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GOVERNMENT NOTICE GOEWERMENTSKENNISGEWING

DEPARTMENT OF TRADE AND INDUSTRY DEPARTEMENT VAN HANDEL EN NYWERHEID

No. 19

3 February 2010

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

Declaration

1. 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, 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.

2. 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;
- (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.

Definitions

3. 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.

Application forms

4. Application forms for permits contemplated in paragraph 2 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.

Repeal

5. Government Notice No. 712 of 8 June 2004 is hereby repealed.



DR ROB DAVIES, MP

MINISTER OF TRADE AND INDUSTRY

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

- a. Viruses, whether natural, 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, 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, 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:

Any goods specified in (I.c) in the form of a vaccine or toxoid.

e. Fungi, as follows:

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

II. ANIMAL PATHOGENS, AS FOLLOWS:

a. Viruses, whether natural, 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 horsesickness 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.

- b. *Mycoplasma mycoides* subspecies *mycoides* SC (small colony), whether natural, 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).
- c. *Mycoplasma capricolum* subspecies *capripneumoniae* ("strain F38")

except:

Any goods specified in (II) in the form of a vaccine.

III. 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 (IV).
- 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.

IV. PLANT PATHOGENS, AS FOLLOWS:

- a. Bacteria, whether natural, 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, 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, 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.

ANNEXURE B**I. EQUIPMENT CAPABLE OF USE IN HANDLING BIOLOGICAL MATERIALS, AS FOLLOWS:**

- a. Complete biological containment facilities at P3, P4 containment level.

Technical Note:

P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, 1983).

- b. Fermenters capable of cultivation of pathogenic micro-organisms, viruses or capable of toxin production, without the propagation of aerosols, and having a total capacity of 100 litres or more.
- c. Fermenters of less than 100-litre capacity with special emphasis on aggregate orders or designs for use in combined systems.

Technical Note:

Fermenters include bioreactors, chemostats and continuous-flow systems.

- d. Centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:
- (i) flow rate exceeding 100 litres per hour;
 - (ii) components of polished stainless steel or titanium;
 - (iii) double or multiple sealing joints within the steam containment area; and

- (iv) capable of in-situ steam sterilisation in a closed state.

Technical Note:

Centrifugal separators include decanters.

- e. Cross-flow filtration equipment, capable of continuous separation without the propagation of aerosols, having all the following characteristics:
- (i) a total filtration area equal to or greater than 1 m²; and
 - (ii) having any of the following characteristics:
 - capable of in-situ sterilisation;
 - using disposable or single-use filtration components.
- f. Steam sterilisable freeze-drying equipment with a condenser capacity exceeding 50 kg of ice in 24 hours and less than 1 000 kg of ice in 24 hours.
- g. Equipment that incorporates or is contained in P3 or P4 containment housing, as follows:
1. Independently ventilated protective full suits;

Technical Note:

This does not include suits designed to be worn with self-contained breathing apparatus.

2. Biological safety cabinets or isolators, which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection.

Technical Note:

Isolators include flexible isolators, drying boxes, anaerobic chambers, glove boxes, or laminar flow hoods.

- h. Chambers designed for aerosol challenge testing with micro-organisms or toxins and having a capacity of 1 m³ or greater.
- i. Equipment for the micro-encapsulation of live micro-organisms and toxins in the range of 1-10 µm particle size, specifically:
 - Interfacial polycondensors;
 - Phase separators.
- j. Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 containment facilities.

**WET OP DIE NIE-PROLIFERASIE VAN WAPENS VAN GROOTSKAALSE
VERNIETIGING, 1993 (WET NO. 87 VAN 1993)**

**VERKLARING VAN SEKERE BIOLOGIESE GOEDERE EN TEGNOLOGIEË TOT
BEHEERDE GOEDERE EN BEHEERMAATREËLS WAT OP SODANIGE
GOEDERE VAN TOEPASSING IS**

Verklaring

1. Ek, Dr Rob Davies, Minister van Handel en Nywerheid, kragtens artikel 13(1) van die Wet op die Nie-proliferasie van Wapens van Grootsekaalse Vernietiging, 1993 (Wet No. 87 van 1993), en op aanbeveling van die Suid-Afrikaanse Raad vir die Nie-proliferasie van Wapens van Grootsekaalse Vernietiging, verklaar hierby mikrobiiese of ander biologiese agense, toksiene en verwante toerusting en tegnologie wat in die vervaardiging van biologiese en toksienwapens gebruik kan word, soos gelys in Aanhangsels A en B in Engels aangehaal by hierdie kennisgewing, tot beheerde goedere.

2. Ek, handelende —

(a) ingevolge artikel 13(2)(a) en (e) van die Wet en ooreenkomstig Suid-Afrika se verpligtinge kragtens die Konvensie oor Biologiese en Toksienwapens—

(i) verbied hierby voorts die invoer, uitvoer, heruitvoer, deurvoer (ook oorlaai), besit, ontwikkeling, vervaardiging, produksie, verkryging op enige wyse, gebruik, bedryf, opberging, onderhoud, vervoer, beskikking, handel en retensie van biologiese wapens;

(ii) verbied enige persoon om 'n Staat, groep State, internasionale

organisasies of nie-Staat-daders by te staan, aan te moedig of in te lyf om biologiese wapens te vervaardig of andersins te verkry;

- (b) ingevolge artikel 13(2)(b) van die Wet, bepaal dat die uitvoer, heruitvoer of deurvoer (ook oorlaai) van beheerde goedere gelys in die aanhangsels by hierdie kennisgewing, slegs mag plaasvind kragtens 'n permit wat deur die Raad uitgereik is;
- (c) ingevolge artikel 13(2)(c) van die Wet, bepaal dat die Raad 'n Staat-tot-Staat-versekering of 'n eindgebruiker- of eindgebruiksertifikaat kan vereis vir die uitvoer of heruitvoer van beheerde goedere gelys in die aanhangsel by hierdie kennisgewing; en
- (d) ingevolge artikel 13(2)(d) van die Wet, bepaal dat alle vervoer van beheerde goedere binne die Republiek van Suid-Afrika binne 21 kalenderdae na sodanige vervoer aan die Raad verklaar moet word.

Woordomskrywing

3. In hierdie kennisgewing het 'n uitdrukking waaraan die Wet 'n betekenis heg, daardie betekenis en, tensy uit die samehang anders blyk, beteken—

"biologiese wapens" mikrobiese of ander biologiese agense of toksiene, ongeag die oorsprong of produksiemetode daarvan, waarvan die soorte of hoeveelhede geen regverdiging bied vir profilaktiese, beskermende of ander vreedsame doeleindes nie, en wapens, toerusting en metodes van aflewering wat ontwerp is om sodanige agense of toksiene vir vyandelike doeleindes of in gewapende konflik te gebruik;

"dienste" ook vragversending, -berging en -opberging (indien nie deel van die vervaardigings- en oordragprosesse nie), vervoer, onderhoud (herstel, opknapping, heropknapping), handel, oorlegpleging, beskikking en tegniese bystand;

"die Wet" die Wet op die Nie-proliferasie van Wapens van Grootsekaalse Vernietiging, 1993 (Wet No. 87 van 1993);

"Konvensie oor Biologiese en Toksienwapens" die *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, wat as 'n bylae in Engels by die Wet gevoeg is;

"ontwikkeling" alle fases vóór produksie, ook konseptualisering, navorsing, analise, toetsing, konfigurasie of loodsproduksieskemas;

"oordrag" die verandering van besit of bewaring, of verandering in die ligging, van beheerde goedere, of dit 'n internasionale grens kruis al dan nie.

Aansoekvorms

4. Aansoekvorms vir permitte bedoel in paragraaf 2 van hierdie kennisgewing is verkrygbaar by enige van die volgende adresse:

(a) Posadres:

Die Sekretariaat

Suid-Afrikaanse Raad vir die Nie-proliferasie van Wapens van Grootsekaalse

Vernietiging

Privaat Sak X84

PRETORIA

0001; of

(b) fisiese adres:

Die Sekretariaat

Suid-Afrikaanse Raad vir die Nie-proliferasie van Wapens van Grootsekaalse

Vernietiging

Meintjiesstraat 77

Sunnyside

PRETORIA.

Herroeping

5. Goewermentskennisgewing No. 712 van 8 Junie 2004 word hierby herroep.

A handwritten signature in black ink, appearing to read 'R. H. Davies', with a stylized flourish at the end.

DR ROB DAVIES, MP

MINISTER VAN HANDEL EN NYWERHEID

AANHALING

ANNEXURE A

I. HUMAN PATHOGENS, ZOOSES AND TOXINS, AS FOLLOWS:

- a. Viruses, whether natural, 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, 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, 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:

Any goods specified in (I.c) in the form of a vaccine or toxoid.

e. Fungi, as follows:

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

II. ANIMAL PATHOGENS, AS FOLLOWS:

a. Viruses, whether natural, 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 horsesickness 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.

- b. *Mycoplasma mycoides* subspecies *mycoides* SC (small colony), whether natural, 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).
- c. *Mycoplasma capricolum* subspecies *capripneumoniae* ("strain F38")

except:

Any goods specified in (II) in the form of a vaccine.

III. 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 (IV).
- 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.

IV. PLANT PATHOGENS, AS FOLLOWS:

- a. Bacteria, whether natural, 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, 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, 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.

ANNEXURE B**I. EQUIPMENT CAPABLE OF USE IN HANDLING BIOLOGICAL MATERIALS, AS FOLLOWS:**

- a. Complete biological containment facilities at P3, P4 containment level.

Technical Note:

P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, 1983).

- b. Fermenters capable of cultivation of pathogenic micro-organisms, viruses or capable of toxin production, without the propagation of aerosols, and having a total capacity of 100 litres or more.
- c. Fermenters of less than 100-litre capacity with special emphasis on aggregate orders or designs for use in combined systems.

Technical Note:

Fermenters include bioreactors, chemostats and continuous-flow systems.

- d. Centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:
- (i) flow rate exceeding 100 litres per hour;
 - (ii) components of polished stainless steel or titanium;
 - (iii) double or multiple sealing joints within the steam containment area; and

(iv) capable of in-situ steam sterilisation in a closed state.

Technical Note:

Centrifugal separators include decanters.

- e. Cross-flow filtration equipment, capable of continuous separation without the propagation of aerosols, having all the following characteristics:
 - (i) a total filtration area equal to or greater than 1 m²; and
 - (ii) having any of the following characteristics:
 - capable of in-situ sterilisation;
 - using disposable or single-use filtration components.
- f. Steam sterilisable freeze-drying equipment with a condenser capacity exceeding 50 kg of ice in 24 hours and less than 1 000 kg of ice in 24 hours.
- g. Equipment that incorporates or is contained in P3 or P4 containment housing, as follows:
 - 1. Independently ventilated protective full suits;

Technical Note:

This does not include suits designed to be worn with self-contained breathing apparatus.

- 2. Biological safety cabinets or isolators, which allow manual operations to be performed within, whilst providing an environment equivalent to Class III biological protection.

Technical Note:

Isolators include flexible isolators, drying boxes, anaerobic chambers, glove boxes, or laminar flow hoods.

- h. Chambers designed for aerosol challenge testing with micro-organisms or toxins and having a capacity of 1 m³ or greater.
- i. Equipment for the micro-encapsulation of live micro-organisms and toxins in the range of 1-10 µm particle size, specifically:
 - Interfacial polycondensators;
 - Phase separators.
- j. Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 containment facilities.

SLUIT AANHALING
