

Executive Summary

The U.S. Food and Drug Administration (U.S. FDA or the Agency) uses the Systems Recognition process to evaluate and compare foreign countries' domestic food safety systems and assess the effectiveness of their food safety controls. Australia meets the criteria for Systems Recognition as it has, over time, demonstrated that it takes a proactive, preventive approach to food safety management and works to minimize adverse events when they occur. Once Systems Recognition is implemented through a mutual agreement, both the U.S. FDA and the government of Australia will be able to more appropriately target inspectional resources to higher risk country-commodity combinations and leverage resources to address common food safety concerns.

The U.S. FDA's review of Australia's food safety program started in 2014 and consisted of several steps. First, the U.S. FDA reviewed the country's history of trade with the U.S. and related compliance data. Second, the U.S. FDA used its International Comparability Assessment Tool (ICAT) to examine key elements of Australia's food safety system. Finally, once the ICAT document review was complete, the U.S. FDA conducted an in-country audit to verify that the implementation of the food safety program was consistent with the information submitted for review.

This report describes the review of the Australian food safety system and supports a finding of comparability and a recommendation that we recognize the Australian food safety system as providing at least the same level of public health protection as the U.S. FDA's system.

Contents

Executive Summary.....	1
Introduction	3
International Comparability Assessment Tool.....	3
Overview of Australia Review Process.....	4
Using the ICAT to Evaluate Countries’ Regulatory Programs and Approaches	4
In-Country Assessment	6
ICAT Audit Team	7
Standard 1. Regulatory Foundation.....	7
Standard 2. Training.....	8
Standard 3. Inspection Program	9
Standard 5. Food-related Illness and Outbreaks	10
Standard 6. Compliance and Enforcement	10
Standard 8. Program Resources.....	11
Field Audit Teams.....	11
Evaluation Criteria.....	11
Standard 4. Program Assessment and Inspection Audit Program.....	12
Laboratory Audit Team	18
Standard 10. Laboratory Support	18
Conclusions	25
The System Recognition Arrangement and the Work that Follows	26
Glossary of Acronyms	27
Appendix 1. In-Country ICAT Review Personnel.	29
Appendix 2. Biographies of the FDA personnel that participated on the Australia ICAT review	30
Appendix 3. Timetable of the ICAT Review Process.	34
Appendix 4. List of documents reviewed by the Laboratory Team during the Australia ICAT In-Country Review.....	35

Introduction

Systems Recognition provides a tool for the U.S. FDA to identify and partner with foreign governments based on mutual recognition of effective food safety systems. Recognition will be applied to countries that have demonstrated over time that they have implemented strong domestic preventive controls and that they are proactive in managing food safety. These countries can also be relied on to respond when adverse events occur. Systems Recognition uses the International Comparability Assessment Tool ([ICAT](#)) to compare food safety systems and guide FDA in its evaluation as to whether those systems contain the essential regulatory elements and levels of oversight needed to ensure effective food safety and public health outcomes.

Through the ICAT, a country seeking Systems Recognition with the U.S. FDA has the opportunity to systematically evaluate whether its food safety system is science-based; comparable to that of the United States; has ongoing processes to ensure the sustainability of preventive controls; provides competent oversight; and addresses public health concerns. The reciprocal recognition of effective food safety systems can provide benefits to consumers and regulators in both countries.

International Comparability Assessment Tool

The ICAT was created as an objective framework for assessing the robustness of trading partners' overall food safety systems and determining whether their systems are comparable to the U.S. system. The ICAT has its foundation in the [Manufactured Food Regulatory Program Standard](#) (MFRPS), an assessment tool used for evaluating states within the U.S. The U.S. FDA modified the MFRPS to create the ICAT to make it more suitable to international assessments. The ICAT contains a narrative that describes the purpose and requirements of each standard as well as the program elements necessary to satisfy the requirements. Each of the ten ICAT standards is comprised of one or more elements that are necessary for a country to satisfy the standard. The standards include: Regulatory Foundation; Training Program; Inspection Program; Program Assessment/Inspection Audit Program; Food-related Illness and Outbreaks; Compliance and Enforcement; Industry and Community Relations; Program Resources; International Communication and Harmonization; and Laboratory Support. Review of the

system of regulatory controls is intended to provide confidence that the national food safety system contains the elements that are comparable to the U.S. FDA.

Overview of Australia Review Process

On the spring of 2014, the Australian Department of Agriculture (ADA) requested that the U.S. FDA consider the country for the Systems Recognition Pilot Program. The U.S. FDA conducted an internal pre-screening evaluation, which included reviewing the volume of food products Australia exports to the U.S., its food safety program, and the compliance history of those products. The evaluation included information on the number of products subject to refusals of admission or import alerts from U.S. FDA's Office of Regulatory Affairs (ORA) and Office of Enforcement and Import Operations (OEIO). The U.S. FDA also reviewed information from the U.S. Department of Agriculture's Global Agricultural Information Network and other available documents. At the conclusion of the pre-screening process, the evaluators recommended that Australia's food safety program would be a viable candidate to proceed with a Systems Recognition assessment. As part of the process, the U.S. FDA compiled a list of Australian firms registered with the Agency that ship food to the U.S., which totaled 57 firms from four States and one Territory (Figure 1).

In April 2014, Australia was invited to submit the ICAT to provide the U.S. FDA with information to compare the two countries' food safety systems.

Using the ICAT to Evaluate Countries' Regulatory Programs and Approaches

Systems Recognition requires an inter-disciplinary team of subject matter experts (the ICAT Submission Review Team) to conduct the comparability assessment of the country requesting recognition. The review team for the Australian ICAT submission included experts from CFSAN and ORA chosen for their subject matter expertise in relevant areas; their knowledge of the U.S. FDA regulations, policy, and guidance; and their understanding of Systems Recognition and the ICAT.

Australia Import Firms

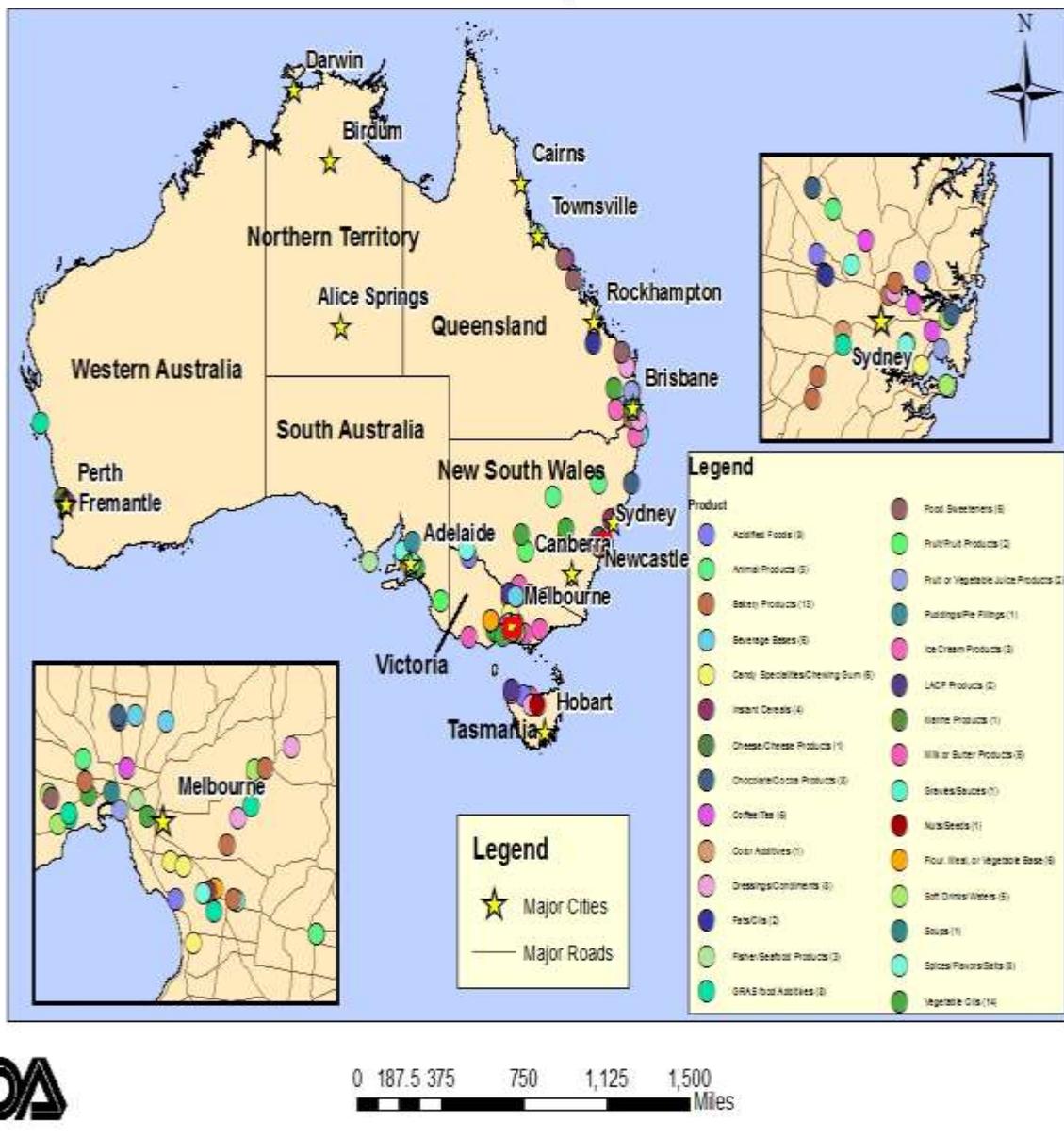


Figure 1. Location of firms registered with the U.S. FDA by product, as of March 2014.

Over an 8-week period, the team analyzed the information received from Australia and compared it to the U.S. FDA system of food safety regulation to assess the comparability of the programs and identify potential gaps and lapses in information. Throughout the ICAT submission review, the ADA and the U.S. FDA maintained an open line of communication to facilitate understanding of the materials received.

The U.S. FDA team members also independently researched and located information on the Australian program from government and public sources. For example, the team researched and accessed several official Australia government websites to obtain documents that clarified the information provided or addressed gaps in the submission, in order to gain a better understanding of Australia's programs and practices. The U.S. FDA's team of experts provided oversight and peer review of decisions as they were being made, utilizing their knowledge of the U.S. system. The review by the expert team ensured that the information provided and the observations made supported a recommendation that Australia's system provided at least the same level of protection as the U.S. system.

In-Country Assessment

Once the ICAT review was completed, the U.S. FDA review team concluded that the documentary evidence supported an in-country assessment. The purpose of an in-country audit is to verify that the programs described in the ICAT submission are effectively implemented and to examine any areas identified during the ICAT review warranting further investigation. Members of the U.S. FDA in-country audit team were selected from the ICAT Submission Review Team because they were knowledgeable and well prepared to assess the implementation of the Australian program.

In September 2014, four multi-disciplinary teams conducted the Australia International Comparability Assessment Tool (ICAT) in-country review (Appendix 1). These teams were composed of nine FDA subject matter experts (Appendix 2) from the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA). Planning for the in-country assessment was based on the findings from the ICAT review (Appendix 3), and the

terms of the visit were discussed with ADA representatives. One team (three members) verified the implementation of the comparable ICAT elements as submitted by ADA; two field audit teams (three members in one team and two members on the other team) verified implementation of the regulatory programs by accompanying Australian personnel on inspections and audits at processing facilities; and one team (one member) audited Australia's laboratories and their capacity to perform accurate and robust food/environmental testing and provide reliable results.

ADA supplied the list of processing firms that FDA visited based on FDA's interest in visiting establishments that produce foods that would be covered by a Systems Recognition arrangement. The firms were located at the two states, New South Wales and Victoria, which produce the most food exported to the U.S. Also, one member of the ICAT team visited locations in South Australia upon request of the Australian government, and the member of the laboratory team included a visit to Queensland to a government laboratory is located in Brisbane.

ICAT Audit Team

The ICAT Team visited the Capital Territory (Canberra) and three states (New South Wales, Victoria, and South Australia) while doing the ICAT In-Country review. Visits included federal, state and local offices, as well as one of the universities described by the competent authorities as a national leader on training food safety specialists (Swinburne University of Technology in Melbourne, Victoria). The programs and documentation review verified the implementation of Australia's regulations on food safety (Standard 1); the training of their food safety inspectors/auditors (Standard 2); the implementation and verification of their inspection, compliance, and enforcement programs (Standards 3 and 6); the tools the competent authorities use to identify, prevent, and/or reduce food-related illness and outbreaks (Standard 5); and funding to support all aforementioned programs (Standard 8).

Standard 1. Regulatory Foundation

This standard was reviewed by all members of the ICAT review workgroup before visiting Australia by verifying that the submitted information on Australia's laws and regulations were comparable to the U.S. regulations. This standard is the most detailed. During the in-country

review, regulatory officials were queried to verify their awareness of the ADA's regulatory authority.

The regulatory foundation, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Standard 2. Training

The team reviewed the overall training program for inspectors, which are known as auditors in Australia. Food auditors perform both audits and inspections.¹ Australia has established guidelines for auditor training through their National Regulatory Food Safety Auditor Framework. This framework describes the minimum requirements for overall auditor competencies; technical and educational qualifications; specialized auditing competencies; witness inspections and audits (where a senior auditor observes the conduct of an inspection or an audit); legislative understanding and assessment; and code of conduct. The requirements are implemented by the national and state governments in Australia; and by local governments when inspection responsibility has been delegated to the local level by the state. This training program is mandated for government employees (known as authorized officers) and to private third party auditors that conduct regulatory inspections and audits under Australia's food safety system.

The team reviewed the implementation of training at the ADA, for national level, and at the New South Wales Food Authority (NSWFA), the Victoria Department of Health (VDH), and Dairy Food Safety Victoria (DFSV). The team reviewed training records of employees from all these organizations. At the ADA, the team also observed their Learning Management System (LMS) that tracks employee training requirements. At NSWFA the team also reviewed training records for employees and third party auditors.

The team visited Swinburne University of Technology in Melbourne and reviewed the curriculum for their Bachelor of Health Science (Public and Environmental Health) degree program. This program prepares graduates to work as food safety auditors in Australia and

¹ Audits involve document reviews of facility operations. Inspections are in-depth food safety reviews of facility operations, including both a document review and on-site assessments.

fulfills the educational requirements for auditors under the National Regulatory Food Safety Auditor Framework.

The training program, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Standard 3. Inspection Program

The team reviewed the overall audit/inspection program as implemented by ADA, NSWFA, VDH, DFSV, and the City of Melbourne Council (local level). In Australia, the term “audit” is also used to describe what FDA would typically call an inspection. ADA has regulatory oversight for all food imported into Australia and has responsibility for facilities that export food products from Australia. The states oversee facilities within their jurisdiction that are not exporting products from Australia, and the states also oversee some export facilities for ADA under Memoranda of Understanding (MOUs). In Victoria, the local councils can perform regulatory audits/inspections for VDH under MOUs. The national, state, and local governments in Australia have detailed arrangements between each other to outline which government entity will oversee which facilities. These arrangements prevent duplication of regulatory effort in Australia. ADA and the states also share information on a regular basis and hold periodic meetings through the “Food Export Regulators Steering Committee” to maintain consistency in the overall approach to food safety in Australia.

The national, state, and local governments demonstrated their IT systems for maintaining records of audit/inspection history; reports; facility profiles; and licensing/registration information. The team reviewed the overall operation of the IT systems as well as the information contained in the systems for selected facilities, including facility audit/inspection reports. Audit/inspection frequencies are based on risk and can vary by commodity.

Audits/inspections are conducted every 6 months at high risk manufacturers, but every 24 months at a dairy farm which is considered lower risk. All IT systems reviewed have notifications for when a facility is due for audit/inspection. These notifications allow for the jurisdictions to conduct proper planning for their audit/inspection responsibilities.

The inspection program and the work planning process, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Standard 5. Food-related Illness and Outbreaks

The team reviewed the foodborne illness/outbreak response activities at the national and state levels in Australia. National foodborne outbreak response is coordinated by Food Safety Australia New Zealand (FSANZ) as part of the National Food Safety Network. Foodborne outbreaks within a state or territory are coordinated internally. Regardless of where the response is coordinated, all actions taken to respond to the outbreak are performed by the state or territory under their own legislation.

At NSWFA and VDH, the government officials presented several case-studies of foodborne outbreaks which demonstrated all aspects of the process, including identification, complaint handling, investigation, and recall. States and territories have mandatory recall authority. The case-studies also showed how the various levels of government work together to coordinate activities.

FSANZ also coordinates industry recalls and works with the recalling firms to help manage the process. FSANZ disseminates information throughout Australia and foreign governments when the recalled product has been exported. Since FSANZ does not have any enforcement powers, the states take any necessary actions and determine the ultimate disposition of recalled goods. The illness/outbreak activities, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Standard 6. Compliance and Enforcement

The ICAT audit team reviewed the enforcement and compliance activities at ADA, NSWFA, VDH, DFSV, and the City of Melbourne Council. All government levels and jurisdictions were observed to have sufficient enforcement authorities under the applicable national or state laws and regulations. Based upon the review, they were utilizing their authorities in an appropriate manner to address food safety violations within their purview. By petition of the ADA, the team also reviewed some examples of regulatory actions taken against firms and products, and one team member visited the quarantine station at Yamba, South Australia, located between the states of Victoria and South Australia. Although not an FDA regulated activity, the quarantine station was located close to the citrus firms visited, and the ADA officials recommended a courtesy visit of the station. This quarantine station is one measure taken by

the Government of South Australia to keep the state's fresh fruit free of the Mediterranean fruit fly.

The implementation of the compliance and enforcement actions, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Standard 8. Program Resources

National and state governments in Australia have the ability to charge user fees from industry to recover costs associated with their regulatory programs. While the user fees are not sufficient to cover the full expense of the agencies, they can comprise approximately 50% of the annual operating budget for the agency. The remaining operating funds are provided by the legislature as appropriated funds.

The program resource actions, supported by a steady reliable income base, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

Field Audit Teams

Evaluation Criteria

In order to ensure that evaluations covered uniform and common points, both teams used the same format for conducting and reporting their evaluations. The criteria were designed to emphasize a systems review approach, while covering key safety concepts, applicable across commodities, including sanitation, inspection performance, communication skills, and documentation of findings.

FDA selected performance criteria based on legislation and guidance that are the foundation for Australia's food safety oversight. The competent authorities were evaluated against the Act, Codes and Guidelines referenced below. The ADA implements MOUs with each state authority for prescribed goods (goods that are regulated by specific export control orders that set conditions that must be met in order to export). Some state authorities choose to further delegate inspectional authorities to local city councils. The federal, state, and local authorities were selected to represent a broad cross-section of agencies responsible for the oversight and implementation of food safety laws and standards in Australia. Food Standards 3.2.1, 3.2.2, and 3.2.3 (Food Safety Standards, Australia New Zealand Food Standard Code) were considered the

baseline used to perform inspections and audits. The National Regulatory Food Safety Auditor Guideline, Ver. 1.2, was used to evaluate auditor performance against established protocols. ADA facilitated the selection of manufacturers and auditees with State and local governments based on FDA's request. FDA requested that facilities be limited to manufacturers, re-packers, and warehouses to remain consistent with FDA's oversight of industry. Many of the visited facilities manufacture products considered high risk commodities by FDA.

For the most part, all food facilities visited were inspected under two primary regulatory requirements with other commodity or export specific requirements added as necessary. These included:

- Food Standards Australia New Zealand Act 1991
- Australia New Zealand Food Standards Code (Australia only)
- Victoria Food Act 1984 New South Wales Food Act 2003 (No 43)
- Export Control Act 1982
- Export Control (Prescribed Goods – General) Orders 2005
- Export Control (Milk and Milk Products; Pasteurization) Orders 2005
- Dairy Act 2000
- Victoria Seafood Safety Act 2003

Standard 4. Program Assessment and Inspection Audit Program

The purpose of the on-site observation of Australian inspection staff was to assess their ability to implement their food inspection programs and protocols as outlined in the ICAT. Through interview and observation, the teams' goal was to determine if Australia's auditors: had appropriate training and technical knowledge; were able to recognize and evaluate deficiencies based on Australian requirements; and assess the abilities of the inspector to implement Australia's Food Safety Act and Standards and procedures during in-plant visits. FDA observed Australian auditors in two States (New South Wales and Victoria) perform inspections and audits of a cross-section of food manufacturers under various commodity-specific regulatory programs (Table 1). ADA supplied the list of processing firms based on FDA's interest in visiting establishments that produce foods that would be covered by a Systems Recognition arrangement. The firms were located in the two states that produce the most food for export

to the U.S., New South Wales and Victoria. The on-site observations were not intended to evaluate whether the States’ inspection/audit program elements met FDA's requirements, but rather how they implemented their programs which had been reviewed and deemed comparable to FDA. However, it did evaluate the auditors’ abilities to recognize food safety and sanitation concerns. Through the completion of site visits, the field audit teams were able to verify implementation of the Australian inspection/audit system outlined in the ICAT.

Table 1. Activities observed by the FDA audit teams to assess the ability of the Australian competent authorities to implement their food inspection programs and protocols.

Team	Activity Observed	Location	Firm	Industry
I	Audit	New South Wales	Taylor Farms	RTE vegetables
I	Audit	Victoria	Bega Cheese Limited	Cheese
I	Inspection	New South Wales	Arnott’s Biscuits Ltd	Bakery products
I	Inspection	New South Wales	Beak & Johnston Pty Ltd	RTE meals and soups
I	Inspection	New South Wales	The Commissary Food Company Pty Ltd	RTE meals and soups
I	Inspection	Victoria	Natural Confectionary Company	Candy
I	Inspection	Victoria	Boundary Bend Olive Growers	Olive Oil
I	Inspection	Victoria	Coca Cola Amitil	Beverages
II	Audit	New South Wales	General Mills Australia Pty Ltd	LACF
II	Audit	New South Wales	Primo Moraitis Fresh Pty Ltd	Fresh cut salads
II	Audit	Victoria	Jade Tiger Abalone	Fish
II	Audit	Victoria	Southern United Seafood	Seafood
II	Inspection	New South Wales	George Weston Foods Pty Ltd (Speedibake)	Bakery products
II	Inspection	Victoria	Allseps	Candy
II	Inspection	Victoria	Schowb’s	Bakery Products
*	Visit	Victoria	Mildura Fruit Company	Citrus
*	Visit	South Australia	AgriExchange/Vitor/Costa	Citrus

*These firms were only visited and no inspection/audit was performed. Only one member of the ICAT audit team visited these locations.

During the interaction with the different government levels, the FDA audit teams observed differences in the evaluation of “risk” and the identification of critical control points between the Australian food safety system and FDA’s approach to food safety. The Australian system of risk assessment is not controlled by the safety hazard risk associated with the food, but by the risk to the consumer and the percentage of distribution to high risk consumers. “Risk” is unique to each facility dependent upon the controls within that facility and the distribution of the

products. For example, manufacturers of food distributed to “vulnerable persons” (i.e. hospitals, day care for children, nursing homes, and assisted living facilities) are classified as the highest risk facilities (defined as Class 1), if these facilities receive the highest percentage of sales at the manufacturing facility. If the percentage is not the highest, then the facility is classified as a Class 2 or lower risk. Unlike Australia’s, FDA’s identification of “risk” is based on the severity of the food safety hazard associated with a particular food and the likelihood of its occurrence without qualifying the risk based on the end consumer.

Another distinction noted is that there are no legislative requirements similar to 21 CFR 113 (Low Acid Canned Foods (LACF)) or 114 (Acidified Foods). The parameters for the thermal process and containers are incorporated into the food safety plan that is reviewed by the regulatory authority prior to initiating manufacturing operations. Government staff responsible for evaluating and approving those programs must complete a one week training to become a “process authority”. Staff who operate the equipment within a processing facility or oversee its operation must also complete this training.

New South Wales

The audit teams assessed the implementation of New South Wales (NSW) inspection/audit program based on Australia’s Food Safety Act, Food Safety Standards (Food Standards Code Australia New Zealand – Australia only), and NSW Field Staff Operations Manual.

Inspection/audit frequency for manufacturers and wholesalers are dependent on the food facility’s classification which is based on risk. Highest-risk facilities are inspected every six months and lower-risk facilities are inspected annually. All food facilities can be inspected at any time based on complaints. Deficiencies or Corrective Action Requests (CARs) are issued to the facility for violations that are identified during the inspection/audit. The inspectors/auditors use a priority rating system for CARs of minor, major and critical, and each is assigned a timeframe for correction. The food facility risk rating is used together with the priority rating system to set the inspection/audit frequency. In general, follow-ups on previous CARs are conducted during scheduled visits, unless a CAR warrants a more expeditious follow-up.

While Systems Recognition examines the domestic regulatory program, it should be noted that for the U.S. FDA purposes, only certain facilities fall into the category of products exported to the U.S. All export facilities must be licensed following an audit by the NSW Food Authority. The audit is performed to determine if the premise complies with all legislative requirements; is fully operational; and has a fully implemented food safety program. All the information from inspections and audits is entered into a common database developed by NSW to track findings and observations and to follow up on the CARs. NSW inspectors/auditors use a hand held device during the inspection/audit to simultaneously record data and to collect evidence (photos) for the CARs. At the end of the inspection/audit, results of the findings are reviewed with the facility management and a copy of the report is provided prior to NSW leaving their facility. This electronic system appears to assure that all aspects of the inspection/audit protocols are covered within the timeframe specified by NSW programs and policies.

Victoria

Under Standard 3.2.1, food safety plans, which include scheduled processes (i.e., LACF) are not mandatory in all situations. Food safety plans (Standard 3.2.1) are required for Class 1 and Class 2 firms, and for “prescribed goods” where they are legislatively mandated. These include seafood, meat, dairy, eggs, and plant products. Victoria, however, has mandated that food safety plans be implemented in all situations when food safety hazards are identified. Food safety plans must be submitted to the competent authority for review. Once the submitted plans are found to be adequate, the facility gets registered for operation. The implementation and documentation associated with food safety plans are the focus of the inspections or audits by the regulatory authorities. During the audit or inspection, the inspector or auditor compares the food safety plan against the current operation of the facility and the records maintained by the facility that demonstrate the implementation of the program. The auditor or inspector is not responsible for determining the adequacy of the food safety plan; this is done during the initial approval and registration process by the regulatory authority. Inspectors and auditors determine if the facility’s operations have changed from the food safety plan and if the appropriate amendments have been filed with the competent authority and documented in the

plan. Failure of the facility to fully implement the food safety plan as written will result in the identification of a non-conformity by the inspector or auditor.

Victoria's councils (local governments) have programs that include inspection frequency; pre-inspection; inspection and post inspection procedures; reporting requirements; and an enforcement strategy. They also use a CAR protocol to identify deficiencies and timelines for corrective actions. These systems, despite their differences, appear to assure that all aspects of the inspection protocols are covered within the timeframe specified in their particular programs and policy documents.

Field Audit Team I

Field Audit Team I's verification activities included meetings at the local offices in both NSW and Victoria to review aspects of the particular commodity to be inspected, review inspector training records, and to discuss how the inspector prepared for the inspection. The team observed State inspectors performing inspections and/or audits in several processing facilities. The types of products manufactured in the facilities included fresh mixed greens and vegetables, soup, confectionery/candy, bakery crackers and biscuits/cookies, bottled beverages and water, olive oil and processed cheese products. While in the facilities, the team observed the inspector or auditor engaged in discussions at multiple points during a site visit, including on the scope of the inspection, and ongoing processing operations. The team also observed the interaction of the inspectors and auditors with key employees, how they reviewed records and how they closed out with the facility (with the exception of one facility where the audit was not complete prior to the team's departure).

Field Audit Team I assessed three city or area councils implementing Australia's Food Safety Acts and Food Safety Standards (Food Standards Code Australia New Zealand – Australia only), but their procedures for assessing food facilities to baseline regulatory requirements differ (for example, each council develops inspection procedures and reporting formats that fit their particular location and types of food facilities). However, the team's focus was whether the overarching Food Safety Standards are applied to assess the facility. Field Audit Team I also assessed an audit by an "approved food safety auditor". These auditors are used to ensure the requirements of Australia's export certificate are met. During the assessment, Field Audit Team

I found that the audit also met the criteria outlined in both the Food Safety Act and Food Safety Standards, adding to those specific requirements under the Export Control Program.

Conclusion

In all instances, auditors in NSW and Victoria observed during these on-site audits followed the appropriate inspection protocols, performed their duties in a competent manner, were thorough in the preparation and execution of their work, and effectively communicated with plant personnel during the course of the inspection.

Identification and classification of deficiencies by NSW Food Authority and Victoria Council inspectors/auditors were consistent with FDA observations, indicating that when implemented, Australia's inspection program is likely to result in outcomes comparable to FDA inspection results.

Field Audit Team II

Competent authorities evaluated included ADA, NSWFA, and three city councils (Melbourne, Greater Dandenong, and Glen Eira) in Victoria (Table 1). These regulatory agencies encompass the national, state, and local food safety enforcement authorities. Processes observed included tortilla wraps and taco shells, ready-to-eat hot filled salsa, ready-to-eat bread products, cookie products, muesli (cereal) bars, raw aquaculture abalone, LACF, ready-to-eat pasteurized hot filled soups, ready-to-eat fresh cut salads and wet salads (e.g. potato salad).

Field Audit Team II observed an inspection by state authorities of a firm that manufactured both LACF and a hot-filled acidified food. The firm was processing the acidified food, but not the LACF during the inspection. The state auditor briefly observed the processing of acidified food, and reviewed some components of the food safety plans for the acidified food and the LACF, including thermal process validation.

Field Audit Team II also observed an audit by an ADA auditor of a low-acid canned seafood processor. The firm was not processing canned seafood during the audit. The ADA auditor reviewed the food safety plan and associated records for the canned seafood product.

Conclusion

Field Audit Team II observed that the auditors followed the criteria defined for inspections and audits. The application of the standards and guidelines was uniform among agencies. They correctly identified deficiencies within the context of their laws and guidance. They displayed appropriate ethical behavior and professionalism during the audits and in some cases redirected the audit appropriately when conditions required. The auditors observed displayed an overall understanding of the laws and requirements necessary to implement their programs. The team did not identify any major non-conformities between the auditors' performance against their requirements, and FDA's identification of deficiencies.

General Conclusion

The overall implementation of the field inspection/audit protocols was consistent among the various auditors that were observed, and the execution of Australia's food safety programs, as observed by the U.S. FDA team, can be recommended as comparable to that of FDA.

Laboratory Audit Team

Standard 10. Laboratory Support

The Laboratory Audit Team visited the Capital Territory (Canberra) and three states (NSW, Victoria, and Queensland) while doing the ICAT In-Country Review. Visits included federal and state offices as well as federal and private laboratories to verify the implementation of Australia's regulations on food safety. A list of all reviewed documentation can be found in Appendix 4.

National Association of Testing Laboratories

The Laboratory Audit Team visited the ADA main headquarters in Canberra, and met with the department in charge of laboratory accreditation. ADA requires that all laboratories performing food safety analytical work maintain accreditation through the National Association of Testing Authorities (NATA). NATA is a signatory of both the International Laboratory Accreditation Cooperation (ILAC) and the Asia-Pacific Laboratory Accreditation Co-operation (APLAC). NATA is in compliance with ISO/IEC 17011 and is audited every four years. NATA has signed a Memorandum of Understanding (MOU) with ADA to monitor each laboratory's Quality

Management System, and also has an MOU with specific states to include the monitoring of compliance with regulatory standards.

NATA performs accreditation audits for compliance with ISO/IEC 17025 at a minimum of 18 months, which can be either a Surveillance Audit or Reassessment Audit. The Surveillance audit is completed by the Lead Auditor (NATA staff) and focuses on the management system elements, while the Reassessment Audit is completed by the Lead Auditor and Technical Assessors (voluntary experts in specific fields), and focuses on the technical elements, with limited focus on the management system elements. The Reassessment Audit is a duplication of the Initial Assessment and requires all major non-conformances to be closed out with evidence of corrective actions within four weeks. Any changes in the status of accreditation by NATA are disseminated to ADA for consideration.

The Surveillance Audit includes review of Quality Manual; Maintenance Schedules; and Management System, and is usually performed as a vertical audit where samples are traced through the entire system to ensure adherence. The Reassessment Audit focuses on the details within section 5 of the ISO 17025 Standard for each method within the lab's scope. The competency is traced through the lab's system to ensure the technical aspects are compliant with both the ISO 17025 Standard and the laboratory's Quality Management System.

The Australian audit team conducting the laboratory audits includes a team lead, which is a member of the NATA staff, and technical assessors, which are volunteers accepted based on specific expertise. The training program for the team lead includes six months of on the job training, internal audit training course, and refresher training for any leave of absences. The approval process for the technical assessors includes submission of their curriculum vitae showing educational expertise within specific scientific areas, which is reviewed by the NATA Advisory Committee. Upon acceptance, the technical assessors are required to participate in various audits as observers with increasing independent audit responsibilities over time along with the internal auditor training course provided by NATA. Following each audit, the team lead is required to complete the technical assessor evaluation identifying and recording any issues for NATA Sector Manager review and follow-up. The audit team is evaluated every two years through internal audit by NATA Sector Manager. The procedure for new applicants

applying for accreditation includes an initial advisory meeting with the laboratory to explain the requirements; assessment conducted by the audit team with all non-conformances addressed with supporting evidence submitted; review by the audit team; approval by the Accreditation Advisory Committee; and final approval by NATA Management Staff. The newly accredited laboratory is added to the NATA maintained website along with the scope of accreditation. The NATA website is updated following each laboratory audit (if necessary) and will include any changes to the scope or the suspensions of the laboratories. Any suspensions of laboratories are sent to ADA for consideration and regulatory decisions.

ADA allows the individual laboratories to determine the methodology to be used for food safety testing; however, NATA and ISO 17025 have a requirement that all methods must show proper validation. NATA has provided guidelines (Technical Notes) on their website for all method validation requirements. Individual laboratory method validations are reviewed by the technical assessor as part of the audit to determine acceptability. Proficiency testing is another requirement of each laboratory to demonstrate competency; therefore, NATA includes a minimum requirement of all methods within scope to participate in proficiency testing within a two year timeframe.

The National Residue Survey

The National Residue Survey (NRS) is an industry funded program and it is the operational unit of the ADA that monitors the residues of pesticides and veterinary drugs in grains and citrus. NRS is responsible for the program development; verification of good agriculture practices; sample collection and shipments; and recommendations to the state authorities for trace-back investigations. NRS maintains a network of eight contract labs with various scopes of testing and is ISO 9001 Certified. The contract laboratories share an electronic information management system with NRS allowing all interpretation of the analytical results to be completed by NRS, in addition to automatic email notifications to the appropriate regulatory officers of violative levels. As a proficiency provider, NRS maintains ISO 17043 accreditation. Laboratory performance is monitored by NRS through a variety of mechanisms including NRS proficiency testing, blind samples, Check Sample Program of Intra-lab Comparisons, and On-site Audits. All NRS Contract Laboratories are required to participate in proficiency testing offered

by NRS, which include every six months for grains and every three months for horticulture products (citrus). Training is provided by NRS to authorized officers on-site to address any non-conformances and provide yearly refresher training. Annual, quarterly, and monthly reports of findings are provided to the state authorities by NRS for review.

Grain Proficiency Testing Program

The Grain Program consists of approximately 6,000 samples per year. All sample collections are conducted by authorized officers from 100% of export bulk hatches and containers. The domestic testing consists of approximately 1,000 samples per year. The grains are tested by Symbio Alliance in Brisbane, Queensland, for insecticides, fungicides, herbicides, fumigants, and environmental contaminants against the Maximum Residue Levels (MRLs) written within the Food Acts. Sample results are to be reported within ten days. For any levels reported at $\frac{1}{2}$ MRL, NRS will notify the appropriate state authority through the initiation of a trace-back investigation. The results of the trace-back investigations are shared with NRS for review and filing.

Citrus Proficiency Testing Program

The Citrus Program is monitored by NRS and includes testing for insecticides, fungicides, herbicides, and a biocide for exports. These sample collections are conducted by either the state officers or the firms Quality Assurance Manager following NRS' Collection Procedures. Sample results are to be reported within three days. For any levels reported at $\frac{1}{2}$ MRL, NRS will notify the appropriate state authority through the initiation of a trace-back investigation. The results of the trace-back investigations are shared with NRS for review and filing.

National Measurement Institute

The National Measurement Institute (NMI), Melbourne, Victoria, is an ISO 17025 accredited government laboratory for various programs including food testing and metrology. It is also one of the contract laboratories for the NRS program that shares the information management system for sample reporting. MRLs are set by the ADA and written within the Food Acts. When a laboratory detects $\frac{1}{2}$ the level of MRL, the IMS automatically notifies the ADA via email for follow-up instructions; however, the laboratory is required to proceed with confirmatory testing. All testing results are verified by secondary review or visual confirmation for

correctness, including reporting of the final results. NRS provides the scientific interpretation of all results under their purview.

Dairy Food Safety Victoria

Victoria contains 64% of Australia's dairy industry, and 84% of the total Australia's dairy exports. Dairy Food Safety Victoria (DFSV) is the independent regulatory office for dairy safety within the state of Victoria and maintains ISO 9001 Certification. The office enforces the Dairy Act 2000 through dairy industry funding. DFSV has provided approximately 4,500 licenses to facilities within Victoria to include farms, tankers and distributors of dairy products. The requirement for license approval includes a CODEX HACCP Program and Food Safety Program that are audited by DFSV. Manufacturers are audited at six month intervals and farms at twenty-four month intervals. DFSV responsibilities include incident response of the products prior to retail distribution, verification of quality within the facilities and auditing of the auditors at twelve month intervals. DFSV monitors compliance of the licensees.

DFSV is the national coordinator of the Australian Milk Residue Analysis Survey program (AMRA), which is the national residue program for raw milk. They supply export assurance through an MOU with the ADA and provide verification of the six dairy producing states. The results of the survey testing are communicated to both the ADA and the dairy industry during a yearly annual Strategic Planning meeting to discuss any follow-up.

Random sample collections, based on volume of production, are performed by authorized officers in conjunction with the ADA and require testing by NATA ISO 17025 accredited laboratories. These authorized officers are DFSV staff members and are required to monitor the authorized samplers employed by the firms to determine continuing competency. The samples are sent to one of two DFSV contract laboratories (NMI and Dairy Technical Services) for residue testing. The AMRA Program Manager manages the sampling equipment and consumables, the sampling schedule and collections, and provides any follow-up needed for collection non-conformances or issues. Twice per month the sample collection schedule is issued to both the contract labs as well as the authorized samplers at the firms. Each result must be submitted to DFSV (per the MOU); in addition, each positive result must also include telephone communication with DFSV for quicker regulatory response.

Contract laboratory selection is based on pre-determined criteria written into the Request for Tender (RFT) contracts. The contracts are reviewed by DFSV every three years with bimonthly meetings for any updates during the contract period. Within the RFT, laboratory specifications include quality assurance requirements; result reporting; proficiency testing; and NATA accreditation. DFSV has a specific requirement that the contract laboratory must submit method validation data for program management review prior to implementation. Positive results (including ½ MRL) are communicated between DFSV, the state authorities, and the ADA for consideration.

DFSV also monitors microbiological testing of finished products, as a non-regulatory function; however, if positive results are obtained, they can take regulatory action. This testing is voluntarily performed on dairy products and the information is generally used for trending of factory hygiene and is shared with the Victoria Department of Health (if necessary). The planning of this program is performed annually under a voluntary basis dependent upon seasonal manufacturing and results shared with the factories. The program includes both targeted testing and establishing a baseline reading of hygiene based on the factory production schedule. The targeted (*Listeria*, *E. coli*, *B. cereus*, and *Salmonella*) testing samples are collected by authorized officers with limited factory notification whereas the baseline testing samples are collected by the factory specifically for hygiene (Total Plate Count, Coliforms, *Enterobacter* spp, Yeast and Mold) testing. All sample testing is performed by Dairy Technical Services.

Dairy Technical Services

Dairy Technical Services (DTS) is a high throughput laboratory processing approximately 90,000 microbiology samples and approximately 33,000 chemistry samples per month. The laboratory is required to maintain NATA ISO 17025 Accreditation for both the microbiology and chemistry methods. The laboratory has an electronic barcoding system that allows all samples to be traced throughout its analytical track. All methods, media, testing, and temperatures are entered into the system prior to receipt, allowing the system to barcode all steps in the process from labeling plates, using conveyor belts for proper temperature storage locations, and filling appropriate plates/tubes for testing. Any deviations from the automated system will not allow the sample to be completed within the reporting system. The system automatically alerts the

analyst and management of both presumptive positives and confirmatory results. This alert requires a secondary verification by laboratory management, which will alert the client and DSFV. The laboratory maintains an electronic information management system (Labware) that will interface with the factories' registration through one-way communication only. Upon test completion, DTS uploads the results that can be viewed directly by the clients; however, DFSV also receives analytical results via email.

Safe Food Production Queensland

Safe Food Production Queensland (SFPQ) is the state regulatory office responsible for enforcing food safety in meat, dairy, seafood, horticulture and eggs in Queensland. They conduct two audits per year for each location with all sample collections performed by SFPQ staff and tested by NATA ISO 17025 accredited laboratories. There are three different types of sample collections, including: Enforcement/Regulatory Samples; Surveillance Samples; and Project Work Samples. The Enforcement Samples are tested strictly by the government laboratory (NMI). Surveillance Samples are the result of complaints and tested by the contracted laboratories following all RFT requirements. The Project Work Samples are written as specific assignments and tested by the contracted laboratories following all RFT requirements. SFPQ provides accreditation to over 8,000 businesses based on approval of their food safety program or food safety management statement and covers all specified activities. The requirements for this accreditation are explained within the Queensland Food Production (Safety) Act 2000. SFPQ provides a training program to all auditors, including third party auditors. Monitoring of the food safety programs consist of audits, inspections, compliance assessments, responding to notifications (positive results) and planned surveillance activities. Enforcement of the Act consists of fines; seizures; suspensions; or revocations of accreditation. All non-conformances of the contract laboratory must be submitted to SFPQ for consideration per the food safety program and Act. For positive results (notifications), the associated firms are required to enter and complete a clearance program consisting of system review, root cause analysis, and acceptable preventive measures to avoid future contamination. The levels of detection are submitted by each facility per the food safety program for review and approval. All information gathered from analytical testing is used to clarify regulations, validate

and verify food safety programs, and determine the risk level to the food supply. This information is provided to FSANZ for risk assessment of public health.

SFPQ works closely with the Department of Health to monitor any foodborne illness outbreaks and positive food testing results. SFPQ coordinates the food recalls associated with the National Food Incident Response Protocol along with participating in policy and standard development and implementation through the Bi-National Food Regulatory Framework of Australia and New Zealand. SFPQ also participates in public education and industry training associated with prevention of foodborne illnesses due to microbial pathogens.

Symbio Alliance Laboratory

Symbio Alliance (SA) laboratory participates in the testing of meat, horticulture and NRS testing, and includes a few satellite labs located within other states. The Brisbane location is the reference or confirmation laboratory for all the satellite locations. Communication exists between the ADA and Safe Food Queensland (SFQ) for any pathogens recovered from the food commodities. SA is a contract laboratory for SFPQ and participates in both export testing for meat, nuts, grains (NRS) and imports for seafood testing.

All non-conformances are reported to the regulatory authority (SFPQ), and the analytical results must be sent to SFQ for review and further instructions. One of the requirements of the laboratory is to maintain NATA ISO 17025 Accreditation for microbiology methods.

Conclusions

The Australia's laboratory capacities, as observed by the U.S. FDA team, can be recommended as comparable to that of the U.S. FDA.

The System Recognition Arrangement and the Work that Follows

Once a foreign country's inspection system is recognized through a Systems Recognition Arrangement, the U.S. FDA and the foreign government will continue, through ongoing bilateral communication and periodic review, to examine the performance of each country's regulatory systems to ensure that they continue to provide the appropriate level of protection.

Additionally, countries are expected to notify each other when significant changes to their food safety systems occur. Significant changes in food safety regulations, legislation, or budgets could trigger a reassessment to determine if the systems remain comparable. Ongoing communication ensures that Systems Recognition is not merely a "snapshot" assessment.

The U.S. FDA's review of the Australian system anticipated legal changes within the U.S., and the ICAT contains standards covering aspects of FSMA, such as preventive controls. While FSMA regulations were not finalized when the reviewers assessed the Australian system, they analyzed the regulatory approaches utilizing preventive controls for consistency with the new U.S. law. Additional FSMA requirements will be addressed during the implementation of Systems Recognition with Australia.

Glossary of Acronyms

ADA	Australia Department of Agriculture
AMRA	Australian Milk Residue Analysis
APLAC	Asia-Pacific Laboratory Accreditation Co-operation
CAR	Corrective Action Request
CFSAN	Center for Food Safety and Applied Nutrition
DFSV	Dairy Food Safety Victoria
DTS	Dairy Technical Services
FDA	United States Food and Drug Administration
FSANZ	Food Safety Australia New Zealand
HACCP	Hazard Analysis and Critical Control Point
HQ	Headquarters
ICAT	International Comparability Assessment Tool
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IMS	Issues Management System
ISO	International Organization for Standardization
LACF	Low Acid Canned Foods
LMS	Learning Management System
LSTS	Laboratory Sample Tracking System
MFRPS	Manufactured Food Regulatory Program Standards
MOU	Memorandum of Understanding
MOUs	Memoranda of Understanding
MRL	Maximum Residue Level
NATA	National Association of Testing Authorities
NMI	National Measurement Institute
NRS	National Residue Survey
NSW	New South Wales
NSWFA	New South Wales Food Authority
ORA	Office of Regulatory Affairs

RFT	Request for Tender
SA	Symbio Alliance
SFQ	Safe Food Queensland
SFPQ	Safe Food Production Queensland
U.S.	United States
USDA	U.S. Department of Agriculture
VDH	Victoria Department of Health

Appendix 1. In-Country ICAT Review Personnel.

Table 2. In-Country ICAT Review Personnel: FDA personnel identifying their involvement during the review, indicating the location and length of time for each activity.

Name [§]	Affiliation	Canberra [‡] (three days)	Sydney (two days)	Melbourne (four days)	New South Wales (three days)	Victoria (four days)	Lab Review (five days)
Jane Cluster	CFSAN/OFS				X	X	
Debra DeVlieger	ORA/OFFO				X	X	
William Jones, Ph.D.	CFSAN/OFS	X	X	X			
Cynthia Leonard	CFSAN/OFS				X	X	
David LeRay	ORA/OFFO				X	X	
Michael Roosevelt	CFSAN/OC	X	X	X			
Angele Smith	ORA/ORS						X
Karen Swajian	CFAN/OFS				X	X	
Socrates Trujillo, Ph.D.	CFSAN/OCD	X	X	X			

[§]All participants reviewed the ICAT as submitted by the Australia Department of Agriculture (ADA). This documentation review started on July 2014 and lasted until September 2014. The in-country document review was done at the Canberra, ATC; Sydney, NSW; and Melbourne, VIC. Audits were done at the States of New South Wales, and Victoria.

[‡]All participants met with the competent authorities at the ADA, Canberra, ATC, for an entry meeting with the competent authorities. After the meeting, the audit and laboratory teams left the premises and travel to other locations to start the in-country audits.

Appendix 2. Biographies of the FDA personnel that participated on the Australia ICAT review

Jane A. Cluster, Consumer Safety Officer

FDA/CFSAN/OFS/DSS/Seafood Processing and Technology Policy Branch

Ms. Jane Cluster has worked as a Consumer Safety Officer with the Division of Seafood Safety (DSS) since September 1999 and has developed expertise in application of FDA's regulations, training, and evaluation of food safety programs. She has developed an extensive knowledge of FDA regulatory requirements, seafood HACCP food safety controls, CFSAN compliance policy, and ORA field investigation procedures. Ms. Cluster has participated in over 60 FDA foreign facility inspections providing technical support to FDA investigators, observing processing operations, and evaluating both seafood-HACCP and GMP compliance. She currently provides technical support to ORA, CFSAN staff, and CFSAN management. She is a board member for the Seafood Certification Board, which develops certification and training criteria for FDA investigators and participates as a trainer for investigators in conducting seafood HACCP inspections. She has assisted in developing prioritization criteria for the FDA PREDICT automated import screening project, and participated in writing the protocols, standards, and guidance for 3rd Party Certification of Foods and Feed in 2008 and the International Comparability Assessment Tool (ICAT). Prior to employment with FDA, Ms. Cluster worked for 13 years as an inspector for the National Marine Fisheries Service (NMFS), Seafood Inspection Program. Ms. Cluster holds a BS on Biological Sciences from the University of Tampa, Florida.

Debra DeVlieger, National Food Expert

FDA/ORR/Office of Food and Feed Operations

Ms. Debra DeVlieger has been a National Food Expert in FDA's Office of Regulatory Affairs for more than 20 years. She has been involved in many high-level FDA programs and projects including the development and implementation of the Seafood and Juice HACCP regulations, the Seafood Hazards and Controls Guide, a Cooperative Arrangement with New Zealand and an Equivalency agreement with the European Union. She participates as a team member in FDA's Systems Recognition program (currently working with Canada and Australia) and is working with China's regulatory authority on their aquaculture seafood program. She has also helped to develop and implement many regulatory food safety training courses. Ms. DeVlieger is currently serving as a co-lead for implementation of the FSMA Preventive Controls regulation for human food and serves as a member of the Steering and Editorial Committees for both the Seafood HACCP and Food Safety Preventive Controls Alliances.

William R. Jones, Ph.D., Acting Deputy Director

FDA/CFSAN/Office of Food Safety

Dr. Jones acts as Deputy Director of the Office of Food Safety at CFSAN. He received his B.A. in Biology from Towson University and his Ph.D. in Biology from the University of Maryland. He conducted post-doctoral research in microbial pathogenesis at the Center for Vaccine Development, University of Maryland School of Medicine, before being appointed to the faculty of the Uniformed Services University of the Health Sciences Department of Medicine at the National Naval Medical Center. There he directed the hepatitis E virus research and vaccine

development program at the Naval Medical Research Institute before joining the faculty at the University of Maryland Biotechnology Institute's Center for Marine Biotechnology. At the Center he served as Senior Scientist and as Head of Educational Programs. His publications include several dozen peer-reviewed abstracts, journal articles, book chapters and reviews. Dr. Jones has represented the FDA on three subcommittees of the President's National Science and Technology Council, on the Interagency Ocean Policy Task Force, the President's Task Force on IUU Fishing and Seafood Fraud and as U.S. Delegate to the FAO/WHO *Codex Alimentarius Commission* Committee on Fish and Fishery Products. He also has experience in the private sector as a founder and owner of four successful businesses, including an ongoing biotechnology research and manufacturing company, AthenaES, serving as President for eight years before joining the U.S. FDA in 2001.

Cynthia (Cindy) Leonard, M.S., Consumer Safety Officer

FDA/ CFSAN/OFS/DDEMP/Milk and Milk Products Branch

Ms. Cindy Leonard is a Consumer Safety Officer and FDA's subject matter expert for Food Safety of Dairy Foods in the Division of Dairy, Egg and Meat Products, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S Food and Drug Administration in College Park, Maryland. Ms. Leonard's responsibilities for FDA include science, policy and regulatory review of dairy products, including cheese, produced in the U.S. and imported. She participates as a dairy food safety expert for foreign inspections and the international systems recognition program. Her work includes food safety risks of raw milk, raw milk products and cheeses, advising management on issues related to dairy product safety, and conducting research on legislative documents, legal precedents, and FDA enforcement history related to raw milk, raw milk products, and dairy product safety. As a dairy and food technologist and microbiologist, Ms. Leonard has extensive experience in the dairy and food industry in technical and management positions. Prior to working with the U.S. Food and Drug Administration, she owned a consulting company and laboratory in Atlanta, Georgia. In June 2013, she participated as an auditor for the interdisciplinary audit ICAT team to Canada's East Coast for the in-country evaluation of the U.S. audit of the food safety inspection system by Canadian Food Inspection Agency (CFIA) which is Canada's competent authority for food safety inspections. Ms. Leonard's educational degrees are M.S. Dairy and Food Science/Microbiology and B.S. Environmental Health Science/Microbiology, University of Georgia, U.S.A.

David J. LeRay, National Food Expert

FDA/ORR/Office of Food and Feed

Mr. David LeRay is a National Food Expert in FDA's Office of Regulatory Affairs, Office of Food and Feed Operations, where he provides technical expertise for development and implementation of national and international programs, develops and instructs at national training courses, and conducts complex inspections of food processors. He began his career with FDA in 1990 as a Consumer Safety Officer (CSO) at the New Orleans District Office (NOL-DO). He became NOL-DO's Seafood/Food Specialist in 1993. Mr. LeRay became a Supervisory CSO in 2006. He was selected as a charter member of FDA's Foreign Food Inspection Cadre in 2009 for which he performed food inspections internationally for three years. His specialties include seafood, low-acid canned foods, and acidified foods. He has conducted over 140

inspections of foreign food processors in 19 countries in North and South America, Asia and Europe. Mr. LeRay has conducted more than 600 domestic inspections of regulated industries including food firms, biologics firms, and medical gas firms. He has collected over 400 physical samples of food products. Mr. LeRay holds a Bachelor of Science Degree from Louisiana College.

Michael W. Roosevelt, Deputy Director

FDA/CFSAN/Office of Compliance

Mr. Michael Roosevelt is the Deputy Director, Office of Compliance, in FDA's Center for Food Safety and Applied Nutrition (CFSAN). In this capacity, he provides leadership for food enforcement, compliance, and programmatic activities in FDA. During his over 22 years with FDA, Mr. Roosevelt has held several operational and management positions within CFSAN and FDA's Office of Regulatory Affairs (ORA). He has nearly ten years of field experience as an investigator in Florida District and a supervisory investigator in New Orleans District. Mr. Roosevelt has over 14 years of management experience with ORA and CFSAN as a field supervisor, Branch Director, Deputy Office Director, Acting Director for the Division of Seafood Safety (12 months), Acting Director for CFSAN's Office of Compliance (26 months), and Acting Deputy Center Director for Operations (5 months). Mr. Roosevelt holds a Master of Public Management degree from the University of Maryland and a Bachelor of Science degree from the University of Florida. In February of 2010, he completed the 30 day residential program "Leadership for a Democratic Society" at the Federal Executive Institute (FEI) in Charlottesville, Virginia.

Angele Smith, Interdisciplinary Scientist

FDA/ORA/Office of Regulatory Science

Ms. Angele Smith has been working within FDA's Office of Regulatory Affairs (ORA) for more than 13 years, both as a bench microbiologist and a program manager. Ms. Smith has been involved in many high-level FDA programs and projects including the modernization of ORA's Pharmaceutical Microbiology Program, harmonization of ORA's microbiological laboratory analytical worksheets, establishment of border screening stations, and the Cooperative Arrangement between Food Emergency Response Network (FERN) State Laboratories and Office of Partnerships to achieve ISO/IEC 17025:2005 accreditation. She is considered a subject matter expert for various ORA food programs and participated as an auditor in FDA's Systems Recognition program (Australia). She has led the development and implementation of several regulatory pharmaceutical microbiology and food safety training courses. She is currently serving as Program Manager for Pharmaceutical Microbiology within ORA's Office of Regulatory Science.

Karen A. Swajian, Consumer Safety Officer

FDA/CFSAN/OFS/DSS/Seafood Processing and Technology Policy Branch

Ms. Karen A. Swajian has worked as a Consumer Safety Officer (CSO) in the Seafood Processing and Technology Policy Branch, Division of Seafood Safety, Office of Food Safety since 2008. Ms. Swajian is a FDA's subject matter expert for natural marine toxins as well as allergenic and food intolerance substances. As such, she develops policy and guidance for the industry regarding natural marine toxins in finfish. She also works with the International Affairs Staff at CFSAN

auditing Foreign Competent Authorities for Comparability. Prior to August 2008, Ms. Swajian was employed as a CSO with the CFSAN Office of Compliance / Compliance Information Branch and Field Programs Branch. She is also a rehire to the government previously being employed from 2001 – 2003 working in Office of Compliance with Allergens as her primary responsibility in the Field Programs Branch. Ms. Swajian assists with programs outside of the Division of Seafood Safety, working with the International Affairs Staff conducting System Recognition assessments with foreign competent authorities and developing its electronic program. She also works on programs related to the Food Safety Modernization Act such as Third Party Accreditation Program, Preventive Control Rule, Voluntary Qualifier Importers Program, and the Foreign Supplier Verification Program. Ms. Swajian graduated from Mount Ida College with a Bachelor of Science in “Veterinary Technology”. She received a Masters of Science in “Clinical Laboratory Science” with a major in “Microbiology” and a minor in “Adult Education” from the University of Rhode Island. Since then and prior to she has worked as a clinical microbiologist at Tufts University School of Veterinary Medicine and Faulkner Hospital. Ms. Swajian taught Veterinary Microbiology at the Graduate and Undergraduate level with Tufts University and Mount Ida College respectively. Ms. Swajian has also worked in the Dairy Industry as the Regional Quality Systems Specialist with Dean Foods where she conducted system audits of the regional dairies, their co-packers and suppliers as well as organized and oversaw customer audits.

Socrates Trujillo, Ph.D., International Policy Manager

FDA/CFDA/OCD/IAS

Dr. Trujillo is an International Policy Manager at the International Affairs Staff (IAS), Center for Food Safety and Applied Nutrition (CFSAN). As part of the Bilateral Coordination team, he provides advice to the Center regarding international food safety matters, and is the co-Chair on the Produce Safety Partnership, a project between FDA and Mexican Competent Authorities. Before joining IAS, Dr. Trujillo was a Consumer Safety Office at the Produce Safety Staff (now Division of Produce Safety), Office of Food Safety, CFSAN. In this capacity Dr. Trujillo was responsible for developing FDA regulations for microbiological food safety with special emphasis in food microbiology of fresh produce, and traveling to accompany FDA inspectors during outbreaks and surveillance, as subject matter expert. Before joining the Office of Food Safety, Dr. Trujillo spent ten years working as a researcher in food safety at several offices within the FDA. He has organized and coordinated many FDA international food safety extension programs (e.g. International Workshop on Mycotoxins, XI IUPAC Symposium on Mycotoxins and Phycotoxins), as well as hosted several international visitors to train them in the detection of foodborne pathogens using conventional and molecular methods. Dr. Trujillo also volunteers at AOAC INTERNATIONAL, where he has been President of the Mid-Atlantic Section, chair of several committees, scientific advisor for several panels, and selected to lead presidential task groups.

Appendix 3. Timetable of the ICAT Review Process.

Table 3. Timetable indicating the review of the documentation as submitted by the Australia Department of Agriculture, via the ICAT. The document review was performed by the FDA subject matter experts between July and August 2014.

Activity	1-Jul	8-Jul	10-Jul	15-Jul	17-Jul	22-Jul	24-Jul	29-Jul	31-Jul	5-Aug	7-Aug	12-Aug	14-Aug	19-Aug	21-Aug	26-Aug	28-Aug	2-Sep	4-Sep	9-Sep	11-Sep	16-Sep	18-Sep	
Kick-Off Meeting	X ^a																							
Standard 1		X	X	X	X	X	X	X	X															
Standard 2, 3, 4										X	X													
Review Meeting												X												
Standard 5, 10													X											
Standard 6, 7,8,9														X	X									
Review Meeting																X								
Logistics Meeting																	X							
In-Country Review																					X	X	X	X

Appendix 4. List of documents reviewed by the Laboratory Team during the Australia ICAT In-Country Review.

Documents Reviewed at the National Association of Testing Authorities (NATA):

- Reassessment Audit Template
- Surveillance Audit Template
- List of Accredited Laboratories and Scope of Accreditation
- Requirement for Method Validation (Technical Notes)
- Form for monitoring (auditing) the audit team

Documents Reviewed at The National Residue Survey (NRS):

- Procedure for procurement of contract laboratories
- Procedure for monitoring laboratory analytical performance
- List of Proficiency Testing offered by NRS
- Scope of 8 Contract Laboratories
- MOU with NATA to include communication between NATA and NRS
- MOU with NRS and states for trace-backs
- One trace-back investigation
- IMS (information management system) showing automatic notifications
- Last surveillance audit of NRS lab
- Proficiency Testing Handbook
- NRS Laboratory Visit/Review/Audit Checklist
- Guidelines for Contract Laboratories
- Sample Handling, Analysis, Data Interpretation and Reporting, Turnaround Times, Payment, Quality Assurance, Sample Retention

Documents Reviewed at The National Measurement Institute (NMI):

- NATA Audit Reassessment Report 2013
- Scope of Accreditation (microbiology and chemistry)
- Several non-conformances and root cause analyses

- Sample Entry into Information Management System
- Quality Manual
- Method Validation Procedure based on NATA's Technical Notes
- Organizational Chart (within lab and within government)
- Quality Control Procedure for Positive Results
- Proficiency Plan and Schedule
- Procedure for Chain of Custody

Documents Reviewed at Dairy Food Safety Victoria (DFSV):

- Proficiency Test Program Performance Report
- Tender Proposal for Contract Labs
- Certificate of Analysis for all testing conclusions
- Proficiency testing requirements from NRS
- Request for Tender
- Strategic Review Meeting Agenda (Management Review of Programs)
- Lab Specifications for Contracting Labs (Validation)
- Services Agreement
- Procedure for AMRA (Authorized Sampler, Sampling SOP, Schedule)
- AMRA Annual Report (Monitoring) 2012-2013
- AMRA Survey Plan (7/2014-6/2015)

Documents Reviewed at Dairy Technical Services (DTS):

- NATA Report (Microbiology Surveillance 2013 and Chemistry Reassessment 2014)
- Scope of Accreditation 2013
- Quality Manual
- Two non-conformances with root cause analyses
- Method Validation Procedure (Microbiology uses standard methods with verification required)
- Verification and Validation of Chemistry Methods
- Registration Procedure (Chain of Custody)
- Organizational Chart

- Proficiency Plan (microbiology and chemistry)

Documents Reviewed at the State Regulatory Office for Food Safety in Queensland (SFPQ):

- Food Export Regulators Steering Committee for Dairy, Meat and Seafood
- National Food Incident Response Protocol
- Food Safety Fact Sheet 45 (Roles and responsibilities of Queensland food safety regulators)
- Safe Food Production Queensland overview
- Compliance Policy 2013
- Response to Notifications Procedure
- Nonconforming Production Procedure
- Collection & Submission of Listeria from RTE foods Procedure
- Listeria Clearance Program Procedure
- Enforcement seizure of evidence Procedure
- Guideline for collection of food sample for microbial samples
- Sample Submission Form
- A guide to completing the sample form
- Temperature log procedure for microbial samples Procedure
- Evidence Receipt & Chain of Evidence Form
- Collection & Submission of food samples Procedure
- Collection & Submission of environmental samples Procedure
- Approved laboratory service providers Procedure
- AMRA Sampling Equipment distribution Procedure
- Verification Project Plan
- Statement of Comprehensive Income end 30 June 2014
- Safe Food Organizational Chart
- Approved Auditor Register
- Comparison of U.S. FDA Responsibilities and Tools vs SFPQ
- Food Production (Safety) Act 2000
- Food Production (Safety) Regulation 2014

- Food Production (Safety) Regulation Explanatory Notes
- Schedule 1 – State Penalties Enforcement Regulation 2014 pg 1
- Schedule 1 – State Penalties Enforcement Regulation 2014 pg 2

Documents Reviewed at Symbio Alliance (SA):

- NATA Reassessment Report 2013
- Scope of Accreditation
- Two non-conformances with root cause analyses
- Sample Receipt Procedure
- Sample Reporting Procedure
- Method Validation Procedure
- Organizational Chart
- Training record of signatory analyst
- Out of specification (OOS) Procedure
- Proficiency Testing Plan and Schedule