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 ENSURING COMPLIANCE WITH THE PRESCRIBED COMPOSITIONAL STANDARDS FOR DAIRY 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).
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 comparisons	Performance and evaluation of tests on the same or similar 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
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)
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.
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 specific composition** 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 analyses of **Dairy Products** destined for export and 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 risks associated with the quality/ composition of Dairy Products that are destined for export.

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 aspects 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 of a prescribed product from the Republic 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 Dairy Products, the Minister has published new consolidated Regulations Regarding Control of the Export of Animal Products, namely regulation No. R.422 dated 22 May 2015. These Export Regulations determine that an inspector may, amongst other duties, 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, quality control, documentation of results, 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.

A network of laboratories will be appointed with the sole purpose of ensuring compliance of Dairy Products destined for export with the relevant RSA legislative requirements.

4. REFERENCES

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

4.2 Regulation Regarding control of the Export of Animal Products, No. R.422 of 22 May 2015.

4.3 Standards and Requirements Regarding the Export of Dairy Products, stipulated by Government Notice No. R. 1983 of 23 August 1991, as amended by Government Notice No. 713 of 14 August 2015.

4.4 Regulations Relating to the Classification, Packing and Marking of Dairy Products and Imitation Dairy Products Intended for Sale in The Republic of South Africa, No. R.260 of 27 March 2015.

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

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

4.7 Recommended Methods of Analysis and Sampling (Codex Stan: 234-1999)

5. OBJECTIVE 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 Every approved laboratory shall test for all the compositional parameters specified in regulation R.260 of 27 March 2015 for the type/ class of Dairy Product concerned.

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 the methods and/or identify solutions to problems and shall 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 analyses and sample storage.

(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 the analyses of Dairy Products.

(h) Maintain good hygienic practices and good housekeeping procedures.

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

(j) Establish and maintain a documented record control procedure that will enable the identification, storage, protection, retrieval and disposition of records as well as indicate the retention time of such records.

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

(l) Whenever available, use the recommended methods of analyses as set out in the latest Codex Stan: 234-1999.

(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 additional 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 in accordance with SANAS rules and timelines for 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 methods of analyses.

(d) Comply with the additional 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, e.g. applied to another matrix, then it must be validated.

8.3. Significant modifications of a recognized method of analyses (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 validation procedure used must be compatible with the conditions of method of analyses.

9. PERSONNEL REQUIREMENTS

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

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

(b) The laboratory personnel shall have relevant academic qualifications, 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 specified methods of analyses 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 are 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 a waste management plan.

(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 equipments and instruments.

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 analyses results shall not be used until they have been inspected or otherwise verified as complying with standard specifications.

13. CHANGES IN KEY TECHNICAL PERSONNEL

13.1 Any changes in key technical personnel responsible for overseeing operation and performance of the recognised method of analyses (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 directions 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.

(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. E-mail: AlbertS@daff.gov.za 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 concerned.

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 analyses on samples taken during controls and other official activities in the Republic.

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

(a) the tasks that the laboratory concerned 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 with 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 PPECB and the Scientific Manager: National Analytical Services within 24 hours about the results of an analyses or test carried out on samples from the Food Business Operator.

17.2 Upon request by the NRL, 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 NRL indicating all analyses done and summary of all tests results in a format agreed upon.

18. MAINTAINING APPROVAL

18.1 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 may advertise/ promote itself as an officially recognised laboratory for the purpose of analysing Dairy Products destined for export only.

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 NRL 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 on Dairy Products destined for export.

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 PPECB shall be notified of such suspension or removal.

20.2 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 Standard Operating Procedure.

21. ASSESSMENT AND ACCREDITATION

21.1 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 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 NRL (or any of its designated laboratories to which the dispute has been referred to~~e~~) shall be the final result of the particular consignment.

23. SUBMISSION OF TEST RESULTS

23.1 On completion of the analyses 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 NRL 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 the Dairy Products analysed which shall provide an overview of the compositional breakdown of the Dairy Products analysed for export.

24. PAYMENT FOR SERVICES

The following fees payable for analyses shall be paid by the exporter/ owner of the Dairy Products submitted for inspection:

(a) The laboratory analyses fee when samples of Dairy Products are analysed for export purposes.

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

25. APPROVAL

GJ Lombard

EXECUTIVE OFFICER: (Acting)
AGRICULTURAL PRODUCT STANDARDS

24 April 2017

DATE

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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 Web Page: www.daff.gov.za.