agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

STANDARD OPERATING PROCEDURES ON THE NOMINATION, OFFICIAL RECOGNITION AND APPOINTMENT OF ACCREDITED, PRIVATE AND PARASTATAL SOUTH AFRICAN LABORATORIES TO ASSIST IN MANAGING THE FOOD SAFETY RISK ON GRAINS AND FEED PRODUCTS DESTINED FOR EXPORT.

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1. ACRONYMS AND DEFINTIONS

Accreditation	Means a procedure by which an authoritative body gives formal recognition that a laboratory is competent to carry out specific tasks or tests. Accreditation is thus the recognition for specific competence, whereby people, skills, knowledge and supporting management systems are assessed against an international standard.
Accreditation criteria	The set of standards against which a laboratory is measured when applying for accreditation
Accredited Laboratory	A laboratory that was found to be competent in the performance of their scope of activities, according to ISO/IEC 17025:2005 and SANAS regulatory requirements.
APS	Agricultural Product Standards
Audit	The process whereby a quality system is audited against a standard e.g. ISO/IEC17025:2005 or a national standard
Competence	Demonstration through skills and/or expertise to produce accurate results
DAFF	Department of Agriculture, Forestry and Fisheries
Executive Officer	The officer designated under section 2(1) of the Agricultural Product Standards Act, 1990 (Act No. 119 of 1990)
Export Programme	Means controls and programmes associated with the export of regulated agricultural products destined to the European Union, USA, Canada, Far East (Asia) (Indonesia, Vietnam and Malaysia, etc) and China
Food Business Operator (FBO)	The person or persons responsible for ensuring that the prescribed requirements of these standards are met within the food business under his or her control and include both the management of the food business as well as the person with overall authority on site or in the specific establishment.
IEC	International Electrochemical Commission
Inter-laboratory	Performance and evaluation of tests on the same or similar

comparisons	test samples by two or more laboratories in accordance with pre-determined conditions
ISO	International Organization for Standardization
ISO/IEC17025	Document that contains all the standards and requirements that a laboratory have to meet if it wish to be accredited.
LAL	List of Approved Laboratories
NRL	National Reference Laboratory - means an official laboratory of the Department of Agriculture, Forestry and Fisheries that has been nominated in writing by the Executive Officer for the testing of compliance
Official Recognised Laboratories	Means any laboratory that is nominated by the Executive Officer in writing as being suitable for the testing of compliance.
PPECB	Perishable Products Export Control Board
PPP	Plant Protection Products
Proficiency testing program	A formal program that includes the following: • Qualitative schemes (where a laboratory is required to identify a component of a test sample • Continuous program (where laboratories are provided with test samples at regular intervals on a continuous basis)
QMS	Quality Management System
Quality Assurance	All planned and systematic activities implemented within the Quality System and demonstrated as needed to provide adequate confidence that an entity will fulfil requirements for quality
SABS	South African Bureau of Standards
Sample	One or more units selected from a population of units, or a portion of material selected from a larger quantity of material. For the purposes of these recommendations, a representative sample is intended to be representative of the consignment, the bulk sample, etc., **in respect of its agro-chemical residue content and mycotoxins levels** and not necessarily in respect of other attributes.

SANAS	South African National Accreditation System

2. PURPOSE

The purpose of this Standard Operating Procedure is to --

(a) lay down the procedures that an analytical laboratory must follow in order to be recognized as a an accredited and competent laboratory for the analysis of Grains and Feed Products destined for export regulated in terms of the Agricultural Product Standards Act, 1990(Act No. 119 of 1990); and

(b) set out requirements and criteria which should be met in order for a laboratory to be recognised and nominated as an officially recognised laboratory.

The implementation of this Standard Operating Procedure will assist in managing the level of risks associated with food safety and trade for Grains and Feed products, covering all regulated agricultural commodities that are exported to all markets.

A written agreement shall be entered into between the Department of Agriculture, Forestry and Fisheries (DAFF) and the designated/appointed laboratories. This agreement will amongst other things cover the performance criteria of the required analytical testing and matters related thereto.

3. BACKGROUND

Section 4 of the Agricultural Products Standards Act (Act 119 of 1990) determines that "the Minister may prohibit the export, from the Republic, of a prescribed product unless each quantity of that product, intended for export, has been approved by the Executive Officer (of the APS Act) for that purpose.

Therefore, in order to ensure compliance with the latest Export Standards and Requirements for Grains and Feed products, the Minister has amended the Regulations Regarding Control of the Export of Feed products(No. R.1031) and Regulations Regarding Control of the Export of Grains (No. R1026) on the 19th December 2014. These

Regulations determine that "an inspector may, amongst other things, open as many containers and inspect the contents thereof and remove samples of such contents for the purpose of further inspection or analyses as he/she may deem necessary.

The requirements for facilities, management, personnel, quality assurance and quality control, documentation of results and raw data, and other relevant subjects, which are considered to be prerequisites for obtaining reliable and traceable test results, are described in general in the ISO/IEC 17025:2005 Accreditation Standard.

In order to address this shortcoming, a network of laboratories will be appointed with the sole purpose of ensuring compliance with RSA and Importing countries legislation and other countries' maximum pesticide residue and mycotoxin requirements.

4. REFERENCES

4.1 The Agricultural Product Standards Act, 1990 (Act 119 of 1990).

4.2. Regulation Regarding control of the Export of Feed Products No. R.1030 of 19 December 2014.

4.3. Regulations Regarding control of the Export of Grains No. R1026 of 19 December 2014.

4.4. The Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act, 1947 (Act no. 36 of 1947).

4.5. The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

4.6. ISO/IEC 17025:2005:- "General Requirements for the Competence of Testing and Calibration Laboratories".

4.7. The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories (IUPAC Technical Report, Pure Appl. Chem., 2006, 78(1), 145-196).

4.8. Guidance document on analytical quality control and validation procedures for pesticide residues analysis in food and feed (SANCO/12495/2013).

4.9. Guidelines on Good Laboratory Practices in pesticide residues analysis (CAC/GL40-1993).

4.10 The General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995).

4.11. Regulation (EC) No. 882/2004 (relating to official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules).

4.12. Regulation (EC) No. 1107/2009 (concerning the placing of plant protection products on the market).

4.13. Regulation (EC) No. 1881/2006 (setting maximum levels for contaminants in foodstuffs).

4.14. Regulation (EC) No. 401/2006 (laying down methods of sampling and analysis for the official controls of the levels of mycotoxins in foodstuffs).

5. OBJECTIVES AND SCOPE OF TESTING

5.1. All accredited laboratories shall comply with the general criteria for testing laboratories laid down in the International ISO/IEC 17025:2005 Standard.

5.2 By the 31st December 2016, at least 50% of the full range of authorized pesticides registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (No.36 of 1947) shall be covered in the broadened analytical scope of all the Officially Recognised Laboratories.

5.3. Medium to Long term attainable goals - 75% of the full range of authorised pesticides registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (No.36 of 1947) shall be covered in the broadened analytical scope of all the Officially Recognised Laboratories in 2019.

5.4. Every approved laboratory shall test for all plant protection products (pesticides) that have been registered for use in South Africa. An updated list of registered actives (in South Africa), supplied by the Directorate: Agriculture Inputs Control shall be provided by the DAFF to all approved laboratories. Regular updates will be provided as and when it becomes available.

5.5 Every approved laboratory shall test for mycotoxins in Grains and Feed Products that are regulated in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), relevant European Union Directives and the Codex Alimentarius.

5.6. The Officially Recognised Laboratory shall only be used by DAFF as an assignee for the export programme as set out in item 2.

5.7 An expansion of scope of testing programme should be supplied to the National Reference Laboratory in writing and regular progress reports (as agreed with the NRL) should be supplied.

6. PARTICIPATION IN INTER-LABORATORY COMPARISON TESTING

6.1 All approved laboratories will be required to participate in inter-laboratory comparison testing that has been organized by the National Reference Laboratory.

6.2 Where comparative tests indicate a potential problem the National Reference Laboratory shall provide guidance to the nominated laboratory as to how to improve methods and/or identify solutions to problems and will inform the Executive Officer: APS Act accordingly.

7. LABORATORY REQUIREMENTS

7.1 Every approved laboratory shall :

(a) Have adequate funding for the effective and efficient operation of the laboratory.

(b) Have sufficient safety, security and emergency procedures.

(c) Have fire extinguishing equipment that meets the requirements of local authorities.

(d) Have adequate facilities for performing tests and for storage of samples.

(e) Have adequate equipment and space for refrigeration and freezing of samples due for analyses.

(f) Have adequate lighting.

(g) Maintain environmental conditions that render the facility suitable for pesticide residue and mycotoxins testing.

(h) Maintain good hygienic conditions and housekeeping.

(i) Maintain a waste management system that is in compliance with the relevant legislation.

(j) Control of records shall be established and maintained via a documented procedure that will enable identification, storage, protection, retrieval and disposition of such records and also indicating the retention time of such records.

(k) Participate in proficiency testing schemes for food analysis which conforms to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories".

(l) Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission.

(m) Use internal quality control procedures, such as those described in the "Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories".

(n) Operate in accordance with any conditions that may be specified by the National Reference Laboratory from time to time.

7.2 To maintain the laboratory approval status, the laboratory must:

(a) Ensure that it is regularly assessed by SANAS and in accordance with SANAS rules and timelines as it pertains to testing laboratories.

(b) Forward a summary of the SANAS assessment report to the Sub-Directorate: National Analytical Services within one (1) month after the assessment.

(c) Use recognized test methods.

(d) Meet all the requirements that may be set from time to time by the Directorate: Food Safety & Quality Assurance.

8. TEST METHOD REQUIREMENTS

8.1. Every test method must be accredited by SANAS in accordance with ISO/IEC17025:2005. If a test method has not been accredited by SANAS then it must at least be validated to prove fitness-for-purpose. Such validation report/s must be available during the audit of the laboratory.

8.2. If a standard test method has been modified even slightly or applied outside its intended scope for an a example, applied to another matrix then it must be validated.

8.3. Significant modifications to a recognized test method (e.g. changes in the validated range of analytes able to be measured, changes in the analytical equipment used, and changes on the method sensitivity) must be reported to the Sub-Directorate: National Analytical Services within a reasonable period.

8.4. If non-standard methods are used then they must be validated in order to verify and confirm fitness-for-purpose.

8.5. The procedure used to validate test methods must be appropriate to the testing field.

9. PERSONNEL REQUIREMENTS

9.1 The laboratory shall comply with the following requirements as it relates to staffing:-

(a) The laboratory shall be competent and shall have a sufficient number of permanent and contract staff to carry out its duties and responsibilities.

(b) Staff shall have appropriate education, experience and training to carry out their duties and responsibilities.

(c) The laboratory shall maintain appropriate records of training and actions described in (b) above.

10. EQUIPMENT AND MAINTENANCE

10.1 The laboratory shall have:

(a) The appropriate equipment and related items / supplies that are needed to perform all the tests at the required level of performance. The equipment used must be fit for use/purpose supported by evidence.

(b) Updated instructions for the use and maintenance of all the equipment.

(c) Updated equipment manuals (provided by the manufacturer) that is accessible by all appropriate laboratory personnel.

(d) Records of all equipment which shall include the following:

- Identity of the equipment
- Manufacturer's name
- Serial number
- Dates, results and reports / certificates of all maintenance, service and calibration.
- Damages, malfunctions, modifications and/or repairs to the equipment

(e) Verification / calibration programs for key equipment where these properties have a significant effect on the results. Calibration of the equipment shall be performed by competent and approved service providers. Verifications shall be performed according to a defined procedure.

(f) A maintenance procedure for all relevant equipment which will also make provision for the identification and labelling of all equipment due for service as a result of damages and / or malfunctioning.

11. HANDLING OF SAMPLES

11.1 The laboratory shall have procedures in place for:

(a) The receipt, identification, labelling, handling, safeguarding, storage of samples as well as sample waste.

(b) Recording sample information with due consideration of the sample traceability principle.

(c) The identification of all sample defects, the recording thereof and the timely notification to the PPECB and/or DAFF National Analytical Services.

12. SERVICE PROVIDERS AND SUPPLIES

12.1. Competent and approved service providers shall be used for calibration and verification of equipment.

12.2. Procedures shall exist for the reception and storage of reagents and consumable items.

12.3. Reagents and consumables that affect the quality of the test results shall not be used until they have been inspected or otherwise verified as complying with standard specifications.

13. CHANGES IN KEY TECHNICAL PERSONNEL

Any changes in key technical personnel responsible for overseeing operation and performance of the recognised test method (and the validity of the results) must be notified to the Sub-Directorate: National Analytical Services within a reasonable period.

14. SYSTEMS AND PROCESSES

14.1 Every approved laboratory must establish, document and maintain systems and processes to ensure that:

(a) Any relevant direction/s given by the DAFF are implemented

(b) Key technical personnel are able to perform or direct effective and timely actions when non-conformances are identified; and

(c) DAFF is notified of any non-complying events without delay.

15. APPLICATION FOR RECOGNITION AND SUPPORTING INFORMATION

15.1. A laboratory that wishes to become a DAFF approved testing laboratory shall apply (in writing) to Mr Albert Smith, Scientific Manager: National Analytical Services, Private Bag X5025, Stellenbosch, 7599. Evidence of ISO/IEC 17025:2005 accreditation (if accredited by SANAS) for each analytical method for which recognition is requested shall accompany such an application.

15.2. If the laboratory meets all the requirements as laid down in this Standard Operating Procedure then the Scientific Manager of the Sub-Directorate: National Analytical Services will provide a recommendation to the Executive Officer for the official appointment of the laboratory.

15.3. The application shall further be accompanied by the declaration from the prospective applicant laboratory undertaking to progressively increase its scope of testing in accordance with item 5.

16. DESIGNATION OF OFFICIALLY RECOGNISED LABORATORY

16.1. The Executive Officer in consultation with the Scientific Manager: National Analytical Services shall approve laboratories and designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during controls and other official activities, in the country.

16.2. The designation shall be in writing and shall include a detailed description of:

(a) The tasks that the laboratory shall carry out as an officially recognised laboratory; and

(b) The conditions under which it shall carry out those tasks.

16.3. The Executive Officer may only designate as officially recognised laboratory, a laboratory which fully complies with item 5, 6, 7, 8, 9, 10, 11, 12, 13 and 14 as set out in this Standard Operating Procedure.

16.4. Only laboratories that are impartial and free from any conflict of interest as regards to the exercise of its tasks shall be appointed as officially recognised laboratories.

17. OBLIGATION OF OFFICIALLY RECOGNISED LABORATORIES

17.1. Officially Recognised Laboratories shall immediately inform the Perishable Products Export Control Board and the Scientific Manager: National Analytical Services within 24 hours about the results of an analysis or test carried out on samples from the Food Business Operator.

17.2. Upon request by the National Reference Laboratory, approved laboratories shall take part in inter-laboratory comparative tests organised for the analyses or tests they perform as officially recognised laboratories.

17.3. Officially recognised laboratories must communicate on a quarterly basis with the National Reference Laboratory indicating all analyses done and summary of all tests results in a format agreed upon.

18. MAINTAINING APPROVAL

1.8.1. In order to remain an approved laboratory, a laboratory must maintain accreditation for the specified approved methods and participate in proficiency testing rounds.

18.2. An approved laboratory can identify itself as an officially recognised laboratories for the purpose of testing Grains and Feed Products destined for export certification.

18.3. A laboratory may never state or imply that being an approved laboratory is an endorsement by the Executive Officer of its performance in relation to testing outside the testing carried out under the Agricultural Product Standards Act.

18.4. The laboratory will remain an officially recognised laboratory until it requests to be removed from the list or until such time as the laboratory is removed from the list by the Executive Officer.

18.5. Any requests by the laboratory to change the conditions or scope of its approval/accreditation must be made in writing to the Executive Officer as appropriate. The Executive Officer will then consider changes to the laboratory's scope of approval.

18.6. Approved laboratories must notify the National Reference Laboratory of any changes in their scope of accreditation or any other changes that may reasonably be expected to impact on the competency of the laboratory in relation to tests carried out as part of export programme.

19. SUSPENSION/REVOCATION OF APPROVAL

19.1 The Executive Officer will automatically suspend or remove a laboratory from the List of Approved Laboratories (LAL) if the laboratory's accreditation is suspended by SANAS. The laboratory is required to re-apply to the Executive Officer as soon as

corrective action measures are implemented as per SANAS requirements and as the accreditation status is reinstated.

19.2. The Executive Officer may, on recommendation of the NRL, suspend or remove a laboratory from the LAL if it does not meet all the requirements of an approved laboratory.

19.3. The Executive Officer may, on recommendation of the NRL, suspend or remove a laboratory from the LAL if it considers that a laboratory is not competent in any aspect of its work that would reasonably be expected to impact on the reliability of test results.

20. PROCEDURE FOR SUSPENSION

20.1. On notification from the Executive Officer of suspension or removal of a laboratory from the LAL, the laboratory must immediately cease all testing relating to scope of approval, and the assignee, PPECB, shall be notified of the suspension or removal from the export programme of pesticide testing.

20.1. In order for the laboratory to be reinstated as an approved laboratory it must meet all conditions specified by the Executive Officer in relation to its suspension/removal and re-apply for consideration as an approved laboratory following the procedures set out in this document.

21. ASSESSMENT AND ACCREDITATION

Officially Recognised Laboratories should be accredited by SANAS to undertake such testing and meet the standard of accreditation as set out in ISO/IEC 17025:2005. Laboratories that are not accredited by SANAS may also be provisionally recognised as approved laboratories to undertake specific testing for a limited period if they undertake to take necessary measures to fulfil with the requirements as set out in ISO/IEC 17025:2005.

22. SETTLING OF DISPUTES OVER ANALYTICAL TEST RESULTS

22.1. In the event that a dispute arises between the exporting and importing country over

the analytical test results then such disputes should be referred to the National Reference laboratory that will coordinate all efforts in settling the dispute in accordance with the Codex Alimentarius Commission Guidelines for settling disputes over analytical (test) results.

22.2. In the event that a dispute arises between the exporter and the officially recognised laboratory over the analytical test results then such a dispute should be referred to the National Reference laboratory that will coordinate all efforts in settling the dispute over the analytical test results. The results of the National Reference laboratory (or any of its designated laboratories to which the dispute has been referred too) shall be the final result of the particular consignment.

23. SUBMISSION OF TEST RESULTS

23.1. On completion of the analysis the approved laboratory shall report the test results to the PPECB in a format that has been mutually agreed to between the approved laboratory and the PPECB.

23.2. PPECB shall submit summaries of all results to the Executive Officer and National Reference Laboratory on a weekly basis and in a format that has been mutually agreed to between the PPECB and DAFF.

23.3. The official laboratory shall maintain a database of all results and shall compile an Annual Report on Pesticide Residues and Mycotoxins levels which shall provide an overview on the pesticide residues in products presented for export.

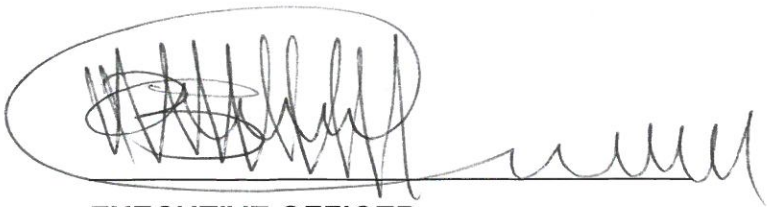
24. PAYMENT FOR SERVICES

The following fees payable for analysis shall be paid by the Food Business Operator:

(a) The laboratory analysis fee when samples of Grains and Feed products are analyzed chemically, physically or for microbiologically testing, for export purposes.

(b) The courier (transport) fee when samples are dispatched to the laboratory.

25. APPROVAL



30/01/15

EXECUTIVE OFFICER: **DATE**

AGRICULTURAL PRODUCT STANDARDS

DOC NO /AMENDMENT RECORD

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DISTRIBUTION

Copies of this Standard Operating Procedure will be distributed to all interested parties by the Secretariat upon request. Alternatively it will also be available on the DAFF's intranet and on the Web Page: www.daff.gov.za.