

## DEPARTMENT OF TRADE AND INDUSTRY

NO. 494

29 MARCH 2019

**NON-PROLIFERATION OF WEAPONS OF MASS DESTRUCTION ACT,  
1993 (ACT NO. 87 OF 1993)****DECLARATION OF CERTAIN BIOLOGICAL GOODS AND TECHNOLOGIES AS  
CONTROLLED GOODS AND CONTROL MEASURES APPLICABLE TO SUCH  
GOODS****Definitions**

1. In this Notice any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, unless the context otherwise indicates—

**"Biological and Toxin Weapons Convention"** means the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, added as a schedule to the Act;

**"biological weapons"** means microbial or other biological agents or toxins, regardless of the origin or method of production thereof, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, and weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;

**"development"** means all phases before production, and includes conceptualisation, research, analysis, testing, configuration or pilot production schemes;

**"services"** includes freight forwarding, storing and stockpiling (if not part of the manufacture and transfer processes), transporting, maintaining (repairing, overhauling, refurbishing), trading, consulting, disposing, and technical assistance;

**"the Act"** means the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993);

**"transfer"** means the change of ownership or custodianship, or change in the location, of controlled goods, whether or not they cross an international border.

### **Declaration**

2. I, Dr Rob Davies, Minister of Trade and Industry, under section 13(1) of the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), and on the recommendation of the South African Council for the Non-Proliferation of Weapons of Mass Destruction, (hereinafter referred to as the "Council"), hereby declare microbial or other biological agents, toxins and related equipment and technology that may be used in the manufacture of biological and toxin weapons as listed in Annexures A and B to this Notice, to be controlled goods.
  
3. I hereby—
  - (a) in terms of section 13(2)(a) and (e) of the Act and pursuant to South Africa's obligations under the Biological and Toxin Weapons Convention, further prohibit—
    - (i) the import, export, re-export, transit (including transshipment), possession, development, manufacture, production, acquisition in any manner, use, operation, stockpiling, maintenance, transport, disposal, sale, and retention of biological weapons;
    - (ii) any person to assist, encourage or to induce any State, group of States, international organisations or non-State actors to manufacture or otherwise acquire biological weapons;
  - (b) in terms of section 13(2)(b) of the Act, determine that the export, re-export or transit (including transshipment) of controlled goods listed in the annexures to this Notice, shall take place under a permit issued by the Council. A permit is not required for quantities of 5 milligrams or less of saxitoxin, if the transfer is made for medical or diagnostic purposes, in which case a notification to that effect shall be made to the Council before the transfer.

- (c) in terms of section 13(2)(c) of the Act, determine that the Council may require a State-to-State assurance or an end-user or end-use certificate for the export or re-export of controlled goods listed in the annexures to this Notice; and
- (d) in terms of section 13(2)(d) of the Act, determine that all transport of controlled goods within the Republic of South Africa be declared to the Council within 21 calendar days of such transportation.

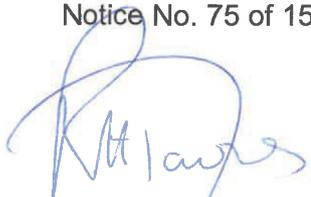
#### **Application forms**

4. Application forms for permits contemplated in paragraph 3 of this Notice can be obtained from any of the following addresses:

- (a) Postal address:  
The Secretariat  
South African Council for the Non-Proliferation of Weapons of Mass  
Destruction  
Private Bag X84  
PRETORIA  
0001; or
- (b) Physical address:  
The Secretariat  
South African Council for the Non-Proliferation of Weapons of Mass  
Destruction  
77 Meintjies Street  
Sunnyside  
PRETORIA or
- (c) The website of the South African Council for the Non-Proliferation of  
Weapons of Mass Destruction at  
<http://www.thedti.gov.za/nonproliferation>.

**Repeal**

5. Government Notice No. 19 of 3 February 2010 as amended by Government Notice No. 75 of 15 February 2015 is hereby repealed.

**DR ROB DAVIES, MP****MINISTER OF TRADE AND INDUSTRY****DATE** 5/3/19

**ANNEXURE A****I. HUMAN PATHOGENS, ZOOSES AND TOXINS, AS FOLLOWS:**

a. Viruses, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such cultures, as follows:

- Chikungunya virus;
- Eastern equine encephalitis virus;
- Western equine encephalitis virus;
- Venezuelan equine encephalitis virus;
- Oropouche virus;
- Rocio virus;
- Dengue fever virus;
- Yellow fever virus;
- Japanese encephalitis virus;
- Tick-borne encephalitis complex viruses, including Russian Spring-Summer encephalitis, Kyasanur Forest, Louping ill, Omsk haemorrhagic fever and Powassan;
- St Louis encephalitis virus;
- Murray Valley encephalitis virus;
- Rift Valley fever virus;

- Crimean-Congo haemorrhagic fever virus;
  - Hantaviruses, including Hantaan, Seoul, Dobrava, Puumala and Sin Nombre;
  - Arenaviruses, associated with haemorrhagic fevers including Lassa fever, Junin, Machupo, Lymphocytic choriomeningitis, Sabia, Flexal, Dandenong, Lujo and Guanarito;
  - Variola virus;
  - Monkey pox virus;
  - Ebola virus;
  - Marburg virus;
  - Hendra virus;
  - Nipah virus.
- b. Rickettsiae, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
- *Coxiella burnetii*;
  - *Bartonella quintana* (*Rochalimaea quintana*, *Rickettsia quintana*);
  - *Rickettsia prowazekii*;
  - *Rickettsia rickettsii*.

- c. Bacteria, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
- *Bacillus anthracis*;
  - *Brucella abortus*;
  - *Brucella melitensis*;
  - *Brucella suis*;
  - *Chlamydia psittaci*;
  - *Clostridium botulinum*;
  - *Clostridium perfringens*, epsilon toxin producing types;
  - *Clostridium tetani*;
  - Enterohaemorrhagic *Escherichia coli*, serotype 0157 and other verotoxin producing serotypes;
  - *Francisella tularensis*;
  - *Legionella pneumophila*;
  - *Burkholderia mallei* (*Pseudomonas mallei*);
  - *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*);
  - *Salmonella typhi*;
  - *Shigella dysenteriae*;
  - *Vibrio cholerae*;

- 
- *Yersinia pestis*;
  - *Yersinia pseudotuberculosis*.
- d. Toxins, as follows, and subunits of toxins thereof:
- Abrin;
  - Botulinum toxins;
  - Cholera toxin;
  - *Clostridium perfringens* toxins;
  - Conotoxin;
  - Modeccin;
  - Ricin;
  - Saxitoxin;
  - Shiga toxin;
  - *Staphylococcus aureus* toxins;
  - Tetanus toxin;
  - Tetrodotoxin;
  - Trichothecene mycotoxins, such as T-2 toxin, HT-2 toxin and Diacetoxyscirpenol toxin;
  - Verotoxin;
  - Microcystin (Cyanginosin);

- Aflatoxin;
- Volkensin;
- Viscum album Lectin 1 (Viscumin);

**Except:**

1. Any goods in the form of a vaccine or toxoid.
2. Botulinum toxin used for cosmetic / medicinal purposes

e. Fungi, as follows:

- *Coccidioides immitis*;
- *Coccidioides posadasii*.

**II. ANIMAL PATHOGENS, AS FOLLOWS:**

i. Viruses, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such cultures, as follows:

- African swine fever virus;
- African horse sickness virus;
- Avian influenza virus, which can be:
  1. Uncharacterised; or
  2. Defined as having high pathogenicity, as follows:

- i. Type A viruses with an IVPI (intravenous pathogenicity index) in six-week-old chickens of greater than 1.2; or
  - ii. Type A viruses, H5 or H7 subtype, for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin;
- Bluetongue virus;
  - Foot-and-mouth disease virus;
  - Goat pox virus;
  - Porcine herpesvirus (Aujeszky's disease);
  - Swine fever virus (Hog cholera virus);
  - Lyssaviruses;
  - Newcastle disease virus;
  - 'Peste des petits ruminants' virus;
  - Porcine enterovirus type 9 (swine vesicular disease virus);
  - Rinderpest virus;
  - Sheep pox virus;
  - Teschen disease virus;
  - Vesicular stomatitis virus;
  - Lumpy skin disease.

- ii. *Mycoplasma mycoides* subspecies *mycoides* SC (small colony), whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such *Mycoplasma mycoides* (*mycoides* SC).
- iii. *Mycoplasma capricolum* subspecies *capripneumoniae* ("strain F38")

**Except:**

Any goods in the form of a vaccine or toxoid.

**III. PLANT PATHOGENS, AS FOLLOWS:**

- a. Bacteria, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material which has been deliberately inoculated or contaminated with such cultures, as follows:
  - *Xanthomonas albilineans*;
  - *Xanthomonas campestris* pv. *citri*, including strains referred to as *Xanthomonas campestris* pv. *citri* types A, B, C, D, E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv. *aurantifolia*, *Xanthomonas campestris* pv. *citrumelo*, *Xanthomonas axonopodis* pv. *citri*, *Xanthomonas axonopodis* pv. *citrumelo*, *Xanthomonas axonopodis* pv. *aurantifolii*;
  - *Xanthomonas oryzae* pv. *oryzae*;
  - *Xylella fastidiosa*;
  - *Clavibacter michiganensis* subspecies *sepedonicus* (*Corynebacterium michiganensis* subspecies *sepedonicum* or *Corynebacterium sepedonicum*);

- *Ralstonia solanacearum* races 2 and 3 (*Pseudomonas solanacearum* races 2 and 3 or *Burholderia solanacearum* races 2 and 3).
- b. Fungi, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material which has been deliberately inoculated or contaminated with such cultures, as follows:
- *Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*);
  - *Cochliobolus miyabeanus* (*Helminthosporium oryzae*);
  - *Deuterophomonas tracheiphila* (syn. *Phoma tracheiphila*);
  - *Microcyclus ulei* (syn. *Dothidella ulei*);
  - *Monilia rorei* (syn. *Moniliophthora rorei*);
  - *Puccinia graminis* (syn. *Puccinia graminis* f. sp. *tritici*);
  - *Puccinia striiformis* (syn. *Puccinia glumarum*);
  - *Magnaporthe grisea* (*Pyricularia grisea*/*Pyricularia oryzae*).
- c. Viruses, whether natural, synthetic, enhanced or modified, either in the form of isolated live cultures or as material, including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
- Banana bunchy top virus;
  - Potato Andean latent tymovirus;
  - Potato spindle tuber viroid.

**IV. GENETICALLY MODIFIED MICRO-ORGANISMS, AS FOLLOWS:**

- a. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity of organisms specified in **(I.a)** to **(I.c)** or **(II)** or **(III)**.
  
- b. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins specified in **(I.d)** or subunits of toxins thereof.

## ANNEXURE B

### I. EQUIPMENT CAPABLE OF USE IN HANDLING BIOLOGICAL MATERIALS, AS FOLLOWS:

- a. Complete biological containment facilities at Biosafety Level 3 or 4 containment level (BSL3/4).

#### **Technical Note:**

Biosafety Level 3 or 4 containment levels are as specified in Government Notice No. R. 178 of 02 March 2012 promulgated in terms of the National Health Act, 2003 (Act No. 61 of 2003)

- b. Major components that can be used to build a functional Biosafety Level 3 or 4 facility as follows:
- i) Safe-change filter-housings [Bag-in-Bag-out (BIBO)] with in-situ filter test system and filtration efficiency greater than 99,99% at Most Penetrating Particle Size (MPPS) (Leakage less than 0.01%);
  - ii) Effluent Decontamination Systems (EDS) (thermal or chemical process).
- c. Fermenters, roller/cassette type incubators capable of cultivating biological agents as follows:
- i) Fermenters controlling the release of aerosols and are capable of sterilisation/decontamination in-situ;
  - ii) Incubators that are fitted with disposable/sterilisable sealed culture flasks/bottles/cassettes that have aerosol control devices fitted.

- d. Autoclaves with internal effluent/condensate decontamination and/or sterilisation systems. The autoclaves must be the double door type (as per BSL3/4 laboratory use) or attachable to Biosafety Cabinet Class III isolators.

**Technical Note:**

In this control, 'sterilisation' denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g. steam) or chemical agents. 'Decontamination' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect.

- e. Freeze-drying equipment with condensate collection systems to safely collect potentially contaminated condensate or with disinfection systems (such as EDS) including vacuum line HEPA (High Efficiency Particulate Arrestor/Air) filtration.
- f. Spray Drying equipment that comply with all of the following:
- i) capacity to control/contain aerosols;
  - ii) all internal areas that are in contact with the biological agent are sterilisable / decontaminatable / disposable;
  - iii) used in conjunction with a containment system (BSL3/4 or Class III Cabinet).
- g. Milling equipment with all of the following:
- i) capacity to grind biological material to a powder;
  - ii) capacity to control aerosols; and
  - iii) sterilise/decontaminate internal areas/components.
- h. Biological safety cabinets or isolators, which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection.

The Biological safety cabinets or isolators shall comply with all of the following:

- i) exhaust air ducted to the outside atmosphere or treated (HEPA filtered and activated carbon adsorption) to safely recirculate within the working environment;
- ii) airflow velocity through the glove ports of at least 0.75m/s, when all gloves are detached;
- iii) smooth, rigid, flat and chemically resistant work floor;
- iv) fitted with pressure and/or airflow quantity controls, and/or
  - Interlocking door pass-through chamber, and/or
  - Disinfectant dunk tank, and/or
  - Fitted gaseous decontamination system (for example, formaldehyde gas generator).

**Technical Note:**

Isolators include flexible isolators, drying boxes, anaerobic chambers and glove boxes that can protect the operator from biological agents and toxins (direct contact and/or aerosols exposures) with condensate collection systems to safely collect potentially contaminated condensate or with disinfection systems (such as EDS) including vacuum line HEPA filtration.

- i. Chambers designed for aerosol challenge testing with micro-organisms, viruses or toxins and equipped with any of the following:
  - i) capacity of 1 m<sup>3</sup> or greater;
  - ii) operating under negative pressure and having controllable airflows;
  - iii) equipped with HEPA filtration on the chambers exhaust;
  - iv) fitted with a nebuliser capable for aerosolising controlled biological agents;
  - v) having at least one aerosol sample collector, capable of being controlled from outside of the chamber or live animal attachment/introduction capabilities.

**ISIHLOKOMISO SIKARHULUMENTE****ISEBE LORHWEBO NEMIZI-MVELISO****UMTHETHO I-NON-PROLIFERATION OF WEAPONS OF MASS  
DESTRUCTION ACT 87 KA-1993****UKUBHENGEZWA KWEMPAHLA ETHILE YOHLOBO LWEBHAYOLOJI  
NEZINTO EZITHILE ZOBUCHWEPHESHE NJENGEMPAHLA EMAYILAWULWE,  
NAMANYATHELO OKUZILAWULA ASEBENZA KULOO MPAHLA****Ukuchazwa kwamagama**

1. Kwesi Sihlokomiso naliphi na igama okanye ibinzana elinikwe intsingiselo kuMthetho ongunozala wesi Sihlokomiso liza kuba naloo ntsingiselo nakwesi Sihlokomiso, kuze kuthi, ngaphandle kokuba okanye okubhaliweyo kubonisa ngenye indlela—

**"iBiological and Toxin Weapons Convention"** kube siSivumelwano Sokwalelwa Kokuphuculwa, Nokuveliswa Nokufunjwa Kwezixhobo Zebhayoloji Neziyityhefu Nokutshatyalaliswa Kwazo, esongezwe njengesihlomelo kulo Mthetho;

**"izixhobo zebhayoloji"** ziityhefu zeemayikhrobhu okanye ezinye iityhefu zebhayoloji, kungakhathaliseki ukuba zivela phi okanye indlela eziveliswe ngayo, kungakhathaliseki iintlobo nobungakanani ezingathethelelekiyo, okanye ezinye iinjongo zokukhusela okanye zoxolo, kwakunye nezixhobo okanye iindlela zokuthutha eziyilelwe ukusebenzisa ezo tyhefu zizisebenzisa iinjongo zobutshaba okanye kungquzulwano ekuxhotyiweyo kulo;

**"inkqubela"** ngawo onke amanqanaba ngaphambi kokuveliswa kwento, kwaye eli gama liquka uphando, uhlolisiso, ukuvavanya, okanye iindlela zokuveliswa kweephayilothi;

**elithi "iinkonzo"** liquka ukuthunyelwa kwemithwalo ngezithuthi, ukugcinwa koovimba (ukuba akuyiyo inxalenye yokwenziwa kwempahla efektri nokuthunyelwa kwayo), ukuthutha, ukulondoloza (ukugciba, ukuhlaziya ubume bento), ukurhweba, ukubonisana, ukwahlakana nayo, noncedo lobuchwepheshe;

**elithi "Io Mthetho"** lithetha i*Non-Proliferation of Weapons of Mass Destruction Act* 87 ka-1993;

**"ukudlulisela"** kukwenziwa kotshintsho kubumnini okanye kumntu oyigcinileyo into, okanye utshintsho kwindawo, kwimpahla ephantsi kolawulo, kungakhathaliseki ukuba iwela umda wamanye amazwe kusini na;

### **Ndiyavakalisa**

2. Mna, Gqr Rob Davies, uMphathiswa Worhwebo Nemizimveliso, ngokugunyazwa sisiqendu 13(1) se*Non-Proliferation of Weapons of Mass Destruction* 87 ka-1993. Nangokwesindululo esenziwe seSouth African Council for the Non-Proliferation of Weapons of Mass Destruction (ukususela ngoku eliza kubizwa ngokubha li-"Bhunga"), ngokwenjenje ndivakalisa ukuba izixhobo zeemayikhrowubhu okanye ezinye izixhobo zebhayoloji, iityhefu nezinto eziyelele apho nobuchwepheshe obunokuthi busetyenziswe ekwenziweni kwezixhobo zebhayoloji nezetyhefu njengoko zidweliswe kwiSongezo A no-B kwesi Sihlokomiso, ndizivakalisa ziyimpahla emayilawulwe.
3. Ngokwenjenje—
  - (a) ngokwesiqendu 13(2)(a) no-(e) salo Mthetho, nangokukhumbula iimbophelelko onazo uMzantsi-Afrika ngokweSivumelwano Sezixhobo Zebhayoloji Neziyityhefu, ndiyakwalela kananjalo—
    - (i) uku-odwa kwezixhobo zebhayoloji kwamanye amazwe, ukuthunyelwa kwazo kwamanye amazwe, ukuphindwa kwazo zithunyelwe kwamanye amazwe, ukuhanjiswa kwazo (kuquka ukuhanjiswa kwazo ngenqanawa, ukuba umntu abe nazo kuye, aziphucule, azenze, azivelise, azizuze nokuba kungayiphi na indlela, azisebenzise, asebenze ngazo, azifumbe, azilondoloze, azithuthe, ahlukane nazo, azithengise, azigcine;
    - (ii) ukuba nawuphi na umntu ancedise, akhuthaze okanye athundeze nawuphi na urhulumente, iqela loorhulumente, imibutho yamazwe

ngamazwe okanye amaqumrhu angengokarhulumente, ukuba enze izixhobo zebhayoloji okanye azizue;

- (b) ngokwesiqendu 13(2)(b) salo Mthetho, ndigqiba kwelokuba ukuthunyelwa kumazwe angaphandle, ukuphindwa kwakhona kokuthunyelwa kumazwe angaphandle okanye ukuhanjiswa (kuquka nokuhanjiswa ngenqanawa) kwempahla emayilawulwe edweliswe kwizongezo ezikwesi Sihlokomiso, kuza kwenzeka ngokwegunya lesmvume ekhutshwe iBhunga. Akufuneki mvume xa iyi-5 milligrams okanye ingaphantsi koko isaxitoxin, ukuba ukuthunyelwa kwayo kwenziwa ngenjongo yonyango okanye ngenjongo yokufumanisa unobangela wesifo, ekuya kuthi xa kunjalo kwaziswe iBhunga ngaphambi kokuba impahla ihanjiswe.
- (c) ngokwesiqendu 13(2)(c) salo Mthetho, ndigqiba kwelokuba iBhunga lisengafuna isiqinisekiso esisuka komnye uRhulumente esiya komnye uRhulumente okanye esiya kumntu oza kuyisebenzisa okanye lifune isiqinisekiso sokusetyenziswa, isesokuthunyelwa kwelinye ilizwe okanye ukuphinda ukuthunyelwa kwelinye ilizwe kwempahla emayilawulwe edweliswe kwizongezo ezikwesi Sihlokomiso; kwaye
- (d) ngokwesiqendu 13(2) salo Mthetho, ndigqiba kwelokuba konke ukuthuthwa kwempahla emayilawulwe ngaphakathi kwemida yeRiphabliki yoMzantsi-Afrika makudandalaziswe kwiBhunga zingekapheli iintsuku ezingama-21 zekhalenda zithuthiwe.

#### **lifom zesicelo**

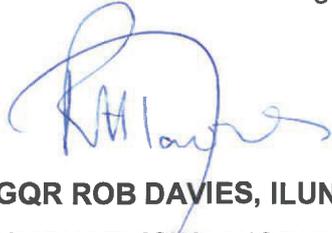
4. lifom zesicelo zokufumana iimvumeo ezixelwe kwisiqendu 3 sesi Sihlokomiso zinokufunyanwa nakweyiphi na yezi dilesi zilandelayo:

- (a) Idilesi yeposi:  
The Secretariat  
South African Council for the Non-Proliferation of Weapons of Mass  
Destruction  
Private Bag X84  
PRETORIA  
0001; okanye

- (b) Idilesi yesitrato:  
The Secretariat  
South African Council for the Non-Proliferation of Weapons of Mass  
Destruction  
77 Meintjies Street  
Sunnyside  
PRETORIA; okanye
- (c) kwiwebsayithi yeSouth African Council for the Non-Proliferation of  
Weapons of Mass Destruction ethi  
<http://www.thedti.gov.za/nonproliferation>.

#### **Ukutshitshiswa**

5. Apha kutshitshiswa iSihlokomiso SikaRhulumente esinguNombolo sikaFebruwari 3, 2010 esathi senziwa utshintsho siSihlokomiso SikaRhulumente esinguNombolo 75 sikaFebruwari 15, 2015.



**GQR ROB DAVIES, ILUNGU LEPALAMENTE  
UMPHATHISWA WORHWEBO NEMIZIMVELISO  
UMHLA**

## ISONGEZO A

### I. IINTSHOLONGWANE EZINOKUBANGELA IZIFO EBANTWINI, IZIFO EZINOKUSULELA ABANTU ZISUKA KWIZILWANYANA, IITYHEFU, NGALE NDLELA ILANELAYO:

a. Iintsholongwane, kungakhathaliseki ukuba zezendalo, zeziyintlanguanisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye, kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge—

- intsholongwane yesifo seengcongconi;
- intsholongwane yasempuma esuleleka ebantwini nasemahasheni ngokulunywa yingcongconi esulelekileyo;
- intsholongwane yasentshona esuleleka ebantwini nasemahasheni ngokulunywa yingcongconi esulelekileyo;
- intsholongwane yaseVenezuela esuleleka ebantwinini nasemahasheni;
- intsholongwane yomkhuhlane ongena ngengcongconi;
- intsholongwane *i-rocio*;
- intsholongwane yomkhuhlane *idengue*;
- intsholongwane *ye-yellow fever*;
- intsholongwane *iJapanese encephalitis*;
- iintsholongwane ezintsonkothileyo *i-encephalitis* ezithwalwa ngamaqhizana, ekukho phakathi kwazo *iRussian Spring-Summer*

*encephalitis*, i-Kyasanur Forest, i-Louping ill, i-Omsk  
*haemorrhagic fever ne-Powassan*;

- intsholongwane i*St Louis encephalitis*;
  - intsholongwane i*Murray Valley encephalitis*;
  - intsholongwane yomkhuhlane iRift Valley;
  - intsholongwane yomkhuhlane i*Crimean-Congo haemorrhagic*;
  - i-Hantaviruses, kunye ne-Hantaan, iSeoul, iDobrava, iPuumala neSin Nombre;
  - iintsholongwane ii-Arena, ezinxulunyaniswa nemikhuhlane yokopha equka umkhuhlane i-Lassa, i-Junin, i-Machupo, i-Lymphocytic choriomeningitis, i-Sabia, i-Flexal, i-Dandenong, i-Lujo ne-Guanarito;
  - intsholongwane i-*variola*;
  - intsholongwane iMonkey pox;
  - intsholongwane ye-Ebola;
  - intsholongwane i-Marburg;
  - intsholongwane iHendra;
  - intsholongwane iNipah.
- b. Ii-Rickettsiae, noba zezendalo, zeziyintlanguanisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye, kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge--

- *Coxiella burnetii*;
- *Bartonella quintana* (*Rochalimaea quintana*, *Rickettsia quintana*);
- *Rickettsia prowazekii*;
- *Rickettsia rickettsii*.

c. Iintsholongwane, kungakhathaliseki ukuba zezendalo, zeziyintlanganisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye, kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge—

- *Bacillus anthracis*;
- *Brucella abortus*;
- *Brucella melitensis*;
- *Brucella suis*;
- *Chlamydia psittaci*;
- *Clostridium botulinum*;
- *Clostridium perfringens*, iintlobo ezivelisa iityhefu eziyi-epsilon;
- *Clostridium tetani*;
- *Enterohaemorrhagic Escherichia coli*, uhlobo olungu-0157 nezinye iintlobo ezivelisa i-verotoxin;
- *Francisella tularensis*;

- 
- iLegionella pneumophila;
  - iBurkholderia mallei (Pseudomonas mallei);
  - iBurkholderia pseudomallei (Pseudomonas pseudomallei);
  - iSalmonella typhi;
  - iShigella dysenteriae;
  - iVibrio cholerae;
  - iYersinia pestis;
  - iYersinia pseudotuberculosis.
- d. iintsholongwane, ezinjengezi zilandelayo, namasuntswana azo:
- iAbrin;
  - iBotulinum toxins;
  - ityhefu iCholera;
  - iityhefu iClostridium perfringens;
  - iConotoxin;
  - iModeccin;
  - iRicin;
  - iSaxitoxin;
  - ityhefu iShiga;
  - iityhefu iStaphylococcus aureus;

- ityhefu iTetanus;
- iTetrodotoxin;
- ii-Trichothecene mycotoxins, njenge-T-2 toxin, i-HT-2 toxin ne-Diacetoxyscirpenol toxin;
- iVerotoxin;
- iMicrocystin (Cyanginosin);
- iAflatoxin;
- iVolkensin;
- iViscum album Lectin 1 (Viscumin);

**Ngaphandle:**

1. kwempahla ekwimo yomgonyo okanye yesibulala-tyhefu.
2. iBotulinum toxin esetyenziselwa nje ubuhle okanye ukunyanga

e. ukungunda, ngale ndlela ilandelayo:

- iCoccidioides immitis;
- iCoccidioides posadasii.

**II. IINTSHOLONGWANE EZINOKUBANGELA IZIFO  
KWIZILWANYANA, NGALE NDLELA ILANDELAYO:**

- i. lintsholongwane, kungakhathaliseki ukuba zezendalo, zeziyintlanganisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye,

kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge—

- intsholongwane yomkhuhlane weehagu yaseAfrika;
- intsholongwane egulisa amahashe yaseAfrika;
- intsholongwane yemfuxane iAvian, enokuthi:
  1. ingabi nazimpawu; okanye
  2. ichazwe njengeneentsholongwane ezininzi kakhulu, ngale ndlela ilandelayo:
    - i. iintsholongwane eziluhlobo A ezine-IVPI (intravenous pathogenicity index) kumantshontsho eenkuku abudala buziiveki ezintandathu ngaphezu kwe-1.2; okanye
    - ii. iintsholongwane zohlobo A, okanye uhlotyana H5 okanye H7, ekuthe ukulandelelana kwe-nucleotide kwabonisa ii-amino acid ezisisiseko ezininzi kwindawo ye-haemagglutinin;
- iBluetongue virus;
- intsholongwane yesifo senyebetu neempuphu;
- iGoat pox virus;
- iPorcine herpesvirus (isifo iAujeszky);
- intsholongwane yomkhuhlane weehagu;
- iLyssaviruses;

- intsholongwane yesifo saseNewcastle;
  - intsholongwane i-'Peste des petits ruminants';
  - iPorcine enterovirus type 9 (swine vesicular disease virus);
  - intsholongwane iRinderpest;
  - intsholongwane iSheep pox;
  - intsholongwane yesifo iTeschen;
  - intsholongwane iVesicular stomatitis;
  - isifo solusu olunamagaqa.
- ii. i-*Mycoplasma mycoides* subspecies *mycoides* SC (small colony), kungakhathaliseki ukuba zezendalo, zeziyintlanganisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye, kuquka ulutho oluphilayo oluginywe ngabom okanye lwangcoliswa ngezinto ezinjenge*Mycoplasma mycoides* (*mycoides* SC).
- iii. I-*Mycoplasma capricolum* subspecies *capripneumoniae* ("strain F38")

### **Ngaphandle:**

Nayiphina na impahla ekwimi yomgonyo okanye isibulala-tyhefu.

### **III. IINTSHOLONGWANE EZINOKUBANGELA IZIFO KWIZITYALO, NGALE NDLELA ILANDELAYO:**

iintsholongwane, kungakhathaliseki ukuba zezendalo, zeziyintlanganisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba

ngazinye okanye ndawonye, kuquka ulutho oluphilayo olungqongwe ngabom okanye lwangcoliswa ngezinto ezinjenge—

- iXanthomonas albilineans;
  - iXanthomonas campestris pv. citri, kuquka nezinto ekuthethwe ngazo njengeXanthomonas campestris pv. citri types A, B, C, D, E okanye ezidweliswe njengeXanthomonas citri, Xanthomonas campestris pv. aurantifolia, Xanthomonas campestris pv. citrumelo, Xanthomonas axonopodis pv. citri, Xanthomonas axonopodis pv. citrumelo, Xanthomonas axonopodis pv. aurantifolii;
  - iXanthomonas oryzae pv. oryzae;
  - iXylella fastidiosa;
  - iClavibacter michiganensis subspecies sepedonicus (Corynebacterium michiganensis subspecies sepedonicum okanye Corynebacterium sepedonicum);
  - iRalstonia solanacearum races 2 no-3 (Pseudomonas solanacearum races 2 no-3 okanye iBurholderia solanacearum races 2 no-3).
- b. ukungunda, kungakhathaliseki ukuba kokwendalo, kokuyintlanganisela, kokuphuculiweyo okanye kokulungisiweyo, kungakhathaliseki ukuba kuhamba ngakunye okanye ndawonye, kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge—
- iColletotrichum kahawae (Colletotrichum coffeanum var. virulans);
  - iCochliobolus miyabeanus (Helminthosporium oryzae);
  - iDeuterophomonas tracheiphila (syn. Phoma tracheiphila);
  - iMicrocyclus ulei (syn. Dothidella ulei);

- iMonilia rorei (syn. Moniliophthora rorei);
  - iPuccinia graminis (syn. Puccinia graminis f. sp. tritici);
  - iPuccinia striiformis (syn. Puccinia glumarum);
  - iMagnaporthe grisea (Pyricularia grisea/Pyricularia oryzae).
- c. lintsholongwane, kungakhathaliseki ukuba zezendalo, zeziyintlanganisela, zeziphuculiweyo okanye zezilungisiweyo, kungakhathaliseki ukuba zihamba ngazinye okanye ndawonye, kuquka ulutho oluphilayo olugonywe ngabom okanye lwangcoliswa ngezinto ezinjenge—
- ntsholongwane iBanana bunchy top;
  - iPotato Andean latent tymovirus;
  - iPotato spindle tuber viroid.

#### IV. IINTSHOLONGWANE ZOKUNGUNDA EZILUNGISIWEYO, NGALE NDLELA ILANDELAYO:

- a. lintsholongwane zokungunda ezilungisiweyo okanye iziqalelo eziqulethe ii-*nucleic acid sequences* ezinxulumene neentsholongwane ezibangela izifo ezixelwe ku-(I.a) ukuya ku-(I.c) okanye (II) okanye (III).
- b. lintsholongwane zokungunda ezilungisiweyo okanye iziqalelo eziqulethe ii-*nucleic acid sequences* zazo naziphi na iityhefu ezixelwe ku-(I.d) okanye amasuntswana eetyhefu zayo.

## ISONGEZO B

### I. IZIXHOBO EZINOKUSETYENZISWA EKUSINGATHENI IZIXHOBO ZEBHAYOLOJI, NGALE NDLELA ILANDELAYO:

- a. Izixhobo ezipheleleyo zokulawula izinto zebhayoloji kwiBiosafety Level Level 3 okanye 4 containment level (BSL3/4).

#### Qaphela:

Ii-Biosafety Level 3 okanye 4 containment levels zixelwe kwiSihlokomiso SikaRhulumente esinguNombolo R. 178 sikaMatshi 2, 2012 esapapashwa ngokwe*National Health Act* 61 ka-2003

- b. Iinxalenye eziphambili ezinokusetyenziselwa ukwakha i-Biosafety Level 3 okanye 4 esebenzayo ngale ndlela ilandelayo:
- i) Ii-filter-housing ekungenabungozi ukuzitshintsha [Bag-in-Bag-out (BIBO)] ezine- in-situ filter test system nezikwazi ukuhluza ezinkulu kune-99,99% eMost Penetrating Particle Size (MPPS) (ukuvuza kungaphantsi kwe-0.01%);
  - ii) I-Effluent Decontamination Systems (EDS) (thermal okanye chemical process).
- c. Izibilisi, uhlobo lwezifukamisi eziyi-roller/cassette ezikwazi ukukhulisa amachiza ebhayoloji ngale ndlela ilandelayo:
- i) Izibilisi ezilawula ukukhululwa kwezitshizi nezikwaziyo ukubulala iintsholongwane;
  - ii) Izifukamisi ezifakelwe iiflaski ezilahlwayo okanye ezinokubiliselwa iintsholongwane ezifakelwe iziciko.

- d. Iziphatho ezishushu. Iziphatho ezishushu mazibe ngcango-mbini (njengasekuetyenzisweni elaboratri BSL3/4) okanye ixokomezelelwe kwiBiosafety Cabinet Class III isolators.

**Qaphela:**

Kolu lawulo, 'ukubulawa kweentsholongwane' kuthetha ukupheliswa kwazo zonke iimayikrobhu ezivela kwizixhobo ngokusetyenziswa kwezinto ezibonakalayo (ezinjengomphunga) okanye amachiza. 'Ukuphelisa ungcoliso' kuthetha ukutshatyalaliswa kweemayikrobhu ezinokuthi zibekho kwizixhobo ngokusetyenziswa kwamachiza abulala iintsholongwane.

- e. Izixhobo ezomisa ngokukhenkcisa nesineendlela zokuqokelela ngokuyondelelanisa umphunga ukuze kuqokeleleke ngendlela engenabungozi okanye ngeendlela eziphelisa ukusuleleka (ezinjengeEDS), kuquka iHEPA (High Efficiency Particulate Arrestor/Air).
- f. Izixhobo zokomisa ngesitshizo esihlangabezana nako konke oku kulandelayo:
- i) ukukwazi ukulawula/ukuqulatha izitshizo;
  - ii) konke okungaphakathi okudibanayo nesixhobo sebhayoloji kunako ukuba kwenziwe kungabi nazintsholongwane / kususwe ukungcoliseka / kulahlwe;
  - iii) kusetyenziswe kunye nendlela yokukuqulatha ngaphakathi (BSL3/4 okanye Class III Cabinet).
- g. Izixhobo zokusila ezinako konke oku:
- i) ukukwazi ukulusila ulutho lwebhayoloji lube ngumgubo;
  - ii) ukukwazi ukuzilawula izitshizo;
  - iii) nokuziphelisa iintsholongwane iindawo zangaphakathi..
- h. Iikhabhinethi zebhayoloji zokhuseleko ezivumela ukuba ukusebenza ngezandla kwenzeke ngaphakathi, ngoxa kwangaxeshanye kusakhiwa imekobume elingana noClass III wokhuseleko lwebhayoloji.

likhabhinethi zebhayoloji zokhuseleko ziza kuhlangebezana nako konke oku kulandelayo:

- i) umoya we-ekzostiokhutshelwa ngaphandle okanye olungisiweyo (ohluzwe ngokweHEPA nokufunxwa kwekhabhoni) kufuneka ujikeleze ngendlela engenabungozi ngaphakathi kwindawo yokusebenzela;
- ii) ukutyhutyhumeza komoya ngee-glove ports eziyi-0.75m/s ubuncinane, xa zonke iigloves zahlukanisiwe;
- iii) umgangatho wokusebenzela otyibilikayo, omcaba nokwaziyo ukumelana namachiza ;
- iv) ofakelwe umoya otyhala ngamandla nezixhobo zokuwulawula,
  - igumbi elineengcango zokudlula,
  - itanki lechiza elibulala iintsholongwane, and/or
  - ubuxhakaxhaka obuxokonyezelelweyo begesi (umzekelo, *igenerator yeformaldehyde*).

### **Qaphela:**

li-ayisoleyitha ziquka ii-ayisoleyitha ezithe ngxi, iibhokisi ezomayo, amagumbi angenayo i-oksijini neebhokisi zeeglavu ezinokumkhusela osebenzayo kumachiza ebhayoloji neetyhefu (ngokudibana ngqo nangokubhenceka kwizitshizo) neendlela zokuyondelelanisa ukuqokelela ngendlela engenabungozi imixube enokuthi kanti ingcolisiwe (EDS) kuquka *i-vacuum line HEPA FILTRATION*.

- i. Amagumbi awenzelwe ukuvavanyelwa izitshizo aneemayikro-oganizm okanye iityhefu aze axhotyiswa ngenye yezi zintio zilandelayo:
  - i) ngento engange-1 m<sup>3</sup> okanye ngaphezulu;
  - ii) ukusebenza phantsi koxinxelelo olungeluhle nokuba nokutyhutyha komoya okulawulekayo;
  - iii) xhotyiswe ngeHEPA *filtration* kwi-ekzosti yegumbi;
  - iv) fakelwe inqawa yokutsal' umoya ekwaziyo ukujikwa ibe sisitshizo;
  - v) enesampulu enye ubuncinane ekwaziyo ukuba ilawulwe ngaphandle kwegumbi.