agriculture, land reform
& rural development
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To whom it may concern

THE USE OF NON-VALIDATED TESTS AND TEST METHODS TO REACH A DIAGNOSTIC CONCLUSION IN RESEARCH PROJECTS ON CONTROLLED ANIMAL DISEASES

According to the prescripts of the Animal Diseases Act (Act 35 of 1984) and the accompanying Regulations, only Directorate: Animal Health of DALRRD (DAH) approved laboratories, with the applicable tests listed on their testing schedule, may be utilised for the diagnostic testing of controlled and notifiable animal diseases. The use of unapproved methods as diagnostic tests for controlled and notifiable diseases is in contravention of the Animal Diseases Act (Act 35 of 1984), and this may have potential criminal and civil liability legal consequences. However, in order to promote the acquisition of further knowledge about such animal diseases, the DAH may allow for unaccredited and unapproved tests to be utilised in research projects subject to the provisions of permit issued in terms of Section 20 of the Animal Diseases Act 1984 (Act no 35 of 84).

Through the applications for and outcomes of a number of Section 20 applications and approvals, it has come to our attention that there is an increasing tendency for researchers to come to diagnostic conclusion for controlled and notifiable animal diseases based solely on the outcomes of non-validated tests and test methods that are deployed for research purposes. A test result is only one aspect of a comprehensive toolkit that must be deployed in order to make a diagnosis and come to any conclusion about the present or past disease status of an animal. The outcome of test results must always be interpreted in the context of a comprehensive combination of proper history, clinical examination, epidemiological investigation as well as follow up sampling of the individual and/or the herd, as required. Such cautious approach to the interpretation of test results is especially important when non-validated and non-approved test methods were deployed and when the samples were collected from clinically healthy animals or opportunistic samples were used.

In order to ensure that ethical research protocols and follow up procedures are followed, and to mitigate the potential impact that false positive test results will have on both the owner of the animals and potentially the disease status of the country, the DAH has resolved as follows:

1. If a researcher wishes to pursue research on controlled or notifiable animal diseases, the following is required in addition to the requirements as contained in the latest official version of the "*Guidelines for Section 20 applicants*" as part of the Section 20 research application:
   1.1. A letter of support from the responsible state veterinarian of the area where the animals reside. The letter must confirm the following:
      1.1.1. Samples will be collected under state veterinary supervision to ensure that proper clinical history and exact location of the animals are taken into account;
      1.1.2. The state veterinarian has no objection to the sampling and testing taking place;
      1.1.3. The state veterinarian has no objection to conducting the necessary investigation of any suspect animals, if required.
   1.2. Results will have to be sent to epidemiology@dalrrd.gov.za and may not be shared with the owners of the animals nor be reported as diagnostic results.
   1.3. The owner of the animals has to sign a consent form stating that they are aware:
      1.3.1. That their property and animals may be placed under precautionary quarantine, pending subsequent investigations, should an animal not test negative as part of the research, and
      1.3.2. Where a property is already infected with a disease, a negative test result using the unregistered test may not be sufficient to allow the lifting of quarantine or movement of animals or products from the property.
   1.4. Fit for purpose samples have to be collected for confirmatory testing purposes at a DAH approved laboratory should an animal not test negative.
   1.5. A DAH approved laboratory needs to be identified that can perform confirmatory testing for the disease under investigation. Should no accredited test be available, the researcher has to approach the DAH for an exemption by submitting a motivation together with scientific backing for the request to accept the results as a diagnostic conclusion.
   1.6. An SOP needs to be provided on how a valid diagnostic conclusion will be reached as an outcome of the study.

2. We need to emphasise that a test result for a controlled or notifiable animal disease cannot be considered a diagnosis in absence of:
   2.1. Interpretation by a registered veterinary professional;
   2.2. Confirmatory testing using validated tests methods in DAH approved facilities on relevant sample material.
   2.3. A clinical and epidemiological investigation by the responsible state veterinarian, followed by an official outcome report.

3. Research results on controlled and notifiable animal diseases may not be published in any format unless consent is received from the Director: Animal Health of the DALRRD in terms of the Animal Diseases Act (Act 35 of 1984).
   3.1. Failure to adhere to this requirement may result in the DAH approaching the relevant editor or publishing entity and taking further legal action.

We support fruitful collaboration between researchers, Veterinary Services and policy makers provided that an ethical and responsible procedure is followed. Research is a critical driver for disease investigation, but it would be considered unethical to report research findings that have not been substantiated as a diagnosis. It would be irresponsible of DALRRD to allow this as this may have detrimental effects on the livelihoods of animal producers and owners, on the welfare of animals and on local and international trade dependent on the disease status of the South African animal population and it may even lead to legal action for damages ensuing from such irresponsible reporting.

Prospective researchers and investigators are requested to familiarize themselves and ensure compliance with the above. Thanking you in advance for your assistance.

Regards,

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Reason: .
Date: 2021.02.03 16:43:56 CAT

Dr Mpho Maja
DIRECTOR: ANIMAL HEALTH
Date: _____

Cc: The Registrar: South African Veterinary Council (SAVC)