Edition: 1

Department of Agriculture, Forestry and Fisheries

Directorate Animal Health

Notice No. VPN/51/2016-01

SUBJECT: Standards for research facilities that want to maintain imported fleas for research and/or breeding purposes

.....
Director: Animal Health

2016 -07- 11
.....
Date

PART I

DEFINITIONS AND ABBREVIATIONS

FOR THE PURPOSES OF THIS STANDARD DOCUMENT

Arthropod	Any invertebrate of the phylum Arthropoda, having a segmented body, jointed limbs, and a mineralized chitinous shell covering, including insects
Flea	Any of various small, wingless, bloodsucking insects of the order *Siphonaptera* that are parasitic on mammals and birds and can jump long distances.
DAFF	Department of Agriculture, Forestry and Fisheries
IATA	International Air Transport Association
PPE	Personal protective equipment
Red Cross Permit	A veterinary movement permit in terms of Regulation 20 (1) (a) of the animal diseases act, 1984 (Act No. 35 of 1984). It is used where animals or products to be moved are potentially infected and therefore subject to one or more restrictions en route or at destination. The animals or products must be loaded under the supervision of and sealed by a state veterinary official. The state veterinary official at origin must inform the state veterinarian or veterinary official at destination either telephonically or by facsimile or e-mail of the consignment and provide a copy of the red cross permit. The state veterinary official at destination is responsible for receiving of the animals or products and breaking of the seals prior to releasing the consignment.
In vitro	In an artificial (laboratory) environment outside a living organism
In vivo	Biological processes or experiments carried out in the living organism

REFERENCES

REFERENCES USED TO COMPILE THIS STANDARD DOCUMENT

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

Arthropod Containment guidelines (Version 3.1). A project of the American Committee of Medical Entomology of the American Society of Tropical Medicine and Hygiene.

National Road Traffic Act, 1996 (Act No. 93 of 1996).

OIE - Terrestrial Animal Health Code, 24th edition. 2015.

Science Encyclopedia. http://science.jrank.org/pages/3541/In-Vitro-in-Vivo.html.

US Centers for Disease Control and Prevention (CDC). 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th edition.

The free dictionary by Farlex. www.thefreedictionary.com

PART II

RISKS ASSOCIATED WITH THE MAINTENANCE OF FLEAS AND PURPOSE OF THIS VPN

Laboratories in which living insects of veterinary importance, including fleas, are reared and maintained for research purposes, have been in existence for decades with few reports of harm to their workers or to the communities in which they are located.

DAFF will only consider the importation and maintenance of laboratory bred flea strains and not field caught fleas for research purposes. The importation of foreign flea species, or foreign strains of taxa endemic to South Africa, pose a potential risk should they escape from laboratories/research facilities. Such fleas may potentially act as vectors of infectious disease or form a crucial link in completing the transmission cycle of such diseases.

It is considered essential that sufficient containment measures are in place at laboratories and research facilities that want to import, conduct studies and/or breed with flea species, including foreign strains of taxa endemic to South Africa. In this regard "containment" refers to safe methods, facilities and equipment with the purpose to reduce or eliminate exposure of laboratory workers, other persons and the outside environment to potentially hazardous agents. Safety equipment and personal protective clothing form part of the primary barriers, and facility design and construction the secondary barriers.

Arthropod Containment Level 2 (ACL-2) procedures were used as guideline with reference to breeding and research purposes, as will be discussed in the sections that follow. In addition distinction is made between *in vivo* breeding and research where host animals are involved and *in vitro* research where no host animals are involved.

Section 20 applications need to be submitted for individual studies prior to the start of any studies.

The flea species applicable and the nature of the research performed must be described in the individual research specific applications. Such Section 20 applications must contain reference to this VPN and include a statement on compliance with the recommendations contained herein.

PART III

PRIMARY BARRIERS

1. PERSONAL PROTECTIVE EQUIPMENT (PPE)

1.1 Insect-Specific and Additional Personal Protective Equipment (PPE)

- An overall covering the whole body and designed to prevent the entering of fleas through the garment (closing method by means of a zipper with tightly fitting elastic sleeves and ankles) and submersible shoes.
- All personnel entering the flea research and/or breeding facility must change into this PPE that must be stored within the double door section of the entrance to the flea breeding and/or research facility.
- When removed for washing the overalls must be treated with a suitable registered insecticide, double bagged and placed in a flea proof waste bin prior to removal.

1.2 Additional Personal Protective Equipment (PPE)

- Must be worn at all times and include examination gloves worn over the sleeves of the arthropod-specific overall, a disposable apron and laboratory head cover to keep jumping fleas from getting into clothing or hair.

PART IV

SECONDARY BARRIERS

1. Location of Flea Research and/or Breeding Areas Within the Facility

- Proper access control to the entire research facility must be in place.
- The flea research and/or breeding areas must be separated from the rest of the facility.
- There must be access control to the flea research and/or breeding areas.
- Ideally both the research and breeding areas must be within the same building to prevent the unnecessary transport of fleas between different buildings. If not possible, recommendations in Section 4 of Part IV must be strictly adhered to.

2. Flea Research and/or Breeding Area Doors

- Entry to the building(s) must be via a double door system where the two doors cannot be opened simultaneously.
- The doors must be self-locking.
- These doors must be access controlled.
- A footbath with a suitable insecticide or an insecticide impregnated mat must be located within the double door section and must be used prior to exiting from the flea research and/or breeding building(s).

3. Additional Barriers at Flea Research and/or Breeding Building(s)

- Windows are not recommended. If present it must not be possible to open these

windows and they must be adequately sealed to preclude flea escape.
- Windows, if present, must also be resistant to breaking (e.g. enforced with wire).
- Walls must have a gloss finish and be of a light colour so that a loose flea can be easily located.
- Floors must be light-coloured, uncovered and smooth.
- Ceilings must also be light-coloured, smooth and as low as possible to detect and capture loose fleas.
- The drain system must be closed.
- All air inlets must be constructed with filters or covered with mesh (with suitable adhesive) of which the holes are ≤ 0.5mm in diameter.
- Ground level flea traps must be installed.
- Pest exclusion program must be in place for wild insects and rodents.

4. Primary and Secondary Container Construction

- Containers used to sort and count adult fleas by means of aspiration should be of suitable height to prevent fleas from escaping when jumping. The minimum height of such a container must be 350mm.
- Containers into which adult fleas are aspirated for use in research or to infest hosts must be non-breakable with a secure lid (only suitable for short term storage with fleas counted out approximately two hours prior to infestation).
- For longer term storage of adult fleas the lid may be modified to allow air to reach the fleas yet preclude escape. The diameter of holes pricked in the lid must be ≤ 0.5mm in diameter. Alternatively a fine mesh with similar aperture (≤ 0.5 mm) may be used and it must be fitted securely using a suitable adhesive. Lids must be tested to ensure that they fit securely. When moved between the breeding and research units for study infestation purposes, these containers must be placed and transported within a secondary container, also with a lid.
- Containers used to hold immature flea life stages (eggs, larvae or pupae) within the breeding facility must be non-breakable and preferably disposable (incineration after use). Such containers must also be fitted with a lid. Larger ventilation holes (≥ 0.5mm in diameter) may be punched into the lids but then these must be stacked into a large secondary container (with a lid) containing a saturated salt solution as an additional containment measure.
- Medium containing larvae should be sieved regularly (at least twice weekly) to remove pupae before they hatch. This will ensure that adult fleas do not hatch in these containers and hence preclude potential escape of adults.
- If egg hatching or viability is assessed for research purposes, petri-dishes may be used, but the lid must be secured along the edge using adhesive aluminum tape. A mesh guard (the ventilation holes ≤ 0.5mm in diameter) must be glued to the lid to allow air to reach the flea stages yet preclude escape.
- Containers must be clearly labelled.
- An inventory must be kept of all the fleas present within the breeding facility. These records must be stored for at least 5 years for auditing purposes.

5. Special flea handling containers and areas

- Handling of fleas must be restricted to a designated area within the flea breeding facility
- The handling of fleas must be conducted within physical containment devices (also see Section 4 of part IV).
- Vacuum aspirators used must be appropriately filtered to prevent transfer and exhausting of fleas.
- For efficacy studies fleas are infested on animals. During flea counts it is thus not possible to work within a containment device, but all counts will be

performed within the dedicated breeding or research buildings. Fleas are individually counted (removal by combing), accounted for and killed by drowning in methylated spirits diluted with water at a minimum of 30% concentration with a minimum contact time of 15 minutes or frozen overnight (-20 °C for 24 hours). Also see Section 8 of part IV for flea disposal procedure.

6. **Use of cats or dogs for feeding of fleas (flea breeding purposes)**
   - Cats or dogs used for flea breeding must be clinically healthy.
   - Cats or dogs (host animals) used for flea breeding must be kept in the flea breeding facility and all the above specified barriers must be in place.
   - The cage/cubicle design must prevent animal host escape.
   - At the end of the feeding cycle, the host animals must be treated with an appropriate veterinary product registered against fleas, combed and kept within the flea breeding facility for 48 hours prior to being removed out of the facility(ies).
   - No rabbits may be used as host animals for flea breeding purposes.
   - No cats or dogs used for flea breeding purposes may be outsourced.

7. **Use of animals for flea research purposes within the flea research and/or breeding facility(ies)**
   - The entire study(ies) utilizing imported fleas must be conducted within the flea research and/or breeding facility(ies)
   - After use of fleas for studies, study animals must be treated with an appropriate veterinary product registered for use against fleas, combed and kept within the flea breeding facility for 48 hours prior to being removed out of the facility(ies)
   - Fleas used during research are killed and incinerated and may not be used for flea breeding to avoid any potential disease introduction into the flea breeding colony.
   - No cats or dogs used for flea research purposes may be outsourced.

8. **Removal of Equipment from the Flea Research and/or Breeding Building(s)**
   - Dedicated equipment clearly marked as such must be located within the flea breeding and/or flea research building(s).
   - The wash room must ideally be located within the flea breeding and/or flea research building(s).
   - Any personal protective equipment must be sprayed with a suitable registered insecticide, double bagged and placed inside a flea proof bin prior to removal to the wash room, if not in the same building.
   - All wastes from the research and/or breeding facilities must be treated with a suitable registered insecticide, double bagged and placed inside a flea proof bin prior to removal and incineration on site.
   - Sharp objects must be placed inside medical waste containers. These containers can then either:
     i. Be decontaminated with a suitable registered insecticide, double bagged, placed into an insect proof waste bin and incinerated on site; OR
     ii. Be treated with a suitable insecticide and stored inside the buildings prior to removal by an accredited medical waste management company.
   - If fleas must be disposed of, these must be immersed in methylated spirits diluted with water at a minimum of 30% concentration with a minimum contact time of 15 minutes, or frozen overnight (-20 °C for 24 hours) to kill them. The fleas must then be double bagged and placed inside a flea proof bin prior to removal and incineration on site.

9. **Movement of Fleas from Breeding Facility to Research Facility**
    - Flea stages may be moved between units for the purpose of infestation or viability assessments (breeding and *in vivo* research) or *in vitro* efficacy testing.
    - For breeding all stages will remain within the flea breeding unit (eggs, larvae pupae and adult).
    - For study infestations adult fleas may be moved between the flea breeding unit and research units. Primary containers for such movement must be non-breakable with a secure lid (also see Section 4 of part IV).
    - For viability assessments collected eggs may be moved between the animal research units and the research incubators (petri dish sealed with aluminum tape as primary container) (also see Section 4 of part IV).
    - The primary containers must in all cases be transported within a secondary container with a lid.

PART V

ESCAPED FLEA MONITORING

- A monitoring program (*in vivo* and *in vitro*) must include regular inspection of the flea breeding and/or research buildings for disrepair that could result in escape, as well as monitoring of other aspects such as pest control and maintenance of footbaths/impregnated mats.
- Monitoring of ground level flea traps.
- Monitoring records must be kept and stored for at least 5 years for auditing purposes.

PART VI

OUTSOURCING OF FLEAS

- Imported flea species may NOT be outsourced to other laboratories or facilities in South Africa for any purpose. Such fleas may be outsourced internationally, however, DAFF must be informed of any such shipments. The outsourcing internationally must be in compliance with the importing country's requirements.
- The imported flea species may only be kept and/or bred for research use and only by the importer of the fleas.
- A flea inventory must be kept and stored for at least 5 years for auditing purposes.

PART VII

FACILITY COMPLIANCE MONITORING

- DAFF reserves the right to inspect the facility to ensure compliance with the above requirements at any time.
- In the event of non-compliance DAFF reserves the right to have the fleas kept in the facility destroyed and refuse to issue further veterinary import permits for the importation of fleas.

PART VIII

COMPLIANCE WITH LEGISLATION

- In terms of Section 6 of the Animal Diseases Act, 1984 (Act No 35 of 1984), the importation of fleas is subject to obtaining a Veterinary Import Permit prior to the importation thereof.
- Veterinary Import Permits will only be issued to research facilities that provide written proof from DAFF that their facility was inspected and they are compliant with the requirements stipulated within this VPN and may therefore work with fleas.
- Fleas must move directly from the port of entry to the research facility under a Red Cross Permit and in compliance with all the conditions as laid out on the permit.
- In terms of Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984), approval to do research with such fleas must be obtained prior to conducting such research.
- Packaging of fleas for transportation during importation must be compliant with IATA requirements as well as the Regulations of the National Road Traffic Act, 1996 (Act No. 93 of 1996).

PART IX

SECTION 6 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO 35 OF 1984)

6.(1)(a) No person shall import into or convey in transit through the Republic any animal, parasite or contaminated or infectious thing except under the authority of a permit and in compliance with any condition imposed in such permit.

(b) A permit referred to in paragraph (a) –

(i) Shall be obtained by an importer before the relevant animal or thing is removed from or out of any place outside the Republic by means of any conveyance or by any other means for the purpose of importing it into or conveying it in transit through the Republic;

(ii) shall, in respect of any animal or animal product referred to in section 16 (1) of the Livestock Improvement Act, 1977 (Act No. 25 of 1977), only be issued if the written authority contemplated in that section has been granted in respect thereof; and

(iii) shall, where the director requires that the animal or thing be detained in a quarantine station, only be issued on proof being adduced to him that a confirmation of accommodation has been furnished and fees have been paid, as contemplated in paragraphs (a) and (b), respectively, of section 5 (4) of this Act.

(c) When any person imports into or conveys in transit through the Republic animals or things of the same class on a regular basis from the same country, the director may, if he is satisfied that it will not defeat a controlled purpose, issue to such a person a permit referred to in paragraph (a) to so import or convey during the period specified therein consecutive consignments of animals or things of the same class.

(2) Any animal or thing in respect of which a permit has been issued –

(a) shall only be imported into the Republic through or at a place of entry referred to in paragraph (a) of the definition of "place of entry" in section 1 (1), or, in the case of any animal, through or at any other place which the director has, subject to the provisions of the Customs and Excise Act, 1964 (Act No. 91 of 1964), determined for purposes of this paragraph;

(b) shall be imported within the period specified in the permit;
(c) shall be detained in the prescribed manner at the relevant place of entry, and shall be made available to the director for purposes of the performance of controlled veterinary acts; and
(d) shall not without the written authority of the director, or contrary to any condition of such authority, referred to in section 8 (1) (a), be removed from such place.

(3)(a) The director may, if he knows or on reasonable grounds suspects, that any animal or thing is, contrary to any provision of this Act, or any condition of a permit –
(i) being removed, or has been removed, from any place outside the Republic for purposes of importing it into the Republic; or
(ii) about to be imported by any person into the Republic; or
(iii) present on or in any conveyance, or forms part of any consignment, which is being or has been brought or sent by any person to the Republic, direct that the animal, thing, consignment or portion thereof determined by him, shall not be imported into the Republic or unloaded or removed from the conveyance, as the case may be, except with his consent and, if he has determined conditions in connection therewith, in accordance with such conditions.

(b) The director may, if he deems it necessary, make such direction known by notice in the Gazette, and shall, irrespective of whether it has so been made known or not, make known the provisions of the direction as soon as may be practicable to all persons who, to his knowledge, are or will be involved in the importation, unloading or removal, as the case may be, or to any person in whose service any such persons are, or who exercises control over them, or in respect of such unloading or removal.

(c) The provisions of subsection (2) (c) and (d) shall mutatis mutandis apply in respect of any animal or thing referred to in subsection (3) (a) which has been imported, unloaded or removed with the consent of the director as contemplated in the last mentioned subsection: Provided that in such application of the said sub-section (2) (d) a removal contemplated therein shall not be effected unless the importer concerned has paid the fees which are in terms of this Act payable in respect of the relevant required permit.

PART X

SECTION 20 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO 35 OF 1984)

"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."

ANNEX A

agriculture, forestry & fisheries

Department
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

APPLICATION FOR PERMISSION UNDER SECTION 20 OF THE ANIMAL DISEASES ACT (ACT 35 OF 1984) TO PERFORM RESEARCH / STUDY

Application must be submitted at least 3 months prior to the proposed starting date of the research

I hereby apply for permission from the National Director of Animal Health, South Africa, to do research under Section 20 of the Animal Diseases Act (Act 35 of 1984)	
1. Researcher	
Name of researcher:	
Address of researcher:	
Contact person: Name:	
Tel:	
Fax:	
E-mail:	
2. Project	
Title and aim of research project:	
Proposed starting date:	
Proposed date of completion:	
3. Institution (Details of research institution where research will be done)	
Name:	
Physical address:	
Postal address:	
Laboratory/ sub-section:	
4. Research/study summary: ***If insufficient space, please provide additional information as attachment/annex to the application form; This information must be signed off as true and complete and representing complete disclosure*** RECORDS RELATING TO THE INFORMATION SUPPLIED IN THIS SECTION MUST BE KEPT FOR AUDITABLE PURPOSES FOR FIVE YEARS	
Pathogen/disease/vector to which study relates:	
Pathogen/disease/vector to which study relates:	
Animal material (vaccine, serum, toxin, anti-toxin, antigen, biological product which consists or originates from animal or parasite) to be used in study:	
Does study involve importation of biological and/or unregistered pharmaceutical products:	

Origin of the pathogen and/or animal material:	
Will field samples be collected:	
Which area will field samples be collected from?	
Attach a letter from the relevant state veterinarian regarding the area and whether it is under restriction	
Describe packaging of samples to be transported in detail:	
Does the study involve genetically modified organisms/material: *If yes, refer to guidelines for information on GMO Act*	
Biosafety level of facility:	
Is facility DAFF approved /compliant (supply certificate no):	
Describe the containment of pathogen at facility in detail (includes handling of food, bedding, waste, access control, vector proof etc.):	
Will live animals be used in study:	
If live animals will be used specify origin of animals and attach animal use and care committee approval:	
Describe containment of live animals in facility in detail:	
Disposal of potentially infectious waste at end of study:	
a) Method	
b) If outsourced provide name of accredited waste contractor	
c) If incinerated on the premises, supply calibration certificate and discuss disposal process from study site to incinerator:	
Fate of live animals/test materials/samples upon completion of study: *Refer to guidelines if to enter human food chain*	
Will any vaccine, serum, toxin, anti-toxin, antigen, biological product which consists or originates from animal or parasite be stored? If yes, specify where	
Will any vaccine, serum, toxin, anti-toxin, antigen, biological product which consists or originates from animal or parasite be distributed? If yes, specify where	
Are relevant SOPs in place for the particular study:	
5. Details of person responsible for research	
Name:	
ID/Passport number:	
Physical address:	

Postal address:	

I confirm that the summary of the research/study as provided with this application is true and correct and represent a complete disclosure. Should there be any deviations to the research/study, the Director Animal Health will be informed immediately.

Signature: _____

8. Details of person responsible for the institution:

Name:	
ID/Passport number:	
Physical address:	
Postal address:	
Designation:	

I am aware of the research referred to on this application form and take responsibility for this project to be done according to the research/study summary provided, at the above mentioned institution. Should there be any deviations to the research/study, the Director Animal Health will be informed immediately.

Signature: _____

IMPORTANT NOTICE:

a) *Please complete this form fully, in block letters, and fax to 012 319 7470 for Attention: Mr Henry Golele (HenryG@daff.gov.za)*

b) *Attachment checklist:*

(i) Completed, signed application form

(ii) If field samples are to be collected - letter from the relevant state veterinarian regarding the area and whether it is under restriction

(iii) If live animals are used in the study - approval from animal use and care committee/ethics committee

(iv) Calibration certificate if to use own incinerator

(v) Copy of approval letter from Director Veterinary Public Health if animals are destined for slaughter for human consumption upon completion of the research/study

ANNEX B

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

Director Animal Health, Department of Agriculture, Forestry and Fisheries, Private Bag x 138 PRETORIA, 0001
Tel: (012) 319 7532 Fax: (012) 319 7470 E-mail: HenryG@daff.gov.za cc SunelleS@daff.gov.za

GUIDELINES FOR SECTION 20 APPLICANTS

1. The following documents must be submitted **at least 3 months** prior to the proposed starting date of the research/study:

   i) Fully completed application form for permission under Section 20 of the Animal Diseases Act (Act 35 of 1984) to perform research/study, **with special attention to the section titled "Research/study summary"**; *If insufficient space is available on the application form, kindly provide the additional information as an attachment/annex to the application form*

   Application forms are obtainable from the office of the Director Animal Health at:

Tel:	*012 319 7456*
Fax:	*012 329 7218*
Email:	*SandraDAC@daff.gov.za*
Website:	*www.daff.gov.za*

   ii) Letter from the responsible state veterinarian regarding state veterinary restricted or quarantined areas, *if field samples are to be collected*; (State Veterinary contact details are available at www.daff.gov.za)

   iii) Calibration certificate *if potentially infectious waste is to be incinerated on site* at the end of the study;

   iv) If live animals are involved in the study, a signed approval letter from the Ethics and/or Animal Care Committee ***(The application may be submitted while awaiting ethics approval, with a note indicating such on the Section 20 application. If Section 20 approval is granted, the ethics approval would however have to be supplied before any Section 20 approval letters will be issued.)***

v) Copy of approval letter from the National Executive Officer in terms of the Meat Safety Act, 2000 (Act No 40 of 2000) *if animals are destined for slaughter for human consumption upon completion of the research/study*

2. The above documents must be submitted to:

Mr Herry Gololo
Admin Clerk
Section 20 Secretariat
Directorate: Animal Health
Department of Agriculture, Forestry and Fisheries
Tel: 012 319 7532
Fax: 012 319 7470
Email: *HerryG@daff.gov.za*

Cc: Dr Sunelle Strydom
State Veterinarian: Epidemiology
Directorate Animal Health
Tel: 012 319 7585
Fax: 012 319 7470
Email: *SunelleS@daff.gov.za*

3. Following evaluation of the information supplied:

(i) No further information may be required; OR

(ii) Additional information may be required; AND/OR

(iii) A full and signed copy of the entire protocol may be required; AND/OR

(iv) An inspection visit by the DAFF audit/compliance team may be requested

The applicant will be notified of any further requirements in writing.

4. Additional information that may be useful to the Section 20 applicant:

i) Any proposed research protocol involving any unregistered pharmaceutical or biological products is also subject to either Section 21 approval obtained from the Medicines Control Council in terms of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), or approval from Act 36 in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

Registrar: Act 36 contact details:

Tel:	*012 319 7303*
Fax:	*012 319 6764*
Email:	*MalutaM@daff.gov.za*
Website:	*www.daff.gov.za*

Medicines Control Council contact details:

Tel:	*012 395 8000*
Fax:	*012 395 8468*
Email:	*webmaster@mccza.com*
Website:	*www.mccza.com*

ii) Any proposed research protocol involving genetically modified organisms (GMO) is also subject to approval from the Directorate: Biosafety under Genetically Modified Organisms **Act,** 1997 (Act No.15 of 1997)

GMO contact details:

Tel:	*012 319 6382*
Fax:	*012 319 6329*
Email:	*NompumeleloM@daff.gov.za*
Website:	*www.daff.gov.za*

(iii) Ensure that the biosafety level of the pathogen corresponds with the biosafety level of the proposed laboratory where the research is to be conducted. The BSL2+ or BSL3 biosafety levels of a laboratory will only be accepted if the laboratory has been inspected and is DAFF/SANAS approved. If diagnostics is conducted on controlled and notifiable diseases in terms of the Animal Diseases Act, 1984 (Act No 35 of 1984), the facility must be DAFF approved/compliant.

For biosafety levels of pathogens, refer to the standards set by the World Organisation of Animal Health (OIE) within the OIE Terrestrial Manual at www.oie.int

To schedule a visit by the DAFF audit/compliance team, contact:

Dr Helen Booker

Tel:	*012 319 7453*
Fax:	*012 319 7470*
Email:	*HelenB@daff.gov.za*

OR

Mrs Riette Theron

Tel:	*012 319 7498*
Fax:	*012 319 7470*

Email: *RietteT@daff.gov.za*

(iv) For vector-borne animal diseases, ensure that precautionary measures with regards to vector protection and seasonality are taken into account in order to limit the spread of disease

(v) For any research where a veterinary import permit is needed for the importation of any animal, parasite or contaminated nor infectious thing into the Republic as per Section 6 of the Animal Diseases Act, 1984 (Act No 35 of 1984), an application form for a veterinary import permit may be submitted together with the Section 20 application. The importation of any of the afore mentioned commodities, will however only be evaluated once Section 20 approval has been granted.

(vi) A copy of the Animal Diseases Act, 1984 (Act No 35 of 1984) is obtainable from www.daff.gov.za

(vii) Packaging of samples to be transported:

a) For transportation by road, samples must be packaged in accordance with the Regulations of the National Road Traffic Act, 1996 (Act No. 93 of 1996)

b) For transportation by air, samples must be packaged in accordance with IATA requirements

(viii) If the fate of live animals upon completion of studies are slaughter for human consumption, approval must be obtained from the National Executive Officer in accordance with Section 80(3) of the Red Meat Regulations pertaining to the Meat Safety Act, 2000 (Act No 40 of 2000). A copy of the approval letter must be supplied with the Section 20 application.

Director Veterinary Public Health contact details:
Dr Tembile Songabe
Tel: (012) 319-7688
Fax: (012) 319 7699
Email: TembileS@daff.gov.za or FortunateD@daff.gov.za

These are guidelines only and does not absolve the researcher from compliance with any other legislation within the Republic of South Africa, or from providing any further information that may be requested during the evaluation process of the Section 20 application.

5. Dispute resolution:

(i) In the event of an appeal against the evaluation process that is still in progress, the appeal must be addressed in writing to either the Deputy Director: Epidemiology or the Deputy Director: Disease Control

(ii) In the event of an appeal against the decision taken by the Director Animal Health with regards to the Section 20 application upon completion of the evaluation process, the appeal must be addressed to the Minister in accordance with Section 23 of the Animal Diseases Act, 1984 (Act No 35 of 1984)