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. <u>Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange</u>

Measure	Nothing to declare	Nothing new to declare
A, part 1	***X***	
A, part 2 (i)	***X***	
A, part 2 (ii)		
A, part 2 (iii)	***X***	
B (I)	***X***	
B (ii)		
C		
D		
E		
F		
G		

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

Date: ***1 August 2011***

State Party to the Convention: ***Republic of Latvia***

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] — *National Microbiology Reference laboratory*

2. **Responsible public or private organization or company** — *State Agency "Infectology Center of Latvia"*

3. **Location and postal address** — *3 Linezera street*
LV-1006, Riga
Latvia

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

State budget covers all financing. State Agency "Infectology center of Latvia" is under the supervision of Ministry of Health.

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

Maximum containment unit is Containment level 3 (BSL-3);
BSL-3 laboratory rooms have total size of 156,60 m^2.

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

As mentioned above – CL3 (BSL-3) laboratory rooms with Dangerous Infectious Diseases Diagnostic Division in it's structure. Laboratory performs rare, dangerous and emerging diseases diagnostic – including potential Bioterrorism agents detection.

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

State agency "Infectology center of Latvia" National Microbiology Reference Laboratory performs infectious diseases laboratory diagnostic for more than 800 Latvian customer organizations (local laboratories, hospitals, GP etc), provides reference services for Latvian local laboratories, Epidemiologic surveillance programs for infectious diseases, advisory service in a field of Laboratory Biosafety, Quality management and auditing, Rare and dangerous pathogen detection in BSL-3 suit. List of pathogens covered: Botulism, Brucellosis, Campylobacteriosis, Chlamydia infections, Cholera, Cryptosporidiosis, Diphtheria, Echinococcosis, Giardiasis, Gonococcal infections, Haemophilus influenza, Hepatitis A, Hepatitis B, Hepatitis C, HIV-infection, Influenza, Legionellosis, Leptospirosis, Listeriosis, Malaria, Measles, Meningococcal disease, Mumps, Nosocomial infections, Pathogenic, E.coli, Pertussis, Plague, Pneumococcal infections, Poliomyelitis, Rabies, Rubella, Salmonellosis, Shigellosis, Spongiform encephalopathies, Syphilis, Toxoplasmosis, Trichinosis, Tuberculosis, Viral haemorrhagic fevers, Yersinosis,

Adenovirus, Bacillus anthracis, Chikungunya, CMV, Francisella, Hantavirus, Hepatitis D, Hepatitis E, HPV, Norovirus, SARS, Staphylococcus/MRSA, Tularemia, West Nile virus, Dengue, Coxiella burnetti, TBE, Borrelia burgdorferi, Rickettsia, Mycoplasmae, Ehrlichiosis, Yellow fever virus, Japanese encephalitis virus, Crimean-Congo fever, Sandfly fever virus, Parvovirus B19, and others.

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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.

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

3. Are aspects of this programme 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 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).

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.

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?

State Agency "Infectology Center of Latvia"
National Microbiology Reference laboratory

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

3 Linezera street
LV-1006, Riga
Latvia

3. Floor area of laboratory areas by containment level:

BL2 2337.90 m^2 (sqM)

BL3 156,60 m^2 (sqM)

BL4 ---------- (sqM)

Total laboratory floor area 2494,50 m^2 (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel ***143***

(ii) Division of personnel:

Military ***0***

Civilian ***143***

(iii) Division of personnel by category:

Scientists ***56***

Engineers ***1***

Technicians ***60***

Administrative and support staff *26*

(iv) **List the scientific disciplines represented in the scientific/ engineering staff.**

Wide spectrum of microbiological investigations including rare, dangerous, emerging and Bioterrorism pathogens.

Testing areas of laboratory are:

Bacteriology, including mycology and TB diagnostic;
Virology;
Parasitology;
Molecular biology;
Serology.

(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?**

State budget covers all financing. State Agency "Infectology center of Latvia" is under supervision of Ministry of Health.

(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:**

Laboratory is working according to ISO 15189 standard requirements. ISO 15190 standard requirements are also implemented.

The hazards are identified and documented in Biosafety Manual Actual Edition as documents describing Hazard Microorganism classification, Room and facilities classification, PPE usage, Utilization and safe waste management etc.

Laboratory continuously carries out internal audits in Biosafety and Biosecurity provision system. Laboratory is audited by National accreditation body LATAK (Latvian National Accreditation Bureau), according to LVS EN ISO 15189 standard requires every year.

(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.)

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.

TRAINING: Laboratory personnel, involved in work with pathogens, are well trained due to continuous training programs within laboratory. Training organized and supervised by vice director in laboratory affairs, laboratory biosafety officer, Quality assurance manager, as well as head's of departments. Staff which is responsible for training of employees who are involved in BSL3(CL3) suite has been trained in the United Kingdom's Health Protection Agency BSL-3/4 laboratory (UK, Salisbury, Health Protection Agency, Centre for Emergency Preparedness and Respons).

The training is on regular basis. Training program consists of two parts – theoretical course of lectures and practical training exercises in laboratory rooms. All personnel undergo training before start to work in laboratory and confirm their skills undergoing training at least ones a year.

DETECTION: According to epidemiological situation and diagnostic needs laboratory is ready to perform "classical" new emerging pathogen detection and characterisation. For the preparedness needs laboratory satisfy investigation needs for group A and B potential bioterrorism pathogen detection.

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.

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[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[#]				
	2006	**2007**	**2008**	**2009**	**2010**
Salmonellosis*	***11/236***	***3/25***	***13/219***	***10/270***	***13/248***
Shigellosis*	***2/14***	***1/19***	***2/21***		
Acute intestinal infection with mixed aetiology*	***3/24***		***1/2***		
Rotaviruss gastroenteritis*	***2/12***	***1/5***	***1/5***	***5/33***	***6/57***
Noroviruss gastroenteritis*		***1/42***	***4/55***	***7/100***	***2/33***
Other acute intestinal infection with certain aetiology*	***1/6***	***2/14***	***1/6***	***2/20***	***2/14***
Acute intestinal infection with unknown aetiology*	***1/13***	***1/6***	***2/21***	***1/12***	
Hepatitis A	***1/13***		***231/522***	***38/396***	***6/54***
Hepatitis B					***3/10***
Yersiniosis			***1/2***		
Mumps					
Pertussis					
Diphtheria**	***5/15***				
Rubella					
Meningococcal infections**				***1/2+1***	***2/4+5***
Viral meningitis	***1/428***	***6/139***			
Scarlet fever	***26/67***				

[#]Given the number of outbreaks/ total number of cases – officially notified by physicians and discovered by epidemiologists during the investigation of the outbreak.
**For the outbreak of the intestinal infections is 5 and more cases, for the other diseases – 2 and more cases.*
***For diphtheria and meningococcal infections – even 1 case and carrier (+ x).*