UCT Biosafety and Biosecurity

Guideline

Applying for Section 20 and Veterinary Import Permits (Section 6) for research purposes under the Animal Diseases Act 35 of 1984 from the Directorate: Animal Health (DAH), Department of Agriculture

SG02-V06	2024_08_19

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1. Animal Diseases Act (Act 35 of 1984) Section 20

1.1 Legislation and Requirements

"*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 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 spread any animal disease or parasite*".

1.2 When should I apply for a Section 20 Permit, and what are the application requirements?

i. Apply for a permit to (a) **conduct any investigation, experiment, or research** with **any of the listed substances** (box above) 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.

ii. **All non-human vertebrates** are included under the Animal Diseases Act Section 20 requirements: mammals, birds, fish, reptiles, and amphibians.

iii. A Section 20 Permit is required for **"non-target" animal models** used in human clinical studies and trials. Clinical Trial Approval or exemption issued by the South African Health Products Regulatory Authority (SAHPRA) must be attached to the application in these cases.

iv. In addition to the Section 20 Permit application, an official letter from the **responsible State Veterinarian (SV)** of the area concerned must be obtained by the researcher in the case of the following:
    a. If any field samples are to be collected from any animal, parasite or vector of animal disease,
    b. If any animals are to be obtained from any property other than the facility where the research will be conducted itself,
    c. If the research is to be conducted on a property not belonging to the research facility and may involve any potentially infectious agent, parasite or vector of any animal disease,

d. If any material that is not passed as fit for human consumption will be removed from an abattoir. In this case the letter must be obtained from the SV responsible for the abattoir.

v. **Each research project** must apply for a separate Section 20 Permit.

vi. Apply for the Section 20 Permit **three (3) months before the research project starts**.

vii. Research projects **may not start** before the permit has been issued.

viii. Section 20 Permit application forms can be submitted before **ethics approval** has been obtained, but research may not commence without ethics approval.

ix. Section 20 Permits are valid for a maximum of **three (3) years**.

x. If any part of the research project or materials will **change** during the project, a *Request to amend the existing permit for research under section 20 of the Animal Diseases Act, 1984 (Act no 35 of 1984)* form with all the required supporting documents can be submitted to apply for the **extension of the expiry date** (one month before the expiry date) and/or an **amendment** (three months before the expiry date).

xi. **If you are unsure** whether a Section 20 Permit will be required, send a **written enquiry** to the Section 20 Secretariat. Include:

a. a summary of the project and
b. a detailed description of the material that will be handled during the study.

You will receive an email or letter to confirm that the permit is required, or you will receive an exemption/waiver for the specific materials/procedures.

xii. Make sure that you comply with **all relevant legislation and regulations**. You may need to apply for permits or registrations under different legislation from more than one government department/directorate for the same work. No permit or registration certificate supersedes or replaces other legal requirements.

1.3 Section 20 Permit information and application forms

Section 20 Permit guidelines, permit application- & request for amendment forms: https://www.nda.gov.za/index.php/publication/429-research-approval-section-20

- Check for the latest version of guidelines and application documents or contact the Section 20 Secretariat to make sure. *The guidelines and application forms were updated in October 2025*.
- Laboratory inspection and approval procedures and checklists: https://www.nda.gov.za/index.php/publication/422-laboratory-approval
- The latest version of the list of controlled and notifiable animal diseases in South Africa.

1.4 Contact details for Section 20 Permit applications and enquiries

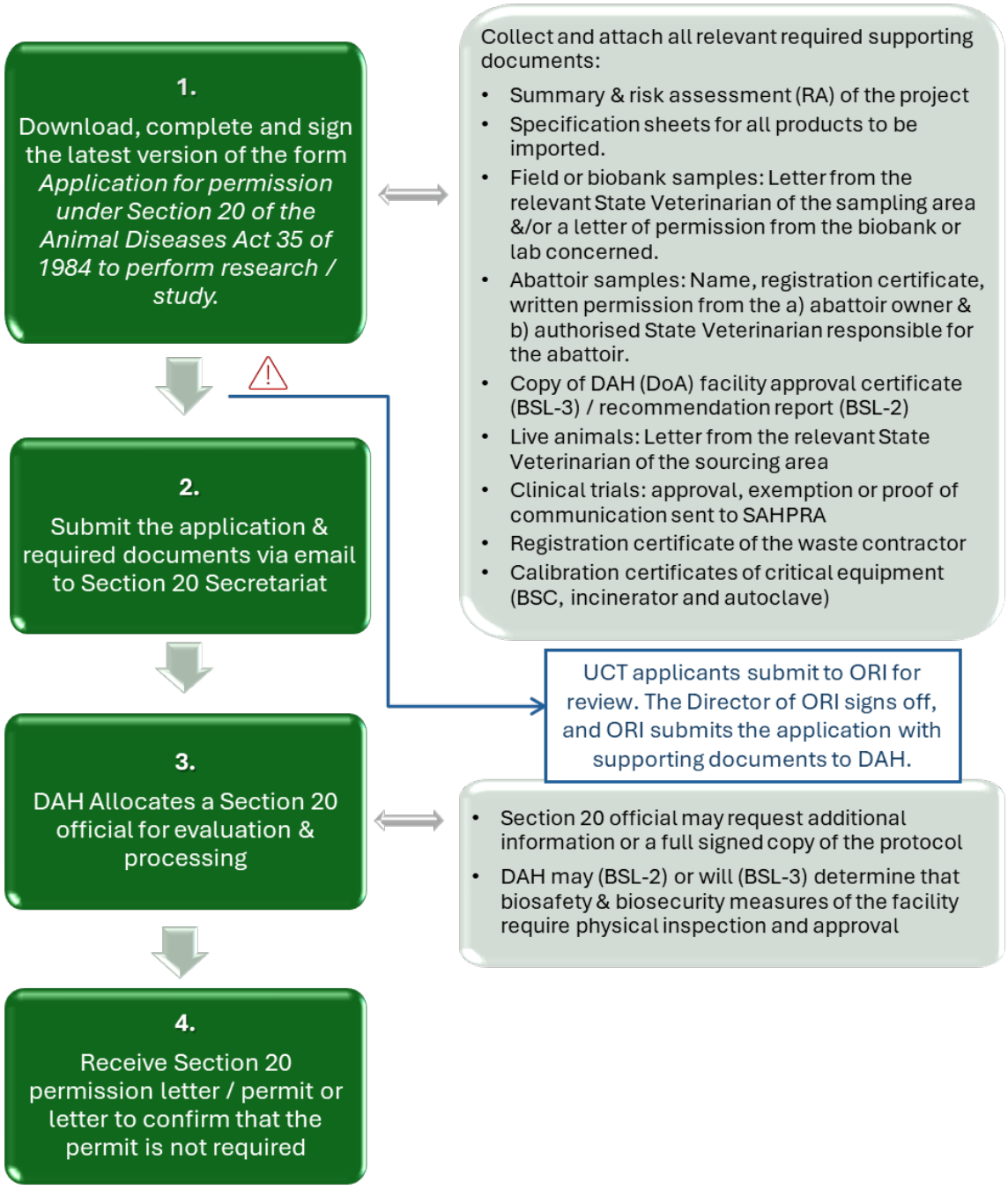
Department of Agriculture (DoA)
Directorate: Animal Health (DAH)
Section 20 Secretariat

Ms Marna Laing
MarnaL@nda.gov.za
Tel. 012 319 7442
https://www.nda.gov.za/index.php/publication/445-animal-health-contact-us

1.5 UCT Section 20 permit applications

Submit applications to the Office of Research Integrity (ORI) for review and feedback
Ms Lisa Williams
lisa.williams@uct.ac.za
Tel. 021 6505739

1.6 Overview of the application process: Section 20 Permits



1.7 Section 20 Permit application form instructions

NB: Follow the instructions & complete each section
Applicants reference (e.g. study/protocol/ethical approval reference number): Provide AREC, HREC, Clinical trial, etc. approval reference number/s with committee or permit name or indicate that an application has been submitted.

1. **Researcher (Principal Investigator):** Provide full address, including building and room number/s. Under the contact details of the relevant person for correspondence, please include the details of the research manager or PI's assistant in the first column (i.e., on the left). The UCT Office of Research Integrity must sign off on all Section 20 permit applications, and Lisa Williams will include her details in the right column.
2. **Project**: The **title of the project** should only refer to or focus on the animals, animal materials or animal-derived biological material that will be used in the coming three (3) years of the project. Only provide the **objective/s** that include the animals or animal materials that will be covered in this permit application. Under the proposed start date, please note that a permit may take up to three months or longer to obtain. Take this into consideration and apply well in advance. Provide a day, month and year for start and completion dates.
3. **List all the facilities that will be involved in the research project (details of all facilities or laboratories where any part of the research will be done):** Include details of **all institutions** or labs where **any part** of the project will be done (other institutions could apply for their own Section 20 permits for the part of the project that will be done at their facilities).
4. **General:** 4.1 List animal pathogens or vectors that will be handled in this project. Do not list diseases if you are not planning to work with diagnosed animals, if you are not planning to culture the pathogens or if the project does not involve diagnosing the disease. If no pathogens, disease or vector are involved, this section does not apply to the project - "NA".
4.2 List all microorganisms, parasites or animal materials or materials derived from these. Include all materials, including names of animal cell cultures, here. This list will be checked when import permit applications for these materials are submitted.
4.3 Biological origin: from which source will the animal cells, materials or microorganisms be isolated?
4.4 Does the study involve GMOs, GM material or synthetic RNA/DNA? Provide the information and include GM cell lines and genome-edited organisms. Yes or No
4.5 Importation of materials listed under 4.2. List materials & exporting country. Attach specification sheets, certificates of origin, declarations of the state vet that there are no notifiable diseases in the areas where samples were collected, etc. Include anything that provides more information on the material you plan to import.
5**. Samples:** *Read Section 20 Guideline Section 7.7* 5.1 Field samples: Will parasites or animal samples be collected from field sites? If yes, provide the requested information and attach a state veterinarian letter.
5.2 Biobanked samples: Will samples from any biobank (including museums) or in storage at a laboratory or other facility be utilised? If yes, provide the requested information and attach a permission letter from the biobank or laboratory, the DAH facility recommendation report and a copy of the Section 20 permit in terms of which the stored samples were collected (if any). If samples are to be inactivated or treated at an external facility, a letter from the facility must be included (*see Section 20 Guidelines Section 7.7.2*).

5.3 Samples collected from an abattoir: Provide the requested information and attach the registration certificate of the abattoir, permission from the abattoir owner and permission from the authorised state veterinarian.
5.4 Will samples be transported according to national and international legal requirements? If no, provide a Transport SOP.
6. **Facilities**: *Read Section 20 Guidelines Section 7.6* 6.1 Indicate BSL-1 to BSL-4 of each facility that was listed in Section 3 and indicate whether the facility is vector-protected or not. If vector-protected, for which vectors?
6.2 Are the facilities DAH-approved or compliant? If not DAH approved, describe the existing containment measures available in your facility to handle the samples safely (e.g., Class II BSC), training & evaluation, storage & inventory management, waste, spill procedures, PPE, access control, etc. If the labs are DAH-approved, please attach the latest DAH certificate (BSL-3) or recommendation report (BSL-2).
6.3 Biosafety and biosecurity containment measures for the animals, microorganisms or parasites as well as material thereof. Relevant Biosafety SOPs can be mentioned and attached
6.4 For each facility listed in Section 3, describe the work that will be performed and the material that will be handled. Use subheadings for clarity.
7**. Live animals**: Indicate whether and which live animals will be used (7.1), the origin of the animals (7.2) and attach a state vet letter stating the disease restrictions of the area where animals are sourced (7.3).
7.4 If the animals are going to be administered an unregistered product under uncontrolled conditions (without veterinary supervision), please also attach a letter from the relevant state veterinarian of the area where the study will be conducted.
7.5 Include the measures in place to ensure safe handling of animals and that animals cannot escape from the facility. Include emergency procedures in the event of escape. Describe the access control system of the facility to prevent unauthorised entry and removal of animals. Refer to and attach the DAH BSL recommendation report or compliance certificate of the animal facility.
7.6 Fate of animals after completion of the study: *No information or guidance about this in the Section 20 Guideline*
7.7 When clinical trials (CT) are done on target species (under controlled or uncontrolled conditions), attach clinical trial approval, exemption or communication with SAHPRA. CT In non-target species, controlled conditions – DAH Director will evaluate animal health risk. See instructions in *Section 20 Guideline Section 7.10*
8. **Disposal of materials &/or animals**: 8.1 Describe disposal of all potentially infectious liquid and solid waste (Relevant Hazardous Waste SOPs can be mentioned and attached) 8.2 Method of disposal or destruction used. 8.3 Name of biohazardous waste contractor (attach municipality registration certificate) 8.4 If there is an incinerator on the premises, it must be registered with DFFE (attach certificate)
9**. Storage &/or distribution**:

9.1 Provide details (what, how much, how, where) of all relevant products that will be stored beyond completion of the study.
9.2 Provide details of animals or samples that will be used in another project, where and why any products will be distributed.

10. **Methodology of the study**: Include a flow diagram of the project (3 years) with all the steps that involve handling, storing & transporting animals, animal materials or animal pathogens and add a biological risk assessment of these materials and the specific procedures (e.g., aerosol-generating activities, etc.). No detailed methods are required. The reviewers must be able to understand the workflow (What? How? Where?) and assess the potential risks. When the project includes the use of registered medicines, rather refer to the class of drug than specific brand names. There may be cases when the specific brand is not available when needed, then another one in the same class may be used without applying for an amendment, which may delay the project unnecessarily.

11. **Person responsible for research**: The principal investigator/researcher/student must sign before submission.

12. **The supervisor** of the student/ researcher must sign before submission.

13. The person **responsible for each lab/facility** listed in Section 3 must sign before submission (you can add more blocks)

14. The **Director of ORI** will sign as the person responsible for the institution (will be added when the ORI Team reviews the application)

1.8 Request to amend an existing Section 20 permit

When to apply for an amendment:

i. To **extend the expiry date** of the Section 20 permit
ii. To **change the researcher**, supervisor or the person responsible for the involved institutions
iii. To **change any part of an approved project if the scope or the risk rating** of the project/study changes
iv. Amendment requests must be submitted at least **three months** before the proposed commencement of the amended research protocol.
v. If the request is only to extend the expiry date, the request must be submitted at least **one month** before the expiry date.

Extension of the expiry date

The following information is required

i. The new proposed end date (max 3-year period)
ii. A summary of the research that has been completed and that still requires completion (Can be attached in a separate document)
iii. The reason why an extension is required

Changes to the project

When applying for an amendment, select all the relevant changes that will be made from the list in Section 4.2 (Yes or No). Provide more details about all the changes that will be made (options you answered "Yes")

a) Place of sample/animal source

b) Species of animal/sample source
c) Type of sample collected
d) Testing destination of samples
e) Research animal facility
f) Amendment to storage of samples (place, medium, condition, sample type)
g) Analyses or testing of samples
h) Importation of materials required
i) Additional vaccine, reagents or other product to be used
j) Any other amendment not covered above (that will change the scope and the risk rating of the project.

NB. If the change you want/have to make to the original project plan **does not change the scope or the risk rating** of the project, you do not need to apply for an amendment, for example when a different injection method, blood sampling tube or a different animal handling method is used, the scope and risk rating remain unchanged, and no amendment will be required.

The following documents must be attached to all amendment applications

i. A copy of the existing Section 20 permit.
ii. A copy of the original and signed Section 20 application document (based on which the existing Section 20 permit was issued).
iii. A copy of the latest certificate of compliance/ recommendation report if any work is conducted within a DAH-approved or DAH-compliant facility.
iv. Copies of all previous amendments or extensions granted or declined for the Section 20 permit.
v. If previous requests for amendments have been cancelled, withdrawn or declined, provide an explanation and relevant correspondence.
vi. Other supporting documents as required for Section 20 permit applications (See *Section 20 Guidelines*)

Signatures required: See Section 1.7, Points 11-14

2. Animal Diseases Act (Act 35 of 1984) Section 6: Veterinary Import Permits

2.1 Legislation and Requirements

"No person shall import any animal, parasite or contaminated or infectious thing into the Republic except under the authority of a permit and in compliance with any conditions imposed in such permit."

2.1.1 Animal Diseases Regulations (R 2026 of 1986) Annexure 1

"Things included in the definitions of "infectious thing" or "contaminated thing" in the Animal Diseases Act (35 of 1984).

A. Infectious thing

1. The carcass of an animal which died or suspectedly died of a controlled animal disease or which is infected or suspectedly infected with such disease or any portion of such carcass, including the viscera, organs, glands, hair, wool, feathers, skin, hide, hoofs, horns, teeth, bones, eggs, blood, milk, feces, semen, ova, urine and any other fluid, secretions or excretions of such animal.

2. Milk and any dairy product.

3. Meat and any meat product.

4. The organs, glands and viscera of animals and any product thereof.

5. The hides and skins of animals and any product thereof.

6. Unprocessed animal hair, feathers and wool.

7. Eggs of birds, poultry, fish, reptiles and amphibia.

8. Bones, hoofs, horns, ivory, teeth, blood, blood protein, embryos, semen, ova, feces and any secretion or excretion of an animal.

9. Any blood meal, bone meal, hoof meal, horn meal, carcass meal and liver meal.

10. Any virus, bacterium, protozoon, fungus, parasite or any other organism which can cause or transmit an animal disease.

11. Any vaccine, serum, antiserum, toxin, antitoxin, antigen or other product which is manufactured wholly or partially or is derived from any virus, bacterium, protozoon, fungus, parasite, gland, organ, serum, fluid or part of an animal <u>and</u> which is intended for animal use.

12. Any kitchen refuse of animal or vegetable origin originating from any dwelling, hotel, motel, restaurant, eating-house, airport, harbour or any place where food is being prepared for human use."

"B. Contaminated things

1. Second-hand meat cloths and other materials which have been used for the wrapping of animal products.

2. Empty second-hand grain bags and woolpacks.

3. Any bedding which has been used for animals and any grass, hay and straw used for the feeding of animals.

4. Any cage, crate or other container, halter, rope, chain or restraining or securing thing, harness, instrument, tool, fodder or other thing which has been used by or in connection with or could have been in contact with any controlled animal or thing.

5. Any conveyance in which any infected animal or contact animal or any infected or contaminated thing was transported." (Spelling errors corrected)

2.2 When should I apply for a Veterinary Import Permit, and what are the application requirements?

i. When importing **animals**
ii. When importing **animal products, biological samples, animal cell lines or animal pathogens** (virus, bacterium, protozoan, fungus, parasite or any other organism which can cause or transmit an animal disease)
iii. When importing any **vaccine, serum, antiserum, antibodies, toxin, antitoxin, antigen or other product manufactured or derived from an animal pathogen or from a gland, organ, serum, fluid or part of an animal** and which is **intended for animal use**.
iv. When importing **antibodies, diagnostic test kits or reagents** that contain animal-derived products.
v. (Note: Regulation 12B of the Animal Diseases Act (Act 35 of 1984) "*A person or a laboratory that does **diagnostic testing or screening for a controlled animal disease or a notifiable animal disease** in any animal species, shall be registered with the director" and "A person producing, distributing and or importing any reagents or kits for the diagnostic testing or screening of controlled animal diseases or notifiable animal diseases, shall be registered with the director and shall comply with the standards and the reporting procedures as prescribed by the director*.")
vi. To import **animal biological materials, animal cell lines, and raw materials containing animal-derived products**, download and complete the "*Application to import pathology specimens and raw materials for laboratory or pharmaceutical use into the RSA*"
vii. To import **registered diagnostic test kits and pharmaceuticals (excluding vaccines) containing animal-derived products**, download and complete "*Application to import Pharmaceuticals Diagnostic Kits Biological Products cntl disease statements added 02 2018*" or "*Application to import Pharmaceuticals Diagnostic Kits Biological Products sms notification*" (2019)
viii. To apply for **dispensation of a Veterinary Import Permit**, download and complete the "*Application Form for dispensation*".
ix. Import permits are **valid for a limited time** (the expiry date will appear on the permit) and only for a **single consignment**.
x. Applications must be made **at least four (4) weeks**, but no longer than eight (8) weeks prior to introduction.
xi. Veterinary Import Permits are usually issued within 5-10 working days. Applicants are advised to phone the permit office if an email or SMS has not been received two (2) weeks after the application was submitted.
xii. If vendors regularly import the same product/s, they can apply for a **Master Veterinary Import Permit** (SOP available).

2.3 Animal Diseases Act Import/Export Policy Unit information and application forms

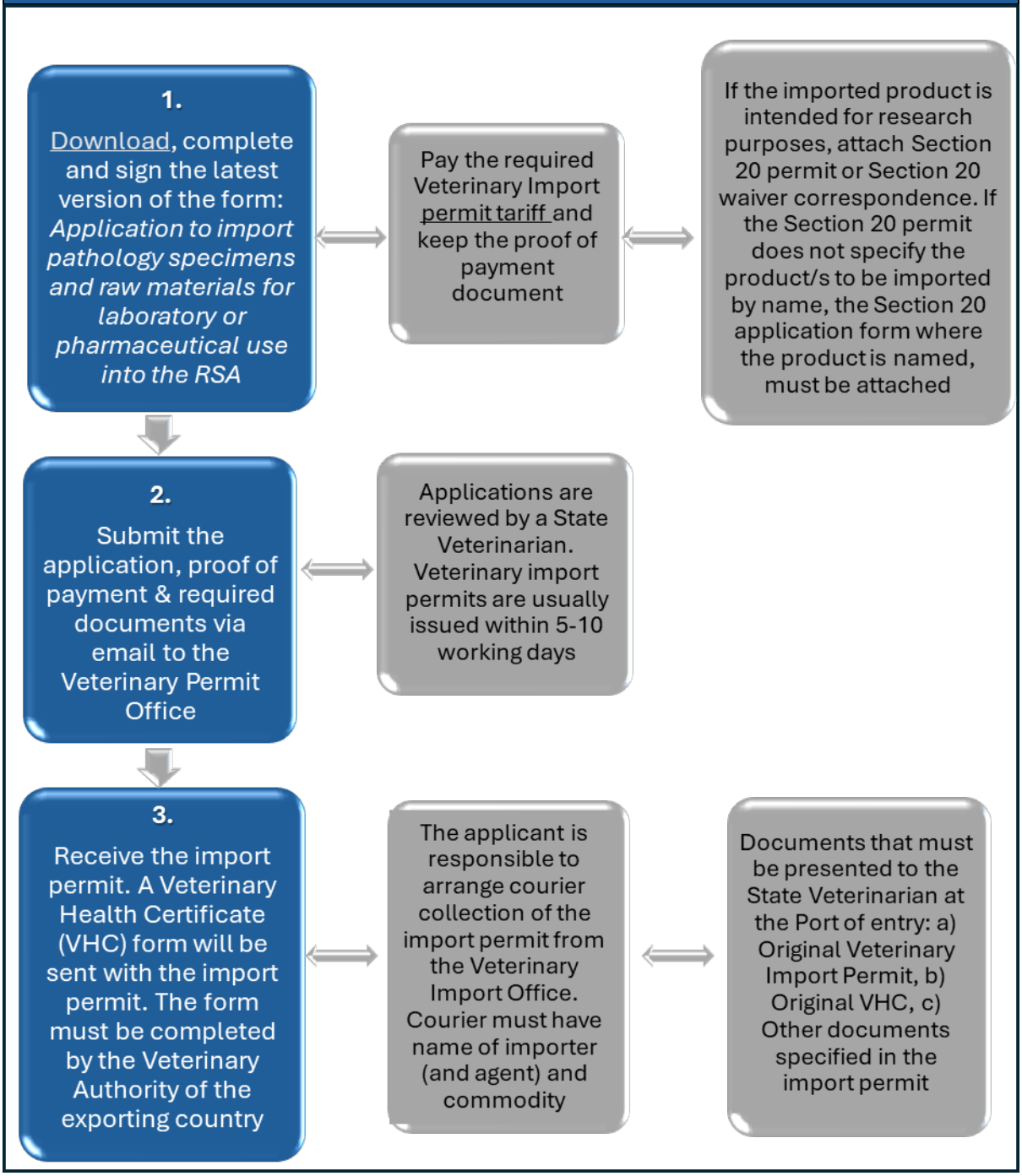
Import/Export Policy Unit, Import application forms, latest tariffs: https://www.nda.gov.za/index.php/publication/423-import-export-policy-unit

2.4 Contact details Import/Export Policy Unit

Veterinary Import and Export Permit applications: VetPermits@nda.gov.za
Office Q-GF-11, Agriculture Place, 20 Beatrix Street, Pretoria, Tel. 012 319 7414
Dr Gretna de Wit
GretnaDW@nda.gov.za
Tel. 021 319 7524
Dr Nadia de Beer
NadiaDB@nda.gov.za

https://www.nda.gov.za/index.php/publication/445-animal-health-contact-us

2.5 Application process: Veterinary Import Permit



2.6 Veterinary Import Permit application instructions: "Application to import pathology specimens and raw materials for laboratory or pharmaceutical use into the RSA"

This application form will usually be used when goods are imported for research purposes.
NB: Follow the instructions & complete each section

B. Importer's details. 1-7. Full name of the contact person and complete address (Building name and room number included) of the location where the imported product will be handled.
8. Customs code of the institution (The university's Foreign Purchasing & Payment Division at the Finance Department can be contacted for the institution's unique customs code)
9. a-b). Product: Complete name as it would appear on the packaging or genus & species name in the case of animals & microorganisms, a) a full product description and b) volume, mass or number of animals, cell lines, pathogens, etc.
9. c) The purpose of import can be research, diagnostic, pharmaceutical or resale. Choose one option & describe what the product will be used for.
10. Origin of product (Where will the product be sent from?): Name and full address
11. Port of entry into RSA (can be an airport, harbour or border post)
12. Destination of product in RSA: Contact person name and full address where product will be handled (Building & room number included). Provide cell number so that DAH can keep you informed.
13. Provincial state veterinary office closest to the final destination. Check the list available at: (https://www.nda.gov.za/index.php/component/content/article/451-provincial-veterinary-services-contacts
14-15. Only for in-transit consignments