2013, Real-time Taqman PCR test for canine parvovirus type 2 molecular identification and typing, Ministry of Agriculture and Rural Development, and Academy of Agricultural and Forestry. Scientific research offer for technology transfer in agriculture, food and forestry, Coordinator Gheorghe Sin, Volume 16/2013, Romanian Academy Publishing House ISSN 1844-0355, pg 190-191

/ Test PCR în timp real (Real-Time PCR) in format Taqman pentru identificarea si tipizarea moleculară a parvovirusului canin tip 2, MADR-ASAS. Oferta cercetarii stiintifice pentru transfer tehnologic in agricultura, industria alimentara si silvicultura, Coordonator Gheorghe Sin, vol. 16/2013, Ed. Academiei Romane ISSN 1844-0355, pg. 190-191

Popa Virgilia, Emilia Simion 2013, Real-time PCR tests for avian infectious rhinotracheitis virus molecular identification and typing, Ministry of Agriculture and Rural Development, and Academy of Agricultural and Forestry. Scientific research offer for technology transfer in agriculture, food and forestry, Coordinator Gheorghe Sin, Volume 16/2013, Romanian Academy Publishing House ISSN 1844-0355, pg 188-189

/ Teste PCR în timp real (Real-Time PCR) pentru identificarea si tipizarea moleculară a virusului rinotraheitei infectioase aviare (Avimetapneumovirus). MADR-ASAS. Oferta cercetarii stiintifice pentru transfer tehnologic in agricultura, industria alimentara si silvicultura, Coordonator Gheorghe Sin, vol. 16/2013, Ed. Academiei Romane ISSN 1844-0355, pg. 188-189

Popa Virgilia, Emilia Simion 2013, Classical PCR test based on 16s rRNA gene sequence for molecular detection of *Ornithobacterium rhinotracheale*, Ministry of Agriculture and Rural Development, and Academy of Agricultural and Forestry. Scientific research offer for technology transfer in agriculture, food and forestry, Coordinator Gheorghe Sin, Volume 16/2013, Romanian Academy Publishing House ISSN 1844-0355, pg 187

/ Test PCR clasic pentru detectia moleculară a *Ornithobacterium rhinotracheale* prin evidentierea unei secvente din gena care codifica subunitatea 16s ARNr. MADR-ASAS. Oferta cercetarii stiintifice pentru transfer tehnologic in agricultura, industria alimentara si silvicultura, Coordonator Gheorghe Sin, vol. 16/2013, Ed. Academiei Romane ISSN 1844-0355, pg. 187

Popa Virgilia, Emilia Simion 2013, Classical multiplex PCR test for concomitant detection of *Mycoplasma gallisepticum* (MG) and *M. synoviae* (MS), Ministry of Agriculture and Rural Development, and Academy of Agricultural and Forestry. Scientific research offer for technology transfer in agriculture, food and forestry, Coordinator Gheorghe Sin, Volume 16/2013, Romanian Academy Publishing House ISSN 1844-0355, pg 184-185

/ Test multiplex PCR clasic pentru detectia concomitenta a *Mycoplasma gallisepticum* (MG) si a *Mycoplasma synoviae* (MS). MADR-ASAS. Oferta cercetarii stiintifice pentru transfer tehnologic in agricultura, industria alimentara si silvicultura, Coordonator Gheorghe Sin, vol. 16/2013, Ed. Academiei Romane ISSN 1844-0355, pg. 184-185

- International cooperation in scientific research**

Responsible from “Pasteur” Institute	Project	Cooperation
Virgilia Popa / Mihai Danes	Discontools, A European technology platform for global animal health, Development of the most effective tools to control infectious diseases in animals.	FP7-KBBE-2007-1

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

Name of legislation, regulations and other measures

No	Specification	No	Year	Topic
1.	Regulation (EU) of the European Parliament and of the Council	388	2012	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
2.	Government Ordinance	12	2012	Modifying Government Ordinance No 119/2010
3.	Law	35	2013	Approving Government Ordinance No 12/2012
4.	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

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: **National Institute of Research and Development for Microbiology and Immunology (NIRDMI) "Cantacuzino"**

2. Location (mailing address): **Independentei 103 – 105, 050096, District 5, Bucharest**

3. General description of the types of diseases covered: **Influenza vaccine (trivalent, pandemic – monovalent), BCG**

Northern Hemisphere Influenza vaccine (Trivalent) is manufactured at this facility - Cultivation of egg adapted influenza virus is performed. During the last influenza pandemic (A/H1N1v) monovalent vaccine has been manufactured.

Vaccine against tuberculosis is manufactured at this facility (using Calmette Guerin strain).

Form G

Declaration of vaccine production facilities

1. Name of facility: **National Society "Pasteur Institute" SA**

2. Location (mailing address): **333, Giulesti Str., 060269 Bucharest, district 6, Romania, phone: +40212206920; fax: +40212206915; e-mail: pasteur@pasteur.ro/ office@pasteur.ro / biomol.pasteur@pasteur.ro**

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

Form G

Declaration of vaccine production facilities

1. Name of facility: **S.C. Romvac Company S.A.**
2. Location (mailing address): **Șos. Centurii, no. 7, Voluntari**
3. General description of the types of diseases covered: **animal diseases (viral, bacterial, parasitic and nutritional diseases)**

Form G

Declaration of vaccine production facilities

1. Name of facility: **S.C. Pasteur Filiala Filipești S.R.L**
2. Location (mailing address): **Strada Principală 944, Filipeștii de Padure, Prahova**
3. General description of the types of diseases covered: **animal diseases (viral, bacterial, parasitic and nutritional diseases)**