



UCT Biosafety and Biosecurity



Guideline

Biosafety and biosecurity compliance in research, teaching, or testing activities in South Africa

SG V1.15

2024_08_19

Introduction

This document can be used to ensure compliance when using or handling potentially hazardous biological organisms and materials in life sciences research, teaching, or testing activities. Biological and environmental safety and biosecurity are included.

If your research involves the use of any of the organisms, materials and activities listed below, you will need to apply for the relevant facility registration or permits to comply with South African national legislation. The table contains an overview of the regulated organisms and materials and the activities that require specific registration, permits or certificates. The administering government department, requirements and links to the relevant legislation, application forms, other guidelines and contact details are provided. Links to relevant international legislation and protocols to which South Africa is a signatory are listed in a separate table.

1. [Genetically modified organisms \(GMOs\), including bacterial hosts for cloning \(rDNA\) and genome editing.](#)
2. [Humans](#)
 - 2.1 Human biological material
 - 2.2 Clinical trials with human participants
 - 2.3 Human pathogens
3. [Animals](#)
 - 3.1 Animals, biological material collected from animals, animal pathogens and clinical trials with animals.
 - 3.2 Stock remedies, veterinary biologicals, and vaccines for animals
4. [Environment and Biodiversity](#)
 - 4.1 Indigenous biological resources, alien, invasive, threatened, or protected species.
 - 4.2 Controlled goods that may cause harm to South African people, animals or the environment when released.
5. [Biosecurity](#)
 - 5.1 Dual use: microbial or other biological agents, toxins and chemicals that may be used in the manufacture of weapons of mass destruction.
6. [International legislation, conventions, and protocols of which South Africa is a signatory](#)

Overview of organisms, biological materials and activities regulated in South Africa

1. GENETICALLY MODIFIED ORGANISMS – GMOs			
Regulated organisms or material	Activities and scope	Legislation or regulation and administering government department or institution	Requirements and instructions
<p>Genetically modified organisms: “GMO means an organism the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both” (GMO Act).</p> <p>Currently includes: Living modified organisms (LMOs), cell lines, bacterial strains used as hosts of gene cloning (recombinant DNA (rDNA) work) and organisms modified through genome editing.</p>	<ul style="list-style-type: none"> Genetically modifying organisms Development, production, release, use and application of GMOs, including cloning and rDNA work in laboratory bacterial strains as hosts. Gene therapy, where recombinant DNA molecules or GMOs are employed. Genome editing 	<ul style="list-style-type: none"> - GMO Act (Act 15 of 1997) - GMO Act as amended in 2006 - GMO Act Regulations (2010) - SOP for Regulation 2(2) of the GMO Act - SOP for Regulation 4 <p>Registration of a facility (Registration of facilities for GMO use. Note that this is Regulation 8 of the GMO Act Regulations, 2010)</p> <p>Department of Agriculture (DoA) Directorate: Genetic Resources, Biosafety</p>	<p>Regulation 8 (2010): All facilities conducting activities must be registered with the Registrar of the GMO Act. Classification of the facility is done according to containment level (1 to 4).</p> <p>Pay the required fee, apply for the registration (application form on the website), and attach all required maps, floor plans, SOPs, proof of payment, etc. (courier hard copies of application documents and include an electronic copy on a flash drive).</p> <p>Registered facilities will receive a registration certificate, and facility registration is valid for 3 years. Apply for a renewal or amendment using the same form (the same tariff).</p>

			<p>Regulation 2(1): Apply for a permit under the GMO Act for any of the following activities involving GMOs:</p> <ul style="list-style-type: none"> • Contained use, including containment levels 3 and 4 research facilities (See Regulation 2(2) for exemption of academic and research facilities (containment levels 1 and 2) and GMO events that have obtained general release (or conditional general release) or commodity clearance authorisations. • Trial releases / Field trials, including clinical trials involving GMOs • Commercial releases / general releases • Commodity imports and exports • Imports and exports of LMOs for contained use or general release (See below for exemption of LMOs used under conditions of contained use in academic and research facilities (Containment levels 1 and 2).
GMOs	Importing GMOs that will be used under conditions of contained use in registered academic and research facilities for research purposes only	<p>- GMO Act (Act 15 of 1997) - GMO Act Regulations (2010) - SOP for Regulation 2(2) of the GMO Act</p> <p>DoA</p>	<p>Regulation 2(2) An import permit is NOT required for GMOs</p> <ul style="list-style-type: none"> • used under conditions of contained use (Containment levels 1 and 2) • within registered academic and research facilities (where the confined area is a laboratory, growth room or greenhouse)

			<ul style="list-style-type: none"> • for research purposes only • that will NOT be removed from the facility or released into the environment and • the necessary measures to effectively contain the GMOs at all times are implemented. <p>When GM animals, plants or seeds are imported for research purposes, apply to the Registrar for a letter of exemption for a GMO import permit and attach it to the relevant import permit application (depending on the legislation, e.g. GM plant seeds will require an import permit under the Agricultural Pests Act, see Section 4.2 of this guideline).</p>
GMOs	Trial or general/commercial release of GMOs into the environment in South Africa	National Environmental Management: Biodiversity Act (NEMBA; Act 10 of 2004), Chapters 2 and 5. Department of Forestry, Fisheries and the Environment (DFFE) Directorate for Biodiversity Assessment. South African National Biodiversity Institute (SANBI) was mandated to “monitor and report regularly to the Minister on the impacts of any genetically modified organism that has been released into the environment,	Chapter 5: If the Minister has reason to believe that the release of a GMO into the environment under a permit applied for under the GMO Act poses a threat to any indigenous species or the environment, the permit may not be issued until the applicant has conducted an environmental assessment.

		including the impact on non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture”.	
	<p>GMO Act (Act 15 of 1997): https://www.gov.za/documents/genetically-modified-organisms-act-0 Guideline, policy, application forms and tariffs: https://www.nda.gov.za/index.php/publication/410-gmo-guidelines-and-policy Biosafety South Africa (provides guidance and assistance with risk analysis and permit applications): http://biosafety.org.za/ National Environmental Management: Biodiversity Act (NEMBA; Act 10 of 2004): https://www.sanbi.org/wp-content/uploads/2018/03/nemba-act-no-10-2004.pdf</p>		
	<p>Registrar of GMO Act: Ms Nompumelelo Mkhonza; Tel: 012 319 6382; e-mail: NompumeleloM@nda.gov.za Biosafety Officer: Ms Bathobile Mahlangu; Tel: 012 319 6364; e-mail: BathobileM@nda.gov.za</p>		

2. HUMANS			
Regulated organisms or material	Activities and scope	Legislation or regulation and administering government department or institution	Requirements
2.1 Human biological material			
Human biological material, including bodies, tissue, blood, blood products, cultured cells, gametes, stem cells or embryos, foetal tissue, zygotes.	Removal and use of biological material, stem cell therapy, genetic health research, DNA, RNA, and chromosome-based genetic testing: (a) Health research referred to in section 69(3) of the Act; (b) Training referred to in section 64(1)(a) of the Act; or	National Health Act (NHA, Act 61 of 2003), Notice R177 (Use of human biological material for purposes of genetic testing, health research and therapeutics) Department of Health (DOH)	No person shall carry out genetic health research unless such research has been approved by a registered health research ethics committee (HREC) referred to in section 73(1) of the Act. Removal and use of human biological material must be done by a competent person at an authorised institution with

	<p>(c) Studies of archaeological, medical or heritage value on DNA obtained from human genetic material, conducted in terms of the National Heritage Resources Act, 1999 (Act No.25 of 1999). Health research includes: any research which contributes to knowledge of -(a) The biological, clinical, psychological or social processes in human beings; (b) Improved methods for the provision of health services; (c) Human pathology; (d) The causes of disease; (e) The effects of the environment on the human body; (f) The development or new application of pharmaceuticals, medicines and related substances; and (g) The development of new applications of health technology."</p>		<p>written informed consent from the donor or relevant representative. An authorised institution that performs genetic research or generates embryonic stem cells, must have separate registers to record such genetic research or generation of embryonic stem cell lines. The authorised institution must submit details of the registers to the Minister by the end of March of each year. An authorised institution that keeps or discloses genetic material records and other individually identifiable or related health information in any form, must ensure that the information is complete and is kept confidential. The information is treated as anonymous if used for research purposes.</p> <p>Research involving stem cell lines requires HREC approval.</p>
	<p>Removal and donation of tissue, blood and gametes from living persons for medical and dental purposes and handling human bodies and tissue after death.</p>	<p>National Health Act (Act 61 of 2003) Section 68, Notice R180 (General control of human bodies, tissue, blood, blood products and gametes) DOH</p>	<p>Written consent is required, registers must be kept and liaise with a health officer appointed by the minister.</p>

	<p>Import or export of any tissue or any blood, blood product, cultured cells, stem cells, embryo, zygotes or gamete.</p> <p>Simulated blood products (for external proficiency testing and QA) and laboratory test kits are only considered if they contain human biological material or microorganisms that cause infection in humans.</p>	<p>National Health Act (Act 61 of 2003) Section 68, Notice R181</p> <p>DOH</p>	<p>Apply for a permit to import or export the listed biological materials and keep a register of all imports and exports. This register must be provided to the DG every six months. In the application form, indicate the exact volume/weight and number of samples in the "Quantity" column and attach any BMTAs and Ethics approvals when the application is submitted. A request for an import permit for teaching, academic or educational purposes does not require HPCSA registration.</p> <p>In accordance with section 4(10)a of R181 of the NHA 61 of 2003: "Each consignment of biological substances of human origin imported into the Republic shall be accompanied by a certificate from the supplier, stating that the substance has been exported in terms of the applicable laws and regulations of the country from which such substance originates." The researcher/s who were granted ethics approval must complete the application form.</p>
	<p>Transfer of human biological material from a provider to a recipient for use in research or clinical trials.</p>	<p>National Health Act (Act 61 of 2003), Notice 719 (Template for MTA of human biological materials)</p>	<p>Providers and recipients of biological material for use in research or clinical trials under the auspices of the Health Research Ethics Committees shall use the template for the Material Transfer</p>

		DOH	Agreement (MTA) of Human Biological Materials.
	Transport of dangerous goods and infectious substances: human biological material, pathogenic microorganisms	<ul style="list-style-type: none"> - National Road Traffic Act (Act 93 of 1996) and regulations as listed in SANS10228. - International Air Transport Association (IATA) and South African Civil Aviation Authority Regulations - Convention on International Civil Aviation Annex 18 —The Safe Transport of Dangerous Goods by Air. 	<p>Follow specific technical instructions for packaging in hazard subclass 6.2: Category A Infectious substances affecting humans – UN2814.</p> <p>Category A Infectious substances only affecting animals- UN2900.</p> <p>Category B Biological substance (Diagnostic specimen or clinical specimens -minimal likelihood of containing a pathogen)- UN3373.</p> <p>IATA presents a certification course for packing and transporting infectious substances (Category A or B).</p>
<div style="display: flex; align-items: flex-start;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"> <input checked="" type="checkbox"/> — <input checked="" type="checkbox"/> — <input checked="" type="checkbox"/> — <input type="checkbox"/> — </div> <div> <p>National Health Act (Act 61 of 2003): https://www.gov.za/documents/national-health-act</p> <p>National Health Act Guide: https://section27.org.za/wp-content/uploads/2019/07/Stevenson-National-Health-Act-Guide-2019-1.pdf</p> <p>Material transfer agreement of human biological materials: https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf</p> <p>Compliance with National Road Traffic Act (Act 93 of 1996 and its amendments) https://dgrcompliance.co.za/national-road-traffic-act-93-of-1996/</p> <p>IATA Infectious Substances Transport certification course: https://www.iata.org/en/training/courses/infectious-substance-transport/tcgp22/en/</p> <p>SANS 10228 (2012) https://ia801603.us.archive.org/32/items/za.sans.10228.2012/za.sans.10228.2012.pdf</p> <p>WHO Guidance on regulations for the transport of infectious substances 2019-20: https://apps.who.int/iris/bitstream/handle/10665/325884/WHO-WHE-CPI-2019.20-eng.pdf</p> <p>Advisory Committee on Dangerous Pathogens (ACDP) Biological agents: Managing the risks in laboratories and healthcare premises, Appendix 1.2. Transport of infectious substances: https://www.gla.ac.uk/media/Media_360368_smxx.pdf</p> <p>Import and export of human biological materials:</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <p>Mr Levy OL Tjale Tel: 012 395 9487; email: Levy.Tjale@health.gov.za or importexportpermit@health.gov.za</p> </div> </div> </div>			

2.2 Clinical trials and research with human participants

Human participants in clinical trials, clinical research, and bioequivalence studies	Research with human participants	<ul style="list-style-type: none"> - National Health Act (Act 61 of 2003), Sections 71 and 90, Notice R719. DOH - Protection of Personal Information Act (POPIA; Act 4 of 2013) (Personal information of human participants) 	Apply for approval by a registered HREC and SAHPRA, if applicable. If it is a clinical trial, register the research in the South African National Clinical Trials Register, and obtain written informed consent from human participants according to Section 5 of R719. Protocols for human participants' research that propose non-therapeutic research with minors must have ministerial consent.
	<p>Clinical trials and bioequivalence studies</p> <p>NHA: “clinical trial” means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.</p>	<p>Medicines and Related Substances Act (Act 101 of 1965). Regulates control of human and veterinary medicines and medical devices, as well as complementary medicines.</p> <p>South African Health Products Regulatory Authority (SAHPRA) regulates medicines and clinical research.</p>	Apply for access to unregistered medicines for the purpose of conducting clinical trials from SAHPRA. South African Good Clinical Practice Guidelines (SA GCP) provide researchers and other interested parties with clearly articulated standards of GCP in locally conducted research to ensure that clinical trials involving South African human participants are designed and conducted according to local requirements as well as according to the sound scientific and ethical standards within the accepted framework for good clinical practice. Researchers must submit a completed clinical trial application on predetermined dates and obtain proof of delivery.

Schedule 5, 6, 7, or 8 substances	Acquire, use, possess, manufacture, or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance for the purposes of education, analysis or research.	Medicines and Related Substances Act no 101 of 1965, as amended, Section 22A (Control of medicines, scheduled substances, medical devices and IVDs) DOH Regulated by the South African Health Products Regulatory Authority (SAHPRA)	Apply for a permit from SAHPRA
All scheduled medicines	Research involving any registered medicines	Medicines and Related Substances Act, Section 22A(9)(a)(i)	Apply for a possession or holding permit Complete the application form (supervisor and student) and include ethics approval, ID copies of all students and personnel involved, motivation or research proposal.
<div data-bbox="215 895 293 995" style="border: 1px solid black; padding: 2px; width: fit-content;"> <ul style="list-style-type: none"> ✓ — ✓ — ✓ — </div> <p>Medicines and Related Substances Act (Act 101 of 1965): https://www.sahpra.org.za/wp-content/uploads/2020/02/Government_Gazette_Medicines_and_Devices_Act_Jun_2017-1.pdf</p> <p>Regulations to the act: http://www.rrfa.co.za/wp-content/uploads/2012/11/Regulations-to-Act-101-published-2003.pdf</p> <p>SAHPRA Clinical Trial Unit: Information, application and report forms and clinical trial guidelines: https://www.sahpra.org.za/clinical-trials/</p> <p>DOH Application to acquire any schedule drugs for educational, analytical or research purposes: https://www.sahpra.org.za/wp-content/uploads/2020/10/Application-for-research_analysis-permit.pdf</p> <p>POPIA ASSAF Code of conduct – How personal information should be processed in the research sector: https://info regulator.org.za/wp-content/uploads/2020/07/Government-Gazette-dated-12-May-.pdf</p> <p>Possession or holding permit applications must be submitted to Sec22a_permits@sahpra.org.za</p> <div data-bbox="215 1251 271 1315" style="display: inline-block; vertical-align: middle;">  </div> <p>Medicines Control Officer Mr Thibedi Mafokwane Tel: 012 501 5471; email: Thibedi.mafokwane@sahpra.org.za</p>			

2.3 Human pathogens

Human pathogens	Microbiological laboratories which acquire, receive, import, handle, manipulate, maintain, store, culture or in any way process, issue or dispose of human pathogens so acquired, received, or imported.	<p>- National Health Act (Act 61 of 2003) Section 68, Notice R178 (Regulations relating to the registration of microbiological laboratories and acquisition, importation, handling, maintenance, and supply of human pathogens)</p> <p>DOH</p> <p>- Occupational Health and Safety Act (OHS Act 85 of 1993), Regulations for Hazardous Biological Agents, R1887 of 2022</p> <p>Department of Employment and Labour</p>	<p>Regulations 3- 6(1): i) Register a microbiological laboratory with the DOH, ii) get assigned an appropriate BSL code. iii) Get a permit for each event to perform the specified activities in respect of human pathogens in accordance with the BSL codes 3, 4 or 5. Permits are not required for registered labs that examine routine diagnostic specimens for human pathogens or BSL codes 1 and 2. An application for i) registration of a microbiological laboratory and ii) authorisation to use, keep or handle cultures or preparations of microorganisms must be submitted to the DOH together with the DOH Checklists of minimum specifications for laboratory biosafety (levels 1-4). The laboratory will be inspected by the DOH inspection team. The certificate must be displayed in the laboratory.</p> <p>Lab registration is valid for 2 years.</p> <p>The OHS Act Regulations cover all workplaces where HBAs are handled, produced, processed, stored, or transported.</p> <p>Risk assessments must be conducted and reviewed every 24 months. Exposure</p>
-----------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

			<p>monitoring and medical surveillance must be done, and records of all these activities must be kept. Written procedures for handling, transporting, storing, and disposing of HBAs must be available.</p>
	<p>Import and export of human pathogens</p>	<p>National Health Act (Act 61 of 2003) Section 68 DOH</p>	<p>Apply for a permit to import or export human pathogens and keep a register of all exports. For Import permits, the application must be accompanied by a letter from the sender of the material, indicating that he/she is sending the material to the applicant (researcher). Import of human pathogens in hazard group 3 or 4 – outer packaging container must display “Human Pathogen - Permit number” and the original permit must accompany the consignment. Permits valid for 90 days.</p>
	<p>National Health Act (Act 61 of 2003): https://www.gov.za/documents/national-health-act Regulations Section 68, National Health Act, Notice R178: https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon178.pdf DOH contact details: http://www.health.gov.za/contact-us/ Application of laboratory registration and import and export permit applications should be submitted to: importexportpermit@Health.gov.za</p> <p> Mr Levy OL Tjale Tel.: 012 395 9487; email: Levy.Tjale@health.gov.za</p>		

3. ANIMALS			
Regulated organisms or material	Activities and scope	Legislation or regulation and administering government department or institution	Requirements
3.1 Biological material collected from animals, animal pathogens and clinical trials with animals			
Biological material collected from animals and animal pathogens	Diagnostic and screening tests for controlled and notifiable animal diseases.	Animal Diseases Act (Act 35 of 1984), R527, Regulation 12B (Registration for diagnostic testing for controlled and notifiable animal diseases) Department of Agriculture (DoA) Directorate: Animal Health (DAH)	Get DoA DAH approval for veterinary laboratories performing diagnostic or screening tests for controlled and notifiable animal diseases. Test results must be reported to the Director. The certificate is valid for 2 years. Specific pathway for the importation of new diagnostic test kits or reagents- register facility and complete a specific form. Apply for a veterinary import permit as well.
	a) Any investigation, experiment or research with any vaccine, serum, toxin, anti-toxin, antigen or other biological product which consists or originates wholly or partially of, or from, any micro-organism, or of or from the glands, organs, fluids, or any other part, of an animal or parasite (excluding any substance that is controlled	Animal Diseases Act (Act 35 of 1984) Section 20 DoA, DAH	Apply for a permit to (a) conduct any investigation, experiment, or research with animals or any of the other listed substances or b) manufacture or evaluate any product or remedy for testing, diagnosis, prevention or cure of any animal disease or parasite or c) infect or contaminate any animal with a disease or parasite, introduce or transport any animal or thing that can spread animal disease or parasite.

	<p>under the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965)); b) for the manufacture or evaluation of a product or remedy used for or intended to be used at or for the testing, diagnosis, prevention, treatment or cure of any animal disease or parasite, or for the maintenance or improvement of the health, growth, production or working capacity of an animal, use any vaccine, serum, toxin, antitoxin, antigen or other biological product; or (c) for the purposes of any investigation, experiment or research referred to (i) infect or contaminate any animal or any other thing with any animal disease or parasite; or (ii) Introduce into or collect in the Republic, or have in his possession, or remove or transport from the place where it is normally found or kept, any controlled animal or thing, or any protozoon, bacterium, virus, fungus, parasite, other organism or agent which can</p>		<p>Each research project must apply for a separate Section 20 permit. Risk assessment to determine appropriate biosafety level.</p> <p>Laboratory approval: Facilities where the investigations, experiments or research will be performed apply for a recommendation report (BSL2) or certificate of compliance (BSL3) for BSL2, BSL3, Animal quarantine (ABSL3), Biobank or vector-protected facilities (Procedure manual available). Valid for 2 years.</p> <p>Section 20 permit has a maximum validity of 3 years, whereafter researchers must apply for an extension. If any part of the project changes and the change will alter the scope and/or the biosafety risk category of the project, researchers must apply for an amendment. A specific amendment application form is available on the website.</p> <p>Make sure that the most recent version of the application forms is used.</p>
--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	spread any animal disease or parasite.		
	Import or export pathology specimens and raw materials (e.g., pathogenic bacteria) for laboratory or pharmaceutical use	Animal Diseases Act (Act 35 of 1984) Section 20 DoA, DAH	Apply for an import or export permit after the Section 20 permit has been issued. Include a copy of the Section 20 permit with data or specification sheets of the product or culture to be imported. Locally produced Bovine Serum Albumin (BSA) and Foetal Bovine Serum (FBS): No permit is required if collected from carcasses that were inspected by a state veterinarian and passed as fit for human consumption in a local abattoir. A certificate of origin should be available to confirm. Local production of monoclonal antibodies: Section 20 permit is required, and the facility may be inspected.
	Animals used for scientific purposes	South African National Standard SANS 10386:2008: The care and use of animals for scientific purposes	AECs should ensure that all animal care and use within the institution is conducted according to this standard and should inspect animal housing and laboratory areas. Apply for a permit to import animals and obtain veterinary health certificates from the Department of Agriculture, the Chief Directorate Veterinary Services and Livestock Improvement, and the Department of Animal Health.

			<p>Crates for the transport of all domestic and wild animals by air shall comply with the International Air Transport Association (IATA) Live Animal Regulations for air transport and the requirements specified by the relevant provincial nature conservation authority.</p>
	<p>Animal Diseases Act (Act 35 of 1984): https://www.gov.za/documents/animal-diseases-act-12-mar-2015-1128 Guidelines and application forms for laboratory approval and research approval (Section 20 permits): https://www.nda.gov.za/index.php/publication/422-laboratory-approval https://www.nda.gov.za/index.php/publication/429-research-approval-section-20</p> <p>Import and export Policy unit: https://www.nda.gov.za/index.php/publication/423-import-export-policy-unit Import and export permit application forms (Pathology specimens & raw materials for laboratory or pharmaceutical use): https://www.nda.gov.za/index.php/publication/439-animal-health Procedure manual: Facility biosafety and biosecurity (Section 20): https://www.nda.gov.za/index.php/publication/429-research-approval-section-20 List of controlled and notifiable animal diseases in terms of the Animal Diseases Act: https://www.nda.gov.za/publication/437-list-of-controlled-disease Procedure manual: DALRRD approval of veterinary laboratories (Regulation 12B): https://www.nda.gov.za/index.php/publication/422-laboratory-approval South African National Standard (SANS): The care and use of animals for scientific purposes: SANS 10386:2008 https://store.sabs.co.za/pdfpreview.php?hash=43ffb947dc6356bccb8b492ec7984cebaa4e818c&preview=yes</p> <p> Marna Laing. Section 20 applications. Control Veterinary Technologist; Sub-Directorate: Epidemiology; Directorate: Animal Health; Department of Agriculture, Tel: 012 319 7442, E-mail: MarnaL@nda.gov.za.</p> <p>Import and export permit applications submitted to: vetpermits@nda.gov.za Dr Gretna de Wit. State Veterinarian: Import Export Policy Unit for Directorate Animal Health, Tel no: 012 319 7524; email: GretnaDW@nda.gov.za Dr Nadia de Beer. State Veterinarian: Import Export Policy Unit for Directorate Animal Health, Tel no: 012 319 7507; email: NadiaDB@nda.gov.za</p>		
<p>Animals and biological materials collected from animals</p>	<p>Research with animals</p>	<p>Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) as amended: Rules relating to the practising of veterinary</p>	<p>Register Animal Research Facilities with the South African Veterinary Council (SAVC). The facilities will be inspected to ensure that they comply with the</p>

		professions. Rule 32: Animal Research Facilities DoA	minimum standards for facilities and that veterinary services are rendered at the required standards. A compliance certificate is issued once compliance with the minimum standards is confirmed. Facilities are inspected on a six-year cycle.
	Unregistered persons that perform any veterinary procedures with animals	Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) DoA	Apply to the South African Veterinary Council (SAVC) for the authorisation of unregistered persons to render the procedures, functions or services pertaining to the profession of a veterinarian or para-veterinary professional.
 <p>Veterinary and Para-Veterinary Professions Act (Act 19 of 1982): https://www.gov.za/sites/default/files/gcis_document/201503/act-19-1982.pdf Rules regarding the practising of the para-veterinary profession of laboratory animal technologist (including Rule 21 Animal Research Facilities): https://savic.org.za/laboratory-animal-technologist/practicing-as-a-laboratory-animal-technician/authorisation-in-terms-of-section-23-1-c-of-the-veterinary-and-para-veterinary-act-act-19-of-1982/</p> <p>Rule 32. Minimum standards for Animal Research Facilities: https://savic.org.za/wp-content/uploads/2021/05/047_Rule-32-Animal-Research-Facilities.pdf</p>  <p>SAVC Contacts: https://savic.org.za/contact-us/</p>			
3.2 Stock remedies, veterinary biologicals, and vaccines for animals			
Stock remedies, veterinary biologicals, and vaccines for animals	Import, manufacture, produce, or sell stock remedies or vaccines for use with domestic animals, livestock, poultry, fish, or wild animals to:	Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)	Apply for registration of stock remedies, veterinary biologicals, and vaccines. You can only apply for registration if your company is registered in South Africa, or

	<ul style="list-style-type: none"> - prevent, treat, and cure unhealthy conditions. - maintain, grow, produce, and improve their health. 	DoA	you are a legal body registered in South Africa.
	Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act: https://www.gov.za/documents/fertilizers-farm-feeds-seeds-and-remedies-amendment-act-19-may-2015-1258 Information, procedure, and application forms: https://www.gov.za/services/fertilizers-farm-feeds-agricultural-remedies/register-stock-remedy		

4. ENVIRONMENT & BIODIVERSITY			
Regulated organisms or material	Activities and scope	Legislation or regulation and administering government department or institution	Requirements
4.1 Indigenous biological resources, alien, invasive, threatened, or protected species			
Indigenous biological resources: Animals, plants, or other organisms of indigenous species (species that occur naturally in a free state in nature within South Africa). Includes: any living or dead organisms, any derivative or genetic material of such organisms whether gathered from the wild, or from indigenous species cultivated, bred or kept in captivity, or altered in any way by means of biotechnology; any cultivar,	Bioprospecting (any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation).	National Environmental Management: Biodiversity Act (NEMBA), (Act 10 of 2004) Chapters 5 and 6 Bioprospecting (Section 81) Alien & Invasive species (Section 70) Department of Forestry, Fisheries and the Environment (DFFE)	Research on indigenous biological resources in South Africa (Discovery Phase): no bioprospecting permit required, but researcher must notify the minister. Export of material for research: Export permit required from Provincial authority. Export of ex-situ material (i.e., from a collection) for research: Must notify provincial issuing authority (MEC) and provide a copy of the research agreement. Commercialisation activities: Bioprospecting permit, benefit-sharing

variety, strain, derivative or fertile version of any indigenous species; any exotic animals, plants, or other organisms altered with genetic material or chemical bio-compounds found in any indigenous species.			agreement and material transfer agreement required.
Alien and invasive species that can pose a potential threat to biodiversity.	Working with alien or invasive, species listed in a public notice (updated from time to time).	National Environmental Management: Biodiversity Act (NEMBA), (Act 10 of 2004), Chapter 5. DFFE	Apply for permits in terms of section 65(1) or 71(1) of the Act to carry out restricted activities for the purpose of research involving listed invasive and alien species and keep a register of the species and activities. National status reports are also required. Import permits and veterinary health or phytosanitary certificates are required when alien or invasive species are imported.
Threatened or protected species (TOPS)	Captive breeding operation, commercial exhibition facility, game farms, nursery, scientific institution, sanctuary, rehabilitation facility or a wildlife trader involving specimens of any listed threatened or protected species.	NEMBA (Act 10 of 2004), Chapter 4, Part 2. DFFE	Register the facility in terms of TOPS, and apply for permits for any restricted activities. The latest version of lists of critically endangered, endangered, vulnerable and protected insect, fish, reptile, birds, mammal and plant species should be consulted.

<p>Endangered Species of Wild Fauna and Flora</p>	<p>International trade in specimens of wild animals and plants</p>	<p>NEMBA (Act 10 of 2004), Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Regulations (2010)</p> <p>DFFE</p>	<p>All imports, exports, re-exports and introductions from the sea of species covered by CITES have to be authorised through a permitting system. A specimen of a CITES-listed species may be imported into or exported (or re-exported) from a State party to the Convention only if the appropriate documentation has been obtained and presented for clearance at the port of entry or exit. Variation in the requirements from one country to another- check on the national laws that may be stricter.</p>
<div style="display: flex; align-items: flex-start;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"> <ul style="list-style-type: none"> ✓ — ✓ — ✓ — </div> <div> <p>National Environmental Management: Biodiversity Act, (Act 10 of 2004), Invasive species regulations: https://invasives.org.za/nemba-alien-and-invasive-species-regulations-and-lists/</p> <p>National Environmental Management: Biodiversity Act, (Act 10 of 2004) Draft Alien and Invasive Species Lists, 2014): https://www.sanbi.org/documents/nemba-invasive-alien-species-regulations/</p> <p>TOPS permit and registration application process for the carrying out of restricted activities in terms of the NEMBA (Act 10 of 2004): https://www.dffe.gov.za/tops-permit-and-registration-application-process-carrying-out-restricted-activities-terms-nemba-10</p> <p>List of threatened or protected species (TOPS), 2007: https://www.dffe.gov.za/sites/default/files/gazetted_notices/nemba_criticallyendangered_specieslis_g30568rg8801gon1187.pdf</p> <p>List of threatened or protected marine species, 2017: https://www.dffe.gov.za/sites/default/files/legislations/nemba10of2004_threatenedoprotectedmarinespecieregulations_gg40876_0.pdf</p> <p>Regulations on bioprospecting, access and benefit-sharing, 2014: https://www.dffe.gov.za/sites/default/files/legislations/nemba10of2004_draftregulations_bioprospecting_gn37331_0.pdf</p> <p>NEMBA: CITES: https://www.gov.za/documents/national-environmental-management-biodiversity-act-regulations-convention-international</p> <p>Information on South Africa CITES https://www.dffe.gov.za/south-africa-party-convection-international-trade-endangered-species-wild-fauna-and-flora-cites#:~:text=South%20Africa%20and%20CITIES&text=South%20Africa%20has%20been%20involved,1975%20to%20the%20Swiss%20government and https://cites.org/eng/parties/country-profiles/za</p> <p>CITES Species checklist: https://checklist.cites.org/#/en/search/country_ids%5B%5D=71&output_layout=alphabetical&level_of_listing=0&show_synonyms=1&show_author=1&show_english=1&show_spanish=1&show_french=1&scientific_name=&page=1&per_page=20</p> </div> </div> <div style="margin-top: 10px;">  TOPS: topspemits@environment.gov.za </div>			

CITES: DFFE Mr Mpho Tjiane Tel +27 (12) 399 95 96 Email: mtjiane@dffe.gov.za
 Chair of Scientific Authority at SANBI: Ms Carmel Mbizvo Tel: +27 (21) 799 8807 Email: c.mbizvo@sanbi.org.za or secretariat.scientificauthority@sanbi.org.za

4.2 Controlled goods that may cause harm to South African people, animals or the environment when released.

Controlled goods: any plant, pathogen, insect, exotic animal, growth medium, infectious thing; honey, beeswax or used apiary equipment. Includes GM plants and seeds.	Import any of the listed controlled goods	Agricultural Pests Act, (Act 36 of 1983) Regulations R.111 of 27 January 1984 as amended DoA Directorate Plant Health	Apply for a permit to import any of the listed controlled goods. Note the published list of plants that do not require import permits.
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------



Agricultural Pests Act (Act 36 of 1983): https://www.gov.za/sites/default/files/gcis_document/201503/act-36-1983.pdf
 Plant health: Importing regulations, import permit application form and the latest Plant Health Tariff list indicating the allowable number of items per permit and tariffs: <https://www.nda.gov.za/component/content/article/299-import-authorisation?catid=19&Itemid=437>

5. BIOSECURITY

Regulated organisms or material	Activities and scope	Legislation or regulation and administering government department or institution	Requirements
5.1 Controlled goods: microbial or other biological agents and toxins that may be used in the manufacture of biological and toxin weapons (dual use) and/or equipment and technology that may be used in the manufacture of biological and toxin weapons. Controlled chemicals, missile technology and nuclear-related dual-use equipment are also included.			
Controlled goods: 1) Microbial or other biological agents (living organisms, including	1) Possession of any controlled goods, 2) Import, export, re-export, transit (including trans-	Non-proliferation of Weapons of Mass Destruction (WMD) Act (Act 87 of 1993). [Convention on the	A person who is in control of any activity with regard to controlled goods (any

<p>viruses or infectious material derived therefrom), toxins and related equipment and technology that may be used in the manufacture of biological and toxin weapons. Biological warfare agents can be used to cause diseases or death in humans, animals, or plants.</p> <p>2) Controlled toxic chemicals and precursors 3) Missile technology 4) Nuclear-related dual-use equipment and technology</p>	<p>shipment), development, manufacture, production, acquisition in any manner, use, operation, stockpiling, maintenance, transport, disposal, sale, and retention of biological weapons or controlled goods that may be used for the manufacture of biological and toxin weapons. No permit is required for quantities of less than 5 mg of saxitoxin if the transfer is made for medical or diagnostic purposes.</p> <p>2) Equipment capable of use in handling biological materials including a) complete biological containment facilities at Biosafety Level 3 or 4 containment level (BSL3/4). b) Major components that can be used to build a functional BSL 3 or 4 facility such as specific filters, effluent decontamination systems, fermenters, incubators, autoclaves, freeze-drying-, spray-drying- or milling equipment, biological safety cabinets or isolators, aerosol challenge testing chambers</p>	<p>Prohibition of the Development, Production and Stockpiling of Bacteriological (biological) and Toxin Weapons and on their destruction (BTWC) attached to the Act].</p> <p>- Government Notice R16 of 2010 (Registration) - Government Notice 4978 of June 2024 (Declaration of certain biological goods and technologies as controlled goods and control measures applicable to such goods), declares certain biological goods and technologies to be controlled goods and control measures applicable to such goods. Lists of organisms and toxins in Annexure A, equipment capable of use in handling biological materials in Annexure B.</p> <p>- Government Notice 4975 (Declaration of certain chemical goods as controlled goods and control measures applicable to such goods) - Government Notice No. R. 4976 of 14 June 2024 (Missile Technology Control Regime (MTCR) equipment, technology and related items)</p>	<p>goods listed in the notices under the Act) or who has controlled goods in his or her possession or custody or under his or her control must register online with the South African Council for the Non-Proliferation of Weapons of Mass Destruction. This includes all BSL3 and BSL4 facilities and specific equipment. A Code of Conduct of persons involved in non-proliferation activities must be signed and submitted to the Non-proliferation Secretariat.</p> <p>The registration is valid for two years. Renewal of the registrations should be done two months before the expiry date.</p> <p>Apply for permits when controlled goods are manufactured, used to provide services, exported, or transported.</p> <p>Register and apply online via the non-proliferation website of the DTIC.</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

		<p>- Government Notice No. R. 4977 of 14 June 2024 (Nuclear-related dual-use equipment, materials and software, and related technology of the Nuclear Suppliers Group (NSG)</p> <p>Department of Trade, Industry and Competition (DTIC)</p>	
	<p>Non-proliferation of Weapons of Mass Destruction (WMD) Act (Act 87 of 1993): https://www.gov.za/documents/non-proliferation-weapons-mass-destruction-act-2-jul-1993-0000 and https://www.gov.za/sites/default/files/gcis_document/201409/32891160.pdf</p> <p>South African Council for the Non-Proliferation of Weapons of Mass Destruction, permit application forms: http://non-proliferation.thedtic.gov.za/</p> <p>Lists of microbial and other biological agents, toxins and related equipment and technology that may be used in the manufacture of biological and toxin weapons (R 4978, June 2024): http://non-proliferation.thedtic.gov.za/wp-content/uploads/2024/06/Government-Gazette-No.-R.-4978-of-14-June-2024.pdf</p> <p>Brochure: Biological controls: http://non-proliferation.thedtic.gov.za/wp-content/uploads/2019/09/BROCHURE-Biological-Controls.pdf</p> <p>Information about the regulations regarding controlled chemicals, missile technology and nuclear-related dual-use equipment, material and software and related technology can also be found on the SA Council webpage: http://non-proliferation.thedtic.gov.za/legislative-framework/regulations-and-notice/</p> <p> nonproliferation@thedtic.gov.za</p>		

6. INTERNATIONAL LEGISLATION, CONVENTIONS AND PROTOCOLS OF WHICH SOUTH AFRICA IS A SIGNATORY

1. Convention on Biological Diversity (CBD) <https://www.cbd.int/convention/>

1.1 Cartagena Protocol on Biosafety: International agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology. <https://bch.cbd.int/protocol>

1.2 Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation. <https://www.cbd.int/abs/>

Fact sheet <https://www.cbd.int/abs/doc/protocol/factsheets/abs-en.pdf>

1.3 Nagoya-Kuala Lumpur Supplementary Protocol on liability and redress to the Cartagena Protocol on Biosafety aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures in the field of liability and redress relating to living modified organisms. <https://bch.cbd.int/protocol/supplementary/>

2. Codex Alimentarius International Food Standards. Guidelines and codes of practice that contribute to the safety, quality and fairness of international food trade. Includes a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. <https://www.fao.org/fao-who-codexalimentarius/thematic-areas/biotechnology/en/>

For more information, contact Dr Sarita Groenewald at sarita.groenewald@uct.ac.za