DEPARTMENT OF TRADE, INDUSTRY AND COMPETITION

NO. R. 4978 **14 June 2024**

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);

Declaration

2. I, Ebrahim Patel, Minister of Trade, Industry and Competition, under section 13(1) of the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993) as amended, 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 declare—

(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 21 days 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. The agents, as listed in Annexure A in an inactivated form, are exempted from permit requirements specified in section 3(b) above, however the notification requirement still applies for the transportation.

(e) For the export, re-export and transit (including transshipment) and domestic transfer of the agents listed in Annexure A in an inactivated form, an inactivation/ destruction certificate should be provided.

Application forms

4. The applications for the permits contemplated in paragraph 3 of this Notice should be submitted through the Non-Proliferation Council Registration and Permit Online System: https://npcos.thedtic.gov.za/fcDTiNPApplicantPortal/Account/LogOn.

Repeal

5. Government Notice No. 494 of 29 March 2019 is hereby repealed.

7/6/2024

MR EBRAHIM PATEL

MINISTER OF TRADE, INDUSTRY AND COMPETITION

ANNEXURE A

i) **HUMAN PATHOGENS, ZOONOSES 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;
- Conotoxins;
- Modeccin;
- Ricin;
- Saxitoxin;
- Shiga toxins;
- Staphylococcus aureus toxins;
- Tetanus toxin;
- Tetrodotoxin;
- Trichothecene mycotoxins, such as T-2 toxin, HT-2 toxin and Diacetoxyscirpenol toxin;

- Verotoxins;
- Microcystin (Cyanginosin);
- Aflatoxins;
- Volkensin;
- Viscum album Lectin 1 (Viscumin);

Except:

1. Any goods in the form of a vaccine or toxoid.
   A vaccine is a medicinal or veterinary product in a pharmaceutical formulation licensed by, or having marketing or clinical trial authorisation from, the relevant South African regulatory authorities, which is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

2. Botulinum toxins and Conotoxins meeting all of the following criteria:
   a) are pharmaceutical formulations designed for testing and human administration in the treatment of medical conditions;
   b) are pre-packaged for distribution as clinical or medical products; and
   c) are authorised by the relevant South African regulatory authority to be marketed as clinical or medical products

e. Fungi, as follows:

- Coccidioides immitis;
- Coccidioides posadasii.

II. ANIMAL PATHOGENS, AS FOLLOWS:

1. 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.

2. *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).

3. *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 AND GENETIC ELEMENTS, AS FOLLOWS:

a. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity, or may lead to pathogenicity of non-pathogenic sequences in 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

1. 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^3 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.