

No. 75

18 February 2015

DEPARTMENT OF TRADE AND INDUSTRY**NOTICE OF AMENDMENT**

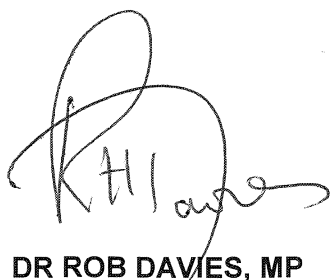
1. By virtue of the powers vested in me in terms of section 13(1) of the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), I Rob Davies, Minister of Trade and Industry, hereby –

(a) amend Notice No. 19 of 3 February 2010 as indicated in the Schedule hereto; and

(b) determine that –

- (i) words in bold type in square brackets indicate omissions from existing enactments;
- (ii) words underlined with a solid line indicate insertions in existing enactments; and
- (iii) the amendments will become operative on the date of publication of this Notice of Amendment.

2. Notice No. 19 of 3 February 2010 as amended (incorporating the amendments indicated in the Schedule hereto) is available on the dti website: www.thedti.gov.za/nonproliferation



DR ROB DAVIES, MP

MINISTER OF TRADE AND INDUSTRY

DATE: 26/1/15

SCHEDULE**[GOVERNMENT NOTICE]****DEPARTMENT OF TRADE AND INDUSTRY****GOVERNMENT NOTICE****No. 19****3 February 2010****PUBLISHED IN TERMS OF THE NON-PROLIFERATION OF WEAPONS OF MASS DESTRUCTION ACT, 1993 (ACT NO. 87 OF 1993), AS AMENDED**

Please note: Although there are many amendments, their nature does not justify the repeal of the current Notice. Therefore, the number and year date of the amended Notice remain the same. A new number and year date have been allocated to the Notice of Amendment. Text that has been deleted is shown in bold between square brackets, [], while new insertions are underlined. Stakeholders can access a "clean amended version" (incorporating all amendments) through the website of the Council.

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

26/1/15

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:

Any goods [**specified in (ic)**] 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, 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 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, 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).

- c. *Mycoplasma capricolum* subspecies *capripneumoniae* ("strain F38")

except:

Any goods [**specified in (ic)**] in the form of a vaccine or toxoid.

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, 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.

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

- a. Complete biological containment facilities at **[P3, P4]** Biosafety Level 3 or 4 containment level.

Technical Note:

[P3 or P4] (BL3, BL4, L3, L4)] Biosafety Level 3 or 4 containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, **[1983]** 2004).

[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]b.** Centrifugal separators, capable of continuous separation of pathogenic micro-organisms, 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]c. 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 being sterilized or disinfected in-situ;
- using disposable or single-use filtration components.

Technical Note:

In this control, 'sterilized' denotes the elimination of all viable microbes from the equipment through the use of either physical (eg steam) or chemical agents. 'Disinfected' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. 'Disinfection' and 'sterilization' are distinct from 'sanitization', the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

[f]d. [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]e. Equipment that incorporates or is contained in **[P3 or P4] Biosafety level 3 or 4** containment housing, as follows:

1. **[Independently ventilated protective full suits;] Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure;**

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.]f. Chambers designed for aerosol challenge testing with micro-organisms, viruses 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 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]