Australian Government

Department of Agriculture

Approved Laboratory Program

(Export meat and meat products)

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1.1 Introduction

Meat can be a vehicle for significant human foodborne diseases such as enterohaemorrhagic *Escherichia coli*, *Salmonella* spp. and *Campylobacter jejuni*. Food safety programs (including inspection programs) associated with meat production provide information on animal health and aid in the control or elimination of zoonoses that impact on public health.

Industry based microbiological testing programs verify the day to day operations at individual establishments and generally use indicator organisms to assess hygienic performance. Government required microbiological monitoring programs, such as the *E. coli* - *Salmonella* monitoring (ESAM) verify industry food safety control programs. They also provide official data to demonstrate equivalence to food safety programs in trading partner countries. To ensure the veracity of the results obtained from regulatory based testing, the department has implemented the Approved Laboratory Program (ALP).The ALP standardises the testing performed by requiring laboratories performing regulatory testing to use approved methods in an approved environment.

1.2 General Information

1.2.1 Scope

The program applies to on-plant and commercial laboratories undertaking microbiological testing of edible meat and meat products to fulfil export requirements for department certification. It includes all testing undertaken as part of the ESAM program and microbiological testing requirements specified in the 'Manual of Importing Country Requirements'.

1.2.2 Eligible Laboratories

All laboratories, both on-plant and commercial, that meet the requirements of the program are eligible to be included on the approved laboratory list. There are no limits on the number of approved laboratories.

1.3 Laboratory Approval

1.3.1 Application

1.3.1.1 Laboratories seeking to be recognised as an approved laboratory must make a written application to: Approved Laboratory Program, Residues and Microbiological Policy, Export Standards Branch, Exports Division, GPO Box 858, Canberra ACT 2601 or Micro_Program@agriculture.gov.au or MID.OpsCord@agriculture.gov.au, using the form in Annex 1 of this document.

1.3.1.2 All laboratories seeking to be recognised as approved laboratories must make available any documentation that the department requests to verify the testing methods used by the laboratory and, if applicable, the laboratories performance in past assessments by the National Association of Testing Authorities, Australia (NATA).

1.3.1.3 Applications should include:

- An application form signed by an authorised company representative (Annex 1);
- The laboratory's proposed scope of accreditation (if applicable to the relevant testing program);
- Details of approved methods that the laboratory intends to use for the testing of meat and meat products (with appropriate NATA accreditation documentation as applicable);
- Agreement to participate in proficiency testing programs;

1.3.1.4 Following written notification of approval of the application (by a desk audit) the laboratory will be granted approval to test meat and meat product as part of an export certification program. Laboratories must receive written advice from the department before commencing testing.

Note: An on-site assessment of the laboratory will be required in most instances prior to approval.

1.3.2 Maintaining Approval

1.3.2.1 In order to remain an approved laboratory, a laboratory must meet the requirements specified in this document and any other document specified by the department. This includes but is not limited to:

- maintenance of accreditation for the specified approved methods (if applicable to the relevant testing program);
- regular assessment by NATA (or where required the department);

- participation in proficiency testing rounds as required/recommended by NATA and/or the department (minimum 6-monthly).

1.3.2.2 An approved laboratory can identify itself as an approved laboratory for the purpose of testing meat and meat products for export certification.

1.3.2.3 A laboratory must never make or imply that being an approved laboratory is an endorsement by the department of its performance in relation to testing outside the testing carried out under the Approved Laboratory Program.

1.3.2.4 The laboratory will remain an approved laboratory until it is removed from the list by the department or requests to be removed from the list .

1.3.2.5 Any request by the laboratory to change the conditions or scope of its approval/accreditation must be made in writing to the department and NATA where appropriate. The department will then consider changes to the laboratory's scope of approval.

1.3.2.6 Approved laboratories must notify the department 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 an export certification program.

1.3.3 Reporting Results to the Department

1.3.3.1 All test results determined under the approved laboratory program must be reported to the department at the same time that they are reported to the export establishment.

1.3.3.2 Where particular aspects of testing are contracted to another approved laboratory the contracting laboratory must notify the contracted laboratory of the requirements to report results directly to the department.

1.3.3.3 Results must be reported as soon as possible (generally within 24 h) after completion of the analytical test. Presumptive positive samples for *E. coli* O157:H7/STEC and *Listeria monocytogenes* should be reported to the department and the company before confirmation so that implicated production lots can be identified and retained or controlled.

1.3.4 Suspension/Revocation of Approval

1.3.4.1 The department may suspend or remove a laboratory from the Approved Laboratory Program if the laboratory loses its NATA accreditation, has its NATA accreditation suspended or NATA notifies the department that the laboratory has not satisfactorily implemented corrective actions identified as part of the laboratory's annual assessment.

1.3.4.2 The department may suspend or remove a laboratory from the Approved Laboratory Program if it does not meet all the requirements of an approved laboratory.

1.3.4.3 The department may suspend or remove a laboratory from the Approved Laboratory Program 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.

1.3.5 Procedure for Suspension/Revocation of Approval

1.3.5.1 On notification from the department of suspension or removal of a laboratory from the Approved Laboratory Program, the laboratory must immediately cease all testing relating to export certification and notify relevant customers (i.e. export establishments) of its suspension or removal.

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

1.4 Assessment/Accreditation

Laboratories testing meat and meat products relevant to department certification should be accredited by NATA to undertake such testing and as meeting ISO/IEC 17025. Laboratories not accredited by NATA may also be recognised as approved laboratories by the department to undertake specific testing if they comply with the requirements set out in "ChoGeneral Requirements for On-Plant Laboratories – Part I: Laboratories Testing Export Meat and Meat Products" available on the department web site. On-plant laboratories undertaking testing under HACCP system that is not covered under Part I of this document should adopt the minimum requirements detailed in Part II: Laboratories Undertaking General Testing.

1.4.1 Accreditation Body

1.4.1.1 NATA is a private, not-for-profit company, governed by its members including representatives from government, professional bodies and industry. The department recognises NATA as the Australian authority for accrediting laboratories for testing. NATA represents Australia in the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Good Laboratory Practice (GLP) compliance monitoring authority representing Australia on the OECD GLP Working Group. NATA has a Memorandum of Understanding with the Australian Commonwealth Government and the relationship between NATA and the department is defined in a Deed of Agreement.

1.4.1.2 NATA accreditation requires laboratories to meet Australian Standard ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" and ISO/IEC 17025 Application Document (Supplementary Requirements for Accreditation) must form the basis for assessment/accreditation purposes.

1.4.1.3 Requirements for laboratories that are not accredited by NATA are summarised in "General Requirements for On-Plant Laboratories – Part I: Laboratories Testing Export Meat and Meat Products" available on the department web site.

1.4.1.4 Approved Laboratory Program requirements include assessment of management systems, quality programs and nominated technical requirements as specified by the department.

1.4.1.5 Laboratories must maintain their accreditation/approval and ensure that staff have appropriate qualifications.

1.4.1.6 Assessment will be carried out on laboratories

- on a regular basis by NATA or the department as determined by national and trading partner requirements;
- whenever NATA or the department deems it necessary.

1.4.1.7 Assessments may be carried out by third parties such as importing country reviewers.

1.4.2 Department Assessments

1.4.2.1 The department will undertake assessments of approved laboratories over a one to three year period depending on the type of testing involved and NATA accreditation. Laboratories that do not have NATA accreditation will be assessed annually by the department[1].

1.4.2.2 Department assessments will generally be in conjunction with a scheduled NATA assessment, although 'Department only' assessments may also be undertaken.

1.4.2.3 NATA or the department will notify the laboratory of the date of assessment prior to the visit.

1.4.2.4 For 'Department only' assessments one weeks' notice will be given where possible and may these assessments may include participation by importing country reviewers.

1.4.2.5 Department assessments will focus on quality systems and approved methods.

[1] In special cases where standard accreditation procedures are not applicable or where laboratories are undertaking testing that is not accredited by NATA, the department may allow alternative procedures for assessment to be used. An example might be research laboratories employing specialised techniques that are used infrequently

1.4.2.6 The laboratory must make available, on request by NATA or the department, all documents relevant to the laboratory's participation in the Approved Laboratory Program, including proficiency testing reports.

1.4.2.7 A technical assessor may be appointed by NATA or the department to help with the assessment. In such a case the technical assessor will be provided with such documentation as necessary to perform their task. Only records relevant to the technical assessor's responsibilities will be provided to the technical assessor. All documentation will be held in confidence and returned to NATA or the department on completion of the assessment.

1.4.2.8 The laboratory has the right to challenge individual technical assessors on the grounds of conflict of interest. NATA or the department will deal with such situations according to their standard procedures.

1.4.3 On-site Assessment

1.4.3.1 Information on the performance of the laboratory will be collected through interviews with staff, examination of documents/records and observation.

1.4.3.2 Assessors can request to observe laboratory staff while performing routine tests.

1.4.3.3 Where applicable all signatories for tests included in the assessment are to be available on the day unless otherwise agreed to by NATA or the department.

1.4.3.4 Where sample collection is part of the laboratory's scope the assessors must review

- the procedure for identifying samples for testing, training records and approval for individuals undertaking sample collection, including non-laboratory staff involved in sampling;
- a nominated Department officer may arrange for a special partial assessment of any or all sample collection programs (relating to testing for export certification) when sampling is not part of the laboratory's scope.

1.4.4 Assessors

1.4.4.1 The Lead Assessor must be a full time employee of NATA or the department and familiar with all requirements of the Approved Laboratory Program.

1.4.4.2 Technical Assessor

- Technical assessors must have the following minimum qualifications:
  - Tertiary qualifications (or equivalent practical experience) in the field relevant to the scope of accreditation of the laboratory being assessed i.e. biological testing;

- A least five years experience working in laboratories with a similar scope of accreditation to the laboratory being assessed and be able to demonstrate a high degree of competency.

- Technical assessors must not have any association with the laboratory that might be perceived as influencing the assessment or that could be seen as a conflict of interest. Any association or conflict of interest must be recorded with the list of technical assessors.

1.4.5 Assessment Findings

1.4.5.1 Assessment findings must be discussed with the laboratory's authorised representative on the day of the assessment, including reference to all non-conformities and applicable requirements.

1.4.5.2 Corrective action requests must be issued in accordance with the requirements of NATA or Department's documented procedures and include a time frame in which the laboratory is required to demonstrate that the corrective action has been implemented.

1.4.5.3 Assessment findings will generally follow an informal ranking procedure agreed to by the Lead Assessor and the Technical Assessor. Non-conformities and observations should be ranked as follows:

- Observation (O) - May simply be an observation or a recommendation or a reminder or flag for follow-up/review at the next assessment;
- Minor Condition (M) - Description of the action taken or intended must be provided in the time negotiated for response. Supporting evidence of this action will not be required as it will be reviewed at the next assessment. The laboratory is encouraged to include the Minor Condition in their corrective action and internal audit program;
- Condition (C) - Response on action taken is required with supporting evidence of this action. This must be provided in the time that has been negotiated for response.

1.4.6 Assessment Reports

1.4.6.1 A final reviewed report will be provided to the laboratory as soon as possible after the assessment.

1.4.6.2 Laboratories must ensure that they

- take the required corrective actions within the agreed time frame;
- provide NATA or the department with supporting documentation demonstrating that corrective actions have been addressed.

1.4.6.3 NATA must ensure that it

- provides the department with copies of the assessment report noting conditions and laboratory response on corrective actions;
- ensures that corrective actions are carried out by the laboratory in the agreed time frame;
- provide the department, on request, with any supporting documentation provided by laboratories in relation to corrective actions.

1.4.6.4 NATA or the department may extend the time allowed for corrective actions but only under special circumstances and where NATA or the department is satisfied that progress is being made in implementing corrective actions and that the non-conformity will not impact on the reliability of analytical test results.

1.4.7 Follow up Assessment

1.4.7.1 Follow-up on-site assessments may be required to verify the implementation of corrective actions that have arisen as a result of the outcomes of the assessment.

1.4.7.2 The time frame for follow-up assessments will be discussed with the laboratory at the time of the assessment.

1.4.7.3 Follow-up assessments can be undertaken by the department either to verify corrective actions or to confirm NATA's on-going competency.

1.4.7.4 Follow-up assessment reporting will follow the same protocols as outlined in section 1.4.

1.5 Laboratory Methods/Tests

1.5.1 Sampling

Sample collection is generally outside the scope of accreditation of commercial laboratories. However, all approved laboratories must ensure that the condition of samples on arrival at the laboratory is consistent with the requirements of the specific program to which they apply (e.g. ESAM).

1.5.1.1 Where sample collection is part of the laboratory's accreditation/approval the laboratory must ensure that it is carried out according to the technical requirements for the program.

1.5.1.2 Laboratories must ensure that sampling carried out for specific programs is undertaken by trained persons and must keep appropriate training records.

1.5.1.3 Department on-plant personnel must verify or for some programs supervise sampling carried out on-plant.

1.5.2 Approved Methods

An integral part of the Approved Laboratory Program is the use of standard microbiological methods for the analysis of meat and meat products. This is necessary to ensure that equivalence with markets is maintained. Approved methods must be used for testing meat and meat products as part of an export certification program.

1.5.2.1 Approved methods are published on the department web site and can be obtained from the department on request. The list will include an outline and specific checklist for each method.

1.5.2.2 Approved methods must be followed without modification, unless such modifications have been agreed to by the department and are under the laboratory's scope of accreditation/approval.

1.5.2.3 Any approved laboratory may undertake testing using approved methods if their scope of accreditation/approval includes the specific tests to be used and the method is included in their annual assessment by NATA or the department. Laboratories must notify the department of any changes to approved methods used by the laboratory for testing of as part of export certification before implementing the methods.

1.5.2.4 Laboratories may 'contract out' specific aspects of testing, including confirmation of presumptive positive samples, however contracted laboratories must be approved laboratories, must be acknowledged on the report of test results and must be instructed to report results to the department at the same time that they are reported to the contracting laboratory.

1.5.3 Variations to the List of Approved Methods

From time to time the department will revise the approved methods list and add and delete methods as appropriate.

1.5.3.1 New methods can be submitted to the department for consideration as approved methods.

1.5.3.2 Methods accredited by standards organisations or governments will not automatically be added to the approved methods list. The following points will be considered:

- The methods must be suitable for the test under consideration;

- Methods should be validated according to ISO 1614:2003 or by an internationally recognised certifying body such as the Association of Official Agricultural Chemists (AOAC) or the Association Française de Normalisation (AFNOR);
- Methods used as national standards in a country may be considered for approval, with the proviso that such methods can only be used for testing as part of a certification program for export to that country.

1.5.3.3 The department will put new methods forward to importing countries for approval as appropriate to ensure maintenance of markets.

1.5.3.4 The time frame for consideration of new methods is dependent on the above factors and cannot be estimated. Methods cannot be used unless they are approved.

1.6 Proficiency Testing (PT) Program

The primary purpose of proficiency testing is to assess a laboratory's ability to competently perform tests for which the department approval is held. Proficiency testing also provides an additional external audit of a laboratories testing capability and is a useful training tool.

1.6.1 PT Providers

Proficiency testing providers must:

- be accredited to ILAC G13:2000 'Guidelines for the requirements for the Competence of Providers of Proficiency Testing Schemes';
- ensure that PT samples are appropriate for the field of testing;
- maintain a quality assurance program that measures both the homogeneity and stability of the samples;
- provide laboratories with clear instructions on how the test must be performed;
- provide timely reports to all participating laboratories.

1.6.2 Participation in PT Programs

1.6.2.1 Approved laboratories are required to participate in PT programs that relate directly to tests included in their scope.

1.6.2.2 The minimum frequency for participation in PT programs is specified by NATA or the department and is typically 6-monthly.

1.6.2.3 Laboratories approved for multiple tests for a single analyte must have a written procedure for ensuring all test methods are regularly included in the appropriate PT program. In the case of multiple methods the minimum frequency referred to in 1.6.2.2 will be based on the analyte.

1.6.3 Performance

1.6.3.1 Performance criteria will be established in line with the policies of the PT provider. Performance measures will include:

- information on the laboratory's results in relation to the "central" or median result for each sample;
- identification of outliers/false negatives;
- false positive results where applicable;
- accuracy of calculations.

1.6.3.2 The PT provider will inform the laboratory of results it deems to be inadequate i.e. results that fall outside the set tolerance interval established for that round of testing.

1.6.3.3 Laboratories must immediately notify the department or NATA of non-conforming results.

1.6.3.4 The department and NATA will review the laboratory's response and either:

- accept that the problem has been rectified, this will require the laboratory to submit documented evidence to support any corrective action taken;
- take further action as appropriate, which may include but is not limited to:
  - further proficiency testing;
  - an assessment of the laboratory;
  - suspension of all or part of the laboratory's approval/accreditation.

Annex 1:

Approved Laboratory Program Application Form

Australian Government
Department of Agriculture

Purpose: **This form is to be completed when apply for listing as an approved laboratory for microbiological testing carried out as part of department export certification**

LABORATORY DETAILS:

Laboratory Name:			
NATA Accreditation Number: (if applicable)		NATA site Number (if applicable)	
Laboratory Address:			
Laboratory Postal Address: (if different)			
Telephone:		Fax:	
e-mail:			
Name of Person Responsible for Lab Approvals (eg.Lab/QA manager)			
Name(s) of Person Responsible for Lab Testings			
NATA Signatories for Approved Methods: (if applicable)			

Full names of all methods with associated references intended to be used under the Approved Laboratory Program (eg. *E. coli* Petrifilm - AOAC 998.08) :

(Note: list may be attached if not sufficient space)

Type of products to be tested under the scope of department approval, e.g. meat surfaces, meat and products, or other products (please specify):

List of department registered meat establishments using this laboratory for the required tests in the past 12 months:

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Laboratory Declaration

I ……*(insert name and position)* wish to apply for the above named laboratory to be listed as an approved laboratory for the purpose of testing meat and meat products (including environmental samples) using the approved methods listed above. I declare:

- That this laboratory has been accredited by NATA to perform the tests listed above in accordance with NATA requirements (strike out if not appropriate).
- That I am required to participate in proficiency testing programs to demonstrate competency and that the frequency of proficiency testing is determined by NATA or the Department of Agriculture (the department). I will inform the department of any non-conforming test results and provide documentary evidence of any corrective action taken.
- That this laboratory will grant the department access to the laboratory, including access to laboratory methods, proficiency testing results and all records relevant to the laboratory's approval for the purpose of review, including:
  - Where available, any accreditation body (i.e. NATA) records relevant to the laboratory's department approval;
  - Laboratory specific proficiency testing records (relating to testing covered under the scope of the laboratory's department approval) released to the department directly by the proficiency provider.
- That this laboratory will report all test results (including potential, presumptive and confirmed results) to the department at the same time that they are reported to the client (department registered meat establishment) and I have obtained appropriate permission from clients to comply with this requirement.
- That this laboratory will keep a copy of results of assessments, proficiency testing, calibrations and any corrective actions taken for areas of non-compliance.
- That this laboratory will grant department accompanied foreign reviewers access to the laboratory, including access to laboratory records relevant to the laboratory's approval for the purpose of review.
- I understand that failure to meet any of the requirements for approval may result in suspension or withdrawal of department approval.

I have attached:

- Evidence of accreditation by NATA for the approved methods listed above (if applicable).

Signature: ……(*signature*) Date: ……(*Day Month Year*)

Signed: ……(*Insert name and position*)

Witness: ……(*Name and signature*)

Date: ……(*Day Month Year*)

I understand that giving false or misleading information is a serious offence

All information provided to the Department of Agriculture will be held in the strictest confidence and comply with the Information Privacy Principles in the Privacy Act 1988 (Commonwealth)

Responses should be sent to: Residues and Microbiological Policy, Exports Division, Department of Agriculture, GPO Box 858, CANBERRA ACT 2601 or submitted electronically at Micro_Program@agriculture.gov.au