

	DEPARTMENT OF AGRICULTURE DIRECTORATE ANIMAL HEALTH
	GUIDELINES FOR APPLICATION FOR A PERMIT UNDER SECTION 20 OF THE ANIMAL DISEASES ACT 1984 (ACT NO 35 OF 84)
THIS VERSION:	Version 25/1
APPROVED BY:	Director Animal Health
APPROVAL DATE:	2025 -10- 0 8
EFFECTIVE DATE	2025 -10- 1 6

CONTENTS	
1. PURPOSE	2
2. LEGISLATIVE CONSIDERATIONS.....	2
4. ENQUIRIES AND OBTAINING THE SECTION 20 APPLICATION FORM	4
5. SUBMISSION OF THE COMPLETED APPLICATION FORM AND THE EVALUATION PROCESS	5
6. AMENDMENTS AND EXTENSIONS	6
7. COMPLETION OF THE APPLICATION FORM AND ATTACHMENTS	7
8. DISPUTE RESOLUTION:	12
9. OTHER FREQUENTLY ASKED QUERIES AND CONSIDERATIONS	12

1. Purpose

- 1.1. The purpose of this document is to provide guidelines for the application procedure for permission to conduct research under Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84). These guidelines are not a guarantee that any permit will be issued for any research.
- 1.2. These are guidelines only and do 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.

2. Legislative considerations

- 2.1. Any research that falls within the scope of Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) will require a permit in terms of Section 20.
- 2.2. The Animal Diseases Act 1984 (Act no 35 of 84) and the Animal Diseases Regulations (R. 2026 of 1986):
 - 2.2.1. *'animal' means any mammal, bird, fish, reptile or amphibian which is a member of the phylum vertebrates, including the carcass of any such animal.*
 - 2.2.2. *'animal disease' means a disease to which animals are liable and whereby the normal functions of any organ or the body of an animal is impaired or disturbed by any protozoon, bacterium, virus, fungus, parasite, other organism or agent.*
 - 2.2.3. *'animal product' means any part or portion of, or product derived from, any animal, including any such part, portion or product in any processed form.*
 - 2.2.4. Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) "*Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products*" states that:

"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 9a); 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."*
- 2.3. Any other relevant Veterinary Procedural Notice and Standard Operating Procedure.
- 2.4. Any other applicable South African legislation.
- 2.5. If permission under the Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) is granted by the Director: Animal Health it will be in the form of a signed letter, on the DALRRD letterhead, entitled "*PERMISSION TO DO RESEARCH IN TERMS OF SECTION 20 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO. 35 OF 1984)*". No other communication may be considered to be a Section 20 permit.
- 2.6. A Section 20 permit may have a maximum validity of 3 years, whereafter the researcher must obtain an extension to continue with the research.
- 2.7. Neither this guideline nor any Section 20 permit issued absolve the researcher from obtaining any other permits, approvals, or permissions in terms of any other Act of the Republic of South Africa.
- 2.8. A Section 20 permit will contain the conditions approved for the research project based on the information provided in the application form as well as any further additions, changes and/or alterations or other information received in writing during the evaluation and processing of the application.
- 2.9. No part of the research, including collection of samples or movement of animals, may commence without a Section 20 permit.
- 2.10. All information received by the Directorate: Animal Health as part of the Section 20 application is managed confidentially, in line with Section 25 "Secrecy" of the Animal Diseases Act (Act No. 35 of 1984).

3. Work that falls outside the scope of Section 20 of the Act

- 3.1. Invertebrates are not defined as an animal in terms of Section 1 of the Animal Diseases Act 1984 (Act no 35 of 84). If research involves ONLY invertebrates AND none of those invertebrates are known to transmit any animal parasite or disease in any form AND they are not known to infest any animal species, the study would not fall within the scope of Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84). **Please note that many arthropods such as mosquitoes, midges, ticks, fleas, mites, lice, and some flies are**

known to transmit animal diseases and/or infest animals and therefore research involving these do fall within the scope of Section 20(c)(ii) of the Act. In all such cases, researchers are advised to apply for a Section 20 permit or make a written enquiry as to whether a Section 20 permit is required for their studies. If the Directorate: Animal Health determines that a study falls outside the scope of Section 20, the researcher will be informed of this in writing.

- 3.2. *Bone fide* teaching and training of students do not fall within the scope of Section 20 which deals with "*investigation, experiment or research*" or "*manufacture or evaluation of a product or remedy*". In the case of *bone fide* teaching and training of students, the institution is required to ensure they always comply with Section 11 of the Animal Diseases Act 1984 (Act no 35 of 84). The institution is also cautioned to ensure that applicants are prevented from attempting to circumvent Section 20 of the Animal Diseases Act 1984 (Act No 35 of 84) by incorrectly describing research as training or teaching. If the institution is unsure, they are advised to apply for a Section 20 permit or make a written enquiry as to whether a Section 20 permit is required for the work to be undertaken. If the Directorate: Animal Health determines that the work falls outside the scope of Section 20, the applicant will be informed of this in writing.

4. Enquiries and obtaining the Section 20 application form

- 4.1. Section 20 application forms may be obtained from the Department of Agriculture website (www.nda.gov.za) or from the Section 20 Secretariat.
- 4.2. Once a Section 20 application has been captured on our database, an automatically generated email will be sent from the Section 20 database to the contact persons listed on the application form. This email will confirm the application has been captured and allocated and will contain the contacts of the Section 20 official to whom the application has been allocated.
- 4.2.1. If you have not received such an email within fourteen working days after submitting your application to the Section 20 Secretariat, please contact the Secretariat to follow up on your application.
- 4.2.2. If you have received such an email but not been contacted by the Section 20 official to whom the application has been allocated within 14 working days after you have received the automatically generated email, please contact the official listed on the email to follow up on your application.
- 4.2.3. Please do check your "spam" or "junk" folders to ensure communication has not been mistakenly moved to these folders by email service providers.
- 4.3. If you are unsure if you require a Section 20 permit or not, please send a written enquiry to the Section 20 Secretariat, which should include a summary of the study methodology.
- 3.1.1. You will be informed of whether a 20 permit is needed in writing via an official letter or email.
- 3.1.2. The enquiry may be assigned to a Section 20 official who will liaise with you further

2025 -10- 0 8

Page 4 of 13

Approval date: _____

regarding the need for a Section 20 permit.

3.1.3. If you have not received any feedback from either the Section 20 Secretariat or a Section 20 official after 14 working days, kindly contact the Secretariat.

4.4. The Section 20 Secretariat may be reached at the following contact details:

Miss Marna Laing

Section 20 Secretariat

Directorate: Animal Health

Department of Agriculture

Email: Marna@nda.gov.za

Hardcopy delivery: Attention Miss M Laing, Office 12, Block O, Agriculture Place, 20 Steve Biko Avenue, Arcadia, Pretoria, 0001.

5. Submission of the completed application form and the evaluation process

- 5.1. Please submit the completed Section 20 application form and all relevant attachments to the Section 20 Secretariat.
- 5.2. Please ensure that the latest, correct version of the Section 20 application form is completed, signed, and submitted, along with the supporting documentation as discussed in these guidelines and the application form as applicable.
- 5.3. Please submit only one Section 20 application per email to accommodate the Section 20 database capturing protocols.
- 5.4. Please note that the departmental servers may not always accept emails larger than 10MB. If a Section 20 application is larger than 10MB the applicant is advised to break the application into multiple, clearly labelled emails or consider hardcopy delivery to the Section 20 Secretariat. Internet file download options and private email options for delivery to the Section 20 Secretariat are not available.
- 5.5. Once received, the Section 20 application will be captured on the Section 20 database and allocated to a Section 20 official for evaluation and processing. Once an application has been captured and allocated, you will receive an automatically generated email from the Section 20 database. This email will confirm the application has been captured and allocated and will contain the contacts of the Section 20 official to whom the application has been allocated.
- 5.6. All Section 20 applications are evaluated on a case-by-case basis due to their varied and unique circumstances and conditions. This evaluation is performed in such a manner as to ensure an acceptable standard of risk mitigation for all research. The type of animal and animal product/material as well as the type of any specific pathogen used in the study determine the measures required to ensure this.
- 5.7. Following evaluation of the Section 20 application and information supplied:
 - 5.7.1. No further information may be required; or
 - 5.7.2. Additional or alternate documentation, clarifications, permissions, communications, confirmations, or other information may be required; and/or

2025 -10- 0 8

Page 5 of 13

Approval date: _____

- 5.7.3. Alternate processes, facilities and locations and materials or may be required; and/or
- 5.7.4. An audit of the facilities by the Directorate: Animal Health Laboratory Inspection Team may be required and/or
- 5.7.5. Any other risk mitigation measures the Directorate: Animal Health deems appropriate may be required.
- 5.8. The applicant will be notified of any further requirements in writing.
- 5.9. If the Director: Animal Health grants permission under the Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) for the research, by it will be in the form of a signed letter, on the Department of Agriculture letterhead, entitled "*PERMISSION TO DO RESEARCH IN TERMS OF SECTION 20 OF THE ANIMAL DISEASES ACT, 1984 (ACT NO. 35 OF 1984)*". No other communication may be considered a Section 20 permit.
- 5.10. If the Director: Animal Health determines that a permit under Section 20 of the Animal Diseases Act 1984 (Act no. 35 of 84) is not required for the research, the applicant will be informed of this in writing by the evaluating official or the Section 20 secretariat. You may not assume that a Section 20 permit is not required unless this has been confirmed in writing.
- 5.11. The turnaround time of the Section 20 evaluation process is unpredictable and depends on several factors such as the completeness of the application form, the risk of the project, the response time of the applicant, the availability of key officials and other factors. It is advised that applications for Section 20 permits are submitted at least three months prior to the proposed start date of the research.
- 5.12. We therefore suggest that applicants submit their applications in a suitable period, ensure the application form is detailed and complete and ensure that they provide a contact person able to respond promptly to queries from the Directorate: Animal Health

6. Amendments and extensions

- 6.1. Written permission from the Director: Animal Health must be obtained prior to any deviation from the conditions approved under a Section 20 permit, and the conditions specified and disclosed within the Section 20 application. This is also relevant for when the expiry date of the Section 20 permit will be reached and an extension to continue with the research is required.
- 6.2. An amendment must be applied for by completing the following form: "*Request to amend existing permit for research under Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984)*". This form is available on the departmental website www.nda.gov.za or from the Section 20 Secretariat. The amendment application form should be sent to the Section 20 Secretariat and must include any relevant supporting attachments as specified on the application form.
- 6.3. The application for an amendment will be allocated to a Section 20 official for evaluation and processing in the same manner as for an application for a Section 20 permit.

- 6.4. The amendment, if granted, will be forwarded to the applicant in writing. If the amendment is not granted or is determined to be unnecessary, the researcher will be informed of this in writing. You may not assume that an amendment to a Section 20 permit is not required or has been granted unless this has been confirmed in writing.

7. Completion of the application form and attachments

- 7.1. It is the responsibility of the researcher to ensure that all supplied information is correct and true.
- 7.2. Please ensure that the contact details provided are correct and that the contact person is available during the Section 20 evaluation process.

7.3. Signatures

- 7.3.1. Please ensure that the researcher signs the application, the supervisor, and the managers of all the laboratories and facilities where the work will be conducted.
- 7.3.2. The supervisor and managers of all the laboratories and facilities should sign the application form *after* the researcher has signed to indicate that they are aware of the contents of the application form and that the contents are correct according to their respective roles.
- 7.3.3. Section 12 of the application form must be signed by the person in South Africa who will be overseeing or supervising the parts of the research to be undertaken in South Africa.
- 7.3.4. Section 13 of the application form must be signed by each manager of the laboratory or facility where any part of the research will be undertaken. Please duplicate the block if more than one laboratory or facility is to be used for the research.

7.4. General:

- 7.4.1. Please provide a summary of the methodology in section 9 of the application form. This should focus on the proposed handling, processing, analyses distribution, laboratories, facilities, and storage to assist the Section 20 official in understanding what will be used, what will be done and where will this take place in relation to the research. Please also ensure that you describe clearly in the Section 20 application form at which facility or laboratory each step of the research will take place.

7.5. Importing material for the research

- 7.5.1. If any micro-organism, parasite or animal materials or material derived from these (including vaccine, serum, test kit, toxin, anti-toxin, antigen, biological product which consists or originates from a microorganism, animal or parasite) is to be imported for the research, this must be indicated on the Section 20 application form.
- 7.5.2. For the material to be imported, the composition of the material, origin and health status of the material must be attached to the Section 20 application. This is usually

contained in specifications sheets which are usually readily available for most materials produced by commercial companies. Specification sheets may not be available for materials not produced at commercial companies. In such cases, veterinary certification of the above should be attached to the Section 20 application, if available.

7.5.3. For material that has already been imported, the Section 20 official may request a copy of the veterinary import permit in terms of Section 6 of the Animal Diseases Act 1984 (Act no 35 of 84).

7.5.4. Applications for Section 20 permits and applications for veterinary import permits may be submitted simultaneously to ease time constraints, however, in general a veterinary import permit will not be issued before a Section 20 permit is obtained.

7.6. Laboratories, facilities, and sample storage considerations

7.6.1. When listing a laboratory or facility, please indicate the room number/laboratory number, laboratory name, building and address and institution.

7.6.2. If a laboratory or facility has been audited by the Directorate: Animal Health Laboratory Inspection Team and has been issued with a DAH Recommendation Report, please attach the latest version of this report to the Section 20 application form. When completing the Section 20 application form, please refer to the laboratory or facility to be used in the research by the designation given to it in the DAH Recommendation Report.

7.6.3. The level of biosafety and biosecurity at a laboratory or facility must correspond with the biosafety level (BSL) of the proposed nature of work to be conducted. Although each country, including South Africa, will set their own requirements depending on their unique animal health status, the World Organisation of Animal Health (WOAH) provides good guidelines in the form of the WOAH Terrestrial or Aquatic Manual and WOAH Terrestrial or Aquatic Code at www.woah.org. The biosafety level that will be required for the handling of animal tissue, and any material that falls within the scope of Section 20 of the Act, depends on several factors which influence the level of risk posed by the material and project, as determined by the Director: Animal Health. The required BSL, as determined by the Director: Animal Health for the project, will be communicated with the applicant during evaluation of their application and is reflected on the Section 20 permit.

7.6.4. For vector-borne animal diseases and/ or the maintenance of relevant vectors, ensure that precautionary measures with regards to vector protection are considered and described in the application form. Please attach any facility SOPs for vector protection to the Section 20 application. A vector protected checklist may be found on the departmental website www.nda.gov.za.

7.6.5. The Director: Animal Health may determine that the biosafety and biosecurity measures, including vector protection where relevant, of laboratories, biobanks and

other relevant facilities to be used for the research project require a physical inspection, or evaluation in another manner determined suitable by the Director: Animal Health, in order to ascertain their suitability for the project.

- 7.6.6. The BSL-3 status of a laboratory will only be accepted if the laboratory has been officially inspected and is in possession of a valid Directorate Animal Health compliance certificate. Please attach this to the Section 20 application form if applicable.

7.7. Samples and sampling considerations

- 7.7.1. If samples are to be obtained from a laboratory or bio-banking facility or any other place where samples are stored, the researcher must obtain and attach to the Section 20 application a letter from the facility manager stating it is aware of the research and gives permission for the samples to be removed and used by the researcher. The letter must also specify all the samples including species of origin for each, location sample collected from, collection date, sample storage date, sample type, reference numbers and preservation media (if any)
- 7.7.2. If samples are to be inactivated or treated at an external facility, the researcher must obtain a letter from the facility to state that it is aware of the relevant risks and is capable and willing to handle and inactivate the samples as required. The method and parameters of inactivation should also be specified. This letter should be attached to the application.
- 7.7.3. For transportation by road, all samples must be packaged and transported in accordance with the Regulations of the National Road Traffic Act, 1996 (Act No. 93 of 1996). For transportation by air, samples must be packaged in accordance with IATA requirements.

7.8. Testing considerations

- 7.8.1. If any tests for controlled or notifiable diseases are to be conducted as part of the research, this must be clearly indicated.
- 7.8.2. Diagnostic tests for controlled and notifiable diseases in terms of the Animal Diseases Act, 1984 (Act No 35 of 1984), must be performed using a validated test at a laboratory that is approved by the Director: Animal Health in terms of Regulation 12B of the Animal Disease Regulations R2026 of 1986.
- 7.8.3. If the researcher would like to use any test is not approved by the Director: Animal Health in terms of Regulation 12B of the Animal Disease Regulations R2026 of 1986 for a controlled or notifiable animal disease, a detailed description of the test procedure must be provided.
- 7.8.3.1. In such cases, the results are not considered diagnostic results and may not be distributed to any person or entity, whether verbally or in writing, other than to the state veterinarian and the Directorate: Animal Health.

- 7.8.3.2. All positive results must be sent immediately to the Directorate: Animal Health (epidemiology@nda.gov.za) and the state veterinarian. Please include the Section 20 reference number and research project title with the test results.
- 7.8.3.3. The Director: Animal Health may require that samples also be tested with a test and at a laboratory approved in terms of Regulation 12B of the Animal Disease Regulations R2026 of 1986, at the cost of the researcher.
- 7.8.4. If "pen-side"/"point-of-care" tests are to be used, the researcher must describe where the kits will be stored, how they will be securely managed and handled, how the tests will be accounted for and how all leftover test kits will be destroyed.

7.9. State Veterinary Letters

- 7.9.1. An official letter from the responsible state veterinarian of the area concerned must be obtained by the researcher and attached to the Section 20 application for the following:
 - 7.9.1.1. If any field samples are to be collected from any animal, parasite, or vector of animal disease.
 - 7.9.1.2. If any animals are to be obtained from any property other than the facility where the research will be conducted.
 - 7.9.1.3. 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.
 - 7.9.1.4. If the research involves the administration of an unregistered product to animals under "uncontrolled conditions."
 - 7.9.1.5. If any material that is not passed as fit for human consumption will be removed from an abattoir, the letter must be obtained from the state veterinarian responsible for the abattoir.
- 7.9.2. The letter from the responsible state veterinarian must state at least the following:
 - 7.9.2.1. That the state veterinarian is aware of the proposed research, sampling, or use of animals from the area.
 - 7.9.2.2. Whether the property or area is under quarantine or any other veterinary restriction for the suspicion or incidence of any controlled or notifiable disease; and
 - 7.9.2.3. Whether the state veterinarian has any objection to this or not and reasons for objection if so; and
 - 7.9.2.4. Whether the state veterinarian deems it necessary to issue any movement permits in the case of animals or material being moved from the property or area and
 - 7.9.2.5. Any other information or control measures the state veterinarian deems necessary, useful, or relevant to the research project.

7.9.3. Contact details for the relevant state veterinarians may be found on the departmental website www.nda.gov.za or on the relevant provincial veterinary services' websites.

7.9.4. State veterinary letters are generally not required for laboratory bred rats and mice.

7.10. Research using unregistered remedies.

7.10.1. Regarding any investigation, experiment, research or evaluation with any unregistered medicine or with a registered medicine used outside of its registered conditions (e.g., clinical trials, safety trials, residue studies, proof of concept studies etc):

7.10.1.1. If a field trial or any investigation, experiment, research or evaluation deemed by the Director: Animal Health to be “conducted under uncontrolled conditions” is to be conducted in a target specie, the applicant must attach proof of Clinical Trial Approval or exemption issued by the South African Health Products Regulatory Authority (SAHPRA) to the Section 20 application form.

7.10.1.2. If any investigation, experiment, research or evaluation deemed by the Director: Animal Health to be “conducted under controlled conditions” is to be conducted in a target specie, the applicant must attach proof that they have contacted SAHPRA with regard to the requirement for Clinical Trial Approval to the Section 20 application form.

7.10.1.3. If a trial, investigation, experiment, research or evaluation is to be conducted in non-target animals (e.g. laboratory rodents, rabbits etc.) in a laboratory under controlled conditions, the animal disease control risk will be evaluated by the Director: Animal Health and the conditions for such approval will be set by the Director: Animal Health.

7.10.2. Where an unregistered medicine, vaccine, feed additive or other product is to be used and animals are to be slaughtered for human consumption at the completion of such a study, the withdrawal period for the substance used must be determined by SAHPRA. It is the responsibility of the researcher to obtain this withdrawal period from SAHPRA and attach it to the Section 20 application form.

7.10.3. “Controlled conditions” are those in which the acquiring, movement, keeping and release of study animals and material will be conducted in a manner that mitigates potential disease transmission opportunities and all relevant safety aspects, to the satisfaction of the Director: Animal Health. Depending on the disease risk and relevant safety risks of the study, “controlled conditions” may require the use of a Director: Animal Health approved facility of appropriate biosecurity standards (e.g. a BSL 2+, vector-protected facility or BSL 3) and safe removal or disposal of the animals and material at the end of the study.

7.11. Waste management and animal release considerations.

- 7.11.1. Only waste removal companies that are registered to transport biohazardous waste may be used for the removal of waste generated during or by the research. A copy of the municipal registration of the waste removal company of biohazardous waste should be attached to the Section 20 application.
- 7.11.2. If waste will be incinerated on site, please provide a copy of the DFFE registration of the incinerator and please also describe the storage, packaging, and transport of the waste to the incinerator.
- 7.11.3. If animals are to be infected with any disease, a testing protocol to confirm that the animals are negative for the disease in question and may be safely released from the research premises must be attached to the application form. Such testing should preferably be conducted at an independent laboratory.

8. Dispute resolution

- 8.1. If the applicant would like to dispute or is dissatisfied with the handling, evaluation or processing of a Section 20 application that is still in the evaluation process, and they do not feel comfortable addressing it with the evaluating official, this should be addressed in writing to the Section 20 Secretariat. Ensure that the complaint clearly references the application and Section 20 database reference numbers, the relevant officials, the matter in dispute or reason for dissatisfaction, attaches the relevant documentation and proposes a solution (if applicable).
- 8.2. If the applicant would like to appeal a Section 20 application that has been decided upon by the Director: Animal Health, they should follow the provisions of Section 23 of the Animal Diseases Act 1984 (Act no 35 of 84). However, applicants are encouraged to engage with the Directorate: Animal Health to resolve any concerns first.

9. Other frequently asked queries and considerations

- 9.1. A copy of the Animal Diseases Act 1984 (Act No 35 of 1984) is obtainable from the Department of Agriculture's website www.nda.gov.za.
- 9.2. Please note that Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) refers to any animal disease or parasite and does not differentiate between controlled diseases and non-controlled diseases. The mandate of the Animal Diseases Act 1984 (Act no 35 of 84) is "to provide for the control of animal diseases and parasites, for measures to promote animal health, and for matters connected therewith." Controlled animal diseases are simply diseases, for which specific control measures have been prescribed in specific animals. The Act does not preclude the application of specific measures for other, non-controlled, animal diseases.
- 9.3. The Directorate: Animal Health does not issue blanket or generalized permits under Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84) including "laboratory level", permits for research.

- 9.4. Section 20 applications may be submitted and processed prior to the issuing of research ethics approval however, a Section 20 permit does not in any way replace, supersede, or alleviate the requirement for the researcher to obtain and comply with the relevant research ethics approvals. Similarly, a Section 20 permit does not in any way replace, supersede or alleviate the requirement for the researcher to obtain approval and comply with the South African Health Products Regulatory Authority (SAHPRA) in terms of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), and/or approval from Act 36 in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) where applicable.
- 9.5. For any research where a veterinary import permit is required for the importation of any animal, animal derived product, parasite or contaminated or infectious thing into the Republic as per Section 6 of the Animal Diseases Act, 1984 (Act No 35 of 1984), you are will be required to obtain a veterinary import permit for this material. Please attach your Section 20 permit to our application for a veterinary import permit.
- 9.6. Researchers are requested to note a Section 20 permit does not replace, supersede or alleviate the requirement for the researcher to comply with the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993), the Veterinary and Para-Veterinary Professions Act 1982 (Act No. 19 of 82), the Genetically Modified Organisms Act, 1997 (Act no. 15 of 1997) or any relevant nature conservation legislation.

END

Signature	
Name	Dr Mpho Maja
Designation	Director: Animal Health
Date	2025 -10- 0 8

