DAFF activities @ UCT

The basics

- Paula Saner, Research Integrity Co-ordinator, Office of Research Integrity is the UCT/DAFF contact person. All correspondence, applications and queries should be directed, in writing, to her office: paula.saner@uct.ac.za.
- There are 3 common types of DAFF applications:
  1. GMO (these applications pertain to laboratory/facility registration, usually for BSL2, 3 or 4 facilities)
  2. Section 20 (these applications pertain to the use either of animal products in research or introducing an animal disease into an animal for research purposes, please see Section 20 of the Animal Diseases Act, Act 35 of 1984, included below as **APPENDIX A**)
  3. Import Permit (these applications provide the necessary permits to import INTO South Africa animal products for use in research)
  - NOTE: It may be the case that both a Section 20 and an Import permit will be needed for your study to commence (the Import Permits Unit will often not issue a permit without proof of a Section 20 permit, if necessary, or formal communication indicating that a Section 20 permit is not needed).

Frequently Asked Questions

Question 1: I am using (xyz) pathogen/virus/disease/reagent/antibody, do I need to apply for a Section 20 permit?

Attached (**APPENDIX B**) to this document is a brief list of items which WILL require a Section 20 application. Please note that this list is not comprehensive. If you are uncertain, please contact Paula who will liaise with DAFF on your behalf. DAFF take a number of factors into account when addressing queries including overall risk; what the pathogen/virus/disease/reagent/antibody is; its origin; its intended use and, how it will be stored and/or destroyed at the end of the project. This means that we cannot give you a simple yes/no answer without contacting our colleagues at DAFF. (Please see the Animal Diseases Act, Act 35 of 1984, for full information.)

Please also refer to "Scope of Section 20" in the notification document.

Question 2: Is there a list of approved/recognised suppliers of animal products?

No, DAFF has indicated that they cannot give us such a list. Please see the answer to question 1 above.

Question 3: I need to apply for a DAFF Section 20 permit, how do I do this?

The application process has recently been simplified, in order to make an application you will need to submit the following to Paula:

1. Completed DAFF Section 20 application form (leave out section 11, Paula will obtain the institutional signature on your behalf), forms can be obtained from Paula or the "Compliance: Animal Rsch" Vula Site
2. Short summary of the project (1-2 pages)
3. Any SOPs mentioned in the application

It is important to note that high quality applications, which address as many of DAFF's queries (or likely queries) as possible and supply the necessary information are likely to progress through the process with

fewer bumps along the way. DAFF are interested in topics like containment, storage, transport and waste disposal, it is therefore important to adequately address these topics in the application form.

Once the above is submitted to Paula, it undergoes an internal check for completeness and consistency. Paula then submits it for institutional signature. Once the institutional signature has been obtained it is then submitted to DAFF. When the application is submitted to DAFF, Paula will cc the applicant/PI/supervisor, as a means to confirm that the application has been submitted.

Question 4: When should I submit my DAFF Section 20 application?

You must make your application to DAFF BEFORE your project starts, DAFF do not consider 'retrospective' applications. You should not start your project until you have received your Section 20 permit. It is possible to make a simultaneous submission to your local AEC and DAFF, and let the processes run in parallel.

Question 4: How long does the DAFF Section 20 application process take?

On average applications take 4 weeks from the date of submission to DAFF. Some applications have been approved in a shorter timeframe, these were high quality applications where DAFF did not need to interrogate any aspects of the projects. Some applications have taken longer than 4 weeks, this is usually because applications are incomplete; do not sufficiently address the points in the application form; do not supply supporting information or, applicants are slow in responding to DAFF's queries. The turnaround process depends on synergy between the applicant, the ORI and DAFF.

Question 6: I have a DAFF Section 20 Permit, but want to make changes to my project, what should I do?

DAFF consider amendments, using processes similar to UCT AEC practices, please contact Paula further assistance. You will need to supply Paula with a copy of the original permit and a document outlining which parts of the approved project are no longer taking place and what is replacing them. This can either take the form of the initial application form using track changes to illustrate the requested amendments or a letter outlining the changes.

Question 7: Are there any costs associated with a DAFF application?

Section 20 applications: No
GMO applications: Yes, a nominal fee, as per the application form
Import permit applications: Yes, a nominal fee, as per the application form
Please note that DAFF are not vendors on UCT's payments system, please take this into account when factoring in any payments associated with GMO or Import Permit applications.

Question 8: What guarantees do I have that the information contained in my application will not get into the wrong hands/be used by government (or other researchers) for to conduct their own research?

The DAFF Section 20 team are conscious of the concerns regarding the confidentiality and privacy of the applications we submit. They are bound by the Public Servants Act and also the Animal Diseases Act, all information is treated as confidential and is protected by these acts. Section 25 of the Animal Diseases Act (Act 35 of 1984) states the following:

1. No person shall, except for the purpose of the performance of his duties under this Act, or for the purpose of legal proceedings thereunder, or when required to do so by any competent court, excluding

a civil court, or under any law, or with the written consent of the Minister, disclose to any other person any information acquired by him in the performance of his duties under this Act, and which relates to the business or affairs of a person.

2. No person shall, except with the written consent of the Minister, give access to any person other than the director, an officer, or any other person entitled thereto in terms of any law, to any records or registers kept in terms of this Act.

The Section 20 team have reviewed the application process and taken UCT researcher's into account during the review process.

Question 9: Who is eligible to apply for DAFF Permits?

All researchers at UCT, planning to conduct projects that will need either GMO, Section 20 or an Import Permit should make applications.

Please note: If you are a RSA PERMANENT RESIDENT, and making an application for an import permit, you will need to supply a copy of your permanent residency document when submitting your application forms.

APPENDIX A

Animal Diseases Act, 1984 (Act No. 35 of 1984)

Section 20. Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products

No person shall, except under a permit and in compliance with the conditions which are prescribed or, in any particular case, determined by the director —

a. conduct 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: Provided that the foregoing provisions of this paragraph shall not apply to any substance in so far as it 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, anti-toxin, antigen or other biological product referred to in paragraph (a); or
c. for the purposes of any investigation, experiment or research referred to in paragraph (a), or for the manufacture or evaluation of a product or remedy referred to in paragraph (b) —
    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 is capable of spreading any animal disease or parasite.

https://www.acts.co.za/animal-diseases-act-1984/20__limitations_on_investigati

APPENDIX B

agriculture,
forestry & fisheries
Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Private Bag X138, Pretoria, 0001
Delpen Building, c/o Annie Botha & Union Street, Riviera, 0084
From: Directorate Animal Health
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Enquiries: Dr Mpho Maja

LIST OF CONTROLLED AND NOTIFIABLE ANIMAL DISEASES IN TERMS OF THE ANIMAL DISEASES ACT, 1984 (ACT NO 35 OF 1984)

Controlled Animal Diseases

- Any animal disease or infectious agent that is not known to occur in South Africa
- African horse sickness (AHS)
- African swine fever (ASF)
- Anthrax
- Aujeszky's disease
- Bacterial kidney disease (in fish)
- Bovine contagious pleuropneumonia (CBPP)
- Bovine spongiform encephalopathy (BSE)
- Brucellosis (in all animal species)
- Classical swine fever (CSF)
- Contagious equine metritis (CEM)
- Contagious haemopoeitic necrosis (in fish)
- Contagious pancreatic necrosis (in fish)
- Corridor or Buffalo disease (Theilerioses)
- Dourine
- East Coast fever
- Equine infectious anaemia (EIA)
- Equine influenza (EI)
- Equine viral arteritis (EVA)
- Foot and mouth disease (FMD)
- Glanders
- Haemorrhagic septicaemia (in fish)
- Johne's disease (in sheep, cattle and goats)
- Koi herpes virus disease
- Nagana (Trypanosomiasis)
- Newcastle disease
- Notifiable avian influenza (NAI)
- Porcine reproductive and respiratory syndrome (PRRS)
- Psittacosis
- Rabies
- Rinderpest
- Salmonella Enteriditis
- Salmonella Gallinarum (Fowl typhoid)
- Salmonella Pullorum (Bacillary white diarrhoea)
- Scrapie
- Sheep scab
- Skin conditions in sheep
- Swine vesicular disease
- Tuberculosis (in all animal species)

Notifiable Animal Diseases

- Bovine malignant catarrhal fever (Snotsiekte)
- Bluetongue
- Lumpy skin disease
- Rift Valley fever
- Strangles
- Swine erysipelas

Mmaja.

Dr Mpho Maja
DIRECTOR OF ANIMAL HEALTH
Date: 2016 -02- 22