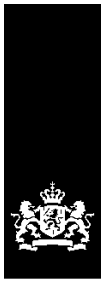

Ministry of Foreign Affairs

CONFIDENCE BUILDING MEASURES

in the framework of the

CONVENTION ON THE PROHIBITION

OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL)

AND TOXIN WEAPONS

THE NETHERLANDS

2015

Introduction

This report contains the Netherlands contribution to the Confidence Building Measures information exchange for the Biological and Toxin Weapons Convention. Over the past few years the Netherlands Ministry of Foreign Affairs has endeavoured to consolidate the information gathering process by strengthening ties with other government departments, research institutions and private companies.

We are pleased to inform State Parties that we can agree to have the attached information published on a public website for information purposes. We encourage other State Parties to do the same, in order to increase mutual trust and confidence.

Date :	April 2015
State Party to the Convention :	The Netherlands

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2015 CBM Report of the Netherlands to the United Nations Department for Disarmament Affairs

Pursuant to the procedural modalities agreed upon at the Second Review Conference (1986) of the Biological and Toxin Weapons Convention, relating to the exchange of Confidence-Building Measures (CBMs), the Netherlands submits the information specified below.

Annex I: Form "0"

Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F		X	2011
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: April 2015

State Party to the Convention: The Netherlands

Date of ratification/accession to the Convention: 22 June 1981

National point of contact: Ms. Ayse Aydin +31 (0)70 348 5664

Annex II: Contributors

The organizations and companies stated in the table below (in random order), have contributed to the Netherlands CBM Report 2015 by filling out and returning the forms specified below.

Governmental Organisations / Public Institutions	Abbreviations	Forms
TNO Defence, Security and Safety	TNO	A, C, E, F
Ministry of Defence	DEF	A (part 2) C, E, F
Food and Consumer Product Safety Authority	VWA	B
National Institute for Public Health and the Environment	RIVM	A (part 1), B, C
Central Veterinary Institute	CVI	C, G
Erasmus MC Rotterdam Laboratory for Infectious Diseases	EUR	B, C, G
Ministry of Infrastructure and Environment	I&M	C, E
Ministry of Social Affairs and Employment	SZW	E
Ministry of Health, Welfare and Sport	VWS	E

Companies	Forms
Abbott Biologicals B.V.	C, G
Bilthoven Biologics B.V.	G
Boehringer Ingelheim Health Operations B.V.	G
Janssen / Crucell Holland B.V.	C, G
Patheon Biologics B.V. (formerly DSM Biologics)	C, G
Intervet / MSD Animal Health	C, G

The following report is a compilation of these CBM returns. The report is compiled in accordance with the order as to be found in Annex 1 (see page 3).

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).

[1] World Health Organization
[2] World Organization for Animal Health

Form A, part 1 (i)

→ **Data from the National Institute for Public Health and the Environment (RIVM)**

Exchange of data on research centres and laboratories[3]

1. Name(s) of facility[4]

   National Institute for Public Health and the Environment
   Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

2. Responsible public or private organization or company

   Ministry of Health, Welfare and Sport
   Ministerie van Volksgezondheid en Sport

3. Location and postal address

   Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, the Netherlands

   P.O. Box 1, 3720 BA Bilthoven, the Netherlands

   http://www.rivm.nl

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

   Ministry of Health, Welfare and Sport.
   Ministry of Economic Affairs, Agriculture and Innovation
   Ministry of Infrastructure and Environment
   Various government inspectorates
   The European Union
   The United Nations

   No funding by the Ministry of Defence

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

   None

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

   Diagnostic research, development of diagnostic methods to detect human diseases or to improve detection methods and research for new or improved vaccines. These activities are about human and zoonotic pathogens belonging to BSL 2 and BSL 3. All in order to:

   - **Detect, control and prevent infectious diseases for the benefit of the public health in the Netherlands.**
   - **Uniform prevention nation-wide, strengthen vigilance and swift response to possible outbreaks through coordinating infectious disease control activities and international cooperation, and direction of the National vaccination program.**

[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] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

- **Stimulate effective prevention and control of infectious diseases by advising professionals and ministries, granting subsidies and by providing information to the public.**

Also activities concerning the procurement, storage and distribution of vaccines for the National Immunization Programme (Rijksvaccinatieprogramma, RVP), the National Influenza Prevention Programma (Nationaal Programma Grieppreventie, NPG) and the other national provisions such as pandemic preparedness and the National Serum Depot (NSD).

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]	**yes**
Biosafety level 2[8] (if applicable)	**yes**

→ **Data from the TNO Defence, Security and Safety**

Exchange of data on research centres and laboratories[9]

1. Name(s) of facility[10]

   TNO Department for CBRN Protection

2. Responsible public or private organization or company

   Netherlands Organization for Applied Scientific Research (TNO)

3. Location and postal address

   Lange Kleiweg 137, 2288 GJ Rijswijk, the Netherlands

   P.O. Box 45, 2280 AA Rijswijk, the Netherlands

   http://www.tno.nl

[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.

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

[10] 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)".

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

   Financed mostly by the Ministry of Defence

5. Number of maximum containment units[11] within the research centre and/or laboratory, with an indication of their respective size (m^2)

   No maximum (BSL4) containment units

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

   - **Development and testing of detection equipment and identification methods using strains of a limited number of category 2 and 3 bacterial pathogens (*Brucella, Francisella, Bacillus, Burkholderia, Staphylococcus, Clostridium, Yersinia, Klebsiella, Acinetobacter species*), the bacterial simulants *Erwinia herbicola, Bacillus* spp, and the viral simulants MS2 and Baculovirus.**
   - **Threat assessment and decontamination testing studies (involving *Coxiella burnettii*). Some efforts are aimed at development of antibacterial coatings for wound-dressing. Analysis of biological warfare agents with advanced mass spectrometry is dealing with low and high molecular weight toxins as well as with bacterial or viral extracts from above mentioned sources.**
   - **Filtration and mask leakage testing with the bacterial weapons simulants *Bacillus globigii, Erwinia herbicola* and *Escherichia coli* K12 as well as the viral simulant MS2. All activities are performed in closed facilities of appropriate biocontainment level.**

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]	**yes**
Biosafety level 2[14] (if applicable)	**yes**

[11] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.
[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.

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.

Part 2 (i)

National biological defence research and development programmes

Declaration

→ **Data from the TNO Defence, Security and Safety and the Ministry of Defence**

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

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, toxicology, physical protection, decontamination and other related research.

CBRN Research Program Description:

The threat coming from application of chemical, biological, radiological and/or nuclear (CBRN) weapons is characterized by a very low incidence and high potential impact, which together provides a significant risk. This threat is highly dynamic, ranges from large scale state-to-state to small scale insurgency and is extremely unpredictable. This implies that governments need a level of preparedness, both in civil as in military settings. However, exactly how high this level must be depends on many factors. Some of these factors are beyond influence, such as global and local violent incidents taking place and political, economic and social factors. However, factors that are closely related to military operations, such as where, how, against whom, which kind of missions take place with which equipment, are within the sphere of influence of the defence organizations governments themselves. That is where they can decide to require specific resilience toward CBRN threats.

The Dutch Armed Forces have three major tasks. In all tasks, they may have to face CBRN threats. According to the national Defence CBRN policy the Armed Forces require a proportional level of CBRN preparedness and countermeasures, which interfere with operational effectiveness at little as possible. However, in view of the dynamics and unpredictability of the CBRN threat, such measures are not readily available. It requires

specific and substantial in-depth knowledge and innovation to provide a proportional level of CBRN defensive measures.

In addition to this, NATO recently endorsed a new CBRN Defence concept (MC 0603/1). This comprehensive, strategic-level policy, not only involves defending against CBRN threats (protection and recovery), but also includes preventing them. The consequences of this high level decision still need to become clear. It is highly unlikely that the Armed Forces have all capabilities in place to act in accordance with the MC 06003/1 decisions. This means that capability development will have to take place for new concepts specifically dealing with prevention of CBRN incidents. It will require dedicated research to define, scope, design, develop and implement such capabilities as disablement, deterrence, counter proliferation and (forensic) investigation.

Program objectives:
The primary objective of the V1408 CBRN-program is to enable the Dutch Armed Forces to adequately defend against the dynamic CBRN threat, in order to maintain operational effectiveness under CBRN threat conditions and to either prohibit, if not mitigate consequences of CBRN on soldier health.

More specifically, the program will build and maintain knowledge that should enable the MoD to optimize three critical CBRN processes:

- **Prevent: activities to prevent use of CBRN means or proactively mitigate the consequences.**
- **Protect: optimize processes and activities taking place during and shortly after CBRN release: timely detection of nature and severity of CBRN incidents, reliable identification and adequate personal protection.**
- **Recover: (on-site) diagnosis and treatment of casualties and hazard management**

The bio threat agent part of this program is focused on:

- **Improvement and harmonization of methods for testing B-detection and identification equipment.**
- **Development of methods for fast and reliable identification of B agents in suspected samples, mainly based on mass spectrometry.**
- **Development of methods for fast and reliable non-clinical diagnosis of B-agents in biomedical samples and assessment of antibiotics resistance, all mainly based on mass spectrometry.**
- **Small parts are aimed integral threat assessment and physical personal protection.**

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

   The funding of the Ministry of Defence CBRN defence research programme is a total of 10 million euro for the period 2014-2017, part of which (3 million euro) is dedicated to biological defence.

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

   Yes

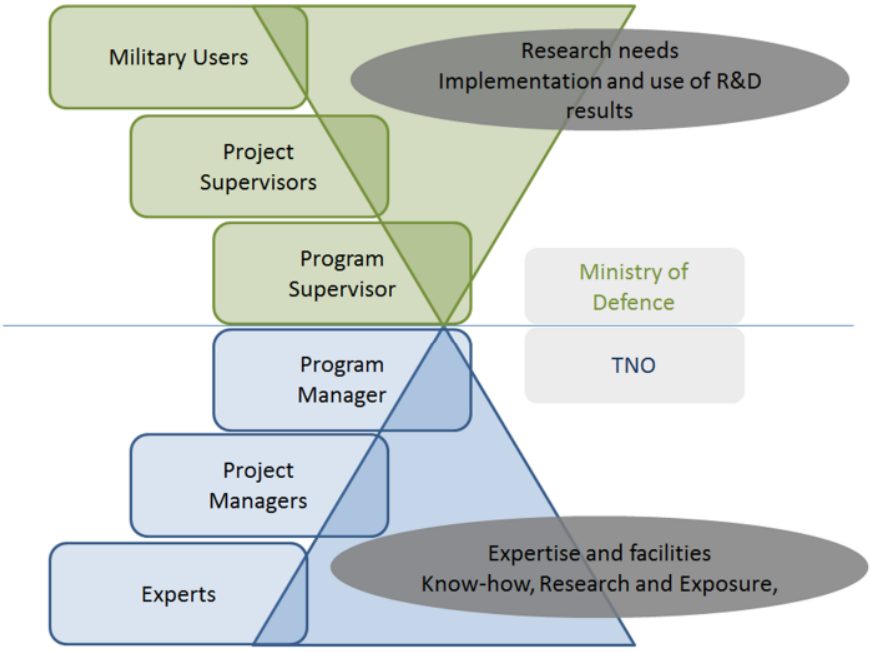
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

Not applicable

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

Not applicable

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.

Not applicable

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?

   TNO Prins Maurits Building; Department of CBRN Protection

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

   TNO premises, Lange Kleiweg 137, 2288 GJ

   City of Rijswijk, Province of Zuid-Holland, the Netherlands

3. Floor area of laboratory areas by containment level:

BL2	**200 (sqM)**
BL3	**200 (sqM)**
BL4	**- (sqM)**
Total laboratory floor area	**400 (sqM)**

4. The organizational structure of each facility.

(i) Total number of personnel	**9**
(ii) Division of personnel:	
Military	**0**
Civilian	**9**
(iii) Division of personnel by category:	
Scientists	**4**
Engineers	**1**
Technicians	**4**
Administrative and support staff	

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

Chemistry, analytical chemistry, toxicology, immunology, molecular biology, microbiology, medical biology, biochemistry, chemical engineering

(v) Are contractor staff working in the facility? If so, provide an approximate number.

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Ministry of Defence approximately	**60%**
Industry + Foreign governments	**40%**

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

Research	**60%**
Development	**10%**
Test and evaluation	**30%**

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

R&D results through hierarchy of TNO, and then to the Assignor (mostly delegates of the Ministry of Defence). Subjects of general or scientific interest may be published in the open literature only if the Assignor agrees.

(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.)

Rapid and generic identification of influenza A and other respiratory viruses with mass spectrometry. Majchrzykiewicz-Koehorst, J.A.; Heikens, E.; Trip, H.; Hulst, A.G.; Jong, A.L. de; Viveen, M.C.; Sedee, N.J.A.; van der Plas, J.; Coenjaerts, F.E.J. ; Paauw, A. Journal of Virological Methods (2015) 213: 75-83.

Bacillus globigii cell size is influenced by variants of the quorum sensing peptide extracellular death factor. Sijbrandij, T.; Kaman, W.E.; Ligtenberg, A.J.M.; Nazmi, K.; Veerman, E.C.I.; Bikker, F.J. Antonie van Leeuwenhoek, International Journal of General and Molecular Microbiology (2014) 105 (1): 221-228

The antimicrobial peptide LL-37 facilitates the formation of neutrophil extracellular traps. Neumann, A.; Berends, E.T.M.; Nerlich, A.; Molhoek, E.M.; Gallo, R.L.; Meerloo, T.; Nizet, V.; Naim, H.Y. ; Köckritz-Blickwede, M. von. Biochemical Journal (2014) 464: 3-11.

OmpU as a biomarker for rapid discrimination between toxigenic and epidemic Vibrio cholerae O1/O139 and non-epidemic Vibrio cholerae in a modified MALDI-TOF MS assay. Paauw, A. ; Trip, H. ; Niemcewicz, M. ; Sellek, R. ; Heng, J.M.E. ; Mars-Groenendijk, R.H. ; Jong, A.L. de; Majchrzykiewicz-Koehorst, J.A. ; Olsen, J.S. ; Tsivtsivadze, E. BMC Microbiology (2014) 14: 158-172.

Fast, generic and specific identification of influenza A and other respiratory viruses with mass spectrometry. Majchrzykiewicz-Koehorst, J.A. ; Trip, H. ; Coenjaerts, F. ; Jong, A.L. ; Hulst, A.G. ; Sedee, N.J.A. ; Heikens, E. ; Paauw, A. TNO 2014-RW-ELSS-CBRN-Proc-008

Mass spectrometry as a successful technique for identification of respiratory viruses such as influenza A. Majchrzykiewicz-Koehorst, J.A. ; Trip, H. ; Coenjaerts, F. ; Jong, A.L. ; Hulst, A.G. ; Sedee, N.J.A. ; Heikens, E. ; Paauw, A. TNO 2014-RW-ELSS-CBRN-Proc-009 014

Electrowetting for improved B-detection using MALDI-TOF mass spectrometry (Electrowetting voor gevoeligere B-detectie met MALDI-TOF massaspectrometrie). Trip, H. Report nTNO 2013 R11259

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[15] and/or toxins studied, as well as outdoor studies of biological aerosols.

- **Development and testing of detection equipment and identification methods using strains of a limited number of category 2 and 3 bacterial pathogens (e.g. *Brucella, Francisella, Bacillus, Vibrio, Staphylococcus, Clostridium, Yersinia*), the bacterial simulants *Erwinia herbicola*, *Bacillus* spp, and the viral simulants MS2 and Baculovirus.**
- **Threat assessment and decontamination testing studies. Some efforts are aimed at development of antibacterial coatings for wound-dressing. Analysis of biological warfare agents with advanced mass spectrometry is dealing with low and high molecular weight toxins as well as with bacterial or viral extracts from above mentioned sources.**

[15] Including viruses and prions.

- **Filtration and mask leakage testing with the bacterial weapons simulants *Bacillus globigii*, *Erwinia herbicola* and *Escherichia coli* K12 as well as the viral simulant MS2.**

All activities are performed in closed facilities of appropriate bio-containment level.

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[16] 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

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

outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern[17]

→ **Data from the Food and Consumer Product Safety Authority (VWA)**

1. Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern
   No outbreaks deviating from the normal pattern

2. Background information on outbreaks of reportable infectious animal diseases

Animal Disease	Number of cases per year				
	2010	2011	2012	2013	2014
Food-and-mouth disease	0	0	0	0	0
Scabies	-	-	-	-	-
Footrot (sheep)	-	-	-	-	-
Anthrax (all cattle)	0	0	0	0	0
Hog cholera	0	0	0	0	0
Pseud. fowl plague	0	0	0	0	0
Fowl cholera	1	1	0	0	0
Atrophic rhinitis	-	-	-	-	-
Rabies	0	0	1	0	0
African Swine fever	0	0	0	0	0
American foul brood	0	0	0	0	4
Infectious anaemia	0	0	0	0	0
Rabies (bats)	10	8	15	4	3
Salmonella enteritidis	64	35	23	18	50
Bovine Spongiform Encephalopathy	2	1	0	0	0
Vesicular swine fever	0	0	0	0	0
Avian Influenza Highly Pathogenic	0	0	0	0	5

[17] See paragraph 2 of the chapeau to Confidence-Building Measure B.

Avian Influenza LP	0	4	3	6	2
Bluetongue	0	0	0	0	0
Psittacosis	38	38	42	34	43
Tuberculosis in mammals(cattle)	6	4	1	4	4
Q-fever in dairy goats/dairy sheep	31	8	1	0	1

→ **Data from the National Institute for Public Health and the Environment (RIVM)**

1. Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern
   No outbreaks deviating from the normal pattern

2. Background information on outbreaks of reportable infectious diseases

Notifications per infectious disease per year (2014 data as available on February 20th, 2015)								
Year								
	2007	2008	2009	2010	2011	2012	2013	2014
Disease								
Antrax	0	0	0	0	0	0	0	0
Botulism	1	7	0	0	0	2	0	0
Brucelloses	6	5	3	6	1	3	6	1
Chikungunya	0	0	0	0	0	0	0	0
Cholera	3	5	4	0	3	4	0	2
Creutzfeldt-Jakob (classic)	15	15	20	27	27	29	29	11
Creutzfeldt-Jakob (variant)	0	1	0	0	0	0	0	0
Dengue	0	0	0	0	0	0	0	0
Diptheria	0	0	0	0	1	1	0	2
Hanta virus	0	2	7	19	7	23	4	34
Hepatitis A	161	185	180	261	116	125	109	95
Hepatitis B Acute	224	225	215	196	156	175	144	119
Hepatitis B Chronic	1570	1592	1774	1574	1551	1320	1149	965
Hepatitis C Acute	41	28	39	30	72	54	64	47
Invasive Group A Streptococcus	1	27	255	211	186	178	203	147

Invasive Hib B	0	0	16	31	20	22	18	22
InvasivePneumococcal disease	0	5	42	57	48	43	28	37
Legionellose	325	339	256	473	315	308	310	343
Leptospirosis	42	29	22	29	29	44	27	88
Listeriosis	0	8	56	69	87	70	74	87
Malaria	229	221	235	244	242	199	166	267

→ **Data from the Erasmus MC Rotterdam – Laboratory for Infectious Diseases (EUR)**

1. Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern
   No outbreaks deviating from the normal pattern

2. Background information on outbreaks of reportable infectious diseases

a.	Time of cognisance of the outbreak	**NA**
b.	Location and approximate area affected	**NA**
c.	Type of disease/intoxication	**NA**
d.	Suspected source of disease/ intoxication	**NA**
e.	Possible causative agent(s)	**NA**
f.	Main characteristics of systems	**NA**
g.	Detailed symptoms, when applicable	
	- respiratory	**NA**
	- circulatory	**NA**
	- neurological/behavioural	**NA**
	- intestinal	**NA**
	- dermatological	**NA**
	- nephrological	**NA**
	- other	**NA**
h.	Deviation(s) from the normal patterns as regards	
	- type	**NA**
	- development	**NA**
	- place of occurrence	**NA**
	- time of occurrence	**NA**
	- symptoms	**NA**
	- virulence pattern	**NA**

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.

→ Data from the TNO Defence, Security and Safety and the Ministry of Defence

Encouragement of publication of results and promotion of use of knowledge

- In general, the Dutch Ministry of Defence (MoD) encourages publication of results and the promotion of knowledge.
- Results obtained are subject to consent of the Managing Director of TNO, Defence, Safety and Security – the institute that carries out BW research on behalf of the MoD. Furthermore, publication is only allowed after consent by the MoD.
- Scientific publications can be obtained from the sources. As far as relevant, data are published in (inter)national scientific manuals, peer-reviewed journals and magazines.
- Where appropriate IPR, will be protected by patents.

→ Data from the National Institute for Public Health and the Environment (RIVM)

The National Institute for Public Health and the Environment (RIVM) is a recognized leading centre of expertise in the fields of health, nutrition and environmental protection. The RIVM works mainly for the Dutch government. The RIVM plays a central role in information exchange with local health services, among other through a national infectious disease bulletin, electronic surveillance systems (for notifiable and voluntarily monitored diseases), yearly seminars targeted and an electronic rapid

alert system. Studies carried out by the National Institute of Public Health and the Environment are published in the public domain (www.rivm.nl.) The dual-use aspect of publications was assessed as described in the Dutch Code of Conduct, as well as in the advisory report of the KNAW 'Improving biosecurity; assessment of dual-use research'.

Besides the above mentioned the RIVM develops and exploits its international knowledge base in various ways:

- International research and projects.
- Contributions to international conferences and publications.
- Activities on behalf of international clients such as the European Commission and its agencies, the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD). RIVM plays an active part in the WHO Collaborating Centres.
- Activities further to formal agreements between the Netherlands and other countries, including 'twinning'-programs designed to provide specific assistance, and collaboration with RIVM's sister organizations in other countries.
- Participation in several UNICRI-projects that aim to strengthen the CBRN-resilience within the field of biosafety and biosecurity through the development of a laboratory information system for research facilities and hospitals in Southeast Asia. Education in biosecurity awareness and biosecurity management are provided in train-the-trainer programs in South East Asia as well as in countries in Northern Africa, including Uganda, South East Europe and Southern Caucasus.
- Participation in ongoing actions of the EU CBRN-action plan.
- Membership of international professional organizations.

Biosecurity office
The Netherlands Biosecurity Office is the national information centre for the Dutch Government and for organizations that work with high-risk biological material. The Biosecurity Office is part of National Institute for Public Health and the Environment (RIVM). The Biosecurity Office evolved from a government-initiated interdepartmental biosecurity project involving the Ministry of Infrastructure and the Environment, the Ministry of Health, Welfare and Sport, the Ministry of Foreign Affairs, the Ministry of Economic Affairs, the Ministry of Social Affairs and Employment, the Ministry of Education, Culture and Science, the Ministry of Defence, and the National Coordinator for Security and Counterterrorism (NCTV).

The Biosecurity Office aims to disseminate the government's new policy on biosecurity; for example, by giving workshops and providing information. To enhance bio-risk management inside organizations working with hazardous biological materials, the Biosecurity Office organized in 2014 two national Biosecurity workshops. The workshops were attended by more than 200 participants from a diversity of organizations working within different fields of expertise. Aim of the workshops was to raise awareness on biosecurity and provide tools to solve biosecurity issues. To exchange knowledge and information internationally, the Biosecurity Office participated in international conferences and meetings and visited e.g. the Danish sister organization 'Centre for Biosecurity and Bio-preparedness'.

→ **Data from the Central Veterinary Institute (CVI)**

- The Central Veterinary Institute is performing statutory tasks for the Ministry of Agriculture, Nature and Food Quality.
- The Netherlands has legal obligation on publication of results of scientific research.
- There are no restrictions whatsoever on the publication of results of scientific research.
- Publication takes place in (inter)national scientific manuals, journal, magazines and other sources.

→ **Data from the Erasmus MC Rotterdam – Laboratory for Infectious Diseases (EUR)**

The default policy in the department of viroscience is that all research will be published in peer-reviewed journals.

→ **Data from the Ministry of Infrastructure and Environment (I&M)**

At the ministry of Infrastructure and Environment (I&M) has no influence in whether or not the result of scientific research related to the Convention is published, I&M does not need to classify or un-classify any publication, nor can I&M promote any given publication. Of course I&M will take the recommendation of the Third Review Convention into consideration in the eventuality of any publication in the future.

→ **Data from Abbott Biologicals B.V.**

Abbott Biological B.V. does not execute any basis research, only clinical studies for the annual update for our influenza vaccine.

→ **Data from Janssen / Crucell Holland B.V.**

Janssen / Crucell very much encourages the publication of results of scientific research. Janssen / Crucell has a general procedure for publication of abstracts, manuscripts, presentations, press releases and any other form of communication of scientific or clinical development result. This procedure ensures, amongst others, consistent language, style, and adequate media content of final publication, adherence to corporate strategy and identity, scientific soundness, statically correctness of the conclusions and identification of possible IP issues.

→ **Data from Patheon Biologics B.V. (formerly DSM Biologics)**

Not applicable, due to DSMB not publishing about our client's products and in view of client confidentiality.

→ **Data from Intervet / MSD Animal Health**

MSD Animal Health believes in science for healthier animals, and as a research driven organisation, encourages publication of scientific research.

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.

→ **Data from TNO Defence, Security and Safety and the Ministry of Defence**

TNO Defence, Security and Safety and the Dutch Ministry of Defence comply to civil legislation, regulations and other measures related to the topics (a) to (d) below, and have issued no additional legislation, regulations or measures on these topics.

Relating to	Legislation	Regulations	Other measures[18]	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	No	No	No	No
(b) Exports of micro-organisms[19] and toxins	No	No	No	No
(c) Imports of micro-organisms[11] and toxins	No	No	No	No
(d) Biosafety[20] and	No	No	No	No

[18] Including guidelines.
[19] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

biosecurity[21]

→ **Data from the Ministry of Infrastructure and Environment (I&M)**

Relating to	Legislation	Regulations	Other measures[22]	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	No	No	No	N.A.
(b) Exports of micro-organisms[23] and toxins	No	No	No	N.A.
(c) Imports of micro-organisms[11] and toxins	No	No	No	N.A.
(d) Biosafety[24] and biosecurity[25]	Biosafety: Yes Biosecurity: No	Biosafety: Yes Biosecurity: No	Biosafety: Yes Biosecurity: No	No

General remark to the above table:
The ministry of Infrastructure and Environment (I&M) is responsible for legislation related to the handling, use and making of genetically modified organisms (GMO). The objective of the GMA Decree is to ensure an adequate level of protection in the field of the safe handling and use of GMOs that may have adverse effects on the environment and human health or the environment. It deals with both the contained use and introduction into the environment of GMOs.

The Decree implements the European Directives 2009/41/EC and 2001/18/EC on the contained use and the deliberate release into the environment of GMOs, respectively. Where appropriate, the decree requires advanced written consent from competent authorities before activities with GMOs may be conducted. On the basis of information gathered by government as a result of the procedures of the Decree, it is possible to pinpoint which GMOs are being handled by research facilities and at which location. The level of detail varies for different categories, but for pathogenic microorganisms comprehensive information is available to the competent authority. This legislation has not been modified in 2014.

The legislation can be found (in Dutch) at: http://wetten.overheid.nl/BWBR0004730.

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[20] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[21] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.
[22] Including guidelines.
[23] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[24] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[25] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

→ **Data from Ministry of Social Affairs and Employment (SZW)**

Relating to	Legislation	Regulations	Other measures[26]	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	No	No	No	No
(b) Exports of micro-organisms[27] and toxins	No	No	No	No
(c) Imports of micro-organisms[11] and toxins	No	No	No	No
(d) Biosafety[28] and biosecurity[29]	No	No	No	No

→ **Data from Ministry of Health, Welfare and Sport (VWS)**

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	No	No	No	No
(b) Exports of micro-organisms[31] and toxins	No	No	No	No
(c) Imports of micro-organisms[11] and toxins	No	No	No	No

[26] Including guidelines.
[27] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[28] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[29] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.
[30] Including guidelines.
[31] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

(d) Biosafety[32] and biosecurity[33]	No	No	No	No

[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.

→ **Data from the TNO Defence, Security and Safety and the Ministry of Defence**

1. Date of entry into force of the Convention for the State Party.

   22 June 1981

2. Past offensive biological research and development programmes:

   No

2a. Period(s) of activities

   Not applicable

2b. 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.

   Not applicable

3. Past defensive biological research and development programmes:

   Yes

3a. Period(s) of activities

   From mid-1980s up to present

3b. 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.

   The increasing importance of BW defence has generated research efforts in all aspects of passive BW defence (threat assessment, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection and identification, physical protection and decontamination). All of this work is of defensive nature; it involves concept development and evaluation of concepts and products. For that purpose TNO has BSL facilities, strain collections. This all fall under running assignments of the NL government of the European Defence Agency.

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.

	Central Veterinary Institute (CVI)
1.	**Name of Facility:** Central Veterinary Institute, part of Wageningen University & Research Centre (UR) FMDV vaccine production unit *NB: The FMDV vaccine production unit is leased since 2009 to Merial SAS, Lyon, France, with permission of the Dutch Government*
2.	**Location:** Houtribweg 39, P.O. Box 65, 8200 AB Lelystad, the Netherlands
3.	**General description of the types of diseases covered:** Foot and Mouth Disease antigen production for vaccine production

	Erasmus MC Rotterdam – Laboratory for Infectious Diseases (EUR)
1.	**Name of Facility:** Erasmus Medical Centre
2.	**Location:** 's Gravendijkwal 230, 3015 CE Rotterdam, the Netherlands www.erasmusmc.nl
3.	**General description of the types of diseases covered:** Diseases caused by viruses

	Abbott Biologicals B.V.
1.	**Name of Facility:** WWP/WWY
2.	**Location:** C.J. van Houtenlaan 36, P.O. Box 900, 1380 DA Weesp, the Netherlands

www.abbottnederland.nl

3. **General description of the types of diseases covered:**
Influenza (human)

Bilthoven Biologicals B.V.

1. **Name of Facility:**
Bilthoven Biologicals B.V. (BBio)

2. **Location:**
Antonie van Leeuwenhoeklaan 9-13, P.O. Box 457, 3720 AL Bilthoven, the Netherlands
www.bbio.nl

3. **General description of the types of diseases covered:**
   - Diphtheria
   - Tetanus
   - Poliomyelitis
   - Bladder cancer

Boehringer Ingelheim Animal Health Operations B.V.

1. **Name of Facility:**
Boehringer Ingelheim Animal Health Operations B.V.

2. **Location:**
C.J. van Houtenlaan 36, 1381 CP Weesp, the Netherlands
http://www.boehringer-ingelheim.nl

3. **General description of the types of diseases covered:**
BSL1 – 3, for animal vaccines after takeover to be developed.
Not yet known.

Janssen / Crucell Holland B.V.

1. **Name of Facility:**
Janssen / Crucell Holland B.V.

2. **Location:**
Archimedesweg 4-6, P.O. Box 2048, 2301 CA Leiden, the Netherlands
http://www.crucell.nl

3. **General description of the types of diseases covered:**
   - Hepatitis B
   - Childhood diseases (Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B)

	Patheon Biologics B.V. (formerly DSM Biologics)
1.	**Name of Facility:** Patheon Biologics B.V.
2.	**Location:** Zuiderweg 72/2, P.O. Box 454, 9700 AL Groningen, the Netherlands http://www.patheon.com
3.	**General description of the types of diseases covered:** Patheon Biologics B.V. is a contract manufacturer that produces antibodies and recombinant proteins for sponsors, who demand our confidentiality on their product information. Therefore this information should be handled accordingly. The proteins manufactured at our facility are aimed at treating or diagnosing general diseases such as inflammatory diseases, cancer, metabolic or genetic disorders. Currently, no proteins for vaccine production are manufactured.

	Intervet / MSD Animal Health
4.	**Name of Facility:** Intervet International B.V., also known as MSD Animal Health
5.	**Location:** Wim de Körverstraat 35, P.O. Box 31, 5830 AA Boxmeer, the Netherlands http://www.msd-animal-health.nl
6.	**General description of the types of diseases covered:** Pathogens from farm and companion animals, including bacteria, protozoa and viruses