agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

VETERINARY PROCEDURAL NOTICE 56/2019-01

MEAT SAFETY ACT, 2000
(Act No. 40 of 2000)

REQUIREMENTS FOR REGISTRATION OF TESTING LABORATORIES RESPONSIBLE FOR THE ANALYSIS OF SAMPLES FOR MONITORING AND VERIFICATION OF HYGIENE OF MEAT AND PRODUCTS OF ANIMAL ORIGIN

The National Executive Officer (NEO) has, in terms of regulations issued under section 22 of the Meat Safety Act, 2000 (Act No. 40 of 2000), made the guidelines regarding meat and products of animal origin inspection compliance criteria for laboratories set out in the Schedule.

ARRANGEMENT OF SECTIONS

APPROVED:

2019 -01- 23

DR M. MOLEFE — **DATE**

NATIONAL EXECUTIVE OFFICER

1. DEFINITIONS

In the compliance guideline any word or expression to which a meaning has been assigned in the Act shall have that meaning and -

''Effective Capacity'' is the achievable level under normal conditions for an extended time.

''Maximum Capacity'' is the highest achievable level under ideal conditions for a limited time;

"Act" means the Meat Safety Act, 2000 (Act No. 40 of 2000);

"Competent authorities" means: the central and/or provincial authorities responsible for the organisation of official controls and of other official activities, in accordance with this Act and any other authority to which that responsibility has been conferred;

"Contamination" means the introduction or occurrence of a contaminant in food or food environment;

"Designated official laboratory" means a laboratory designated by the National Executive Officer (NEO) to carry tests on samples for official regulatory controls;

"Foodborne pathogen" means a biological agent that is associated with serious illness or death when ingested with food or that is resistant to one or more critically important antibiotics for human medicine;

"Hazard" means any agent or condition with the potential to have adverse effect on human, animal or plant health, animal welfare or the environment;

"Inspection" means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;

"Other terms and definitions" Where applicable, terms and definitions in the respective Codex Alimentarius, Meat Safety Act and the respective regulations, Standard Operating Procedures (SOPs) or VPNs shall apply.

"Prescribed laboratory method" means a recognised method by the NEO or internationally recognised method (e.g. Codex Alimentarius or World Organisation for Animal Health (OIE)) used to detect and monitor presence of specified substances (physical, chemical and microbiological) in meat and meat products, water, environmental samples and testing samples for specific diseases;

"Reference Laboratory'' means a laboratory authorized by the NEO as a confirmatory testing laboratory for the area/country.

"Registered laboratory" means a laboratory registered by the NEO, under the Meat Safety Act, 2000 and Veterinary Procedural Notices, to carry out tests to determine the presence of biological or chemical agents, foreign matter or toxic agents or other undesirable substances or conditions in animals and products of animal origin from establishments registered under the Act;

"Specified substance" means any biological or chemical agent, foreign matter, or other substance not intentionally added to products of animal origin that may compromise its safety, fitness, and/or suitability for human and animal consumption;

"Technical Signatory" means a person registered with either the South Africa Council for Natural Scientific Professions (SACNASP) or the Health Professions Council of South Africa (HPCSA) or the South African Veterinary Council (SAVC) and whose competency has been assessed and approved by South African National Accreditation (SANAS) body;

"Verification procedures" means the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance;

"Zoonosis" means diseases and infections that are naturally transmitted between vertebrate animals and humans;

2. APPLICATION FOR REGISTRATION

(1) A laboratory seeking to be registered or designated must apply by completing the relevant application forms obtainable from the NEO;

(2) The NEO shall determine the effective and maximum capacity of each designated official laboratory for the purpose of testing official samples;

(3) All laboratories applying to be registered or designated must make available any documentation requested by the NEO to verify the testing methods used by the laboratory;

(4) Application should include:

(a) address and contact details;

(b) scope of accreditation (if applicable to the relevant testing program);

(c) details of approved methods that the laboratory intends to use for the testing of samples (with appropriate accreditation documentation if applicable);

(d) agreement to participate in inter-laboratory and proficiency testing programs;

(e) a completed application form signed by an authorised representative;

(f) South African National Accreditation System (SANAS) accreditation for specified methods;

(g) if however a laboratory is not SANAS accredited, the NEO may conditionally register or designate the laboratory;

(h) details including the registration number of the individual(s) registered under the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993) as amended;

(5) Written acknowledgment of receipt of application will be provided within 30 working days;

(6) The outcome of the assessment of the application letter must set an appointment date for laboratory inspection by a team nominated by the NEO;

(7) The NEO may grant registration without conducting inspection if there are sufficient grounds to suggest that the laboratory meets the set standard(s);

(8) The NEO must confirm registration in writing and no laboratory must analyse samples for the purpose of monitoring and verification compliance under the Act without proof of registration;

(9) Where an unaccredited laboratory is approved, it and/or its testing methods shall at minimum comply with the requirements of the relevant ISO, ISO 17025; Codex Alimentarius and the World Organisation for Animal Health (OIE).

3. MAINTAINING REGISTRATION/DESIGNATION

(1) In order to remain a registered or designated, a laboratory must meet the requirements specified by the NEO or another applicable regulatory body. This includes but not limited to:

(a) maintenance of SANAS accreditation and/or registration status;

(b) regular inspections by the NEO or other applicable regulatory bodies;

(c) participation in recognised proficiency testing and where stated, inter-laboratory testing schemes;

(d) operating within the specified maximum throughput of the laboratory;

(e) keeping infrastructure in a good state of repair and Good Laboratory Practices (GLPs);

(2) A registered laboratory is recognised for the purpose of testing samples from animals, meat and meat products for zoonotic pathogens, hygiene indicator organisms, chemical residues, contaminants, water, environmental samples, antimicrobial resistance, species identification and testing samples for specific diseases within the scope of its registration;

(3) Laboratory registration or designation does not imply endorsement by the NEO of its performance in relation to testing outside the testing carried out under the Laboratory Registration Programme (LRP);

(4) A laboratory remains that registered / designated as long as it complies with stipulated requirements or until a request for de-registration or until the NEO has reason to de-register it;

(5) A laboratory may request for change of conditions or scope of registration / designation by writing to the NEO.

(6) A registered / designated laboratory must notify the NEO of any changes that may affect its ability to perform tests for which it is registered.

4. SUSPENSION / REVOCATION OF REGISTRATION

(1) The NEO will remove a laboratory from the list of registered laboratories if it is suspended or de-accredited by SANAS or upon notification for voluntary suspension.

A laboratory has to re-apply to the NEO for reinstatement once SANAS accreditation is restored and all conditions specified by the NEO in relation to its suspension / removal are met;

(2) The NEO may suspend or remove a laboratory from the list if:

(a) it defaults from the registration / designation requirements;

(b) the NEO it is not competent and honest in any aspect of its work which would reasonably be expected to impact on the reliability of test results;

(c) it is underperforming at proficiency and/or inter-laboratory comparative tests or in the case of registered / designated laboratories exceeds its authorised capacity without approval by the NEO;

(d) it no longer complies with the registration conditions provided for;

(e) it does not comply with the obligations provided for;

(3) On notification from the NEO of suspension or removal from the list, the laboratory must cease all testing relating to scope of registration and notify all its relevant customers of its suspension or removal;

5. OBLIGATIONS OF REGISTERED AND DESIGNATED LABORATORIES WITH REGARD TO PUBLIC HEALTH RISKS

(1) Listed laboratories shall inform the NEO or his designate within the stipulated time frame where results of an analysis, test or diagnosis carried out on samples indicate non-compliance or point to the likelihood of non-compliance;

(2) The manager of the laboratory shall be responsible for the following:

(a) ensure that the staff of the respective units adhere to existing statutory laws, keep an electronic data base of all potential hazards for Category 3 Notifiable Food Safety and Zoonotic Conditions (Table 3);

(b) to report laboratory confirmed potential hazards for Category 1 Notifiable Food Safety and Zoonotic Conditions (Table 1) within 24 hours to the NEO;

(c) to report laboratory confirmed potential hazards for Category 2 Notifiable Food Safety and Zoonotic Conditions (Table 2) within 7 days to the NEO;

(d) to report Category 3 Notifiable Food Safety and Zoonotic Conditions on a monthly basis to the NEO;

(5) upon request by a South Africa Veterinary reference laboratory or national reference laboratory, registered/designated laboratories shall take part in inter-laboratory comparative tests organised for the analyses, tests or diagnoses they perform as official laboratories in addition to formal Proficiency Testing scheme(s);

(6) ensure that laboratory reports are checked and signed by the respective laboratory signatory before they are dispatched from the laboratory.

(3) A registered/designated laboratory shall keep records for at least 5 years and provide the as may be requested by the NEO indicating all analyses done and summary of all specified tests results;

(4) A registered / designated laboratory must avail to the public the list of methods used for analyses, tests or diagnoses performed in the context of monitoring and verification of regulatory controls and other official activities;

(5) A registered / designated laboratory shall keep the isolates of foodborne pathogens and send them together with relevant information on the laboratory submission form for storage at the national reference laboratory for further analysis;

(6) A laboratory's Quality Assurance system should address how the combination of screening versus confirmation test results are interpreted and reported;

6. INSPECTION OF LABORATORIES

(1) The NEO or his designate shall carry out inspections of the registered/designated laboratories:

(a) on a regular basis;

(b) any time they consider that an inspection is necessary;

(2) If the inspection team is of the opinion that a non-compliance observed during an inspection is of a nature that it poses an imminent and serious risk to the safety of the food intended for sale and requires immediate intervention, the team must report the findings in writing to the NEO without delay.

7. ACCREDITATION BODY

A registered / designated laboratory must maintain accreditation with the SANAS for equipment calibration as mandated by the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act 19 of 2006). It must also ensure that staff members have appropriate qualifications and are registered with applicable professional bodies.

8. ASSESSMENT AND ACCREDITATION

(1) Laboratories testing meat and meat products, water, environmental or animal samples for diseases must be accredited by SANAS to undertake such testing and meeting the SANS 17025 standard, Codex Alimentarius and OIE requirements;

(2) Pathogen testing laboratories should follow minimum requirements for biosafety level (BSL) II laboratory operation, restrict access to the laboratory to trained staff and ensure the laboratory is operating under the supervision of a registered diagnostic veterinarian in case of testing for OIE listed animal diseases) and/or a technical signatory in the case of other food safety conditions;

(3) In some cases, depending on the pathogen, BSL3 and above level is required and the laboratory will be inspected and, if satisfactory, a compliance certificate is issued in terms of the animal health laboratory approval procedures (DAFF 012-F08).

9. APPROVED METHODS OF ANALYSIS

(1) Approved methods must be followed without modification, unless such modifications have been agreed to by the NEO and are under the laboratory's scope of accreditation registration/designation;

(2) A registered/designated laboratory may undertake testing using methods if their scope of accreditation / registration / designation includes the specific tests to be used and the method is included in the regular assessments by SANAS;

(3) A registered/designated laboratory must notify the NEO of any changes to the methods used by the laboratory for testing as part of LRP prior to implementation of the methods;

(4) A registered/designated laboratory may "sub-contract" specific aspects of testing, including confirmation of presumptive positive samples, however contract laboratories must:

(a) be registered laboratories;

(b) be acknowledged on the report of test results;

(c) where applicable, must be instructed to report results to the NEO at the same time that they are reported to the contracting laboratory.

10. METHODS USED FOR SAMPLING, ANALYSES, TESTS AND DIAGNOSES

(1) Methods used for sampling and for laboratory analyses, tests and diagnoses during regulatory controls and other official activities must comply with South African rules establishing those methods or the performance criteria for those methods;

(2) In the absence of rules in the Republic of South Africa, laboratories may use methods for their specific analytical, testing and diagnostic needs, taking into account:

(a) the most recent available methods complying with relevant internationally recognised rules or protocols, including those that the International Organization for standardization or where applicable the Scientific committee for standardisation has accepted; or

(b) in the absence of the rules or protocols referred to subparagraph 10(2)(a), the relevant methods developed or recommended by South African reference laboratories and validated in accordance with internationally accepted scientific protocols; or

(c) in the absence of the rules or protocols referred to in subparagraph 10(2)(b) and the methods referred to in point (b), the methods which comply with relevant rules established by other regulatory organs of State within the Republic of South Africa; or

(d) in the absence of the rules or protocols referred to in subparagraph 10(2)(a), the methods referred to in paragraph (2) and the national rules referred to in subparagraph 10(2)(c), the relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or,

(e) in the absence of the rules or protocols referred to in subparagraph 10(2)(a), the methods referred to in subparagraph 10(2)(b), the national rules referred to in

subparagraph 10(2)(c) and the methods referred to in subparagraph 10(2)(d), the relevant methods validated in accordance with internationally accepted scientific protocols;

(3) In the context of screening, targeted screening and of other official activities, any of the methods referred to subparagraph 10(2)(b) may be used in the absence of rules referred to in subparagraph 10(2)(a) provided that the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories in relation to the methods they use; participate regularly and have satisfactory performance in the inter-laboratory comparison tests or proficiency tests organised by the national reference laboratories in relation to the methods they use; and have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used;

(4) Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in subparagraphs 10(2)(a) and (b) exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory registered/designated may use methods other than those referred to in subparagraph 10(2)(a) and (b) until the validation of an appropriate method in accordance with internationally accepted scientific protocol;

(5) Wherever possible, methods used for laboratory analyses shall be characterised by the appropriate criteria set out;

(6) Samples must be taken, handled, transported and labelled in such a way as to guarantee their integrity, scientific and technical validity;

(7) The NEO may, by means of a Veterinary Procedural Notice (VPN), set down and/or refer to additional requirements for:

(a) the methods to be used for sampling and for laboratory analyses, tests and diagnoses;
(b) performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;
(c) the interpretation of analytical, testing and diagnostic results;

(8) The matrix for validation of testing methods shall be species specific with statistically representative number of samples.

11. DISPUTED ANALYTICAL RESULTS

(1) Where relevant and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or food, to the perishability of the samples or the food and to the amount of available substrate, the owner of the product may apply to the NEO for to subject the product to re-sampling, analysis, test or diagnosis in the context of official controls. Such an application may include:

(a) a sufficient number of additional samples from the consignment taken for an expert opinion, in accordance with standard operating procedure or;

(b) where it is not possible to take a sufficient additional number of samples calculated based on general guidelines on sampling CAC/GL 50- as referred to in point (a), that an independent second analysis selected by the NEO, test or diagnosis on the initial sample(s) be carried out;

(2) The application by the operator shall not preclude the NEO to take prompt action to eliminate or contain the risks to human, animal and plant health, or for environmental and animal welfare;

(3) Where initial laboratory analytical results demonstrate the presence of pathogens or toxic substances in a product, negative subsequent analysis results do not negate the first result, because of possible non–homogenous distribution of such substances within and between the samples;

(4) The NEO may, by means of an SOP, lay down procedures for the uniform application of the rules provided and for the presentation and handling of applications for expert opinion.

12. CONFIDENTIALITY

(1) Confidentiality of all records shall be maintained;

(2) Any records supplied to the NEO by a registered/designated laboratory shall be handled in terms of the Meat Safety Act, 2000 (Act No 40 of 2000) and/or the Animal Diseases Act, 1984 (Act No 35 of 1984);

(3) Where necessary, officials may be requested to sign a confidentiality clause to receive the laboratory results.

Annexure 1

CATEGORIES OF FOOD SAFETY AND ZOONOTIC CONDITIONS[1,2,3,4]

Table 1: Category 1 Food Safety and Zoonotic Conditions that need immediate notification (within 24 hours) as a laboratory-confirmed case (by laboratory)

	Notifiable condition	**Confirmed case by laboratory**
1.	Anthrax	✓
2.	Feed borne illness outbreak	✓
3.	Plague	✓
4.	Brucellosis	✓
5.	Avian and Swine Influenza	✓
6.	Rabies (human)	✓
7.	Rift Valley fever (human)	✓
8.	Waterborne illness outbreak	✓
9.	Viral haemorrhagic fever diseases:,	✓
10.	Lassa virus	✓
11.	Crimean-Congo haemorrhagic fever	✓
12.	Ebola viruses	✓
13.	Any other biological or toxin listed under the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act 87 of 1993) as amended	✓

Table 2: Category 2 Food Safety and Zoonotic Conditions to be notified within seven (7) days of diagnosis as a laboratory-confirmed case (by laboratory).

	Notifiable condition	Confirmed case by laboratory
1.	Schistosomiasis	✓
2.	Brucellosis	✓
3.	Hepatitis A	✓
4.	Hepatitis E	✓
5.	Environmental contaminants (Lead, Cadmium, Arsenic, Radionuclides, polychlorinated biphenyl (PCB), dioxins)	✓
6.	Mercury	✓
7.	Soil-transmitted helminthic infections	✓
8.	*Clostridium botulinum*	✓
9.	*Clostridium perfringens*	✓
10.	Bovine Tuberculosis	✓
11.	Listeria monocytogenes	✓

Table 3: Category 3 Food safety and Zoonotic Conditions that private and public laboratories need to keep a database on and report monthly

	Notifiable condition	**Pathogen/s and or condition to notify**
1.	Other zoonotic pathogens	Any other uncategorized zoonotic pathogen
2.	Endemic arboviral diseases	West Nile virus, Sindbis virus, Chikungunya virus, other imported arboviruses of medical importance
3.	Invasive disease caused by Streptococcus pneumoniae	Streptococcus pneumoniae
4.	Shiga toxin-producing *Escherichia coli*	Shiga toxin-producing *Escherichia coli* including the toxin types
5.	Non-typhoidal Salmonellosis	*Salmonella* spp. other than *S. typhi* and *S.* paratyphi
6.	Leptospirosis	*Leptospira*
7.	Campylobacteriosis	*Campylobacter jejuni/coli/lari*
8.	Bovine and Porcine Cysticercosis	*Taenia solium and Taenia bovis*
9.	Toxoplasmosis	*Toxoplasma gondii*
10.	Tickborne illness	
11.	Johne's disease	Mycobacterium avium subspecies paratuberculosis (MAP)
12.	Botulism	*Clostridium botulinum* including the toxin type
13.	Veterinary Medicines, Pesticides, Agricultural or stock remedy above Maximum Residue Limits	Compound name
14.	Shigellosis	*Shigella* spp.
15.	Healthcare-associated infections or multi drug-resistant organisms of public health importance	• Carbapenemases-producing and extended beta lactamase *Enterobacteriaceae* ; • *Staphylococcus aureus*; • *Clostridium difficile;* • *Escherichiacoli;* • *Salmonella spp;* • *Campylobacter spp;* • *Listeria monocytogenes;* • *Listeria spp;*

[1]Meat Safety Act (40 of 2000) ; [2]Regulations relating to the surveillance and the control of notifiable medical conditions. Vol. 630 15 December 2017 No. 41330; [3]Animal Diseases Act 35 of 1984; [4]The Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act 87 of 1993)