

# CONFIDENCE BUILDING MEASURES

in the framework of the

# CONVENTION ON THE PROHIBITION $\label{eq:convention}$ OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS

THE NETHERLANDS

2021

### Introduction

This report contains the contribution of the Netherlands 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 2021

State Party to the Convention: The Kingdom of the Netherlands

### **Index**

### 2020 CBM Report of the Netherlands to the United Nations Office

### for Disarmament Affairs covering data for 2018

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.

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### 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)			
В			
C			
E		X	2021
F		X	2011
G			

Date: April 6, 2021

State Party to the Convention: <u>The Kingdom of the Netherlands</u>

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

National point of contact: <u>Roos van Keulen +316 50 18 35 58</u>

#### **Annex II: Contributors**

The organizations and companies stated in the table below (in alphabetical order), have contributed to the Netherlands CBM Report 2020 by filling out and returning the forms specified below.

Governmental Organisations / Public Institutions	Abbreviations	Forms
Erasmus Medical Center Rotterdam, Laboratory for Infectious	EUR	B, G
Diseases		
Ministry of Agriculture, Nature and Food Quality	LNV	B, C, E
- Food and Consumers Product Safety Authority	- NVWA	
- Wageningen Bioveterinary Reseach	- WBVR	
Ministry of Defence	DEF	A (part 2)
		C, E, F
Ministry of Health, Welfare and Sport	VWS	Е
Ministry of Infrastructure and Water Management	I&W	C, E
Ministry of Social Affairs and Employment	SZW	Е
National Institute for Public Health and the Environment	RIVM	A (part 1),
		B, C, E
TNO Defence, Security and Safety	TNO	A, C, E, F

Companies	Forms
Abbott Biologicals B.V.	G
Bilthoven Biologicals B.V.	G
Boehringer Ingelheim Animal Health Netherlands B.V. (formerly Merial Lelystad)	C, G
Intervet International B.V. / MSD Animal Health	C, G
Janssen Vaccines & Prevention (formerly Janssen / Crucell Holland B.V.)	C, G
Patheon Biologics B. V.	G
Wacker Biotech B.V. (formerly SynCo Bio Partners B.V.)	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 4).

#### **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<sup>1</sup> Laboratory Biosafety Manual and/or OIE<sup>2</sup> 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).

Contributors	Abbreviations
National Institute for Public Health and the Environment	RIVM
TNO Defence, Security and Safety	TNO

World Health Organization

<sup>&</sup>lt;sup>2</sup> World Organization for Animal Health

#### Form A, part 1 (i)

Exchange of data on research centres and laboratories<sup>3</sup>

The Netherlands do not possess a facility, within its 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 <sup>4</sup> Laboratory Biosafety Manual and/or OIE <sup>5</sup> 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.

For reasons of transparency, Form A, part 1 (ii), will provide the data requested in Form A, Part 1 (i) regarding facilities handling biological agents with biosafety level 2 and 3.

#### 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<sup>6</sup> on a State Party's territory:

#### → <u>Data from the National Institute for Public Health and the Environment (RIVM)</u>

Biosafety level 3 <sup>7</sup>	yes	
Biosafety level 2 <sup>8</sup> (if applicable)	yes	

#### Any additional relevant information as appropriate:

Exchange of data on research centres and laboratories9

#### 1. Name(s) of facility<sup>10</sup>

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

<sup>&</sup>lt;sup>4</sup> World Health Organization

<sup>&</sup>lt;sup>5</sup> World Organization for Animal Health

<sup>&</sup>lt;sup>6</sup> Microorganisms pathogenic to humans and/or animals

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

<sup>8</sup> 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 containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

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)".

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

#### 2. Responsible public or private organization or company

Ministy of Health, Welfare and Sport, Ministerie voor Volksgezonheid, Welzijn en Sport

#### 3. Location and postal address

Antonie van Leeuwenhoeklaan 9, 3721 MA Bilthoven, the Netherlands

Postal address: P.O. Box 1, 3720 BA Bilthoven, the Netherlands

Internet address: http://ww.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 Sports
- Ministry of Infrastructure and Water Management
- Ministry of Economic Affairs and Climate Policy
- Ministry of Agriculture, Nature and Food Quality
- Ministry of Foreign Affairs
- Various Government Inspectorates
- The European Union
- The United Nations

No funding 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 (m²)

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 improver detection methods and research for new or improved vaccines. These activities are about human and zoonotic pathogens belonging to BSL2 and BSL3. All in order to:

- Detect, control and prevent infectious diseases for the benefit of the public health in the Netherlands.
- Uniform prevention nationwide, strengthen vigilance and swift response to possible outbreaks through coordinating infectious disease control activities and international cooperation, and direction of the National vaccination program.
- Stimulate effective prevention and control of infectious diseases by advising professionals and ministries, granting subsidies and by providing information to the public.

<sup>&</sup>lt;sup>11</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

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

#### → Data from TNO

Biosafety level 3 <sup>12</sup>	yes
Biosafety level 2 <sup>13</sup> (if applicable)	yes

Any additional relevant information as appropriate:

1. Name(s) of facility<sup>14</sup>

TNO Department of CBRN Protection

2. Responsible public or private organization or company

Netherlands Organization for Applied Scientific Research (TNO)

3. Location and postal address

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

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 15 within the research centre and/or laboratory, with an indication of their respective size (m²)

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 and viral pathogens (*Brucella, Francisella, Bacillus, Burkholderia, Staphylococcus, Clostridium, Yersinia, Klebsiella, Acinetobacter, Escherichia coli,* 

<sup>&</sup>lt;sup>12</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

<sup>&</sup>lt;sup>13</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

<sup>&</sup>lt;sup>14</sup> 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)".

<sup>&</sup>lt;sup>15</sup> In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

*Influenza species, Corona virus strains: SARS-CoV-2, HCOV OC43, CoV 229E*), the bacterial simulants *Erwinia herbicola, Bacillus* spp, and the viral simulants MS2 and Baculo virus.

Threat assessment and decontamination testing studies (involving *Bacillus anthracis*, *Bacillus globigii*, *Bacillus thuringiensis*, *Corona strains*). 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*, *Bacillus thuringinsies*, *Erwinia herbicola*, *Escherichia coli* K12 as well as the viral simulant MS2. All activities are performed in closed facilities of appropriate biocontainment level. Operational study using *Bacillus globigii*, *Bacillus thuringiensis* to evaluate efficacy of

# Part 2: Exchange of information on national biological defence research and development programmes

decontamination systems in semi-field conditions.

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;
- 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.

Contributors	Abbreviations
Ministry of Defence	DEF
TNO Defence, Security and Safety	TNO

#### Form A, Part 2 (i)

### National biological defence research and development programmes Declaration

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

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.

#### Form A, Part 2 (ii)

#### National biological defence research and development programmes

#### **Description**

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

#### **Program Description:**

Unfortunately the threat coming from chemical, biological, radiological and nuclear (CBRN) agents increased and evolved over the last years and is likely to do so for the foreseeable future. The Ministry of Defence is in need of capabilities that not only provide resilience against agents, but also counteracts new developments such as pharmaceutical based agents and man-modified micro-organisms. The

V1802 program aspires to provide understanding of consequences of novel threats, improve CBRN situational awareness and accomplish more adequate physical and medical countermeasures.

The Ministry of Defence of the Netherlands observes an increasing and evolving CBRN threat. This threat is multifaceted and unpredictable. This is due to geo-political global developments and to advances in technologies. Moreover, the Dutch military operational deployment is subject to significant changes and this will continue, nationally and internationally. This all implicates that innovative solutions are called for, in order to maintain preparedness and ensure adequate responsiveness against CBRN incidents. As the hereto required CBRN knowledge base has been outsourced to TNO, a new 4-year research program has been launched, coded V1802.

The high level objective is to maintain a broad, topical and high quality knowledge base that contributes to the Armed Forces' capabilities to technically interpret the CBRN threat, to create shared situational awareness and to launch adequate countermeasures.

This knowledge base shall be sufficiently comprehensive to cover the problem area and shall also have a number of innovation spearheads ensuring adaptability to developments in the threat area.

The program comprises 4 work packages (WPs). The Threat Analysis WP addresses the threat posed by several classes of agents including toxins and (natural and modified) BioThreat Agents. Especially the exponential progress in possibilities to genetically engineer (synthetic biology) micro-organisms may be of concern. Selected agents will be studied to determine how they pose a risk. Desktop research will perform scenario analyses and use computational models to categorize agents. Experimental research will look into synthesis/harvesting/production, stability, detectability, toxic effects, infectiousness and pathogenicity. Special emphasis will be on agents in the aerosol phase.

In the Situational Awareness (SA) WP, one of the projects aims to improve detection of low volatile agents using contact-less, mostly spectroscopic techniques. Improvement is also sought in the networking of detectors, thereby optimizing detector placement, combinations of detector techniques, and enriching the output of the resulting network. For bio-detection, a detect-to-treat doctrine is being designed, along with a search for relevant technologies. Another ambition is to contribute to international harmonization of bio-detection testing and evaluation methodology. In our view, diagnosis is also part of SA. The ensemble of point-of-care kits, earlier developed for classical warfare agents, will be broadened by including easy-to-use assays for exposure to toxins. The aspiration is to develop a generic approach for pre-symptomatic diagnosis of infection, using representative (protein) biomarkers, most likely to be discovered using mass spectrometry. For this purpose an integral proteomic and genomic approach is foreseen.

The Countermeasures WP aims to improve personal protection against biological aerosols among others. New materials, based on metal organic frameworks (MOFs) may enable the desired combination of filtration/sorption along with a low thermal load. In parallel, the program provides a demonstrator of a test method that is able to determine the penetration of (hot) aerosols through CBRN protective materials, including demonstration of their performance against requirements. In the field of decontamination, the ambition is to demonstrate the applicability of (modified) MOFs as materials capable to degrade a broad spectrum of threat agents. Furthermore, a proof of concept is foreseen for visualizing and measuring (residual) contamination of surfaces, for example with contact-less imaging technology or with colour reactions for disclosure.

The Bio-threat agent part of this program is focused on:

- Studies into potential dangers of gene editing tools and do-it-yourself biology.
- Development of methods to establish whether or not and if so how micro-organisms have been genetically modified. Assessment of the extent to which the TNO Defence Research

establishment is able to detect and characterize genetic alterations applied in micro-organisms of choice.

- 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, most are based on mass spectrometry; new are diagnostic methods based on CRISPR-Cas technology.
- The SARS-CoV-2 pandemics urged to launch several research lines in the portfolio to support
  pandemics mitigating including research into new diagnostics (proteomics and genetics based),
  testing of facial masks and study of decontamination using several decontaminants on some
  surfaces.

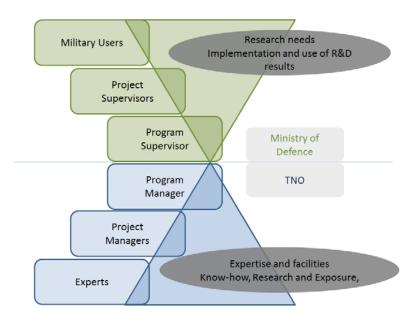
#### 2. State the total funding for each programme and its source.

The funding of the Ministry of Defence CBRN defence research programme is a total of 11 MEURO for the period 2018-2021, part of which (3,6 MEURO) is dedicated to biological defence.

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

No

- 4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
- 5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
- 6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

#### Form A, Part 2 (iii)

#### National biological defence research and development programmes

#### **Facilities**

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

TNO Prins Maurits Building; Department of CBRN Protection

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

TNO premises, Lange Kleiweg 137, 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 (ii) Division of personnel: 0 Military Civilian 9 (iii) Division of personnel by category: Scientists 5 Engineers 2 **Technicians** 3 Administrative and support staff 2

(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 70%

Industry + Foreign governments 30%

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

Research 50%

Development 10%

Test and evaluation 40%

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

Publication of R&D results are processed through the TNO hierarchy, and then to the appropriate delegates of the Ministry of Defence (assignor). 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.)

Bright fluorescent nucleic acid detection with CRISPR-Cas12a and poly(thymine) templated copper nanoparticles Janna F. M. Bogers; , Nicole F. Berghuis; Ruud W. Busker; Angelo van Booma, Armand Paauw and Hans C. van Leeuwen; Biology Methods and Protocols, 2020, 1–7.

DNA-sequencing voor het identificeren van door de mens aangebrachte DNA veranderingen in bacteriën [DNA sequencing for identification of man-made DNA alterations in bacteria]; HC van Leeuwen; N. Berghuis. TNO 2019 R11407.

Biological Detection Capability Architecture; AL van Wuijckhuijse and RW Busker; TNO 2020 R11058.

CANTRIP: detection of pathogens using CRISPR-Cas; HC van Leeuwen; N. Berghuis, A Paauw; TNO 2020 R11146

Heat sterilization dramatically reduces filter efficiency of the majority of FFP2 and KN95 respirators; J.M.B.M. van der Vossen, M. Heerikhuisen, R.A.A.L. Traversari, A.L. van Wuijckhuijse, R.C. Montijn; J Hospital Infection 107 (2021) 87-90.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms <sup>16</sup> 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 ( such as: *Brucella, Francisella, Bacillus, Vibrio, Staphylococcus, Clostridium, Yersinia*), the bacterial simulants such as: *Erwinia herbicola, Bacillus* spp, *Corona virus strains: SARS-CoV-2, HCOV OC43, CoV 229E*) and the viral simulants such as: MS2 and Baculovirus. Threat assessment and decontamination testing studies. 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.

Assessing the level of decontamination after containing surfaces with bacterial spores. Filtration and mask leakage testing with the bacterial weapons simulants such as: *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.

Desk-top study into the definition of synthetic biology and closely related fields, the different types of synthetic biology, and scientific advances therein. The dual use character of synthetic biology was discussed and this was be placed in perspective with the perception of biological threats. Finally the potential implications of synthetic biology for the detection and identification of biological threats was discussed. Experimental research into application of CRISPR-Cas technology for fieldable diagnostic assays.

<sup>&</sup>lt;sup>16</sup> Including viruses and prions.

## Confidence-Building Measure "B"

# Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

No universal standards exist for what might constitute a deviation from the normal pattern.

#### **Modalities**

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

- 1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:
  - When the cause of the outbreak cannot be readily determined or the causative agent <sup>17</sup> 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.

<sup>17</sup> It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

- 3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by 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.

Contributors	Abbreviations
Erasmus Medical Center Rotterdam, Laboratory for Infectious	EUR
Diseases	
Food and Consumer Product Safety Authority	VWA
National Institute for Public Health and the Environment	RIVM

# Form B Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern<sup>18</sup>

#### → Data from the Erasmus MC Rotterdam, Laboratory for Infectious Diseases

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

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

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

Background information on outbreaks of reportable infectious animal diseases

Animal Disease	Number of	Number of cases per year			
	2016	2017	2018	2019	2020
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

<sup>&</sup>lt;sup>18</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

Pseud. fowl plague	0	0	0	0	0
Fowl cholera	0	0	0	0	0
Atrophic rhinitis	-	-	-	-	-
Rabies	0	0	0	0	0
African Swine fever	0	0	0	0	0
American foul brood	0	3	0	0	0
Infectious anaemia	0	1	0	0	0
Rabies (bats)	9	9	2	5	3
Salmonella enteritidis	29	31	18	39	43
Bovine Spongiform Encephalopathy	0	0	0	0	0
Vesicular swine fever	0	0	0	0	0
Avian Influenza Highly Pathogenic	9	1	2	0	10
Avian Influenza LP	2	1	0	0	1
Bluetongue	0	0	0	0	0
Psittacosis	46	38	36	35	42
Tuberculosis in mammals(cattle)	0	0	0	1	0
Q-fever in dairy goats/dairy sheep	0	0	0	0	0

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

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal  $pattern^{19}$ 

Time of cognizance of the outbreak 27 February 2020; first case of COVID-19 diagnosed in the

Netherlands 2. Location and approximate area affected National (and global) epidemic Type of disease/intoxication COVID-19 3. Suspected source of disease/intoxication SARS-CoV-2 4. 5. Possible causative agent(s) SARS-CoV-2 Main characteristics of systems 6. 7. Detailed symptoms, when applicable respiratory X circulatory neurological/behavioural intestinal

1.

<sup>&</sup>lt;sup>19</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

	dermatological	
	nephrological	
	other	
8.	Deviation(s) from the normal pattern as re	egards
	type	
	development	pandemic
	place of occurrence	
	time of occurrence	
	symptoms	
	virulence pattern	
	drug resistance pattern	
	agent(s) difficult to diagnose	
	presence of unusual vectors	·
	other	
9.	Approximate number of primary cases	805164 notifications in 2020
10.	Approximate number of total cases	
11.	Number of deaths	11529 deaths notified in 2020
12.	Development of the outbreak	First wave in March- April, second wave starting in
Septe	mber 2020	
13.	Measures taken	lockdowns, and social distancing measures also applying in
betwe	en lockdowns	

Information on notification of infectious diseases can be found on: <a href="https://www.rivm.nl/meldingsplicht-infectieziekten/overzicht-meldingen">https://www.rivm.nl/meldingsplicht-infectieziekten/overzicht-meldingen</a>

RIVM also reports notification data and shares outbreak information with the ECDC. Notification data are freely accessible through: <a href="https://ecdc.europa.eu/en/surveillance-atlas-infectious-diseases">https://ecdc.europa.eu/en/surveillance-atlas-infectious-diseases</a>

Group A		Number of cases per year						
	2020	2019	2018	2017	2016	2015	2014	2013
MERS-CoV			0	0	0	0	0	0
Smallpox			0	0	0	0	0	0
Polio			0	0	0	0	0	0
Severe Acute Respiratory Syndrome (SARS)		0	0	0	0	0	0	0
Viral Hemorrhagic Fever		2	0	0	0	0	1	0
Group B1		Number of cases per year						
	2020	2019	2018	2017	2016	2015	2014	2013
Diptheria		1	2	4	2	5	1	0
Human infection with animal influenza virus		0	0	0	1	0	0	0
Dlague		0	0	0	0	0	0	0
Plague			0	0	0	0	1	1

Group B2		Number of cases per year						
	2020	2019	2018	2017	2016	2015	2014	2013
Typhoid		28	19	20	18	17	20	25
Cholera		1	2	0	1	1	3	0
Cluster of food infections		24	29	30	29	29	28	36
Hepatitis A		163	187	372	81	79	105	109
Hepatitis B Acute		105	100	115	114	108	141	146
Hepatitis B Chronic		1031	987	1095	1009	1012	1075	1154
Hepatitis C Acute		46	59	61	49	72	53	64
Invasive Group A		313	242	293	187	171	149	203
Streptococcus								
Pertussis		6278	4697	4961	5590	6672	9058	3491
Measles		83	24	16	6	7	140	2659
Paratyphoid A		7	17	11	11	6	9	22
Paratyphoid B		28	28	32	29	23	8	14
Paratyphoid C		5	0	3	0	4	0	2
Rubella		0	0	0	0	1	2	57
STEC/enterohemorrhagic		458	485	394	575	754	754	849
E.coli								
Shigellosis		551	509	427	446	360	473	473

Group C		Numbe	r of case	s per year	r			
	2020	2019	2018	2017	2016	2015	2014	2013
Anthrax		0	2	0	0	0	0	0
Mumps		131	73	46	71	87	40	205
Botulism		0	0	0	2	0	0	0
Brucelloses		7	5	2	4	9	1	6
Chikungunya (*)		1	0	0	13	24	61	0
Dengue (*)		0	0	0	13	32	13	0
Yellow Fever		0	2	1	0	0	0	0
Hantavirus infection		47	37	51	31	10	37	4
Invasive Haemophilius		38	40	33	33	18	20	19
influenzae type b infection								
Invasive pneumococcal		63	68	45	44	43	39	28
disease (in children up to 5								
years of age)								
Legionellose		587	583	575	465	438	370	311
Leptospirosis		121	52	75	87	86	104	27
Listeriosis		114	77	113	95	71	92	74
MRSA (clusters outside		5	6	4	5	12	3	11
hospital)								
Malaria		182	254	211	251	344	285	166
Meningococcal disease		157	201	205	156	95	81	109
Psittacosis		91	63	52	60	47	41	53

Q-fever	18	18	22	14	20	26	20
Tetanus	0	1	1	1	1	0	1
Trichinosis	0	0	0	0	0	0	0
Tularemia	4	2	2	4	0	0	0
West Nile Fever	0	2	0	1	0	0	0
Creutzfeldt-Jakob (classic)		26	21	30	25	25	30
Creutzfeldt-Jakob (variant)		0	0	0	0	0	0
Zika	0	4	9	27	0	0	0

# 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.
- 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.

Contributors	Abbreviations
Ministry of Defence/TNO	DEF
Ministry of Infrastructure and Water Management	I&W
National Institute for Public Health and the Environment	RIVM
Boehringer Ingelheim Animal Health Netherlands B.V.	
(formerly Merial Lelystad)	
Intervet International B.V. / MSD Animal Health	
Janssen Vaccines & Prevention	
Wacker Biotech B.V.	
Wageningen Bioveterinary Research	WBVR

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

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 Ministry of Infrastructure and Water Management (I&W)

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

#### → 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 center of expertise in the fields of health, nutrition and environmental protection. The RIVM plays a central role in information exchange with local health services, amongst others through a national infectious disease bulletin, electronic surveillance systems (for notifiable and voluntarily monitored diseases), yearly seminars 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.). Dual-use aspects of publications has to be assessed as described in the Dutch Code of Conduct, as well as in the advisory report of the Royal Academy of Arts and Sciences (KNAW) 'Improving biosecurity; assessment of dual-use research'.

Besides the above mentioned, 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.
- RIVM actively participates in the EU CBRN Centres of Excellence initiative that aims to strengthen CBRN-resilience. In the past ten years, RIVM participated in several projects dedicated to strengthen biosafety and biosecurity in central Asia and is currently active in this field in South East Asia. In addition, RIVM participates in project on the protection of critical infrastructure in the Middle East. In response to COVID-19, the European Commission expanded all projects mentioned above with an additional work package dealing with COVID response, which lead to additional activities in addition to the activities described in the original projects. Additional activities include assistance in (surge capacity of) COVID diagnostics, infection prevention and control and on Water, sanitation and Hygiene (WASH).
- Within the framework of the Global Partnership against the spread of weapons and materials of mass destruction, RIVM assisted several countries in the implementation of a national inventory of dangerous pathogens. This inventory is a comprehensive overview of all laboratories in a country, the pathogens that are stored by these laboratories and their required laboratory containment levels. To comply with international agreements, such as the the Biological Toxins and Weapons Convention, countries are obliged to have oversight mechanisms, including a national inventory of high risk pathogens. At present, RIVMs GP activities have been transferred to Southeast and Eastern Europe and Central Asia by aligning with ongoing initiatives of regional and international stakeholders, to support countries within this region to strengthen their biosecurity capacities.
- The Netherlands Biosecurity Office, housed by the RIVM, is the national knowledge and information center for the Dutch Government and for organizations that work with high-risk biological materials, and aims to disseminate the government's new policy on biosecurity. The Biosecurity Office provides information to raise awareness on biosecurity issues and to enhance bio-risk management inside the organizations concerned (www.bureaubiosecurity.nl). This is done by organizing workshops and lectures, distribute newsletters to inform the field, by providing tools to assess the organizations current level of biosecurity.

# → <u>Data from Boehringer Ingelheim Animal Health Netherlands BV Lelystad (formerly Merial Lelystad)</u>

Boehringer Ingelheim Animal Health Netherlands BV Lelystad manufacturing and R&D works with different strains of the Foot-and-Mouth Disease Virus. At the site only applied research is performed, no basic or fundamental research. Publication of the results is, given the nature of the research, not in the interest of the company.

#### → Data from Intervet International B.V. / MSD Animal Health

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

#### → <u>Data from Janssen Vaccines & Prevention ((JVP) formerly Crucell Holland B.V)</u>

JVP very much encourages the publication of results of scientific research. JVP 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 Wacker Biotech B.V. (formerly SynCo Bio Partners B.V.)

Wacker Biotech B.V. (formerly SynCo Bio Partners B.V.) is a Contract Development Manufacturing Organization in the (Bio-) Pharmaceutical industry and as such not involved in biological research publications. For this business model reason there is no need for Wacker Biotech B.V. to have a policy on publication of biological research. The process development services Wacker Biotech B.V. can provide are generally only applied after the initial research and 'proof of concept' stages of biological research have been completed.

#### → Data from the Wageningen Bioveterinary Research

Wageningen Bioveterinary Research (Lelystad, The Netherlands) is performing statutory tasks for the ministry of Agriculture, Nature and Food Quality in The Netherlands. The Netherlands has a legal obligation on publication of results of scientific research. There are no restrictions in general on the publication of results of scientific research. Publication takes place in (inter)national scientific manuals, journals, magazines and other sources.

# 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.

Contributors	Abbreviations
Ministry of Defence	DEF
TNO Defence, Security and Safety	TNO
Ministry of Infrastructure and Water Management	I&W
Ministry of Health, Welfare and Sport	VWS
Ministry of Social Affairs and Employment	SZW
Ministry of Agriculture, Nature and Food Quality	LNV
National Institute for Public Health and the Environment	RIVM

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

The Ministry of Defence complies to civil legislation, regulations and other measures related to the topics (a) to (d) below, and has issued no additional legislation, regulations or measures on these topics.

#### Declaration of legislation, regulations and other measures

Relatin	ng to	Legislation	Regulations	Other measures <sup>20</sup>	Amended since last year
acquisit microbi agents, equipm	Development, tion stockpiling, tion or retention of ial or other biological or toxins, weapons, ent and means of y specified in Article		No	No	No
(b) organis	Exports of microms <sup>21</sup> and toxins	No	No	No	No
(c) organis	Imports of micro- ms <sup>11</sup> and toxins	No	No	No	No
(d) biosecu	Biosafety <sup>22</sup> and arity <sup>23</sup>	No	No	No	No

#### → Data from the Ministry of Infrastructure and Water Management (I&W)

Declaration of legislation, regulations and other measures under the responsibility of the Ministry of Infrastructure and Water Management.

Relating to	Legislation	Regulations	Other	Amended
			measures <sup>24</sup>	since last
				year

<sup>&</sup>lt;sup>20</sup> Including guidelines.

<sup>&</sup>lt;sup>21</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>22</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>23</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

<sup>&</sup>lt;sup>24</sup> Including guidelines.

(a)	Development,	No	No	No	N.A.			
production stockpiling,								
acquisiti	ion or retention of							
microbia	al or other biological							
agents, o	or toxins, weapons,							
equipme	ent and means of							
delivery	specified in Article I							
(b) organism	Exports of micro- ms <sup>25</sup> and toxins	No	No	No	N.A.			
(c) organism	Imports of micro- ms <sup>11</sup> and toxins	No	No	No	N.A.			
(d) biosecur	Biosafety <sup>26</sup> and rity <sup>27</sup>	Biosafety: Yes Biosecurity: No	Biosafety: Yes Biosecurity: No	Biosafety: Yes Biosecurity: No	No			

#### General remark to the above table:

The ministry of Infrastructure and Water Management (IenW) is responsible for legislation related to the handling, use and making of genetically modified organisms (GMO). The objective of the GMO 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 contained use and introduction into the environment (deliberate release) 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 GMO's, respectively. Where appropriate, the decree requires advanced written consent from competent authorities before activities with GMOs may be conducted. On the basis of the 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 micro-organisms comprehensive information is available to the competent authority.

This legislation has been slightly modified in 2020. With this modification, some procedures for obtaining a permit were amended. The level of safety was in no way altered or lowered.

The legislation can be found (in Dutch) at <a href="http://wetten.overheid.nl/BWBR0035090/">http://wetten.overheid.nl/BWBR0035090/</a>

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

<sup>&</sup>lt;sup>25</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

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

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

### Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures <sup>28</sup>	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biologic agents, or toxins, weapons, equipment and means of delivery specified in Articl I		No	No	No
(b) Exports of micro- organisms <sup>29</sup> and toxins	No	No	No	No
(c) Imports of micro- organisms <sup>11</sup> and toxins	No	No	No	No
(d) Biosafety <sup>30</sup> and biosecurity <sup>31</sup>	No	No	No	No

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

#### Declaration of legislation, regulations and other measures

Relatin	g to	Legislation	Regulations	Other measures <sup>32</sup>	Amended since last year			
(a)	Development,	No	No	No	No			
1	ion stockpiling,							
acquisit	ion or retention of							
microbi	al or other biological							
agents, or toxins, weapons,								
equipm	ent and means of							

<sup>&</sup>lt;sup>28</sup> Including guidelines.

<sup>&</sup>lt;sup>29</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>30</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>31</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

<sup>&</sup>lt;sup>32</sup> Including guidelines.

delivery specified in Article

(b) organis	Exports of micro- ms <sup>33</sup> and toxins	No	No	No	No
(c) organis	Imports of micro- ms <sup>11</sup> and toxins	No	No	No	No
(d) biosecu	Biosafety <sup>34</sup> and nrity <sup>35</sup>	No	No	No	Yes*

<sup>\*</sup> There has been an amendment since last year due to the classification of SARS-CoV-2. The Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833.<sup>36</sup>

#### → Data from Ministry of Agriculture, Nature and Food Quality

Relating to	Legislation	Regulations	Other measures <sup>37</sup>	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 <sup>38</sup> and toxins	No	No	No	No

<sup>&</sup>lt;sup>33</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>&</sup>lt;sup>34</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>35</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

 $<sup>^{36}</sup>$  http://data.europa.eu/eli/dir/2020/739/oj .

<sup>&</sup>lt;sup>37</sup> Including guidelines.

<sup>&</sup>lt;sup>38</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

(c)	Imports of micro-	No	No	No	No
organis	ms <sup>11</sup> and toxins				
(d)	Biosafety <sup>39</sup> and	No	No	No	No
biosecurity <sup>40</sup>					

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

#### Declaration of legislation, regulations and other measures

Relatir	ng to	Legislation	Regulations	Other measures <sup>41</sup>	Amended since last year
acquisi microb agents, equipm	Development, tion stockpiling, tion or retention of ial or other biological or toxins, weapons, tent and means of y specified in Article		Yes	No	No
(b) organis	Exports of micro- ms 42 and toxins	Yes	Yes	Yes	No
(c) organis	Imports of micro- ms <sup>11</sup> and toxins	Yes	Yes	No	No
(d) biosecu	Biosafety <sup>43</sup> and urity <sup>44</sup>	Yes for Biosafety	orYes for Biosafety	Yes	No
		Under development for Biosecurity	Biosecurity: Under development for Biosecurity	,	

<sup>&</sup>lt;sup>39</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>40</sup> In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

<sup>&</sup>lt;sup>41</sup> Including guidelines.

<sup>&</sup>lt;sup>42</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>43</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>44</sup> 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.

Contributors	Abbreviations
Ministry of Defence	DEF
TNO Defence, Security and Safety	TNO

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

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 falls under running assignments of the Netherlands government or 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.

Contributors	Abbreviations
Erasmus Medical Center Rotterdam – Laboratory for Infectious	EUR
Diseases	
Wageningen Bioveterinary Research	WBRV
Abbott Biologicals B.V.	
Bilthoven Biologicals B.V.	
Boehringer Ingelheim Animal Health Netherlands B.V.	BBio
Intervet International B.V. / MSD Animal Health	
Janssen Vaccines & Prevention (formerly Janssen / Crucell	JVP
Holland B.V.)	
Patheon Biologics B.V.	
Wacker Biotech B.V.	

# Erasmus Medical Center Rotterdam – Laboratory for Infectious Diseases

#### 1. Name of Facility:

Erasmus Medical Center

#### 2. Location (mailing address):

Dr Molewaterplein 50

#### General description of the types of diseases covered:

Zoonotic viruses such as Ebola, Marburg, Crimean Congo, Hanta, SARS-coronaviruses, Avian Influenza.

Arboviruses such as Denque, West Nile, Japanese Encephalitis, Rift Valley, Zika Respirat

#### Wageningen Bioveterinary Research (WBVR)

Wageningen Bioveterinary Reseach (Lelystad, The Netherlands) has nog production facility for vaccines licensed by the State party for the protection of humans

#### Abbott Biologicals B.V.

1. Name of Facility:

WWY/WWP

2. Location (mailing address):

C.J. van Houtenlaan 36, 1381CP Weesp, The Netherlands

P.O. Box 900, 1380 DA Weesp, the Netherlands

3. General description of the types of diseases covered:

Influenza (human)

#### Bilthoven Biologicals B.V.

1. Name of Facility:

Bilthoven Biologicals B.V.

2. Location (mailing address):

Antonie van Leeuwenhoeklaan 9-13

P.O. Box 457

3721 MA Bilthoven

The Netherlands

www.bilthovenbiologicals.nl

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

**Boehringer Ingelheim Animal Health Netherlands B.V.** 

#### 1. Name of Facility:

Boehringer Ingelheim Animal Health Netherlands B.V. (formerly Merial Lelystad)

#### 2. Location:

Houtribweg 39, 8221 RA Lelystad, The Netherlands

#### 3. General description of the types of diseases covered:

Boehringer Ingelheim Animal Health Netherlands BV Lelystad manufactures half product for Foot-and-Mouth Disease (FMD) vaccines and its R&D department develops new strains for vaccine purposes.

The research and production facilities are located on the premises of Wageningen BioVeterinary Research (formerly Central Veterinary Institute of WUR) and have a biocontainment infrastructure, compliant with or above the minimal standards for working with FMD virus (veterinary biosafety class 4).

#### Intervet International B.V. / MSD Animal Health

#### 1. Name of Facility:

Intervet International B.V., also known as MSD Animal Health

#### 2. Location (mailing address):

P.O. Box 31, 5830 AA Boxmeer, The Netherlands

#### 3. General description of the types of diseases covered:

Pathogens from farm and companion animals, including bacteria, protozoa and viruses.

#### **Janssen Vaccines & Prevention**

#### 1. Name of Facility:

Janssen Vaccines & Prevention

#### 2. Location:

P.O. Box 2048, 2301 CA Leiden, The Netherlands

#### 3. General description of the types of diseases covered:

Viral diseases: Ebola, Margburg, Zika, RSV, HIV, HPV, Influenza, SARS-CoV-2.

Bacterial infectious diseases: ExPEC (E. coli) and MRSA (S. aureus).

#### Patheon B. V.

1. Name of facility: Patheon Biologics BV, part of Thermo Fisher Scientific.

- 2. Location (mailing address): Zuiderweg 72/2, 9744 AP Groningen, the Netherlands.
- 3. General description of the types of diseases covered:

COVID-19, multiple types of Cancer.

#### Wacker Biotech B.V. (formerly SynCo Bio Partners B.V.)

#### 1. Name of Facility:

Wacker Biotech B.V. (formerly SynCo Bio Partners B.V.)

#### 2. Location:

Paasheuvelweg 30, 1105 BJ Amsterdam, The Netherlands

#### 3. General description of the types of diseases covered:

It should be noted that Wacker Biotech B.V. does not hold the market authorisation for the products manufactured on site. Products are always delivered to our clients, either for final release to clinic or market or for further processing. As such Wacker Biotech B.V. can provide a list of diseases for which vaccines are produced, but cannot provide all the specifics of the vaccines as defined in the applicable product registration dossiers.

List of diseases for which (intermediate drug substance of) vaccine is produced:

- Cholera
- Haemophilus Influenza type B
- Diphtheria, Tetanus, Pertussis, Hepatitis B, Haemophilus Influenza type B combined vaccine
- Meningitis C
- ZIKA

Lyme disease (borreliosis)

- Covid-19