

## Department of Agriculture, Forestry and Fisheries

## Directorate Animal Health

Notice No. VPN/50/2015-01
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**SUBJECT: Standards for research facilities that want to import and maintain foreign ticks for research and/or breeding purposes using livestock**

<b>PART I</b>	<b>Definitions and References</b>
<b>PART II</b>	<b>Risks associated with the importation of foreign ticks and the purpose of this VPN</b>
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<b>PART V</b>	<b>Escaped foreign tick monitoring</b>
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<b>PART VII A</b>	<b>Sourcing of laboratory animals used for maintenance of/research with foreign tick colonies</b>
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 .....  
**Director: Animal Health**

2016 -02- 15  
 .....  
**Date**

**PART I****DEFINITIONS****FOR THE PURPOSES OF THIS STANDARD DOCUMENT**

<i>Arthropod</i>	Any invertebrate of the phylum Arthropoda, having a segmented body, jointed limbs, and a mineralized chitinous shell covering, including arachnids such as ticks
<i>DAFF</i>	Department of Agriculture, Forestry and Fisheries
<i>IATA</i>	International Air Transport Association
<i>PPE</i>	Personal protective equipment
<i>Red Cross Permit</i>	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.
<i>Stockinets</i>	A means of constraint to restrict foreign ticks to a specified, limited area on the host animal. Stockinets are constructed from a suitably dense (to preclude tick escape) and durable (resistant to tearing) cloth material with a base flange (for example artificial leather) that can be glued to a shaven area on the host animal. The stockinet then effectively creates a "sock" or "stocking" effect with the open end then knotted and/or secured by rubber bands to preclude escape of the ticks placed within.
<i>Tick-proof channel</i>	A modification to the drain system of a large animal housing unit, as an additional measure to further preclude any potential escape of foreign ticks. The "tick-proof channel" must be closed, fitted with a tick trap and allow the drain to be temporarily blocked so the contents (solution of faeces and water resulting from washing activities) can be treated with a suitable acaricide.
<i>Tick-proof wheelie bin</i>	A large impervious container, with wheels for easier movement as well as a lid, in which faeces is collected during

cleaning procedures.

## 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

US Centers for Disease Control and Prevention (CDC). 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th edition. [http://www.cdc.gov/biosafety/publications/bmbl5/bmbl5\\_sect\\_iii.pdf#x2013; Principles of Biosafety \[PDF - 223 KB\]](http://www.cdc.gov/biosafety/publications/bmbl5/bmbl5_sect_iii.pdf#x2013; Principles of Biosafety [PDF - 223 KB])

The free dictionary by Farlex. [www.thefreedictionary.com](http://www.thefreedictionary.com)

## PART II

Laboratories and research facilities where arthropods (including ticks) 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 of laboratory bred foreign ticks and not field caught foreign ticks. The importation of foreign ticks, even though laboratory bred, pose potential risks should they escape from such laboratories or research facilities within the country. Not only do these foreign ticks have the potential to be vectors of infectious human and/or animal diseases, they may also become the crucial link completing the transmission cycle for a disease they vector.

It is therefore essential that sufficient containment measures are in place at laboratories and research facilities that want to import, conduct research and/or breed with foreign ticks. "Containment" refers to safe methods, facilities and equipment with the purpose to reduce or eliminate exposure to 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.

VPN/48/2014-01 has been compiled previously with specific reference to small animals (for example dogs and cats). The current VPN serves to describe procedures relevant to research pertaining to large animals (for example cattle, sheep and horses).

## **PART III PRIMARY BARRIERS**

### **1. PERSONAL PROTECTIVE EQUIPMENT (PPE)**

#### **1.1 Arthropod-Specific Personal Protective Equipment (PPE)**

- An overall covering the whole body and that is specifically designed to prevent the entering of ticks through the garment by way of tightly fitting elastic bands around the waist and ankles and a closing method by means of a zipper.
- All personnel entering the tick research and/or breeding facilities must change into this PPE that must be stored within the double door section at the entrance to the tick research and/or breeding facility.
- These overalls must stay within the tick research and/or breeding facilities unless being removed to be washed, when it must then be treated with acaricide, double bagged and placed into a tick proof waste bin prior to removal from the facility.

#### **1.2 Additional Personal Protective Equipment (PPE)**

- Disposable gloves that are worn over the sleeves of the arthropod-specific overall.
- Disposable plastic aprons.
- Submersible protective shoes

## **PART IV SECONDARY BARRIERS**

### **1. Location of Tick Research and/or Breeding Areas Within the Facility**

- Proper access control to the entire research facility must be in place.
- The tick research and/or breeding areas must be separated from the rest of the facility.
- There must be access control to the tick research and/or breeding areas.
- Ideally both the research and breeding areas must be within the same building to prevent the unnecessary transport of foreign ticks between different buildings. However, for large animal research this will often not be logistically possible/feasible. If not possible, recommendations in Section 4 of part IV of this VPN must be strictly adhered to.

### **2. Tick Research and/or Breeding Area Doors**

- Entrance to the building(s) must be via a double door system where the two doors cannot be opened simultaneously.

- The doors to the entrance of the breeding/research units must be self-locking.
- The doors to the entrance of the breeding/research units must be access controlled.
- Strips or tick traps containing greasy material must surround all door frames leading to the outside environment. These must be monitored on a regular basis to pro-actively identify any potential failures in containment.
- A footbath with acaricide or an acaricide impregnated mat must be located within the double door section and must be used prior to exiting from the tick research and/or breeding building(s).

### **3. Additional Barriers (physical and procedural) at Tick Research and/or Breeding Building(s)**

- Whole body tick infestations on livestock must never be performed when conducting research involving foreign ticks. For such studies infestation must always be contained to only specific areas on cattle using "stockinets". This will allow control over infestations and accountability in terms of the number of ticks infested and again retrieved during counting.
- Windows are not recommended, if present it must not be possible to open these windows and they must be well sealed. Any opening that cannot be sealed by a hinging window must be sealed by another means such as a fine gauze sheet, preferably reinforced by a stronger metal grid (also see reference to fencing material in the point below), to preclude entrance of other arthropods or escape of foreign ticks
- Windows must be resistant to breakage (for example by installing a wire mesh or similar fencing material).
- Walls and ceilings should preferably be of a light colour so that a loose arthropod can be easily located.
- An additional precaution is metal strip (or similar) grease tick traps around the walls in the unit where the animals are kept, to preclude vertical tick movement and escape.
- The faeces must be incinerated to ensure safe disposal of faeces that potentially contain foreign ticks. If the volume and moisture content makes incineration difficult, alternative methods may be considered by DAFF. For alternative methods, scientific evidence must be submitted to DAFF for evaluation. If approved by DAFF, a written dispensation will be granted on the incineration of faeces requirement.
- Tick traps must be installed into the drainage system, or a closed drain system leading into a tick proof channel for the treatment of waste with a registered acaricide must be in place. If the closed drain system is utilized by the facility, the treatment protocol must be approved by DAFF for the specific facility.
- Tick traps must also be installed at aircon and other vents.
- An effective pest-exclusion program must be in place for wild arthropods and rodents.

### **4. Primary Container Construction**

- Containers used to hold ticks must be non-breakable.

- Containers must be clearly labeled.
- Disposable containers are recommended.
- Double-sided tape must be used around the top of the primary containers to prevent the escape of adult and immature ticks from the containers.
- Double-sided tape must be used around the top of the primary containers to prevent the escape of adult and immature ticks from the containers.
- Double-sided tape must be used on the edges of the shelves on which these primary containers are to be stored.
- An inventory must be kept of all the ticks present within the breeding facility.  
These records must be stored for at least 5 years for auditing purposes.

#### **5. Special tick handling containers and areas**

- Handling of ticks must be restricted to a designated area within the tick breeding facility.
- The handling of ticks must be conducted within physical containment devices.
- If vacuum aspirators are used, they must be appropriately filtered to prevent transfer and exhausting of ticks.

#### **6. Use of animals as hosts for feeding of ticks (tick breeding)**

- Animals used for tick breeding must be kept inside the tick breeding facility and all the above specified tick barriers must be in place.
- The cage design of these animal hosts for the feeding of ticks must prevent tick escape. For example, a water bath must be located underneath the cages with a tick trap installed.
- At the end of the feeding cycle, the host animals must be euthanised, sprayed with acaricide, double-bagged and placed inside the tick-proof bins for transport for incineration.

#### **7. Use of animals for research purposes within the tick research and/or breeding buildings**

- These animals must either be subjected to euthanasia or treated with an effective acaricide. In the latter case animals must be kept within the tick research and/or breeding building for 48 hours. After this period they must be carefully visually inspected to ensure that they are tick free prior to being moved out of the building(s).
- Treated animals may only be returned to the research facility's animal colonies and may not be outsourced/sold.

#### **8. Removal of Equipment from the Tick Research and/or Breeding Building(s)**

- Dedicated equipment clearly marked as such must be located within the tick breeding and relevant research building(s).
- The wash room must ideally be located within the arthropod breeding and/or research building(s). Any personal protective equipment must be sprayed with acaricide, double-bagged and placed inside a tick-proof bin prior to removal to the wash room, if the wash room is not located inside the building(s).
- All wastes from the research and/or breeding buildings must be treated

with acaricide, double-bagged and placed inside a tick-proof bin prior to removal for incineration on site. The only exception may be for faecal waste, where a written dispensation is granted for a specific facility by DAFF for an alternative disposal method based on scientific evidence provided.

- Sharp objects must be placed inside medical waste containers. These containers can then:
  - i. Be decontaminated with an acaricide, double bagged, placed into an insect proof waste bin and incinerated on site;
  - ii. Or be treated with a suitable insecticide and stored inside the buildings prior to removal by an accredited medical waste company.
- If ticks must be disposed of (dead or alive), these must be immersed in 70% ethanol to ensure that all ticks are dead. The ticks must then be double-bagged and placed inside a tick-proof bin prior to removal for incineration on-site.

#### **9. Movement of Adult Ticks from Breeding Facility to Research Facility**

- Only adult ticks may be moved between breeding and research buildings if the research part is not located within the breeding facility. No immature foreign ticks may be removed from the tick breeding facility.
- The adult ticks may be transported from the breeding facility to the research facility in non-breakable, properly labelled, secure containers that are placed with a sealed non-breakable carry case for additional security.

### **PART V**

#### **ESCAPED TICK MONITORING**

- The monitoring of the effectiveness of the tick trapping program must be documented.
- Within-building and exterior (tick proof channel) monitoring must be conducted.
- Must include regular inspection of the tick breeding and/or research facility for disrepair that could result in escape.
- Must include regular inspection of tick barriers.
- Monitoring records must be kept and stored for at least 5 years for auditing purposes.

### **PART VI**

#### **OUTSOURCING OF FOREIGN TICKS**

- The imported foreign ticks may only be kept for breeding purposes for research use by the importer and no foreign ticks may be outsourced to other research facilities in South Africa.
- Foreign ticks may be outsourced to international facilities, but only in compliance with any regulatory requirements and after informing DAFF of such parasite transfer.
- A tick inventory must be kept and stored for at least 5 years for auditing

purposes.

#### **PART VII A**

### **SOURCE OF LABORATORY ANIMALS FOR MAINTENANCE OR RESEARCH OF FOREIGN TICK COLONIES**

- Ideally the animals should be from colonies bred and reared at the specific research facility
- If a facility wants to source animals from outside of the research facility, only laboratory born and bred animals may be bought in
- As soon as animals are sourced from outside of the research facility, all animal colonies (both used for maintenance and research purposes) on the research facility must become closed colonies i.e. no animals may be outsourced to other facilities or ever leave the research facility premises alive

#### **PART VII B**

### **SOURCE OF LIVESTOCK FOR RESEARCH OF FOREIGN TICK COLONIES**

- Ideally the animals should be from colonies bred and reared at the specific research facility
- If a facility wants to source animals from outside of the research facility, the facility must submit a risk assessment to DAFF indicating potential disease risks associated with such an introduction with regards to the animals resident at the facility as well as the foreign tick colonies
- Following evaluation of the submitted risk assessment, a research facility may only source animals from outside of the research facility subject to approval by DAFF and in compliance with the screening requirements by DAFF prior to the introduction of such animals into the facility

#### **PART VIII**

### **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 foreign ticks kept on the facility destroyed and refuse to issue further veterinary import permits for the importation of foreign ticks.

#### **PART IX**

### **COMPLIANCE WITH LEGISLATION**

- In terms of Section 6 of the Animal Diseases Act, 1984 (Act No 35 of 1984), the importation of foreign ticks 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 that they are compliant with the requirements stipulated within this VPN and may therefore work with foreign ticks.
- Ticks must move from the port of entry to the research facility under a red cross permit



- In terms of Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984), approval to do research with such foreign ticks must be obtained prior to conducting such research.
- Packaging of foreign ticks 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 X

### 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 XI**

### **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)	
<b>1. Researcher</b>	
Name of researcher:	
Address of researcher:	
Contact person: Name:	
Tel:	
Fax:	
E-mail:	
<b>2. Project</b>	
Title and aim of research project:	
Proposed starting date:	
Proposed date of completion:	
<b>3. Institution (Details of research institution where research will be done)</b>	
Name:	
Physical address:	
Postal address:	
Laboratory/ sub-section:	
<b>4. Research/study summary.</b> <i>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</i>	
<b>RECORDS RELATING TO THE INFORMATION SUPPLIED IN THIS SECTION MUST BE KEPT FOR AUDITABLE PURPOSES FOR FIVE YEARS</b>	
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: <i>If yes, refer to guidelines for information on GMO Act</i>	
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: <i>Refer to guidelines if to enter human food chain</i>	
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:	
<b>5. Details of person responsible for research</b>	
Name:	
ID/Passport number:	
Physical address:	

Postal address:	
I confirm that the <u>summary of the research/study as provided with this application is true and correct and represent a complete disclosure</u> . Should there be <u>any deviations</u> to the research/study, the <u>Director Animal Health will be informed immediately</u> .	
Signature:	
<b>6. Details of person responsible for the institution:</b>	
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 Herry Gololo (HerryG@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: [HerryG@daff.gov.za](mailto:HerryG@daff.gov.za) or [SunelleS@daff.gov.za](mailto: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](mailto:SandraDAC@daff.gov.za)  
Website: [www.daff.gov.za](http://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](http://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.)*

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- 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](mailto: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](mailto: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)

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*Registrar, Act 36 contact details:*

*Tel:* 012 319 7303  
*Fax:* 012 319 6764  
*Email:* [MaljuaM@daff.gov.za](mailto:MaljuaM@daff.gov.za)  
*Website:* [www.daff.gov.za](http://www.daff.gov.za)

*Medicines Control Council contact details:*

*Tel:* 012 395 8000  
*Fax:* 012 395 8468  
*Email:* [webmaster@mccza.com](mailto:webmaster@mccza.com)  
*Website:* [www.mccza.com](http://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](mailto:NompumeleloM@daff.gov.za)  
*Website:* [www.daff.gov.za](http://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](http://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](mailto:HelenB@daff.gov.za)

**OR**

*Mrs Riette Theron*

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

Email: [RietteT@daff.gov.za](mailto: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](http://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](mailto:TembileS@daff.gov.za) or [FortunateD@daff.gov.za](mailto: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)

## ANNEX C

### Strips (tick traps) example



### Examples of “stockinets” to be used:



The base of the stockinets are glued to the animal. Note that the sleeves of these “stockinets” have been rolled down to allow counting of ticks. When ticks are not assessed the sleeves are folded (if long enough knotted) and then also sealed using a strong rubber band to preclude tick escape, as demonstrated below.



**Example of blocked tick-proof channel**



