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

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.

Overview of organisms, biological materials and activities that are 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 & instructions**
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). 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.	• 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	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 Registration of a facility (Regulation 8 of the GMO Act Regulations, 2010) Department of Agriculture (DoA) Directorate: Genetic Resources	**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). **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). Lab registration is valid for 3 years. Apply for a renewal or amendment using the same form. **Regulation 2(1)**: Apply for a **permit** under the GMO Act for any of the following activities involving GMOs: • **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	GMO Act (Act 15 of 1997) GMO Act Regulations (2010) SOP for Regulation 2(2) of the GMO Act DoA	**Regulation 2(2)** An import permit is NOT required for GMOs • used under conditions of contained use (C**ontainment levels 1 and 2**) • within **registered** academic and research facilities (where the confined area is a laboratory, growth room or greenhouse) • 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.

			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).
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, including the impact on non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture".	**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 an **environmental assessment** has been conducted by the applicant.
	GMO Act (Act 15 of 1997): https://www.gov.za/documents/genetically-modified-organisms-act-0 Guideline, policy, application forms and tariffs: https://www.dalrrd.gov.za/index.php/publication/408-gmo-about-us# 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

Registrar of GMO Act: Ms Nompumelelo Mkhonza; Tel: 012 319 6382; e-mail: NompumeleloM@Dalrrd.gov.za.

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 (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	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 **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

	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."		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.
	Removal and donation of tissue, blood and gametes from living persons for medical and dental purposes and handling human bodies and tissue after death.	National Health Act (Act 61 of 2003) Section 68, Notice R180 (General control of human bodies, tissue, blood, blood products and gametes) DOH	**Written consent is required, registers** must be kept and liaise with a health officer appointed by the minister.
	Import or export of any tissue or any blood, blood product, cultured cells, stem cells, embryo, zygotes or gamete.	National Health Act (Act 61 of 2003) Section 68, Notice R181 DOH	**Apply for a permit to import or export** the listed biological materials and keep a register of all imports and exports. 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. 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 was granted ethics approval must complete the application form.
	Transfer of human biological material from a provider to a recipient for use in **research or clinical trials.**	National Health Act (Act 61 of 2003), Notice 719 (Template for MTA of human biological materials) DOH	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 **Material Transfer Agreement of Human Biological Materials**.
	Transport of dangerous goods and infectious substances: human biological material, pathogenic microorganisms	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.	Follow specific **technical instructions** for packaging in hazard subclass 6.2: Category A Infectious substances affecting humans – UN2814. Category A Infectious substances only affecting animals- UN2900. Category B Biological substance (Diagnostic specimen or clinical specimens -minimal likelihood of containing a pathogen)- UN3373. IATA presents a certification course for packing and transporting infectious substances (Category A or B).

National Health Act (Act 61 of 2003): https://www.gov.za/documents/national-health-act
National Health Act Guide: https://section27.org.za/wp-content/uploads/2019/07/Stevenson-National-Health-Act-Guide-2019-1.pdf
Material transfer agreement of human biological materials: https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf
Compliance with National Road Traffic Act (Act 93 of 1996 and its amendments) https://dgrcompliance.co.za/national-road-traffic-act-93-of-1996/
IATA Infectious Substances Transport certification course: https://www.iata.org/en/training/courses/infectious-substance-transport/tcgp22/en/
SANS 10228 (2012) https://ia801603.us.archive.org/32/items/za.sans.10228.2012/za.sans.10228.2012.pdf

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
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

Import and export of human biological materials:

Mr Levy OL Tjale Tel.: 012 395 9487; email: Levy.Tjale@health.gov.za

2.2 Clinical trials and research with human participants			
Human participants in clinical trials, clinical research, and bioequivalence studies	**Research** with human participants	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**, 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.
	Clinical trials and bioequivalence studies 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.	Medicines and Related Substance Act (Act 101 of 1965). Regulates control of human and veterinary medicines and medical devices, as well as complementary medicines. South African Health Products Regulatory Authority (SAHPRA) regulates medicines and clinical research.	**Apply for access** to unregistered medicines for 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. DOH Regulated by the South African Health Products Regulatory Authority (SAHPRA)	**Apply for a permit** from the Director-General of the DOH
Medicines and Related Substance 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 Regulations to the act: http://www.rrfa.co.za/wp-content/uploads/2012/11/Regulations-to-Act-101-published-2003.pdf SAHPRA Clinical Trial Unit: Information, application and report forms and clinical trial guidelines: https://www.sahpra.org.za/clinical-trials/ POPIA ASSAF Code of conduct – How personal information should be processed in the research sector: https://inforegulator.org.za/wp-content/uploads/2020/07/Government-Gazzette-dated-12-May-.pdf			
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.	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) DOH	**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. Lab registration is valid for 2 years.
	Import and export of human pathogens	National Health Act (Act 61 of 2003) Section 68 DOH	**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.
	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		

Mr Levy OL Tjale Tel.: 012 395 9487; email: Levy.Tjale@health.gov.za

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	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

	glands, organs, fluids, or any other part, of an animal or parasite (excluding any substance that is controlled 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**		disease or parasite, introduce or transport any animal or thing that can spread animal disease or parasite. **Each research project** must apply for a separate Section 20 permit. Risk assessment to determine suitable biosafety level. **Laboratory approval:** Facilities where the investigations, experiments or research will be performed **apply for a recommendation report or certificate of compliance** for BSL2, BSL3, Animal quarantine (ABSL3), Biobank or vector-protected facilities (Procedure manual available). Valid for 2 years. Section 20 permit has a maximum validity of 3 years, whereafter researchers must apply for an extension and/or amendment.

	or agent which can 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 is collected from carcasses in a local abattoir that was inspected and passed as fit for human consumption. A certificate of origin should be available to confirm. **Local production of monoclonal antibodies:** Section 20 permit required, and 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.

			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.

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.dalrrd.gov.za/index.php/publication/422-laboratory-approval
https://www.dalrrd.gov.za/index.php/publication/429-research-approval-section-20

Import and export Policy unit: https://www.dalrrd.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.dalrrd.gov.za/index.php/publication/439-animal-health
Procedure manual: Facility biosafety and biosecurity (Section 20): https://www.dalrrd.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://nahf.co.za/controlled-and-notifiable-diseases/
Procedure manual: DALRRD approval of veterinary laboratories (Regulation 12B): https://www.dalrrd.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
Procedure manual: Importation of a new diagnostic test kit or reagent: https://www.dalrrd.gov.za/images/Branches/AgricProducHealthFoodSafety/animal-health/epidemiology/laboratory-approvals/laboratory-approval-procedures/Procedure%20Manual%20Importation%20of%20a%20new%20test%20kit%20or%20reagent-March%202018.pdf

Marna Laing. Section 20 applications. Control Veterinary Technologist; Sub-Directorate: Epidemiology; Directorate: Animal Health; Department of Agriculture, Tel: 012 319 7442, E-mail: MarnaL@dalrrd.gov.za.
Import and export permit applications submitted to: vetpermits@dalrrd.gov.za
Dr Gretna de Wit. State Veterinarian: Import Export Policy Unit for Directorate Animal Health, Tel no: 012 319 7524; email: GretnaDW@Dalrrd.gov.za
Dr Nadia de Beer. State Veterinarian: Import Export Policy Unit for Directorate Animal Health, Tel no: 012 319 7507; email: NadiaDB@Dalrrd.gov.za

Animals and biological materials collected from animals	Research with animals	Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) as	**Register** Animal Research Facilities with the South African Veterinary Council (SAVC). The

		amended: Rules relating to the practising of veterinary professions. Rule 32: Animal Research Facilities	facilities will be inspected to ensure that they comply with the 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)	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.
 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://savc.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/ Rule 32. Minimum standards for Animal Research Facilities: https://savc.org.za/wp-content/uploads/2021/05/047_Rule-32-Animal-Research-Facilities.pdf  SAVC Contacts: https://savc.org.za/contact-us/			
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: - prevent, treat, and cure unhealthy conditions.	Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) Department of Agriculture	**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 you are a legal body registered in South Africa.

	- maintain, grow, produce, and improve their health.		

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, variety, strain, derivative or fertile version of any indigenous species; any	**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 agreement and material transfer agreement required.

exotic animals, plants, or other organisms altered with genetic material or chemical bio-compounds found in any indigenous species.			
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.
Endangered Species of Wild Fauna and Flora	International trade in specimens of wild animals and plants	NEMBA (Act 10 of 2004), Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Regulations (2010) DFFE	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.

National Environmental Management: Biodiversity Act, (Act 10 of 2004), Invasive species regulations:
https://invasives.org.za/nemba-alien-and-invasive-species-regulations-and-lists/
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/
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
List of threatened or protected species (TOPS), 2007:
https://www.dffe.gov.za/sites/default/files/gazetted_notices/nemba_criticallyendangered_specieslis_g30568rg8801gon1187.pdf
List of threatened or protected marine species, 2017:
https://www.dffe.gov.za/sites/default/files/legislations/nemba10of2004_threatenedoprotectedmarinespecieregulations_gg40876_0.pdf
Regulations on bioprospecting, access and benefit-sharing, 2014:
https://www.dffe.gov.za/sites/default/files/legislations/nemba10of2004_draftregulations_bioprospecting_gn37331_0.pdf
NEMBA: CITES: https://www.gov.za/documents/national-environmental-management-biodiversity-act-regulations-convention-international
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
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

TOPS: topspermits@environment.gov.za
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	**Import** any of the listed controlled goods	Agricultural Pests Act, (Act 36 of 1983)	Apply for a **permit to import** any of the listed controlled goods. Note the published

animal, growth medium, infectious thing; honey, beeswax or used apiary equipment. Includes GM plants and seeds.		Department of Agriculture Directorate Plant Health	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.dalrrd.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 goods: microbial or other biological agents (living organisms, including viruses or infectious material derived therefrom), 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 of notice of amendment No. 75, Non-proliferation of Weapons of Mass Destruction (WMD) Act	1) Import, export, re-export, transit (including trans-shipment), possession, 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	Non-proliferation of Weapons of Mass Destruction (WMD) Act (Act 87 of 1993). [Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (biological) and Toxin Weapons and on their destruction (BTWC) attached to the Act]. Notice of Amendment No. 75 of 18 February 2015 and Notice 494 of March 2019 (Declaration of certain biological goods and technologies as controlled goods	A person who is in control of any **activity** with regard to controlled goods 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. The registration is valid for two years. Renewal of the registrations should be done two months before the expiry date.

(Act 87 of 1993). Biological warfare agents can be used to cause diseases or death in humans, animals, or plants.	quantities of less than 5 mg of saxitoxin if the transfer is made for medical or diagnostic purposes. 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	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. Department of Trade, Industry and Competition (DTIC)	**Apply for permits** when controlled goods are manufactured, used to provide services, exported, or transported. Register and apply online via the non-proliferation website of the DTIC.

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
South African Council for the Non-Proliferation of Weapons of Mass Destruction, permit application forms: http://non-proliferation.thedtic.gov.za/
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
Brochure: Biological controls: http://non-proliferation.thedtic.gov.za/wp-content/uploads/2019/09/BROCHURE-Biological-Controls.pdf
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-notices/

nonproliferation@thedtic.gov.za

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, Biosafety & Biosecurity Specialist, UCT Office of Research Integrity (sarita.groenewald@uct.ac.za)