



# agriculture

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All Laboratories  
Research Institutions  
Academic Institutions  
Importing Agencies

## **RE: REQUIREMENT FOR A PERMIT FOR ANY PERSON DOING INVESTIGATIONS, EXPERIMENTS AND RESEARCH WITH, AND MANUFACTURE AND EVALUATION OF, CERTAIN PRODUCTS.**

It has come to the notice of this office that there are some laboratories within South Africa that undertake research work and or diagnostic testing on animal diseases, without the knowledge of the Department of Agriculture (DoA).

It is essential for the DoA, being mandated to monitor and control animal diseases, that an updated database should be maintained with details of all institutions, laboratories and individuals undertaking work related to infectious diseases.

You are hereby notified that Section 20 of the Animal Diseases Act, 1984 (Act No. 35 of 1984), has the following provision:

### **"20 Limitations on investigations, experiments and research with, and manufacture and evaluation of, certain products**

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

- (a) conduct any investigation, experiment or research with any vaccine, serum, toxin, anti-toxin, antigen or other biological product which consists or originates wholly or partially of, or from, any micro-organism, or of or from the glands, organs, fluids, or any other part, of an animal or parasite: Provided that the foregoing provisions of this paragraph shall not apply to any substance in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 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."

A proposal for the compulsory registration of all laboratories doing diagnostic testing or screening of for controlled and / or notifiable animal diseases and the registration of persons who produce, distribute and or import reagents or kits for diagnostic testing or screening of controlled and / or notifiable animal diseases with the Director of Veterinary Services (DVS) is being processed, in order ensure full accountability by the Director for the control of animal diseases within South Africa.

For permission to carry out any investigations, experiments, diagnostic tests or research with, or manufacturing and evaluation of any products as listed in Section 20 of the Animal Diseases Act (Act 35/1984) you would need to apply to the Director of Veterinary Services.

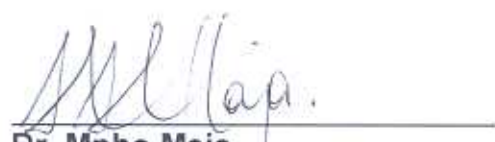
Procedure for applying:

Please complete the attached form (Addendum A) with the following details:

1. Name of institution, laboratory and company
2. Address: Postal and residential
3. Telephone numbers
4. E-mail address
5. Name and contact number of person in charge
5. Full details of work undertaken: Protocols, tests, etc.

Updated details should be supplied to the DoA annually. Should there be additional tests or experiments, the DoA should be notified immediately. The same applies in the case where work is suspended. Where controlled / notifiable disease pathogens are involved, the laboratory concerned will be audited by the audit team from the DoA. You would need to request an application form for the audit. Work may only commence once written permission has been obtained from the Director of Veterinary Services.

Kind regards.



**Dr. Mpho Maja**  
**DIRECTOR: VETERINARY SERVICES**