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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

GOVERNMENT NOTICE

DEPARTMENT OF TRADE AND INDUSTRY

No. 712 **8 June 2004**

NOTICE UNDER SECTION 13 OF THE NON-PROLIFERATION OF WEAPONS OF MASS DESTRUCTION ACT, 1993 (ACT NO. 87 OF 1993): DECLARATION OF CERTAIN BIOLOGICAL GOODS AND TECHNOLOGIES TO BE CONTROLLED AND CONTROL MEASURES APPLICABLE TO SUCH GOODS

I, Mandisi Mpahlwa, Minister of Trade and Industry, on the recommendation of the South African Council for the Non-Proliferation of Weapons of Mass Destruction and under section 13 of the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), hereby –

(a) in terms of South Africa's obligations as a State Party to the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, prohibit –

(i) the import, export, re-export, transit, possession, development, manufacture, production, procurement in any manner, use, operation, stockpiling, maintenance, transport, disposal, acquisition or retention of microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(ii) the import, export, re-export, transit, possession, development, manufacture, production, procurement in any manner, use, operation, stockpiling, maintenance, transport, disposal, acquisition or retention of weapons, equipment or means of dispersion or delivery specifically designed to use such agents or toxins for hostile purposes or in armed conflict;

(b) declare biological agents and toxins and related equipment and technology that may be used in the manufacture of biological and toxin weapons, as listed in Annexures A, B and C of this notice, to be controlled goods;

(c) determine that the export, re-export or transit of goods as listed in Annexures A, B and C of this notice shall only take place under a permit issued by the said Council as provided for in Annexure D to this notice;

(d) prescribe the procedures of registration, in accordance with section 13(3)(a) of the Act, and require that all facilities possessing, having, or maintaining any biological agents, toxins or related equipment as listed in Annexures A, B and C be registered in accordance with the guidelines outlined in Annexure E;

(e) require that all transport of any biological agents, toxins or related equipment as listed in Annexures A, B and C within the Republic of South Africa be declared to the Council within 21 calendar days in accordance with section 13(2)(d) of the Act.

Application forms for permits and registration in terms of section 13(3) of the Act are obtainable from:

The Secretariat
South African Council for the Non-Proliferation of Weapons of Mass Destruction
Private Bag X84
PRETORIA
0001

Government Notice No. 428 of 10 April 2002 is hereby withdrawn.

M B M MPAHLWA
MINISTER OF TRADE AND INDUSTRY
24 May 2004

ANNEXURE A

I. **HUMAN PATHOGENS, ZOONOSES 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, including Lassa fever, Junin, Machupo, Lymphocytic choriomeningitis, Sabia, Flexel and Guanarito;
- Variola virus;
- Monkey pox virus;
- White 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;
- 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;
- 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.

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:

  a. Uncharacterised; or

  b. 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 herpes virus (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 (mycoides SC), 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).

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.

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);
- Sclerotinia sclerotiorum.

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.

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.

[Technical Note:

Fermenters include bioreactors, chemostats and continuous-flow systems.]

c. Centrifugal separators, capable of continuous separation without the propagation of aerosols, having all the following characteristics:

Flow rate exceeding 100 litres per hour:

- Components of polished stainless steel or titanium;
- Double or multiple sealing joints within the steam containment area; and
- Capable of in-situ steam sterilisation in a closed state.

[**Technical Note:**

Centrifugal separators include decanters.]

d. Cross-flow filtration equipment, capable of continuous separation without the propagation of aerosols, having both of the following characteristics:

- Equal to or greater than 5 m^2; and

- Capable of in-situ sterilisation.

e. 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.

f. Equipment that incorporates or is contained in P3 or P4 containment housing, as follows:

1. Independently ventilated protective full or half suits;

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

[**Note:** In (I.f.2), isolators include flexible isolators, drying boxes, anaerobic chambers and glove boxes.]

g. Chambers designed for aerosol challenge testing with micro-organisms or toxins and having a capacity of 1 m^3 or greater.

h. 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.

i. Fermenters of less than 100-litre capacity with special emphasis on aggregate orders or designs for use in combined systems.

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.

ANNEXURE C

I. Technology required for the use of goods specified in **ANNEXURE A**.

II. Technology, including licences, designed for the manufacture of equipment specified in **ANNEXURE B**.

ANNEXURE D

I. In certain circumstances, the following permits may be issued by the South African Council for the Non-Proliferation of Weapons of Mass Destruction to organizations that have been registered with the Council for the export or transfer of goods that have been indicated in **ANNEXURE A** or equipment indicated in **ANNEXURE B**:

a. Individual Permit (for a single transfer of fixed goods, a fixed country, fixed end-user or supplier, and fixed place of export or transfer).

b. Individual Issue-on-request Permit (for a number of approved single transfers of fixed goods, a fixed country, fixed end-user or supplier, and fixed place of export or transfer).

c. Open Multiple Permit (for multiple transfers of fixed goods, a fixed country, fixed end-user or supplier, and fixed place of export or transfer).

ANNEXURE E

Facilities that must be registered include any room, suite of rooms, laboratory, building or part of a building or any other structure or combination of structures operated by a single operator at a single location in which any biological agents, toxins or related equipment that may be used in the manufacture of biological and toxin weapons, as listed in Annexures A, B and C, are present.

Applications for registration must be submitted in accordance with the prescribed format within 21 calendar days of qualifying for registration.

Any registered facility must notify the Secretariat within 21 calendar days of any change in the registration conditions or after any change in the information supplied in the registration application.

A registered facility must notify the Secretariat not less than 21 calendar days after any listed biological agent, toxin or equipment has been transferred within the borders of South Africa or received from another facility within the borders of South Africa, or after any other change in the registration conditions.

Each registered facility must appoint an identified contact person responsible for maintaining registration with the Council, records of activities relating to this regulation, notification of the Council of transfers, and applications for permits.