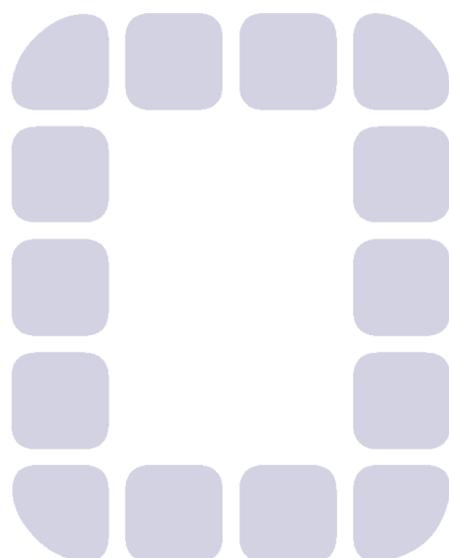
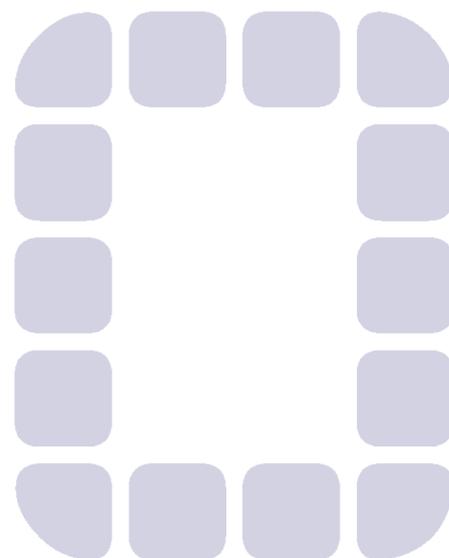
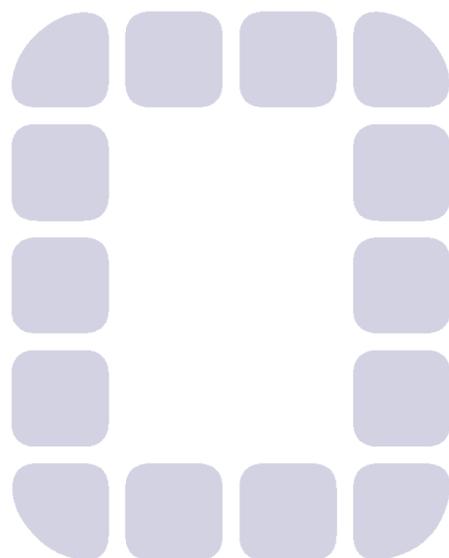
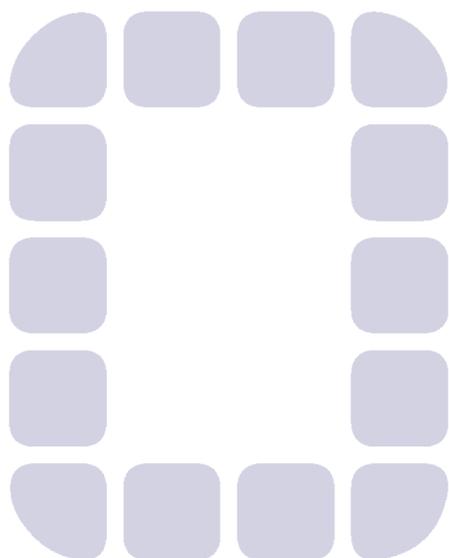


WA Food Regulation: Approval of Laboratories and Analysts

This document details the framework for the approval of laboratories and analysts in accordance with Part 7 of the *Food Act 2008* (the Act). The CEO of the Department of Health may approve laboratories and analysts for the purposes of carrying out analyses under the Act.

Version 1.0: November 2010



Approval of Laboratories and Analysts

1 Glossary of Terms / Definitions

Act	<i>Food Act 2008</i>
CEO	Chief Executive Officer of the Department of Health
Code	<i>Australian New Zealand Food Standards Code</i>
DOH	Department of Health
NATA	National Association of Testing Authorities
Regulations	<i>Food Regulations 2009</i>

2 Objective

To detail the information that the CEO of the Department of Health (DOH) requires in order to determine applications for approval of laboratories and analysts in accordance with Divisions 3 and 4 of Part 7 of the *Food Act 2008* (the Act).

3 Background

The sampling and analysis of food is a critical function undertaken by enforcement agencies in order to ensure that food available for sale in Western Australia is safe, suitable and complies with the requirements of the *Australia New Zealand Food Standards Code* (the Code).

Part 7 of the Act provides the legislative framework for the taking and analysis of food samples. This includes a framework for the approval of laboratories (Division 3) and analysts (Division 4). For the purposes of legal proceedings under the Act, it is essential that the analysis of food samples is carried out by an analyst or laboratory that is approved by the CEO of the DOH.

NATA is recognised by the Commonwealth Government as the sole national accreditation body for assessing and recognising competent laboratory practice. The approval of laboratories and analysts in accordance with the Act should align with the approval or accreditation received through NATA whenever possible.

4 Scope

This guideline applies to laboratories and analysts that undertake assessment of legal samples submitted by enforcement agencies for the purposes of Part 7 of the Act. An analyst or laboratory seeking approval may specialise in chemical, microbiological and/or physical analysis of food.

5 Application Information Required by the CEO

5.1 NATA approval and accreditation

Subject to 5.1.1 and 5.1.2, the CEO requires that laboratories and analysts seek NATA accreditation to be approved to conduct analyses in accordance with the Act. The following information needs to be provided to the DOH to demonstrate NATA accreditation:

- **Division 3 applications (approval of laboratories):**
 - NATA Laboratory Accreditation (AS ISO/IEC 17025-2005) for the relevant tests as specified in the application.
- **Division 4 applications (approval of analysts):**
 - NATA signatory approval.

There may be some instances when laboratories may not be NATA accredited for the particular analysis required, including:

- 5.1.1 Laboratories outside of Australia that are accredited for the specific analysis by one of NATA's Mutual Recognition Agreement partners. These laboratories may be approved by the CEO.
- 5.1.2 Analyses that have not been accredited by NATA or a Mutual Recognition Agreement partner. In these instances the laboratory will need to apply to the CEO for an extension to their scope for that particular analysis. When applying for an extension of scope, the laboratory will need to submit evidence to substantiate that the test is effective and reliable for the purposes of the Act. The laboratory will need to perform the analysis using the best available methodology, stating the limitations (if any) of the methodology on the report and be able to support the results in a court of law.

5.2 Other supporting documentation

Other documentation may need to be submitted, including:

- 5.2.1 For analysts – details of the laboratory in which analyses will be performed.
- 5.2.2 A current copy of any approvals that have been issued by other State

jurisdictions in accordance with their respective Food legislation.

5.2.3 A signed declaration stating:

- a. Agreement to only perform tests for the purposes of the Act that the person in charge of the laboratory or the analyst has the confidence to support any court proceeding; and
- b. Agreement that all applicable test reports will be issued on a certificate that complies with the requirements of Part 7 of the Act.

6 Conditions of Approval

The Act allows the CEO to approve applications from laboratories and analysts with or without conditions. Applications may be approved subject to any of the following conditions:

- 6.1 Approval is conditional upon the applicant retaining NATA accreditation for the specified analyses.
- 6.2 For laboratories, approval is to conduct analyses within its NATA Scope of Accreditation, as current at the time of application.
- 6.3 The CEO of the DOH is to be immediately notified of any changes to the information submitted on application, or any changes to the laboratory or analyst's NATA accreditation or signatory approval.
- 6.4 All results are to be issued on the Certificate of Analysis approved under Section 81 of the Act.
- 6.5 Samples submitted for analysis in accordance with Part 7 of the Act are to be processed in a timely manner.
- 6.6 Approval is subject to ongoing compliance with the Act and the *Department of Health Approval of Laboratories and Analysts Policy*. Approval may be suspended or cancelled on any grounds detailed within section 85 of the Act or within this Policy.
- 6.7 The applicant may apply to the State Administrative Tribunal for review of a decision of the CEO within 28 days after service of approval.
- 6.8 Any other condition considered necessary by the CEO.

7 Cancellation or Suspension of Approvals

Approval of laboratories or analysts will be cancelled or suspended by the CEO for any of the reasons outlined in Sections 85 and 91 of the Act.

Additional reasons that the CEO may suspend or cancel approvals include but are not limited to:

- 7.1 The business or their employees being convicted of fraudulent and/or criminal activities.
- 7.2 A laboratory's NATA accreditation being suspended or terminated in full or for the relevant analyses.
- 7.3 An analyst's NATA signatory approval being revoked for the relevant analyses.

8 Review

This policy will be reviewed on an annual basis and approved laboratories and analysts will be advised of any changes.

9 Useful Resources and Websites

- Department of Health WA <http://www.public.health.wa.gov.au>
- Food Standards Australia New Zealand <http://www.foodstandards.gov.au>
- Food Regulation Secretariat <http://www.health.gov.au>
- NATA <http://www.nata.asn.au>

10 Related Documents

- Certificate of Analysis – Approved Form: Section 81 of the *Food Act 2008*
- Application for Approval of a Laboratory
- Application for Approval of an Analyst

Contact the Food Unit via:

Email foodunit@health.wa.gov.au

Phone +61 89388 4903

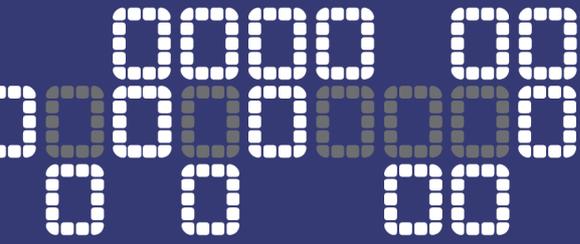
Fax +61 89382 8119

Any feedback or concerns please utilise the “Food Unit Query” form which can be downloaded from our website:

http://www.public.health.wa.gov.au/2/786/3/food_informatio.pm

Note: The information contained in this document covers the food legislation requirements for Western Australia. It is current on the date of publication but may change without notice. The Department of Health is not liable for any costs arising from or associated with decisions based on information here and users should obtain expert advice to satisfy all requirements of the relevant food legislation applicable.

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Government of **Western Australia**
Department of **Health**