

GOVERNMENT NOTICES

DEPARTMENT OF TRADE AND INDUSTRY

No. 428
10 April 2002

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

I, Alec Erwin, 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 (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 development, production, stockpiling, 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 development, production, stockpiling, 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 manufacturing equipment and technology that may be used for 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 such goods shall only take place under a permit issued by the said Council as provided for in Annexure D to this notice;
- (d) control the export, re-export or transit of such goods by -
 - (i) authorising the Council to demand from the applicant, on behalf of the Republic, an end-use certificate -

- (aa) for the controlled goods to be transferred to the territory of another country;
 - (bb) from the end-user(s) in the country of destination;
 - (cc) which provides information and assurance to the Council in issuing the permit; and
 - (dd) which the applicant must prove to be authentic.
- (ii) requiring the registration of all applicants with the Council in accordance with Section 13(3) of the above-mentioned Act.

Application forms for permits and registration in terms of Section 13(3) of the above-mentioned Act are obtainable from:

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

signed
A ERWIN
MINISTER OF TRADE AND INDUSTRY

ANNEXURE A

I. HUMAN PATHOGENS, ZOOZOSES 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;
- Rift Valley fever virus;
- Crimean-Congo haemorrhagic fever virus;
- Hantaviruses, including Hantaan;
- Arenaviruses, including Lassa fever, Junin, Machupo and Lymphocytic choriomeningitis;
- Variola virus;
- Monkey pox virus;
- White pox virus;
- Ebola virus;
- Marburg 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 O157 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 "sub-unit 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;
- Teschén disease virus;
- Vesicular stomatitis virus;

- 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 "sub-units 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 square metres; 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:

Independently ventilated protective full or half suits;

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 m³ 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 polycondensators;

Phase separators;

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

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. Depending on the circumstances, the following permits may be issued by the South African Council for the Non-Proliferation of Weapons of Mass Destruction to organisations 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).