

**REPORT OF THE COMPARABILITY* DETERMINATION OF THE FOOD
SAFETY COMPONENT OF THE NEW ZEALAND MINISTRY FOR PRIMARY
INDUSTRIES
(formerly the New Zealand Food Safety Authority)**

At the time of this report's drafting, FDA was using the term "comparability" to describe the process of food safety systems evaluation as outlined in this document. FDA has since adopted the term "systems recognition" as a more widely understood and accepted term used to describe the same process.

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Executive Summary

Comparability of food safety systems (“Comparability”) is a new concept, currently under development within the US Food and Drug Administration (FDA or the Agency), that allows the Agency to evaluate the competency of a foreign country’s food safety control system. The use of comparability assessments will allow FDA to proactively ensure the safety of food imported into the United States (US) and to leverage scarce FDA resources to ensure the safety of all foods available to US consumers.

The International Comparability Assessment Tool (ICAT) is modeled after the Agency’s state-based *Manufactured Food Regulatory Program Standards*, with modifications to allow for international use. The ICAT may be used to evaluate key elements (standards) of a country’s food safety system including: its regulatory foundation; inspection and enforcement capabilities; training; verification and audit programs; illness outbreak response capability; program and laboratory resources; industry and consumer outreach programs; and international engagement.

Comparability review consists of: a thorough paper review of materials submitted by the country to FDA (through completion of the ICAT) to demonstrate what food safety authorities and controls are in place; a review of the country’s trade history, including volume of foods shipped to the U.S. and related compliance data; and an in-country review to verify that the implementation of the food safety program elements reflects the information submitted for paper review.

To test the concept of comparability, a pilot project was carried out with the New Zealand Ministry for Primary Industries (known as the New Zealand Food Safety Authority (NZFSA) at the time of the comparability assessment). Based on discussions with New Zealand (NZ), the pilot comparability assessment of NZ covered the overall food safety system. In addition, the team completed a review of the implementation of controls for seafood (including molluscan shellfish) and dairy¹ products. Several teams in the U.S. and NZ participated in this pilot comparability review and audits of seafood, molluscan shellfish and dairy programs. While the review was conducted as a pilot program, the findings will have status as an FDA Agency determination. A successful paper review of the NZ food safety system was conducted during the summer of 2010 that included in-house review of documents by FDA food safety experts, and a follow-up meeting at FDA with NZFSA representatives. This meeting was very useful, in that FDA was provided clarification and follow-up information prior to scheduling the in-country review.

The in-country review of NZ’s food safety system involved verification of the implementation of the NZ food safety system through documentation review of the program’s records, as well as on-site visits. In conjunction with the comparability

¹ New Zealand has a single food control system that applies to all dairy products. The United States maintains a dual system in which dairy products may be produced solely under general food law requirements or to a system that includes the additional requirements of the Grade “A” Pasteurized Milk Ordinance (PMO). Products produced according to the PMO are termed Grade “A” products and are not included in this comparability assessment.

review, site visits focused on the observation of inspection and systems audit programs at seafood and dairy processing firms and a review of the NZ shellfish sanitation program for growing area classification and related controls.

The overall findings and recommendation to the Agency from all teams is that the food safety system implemented by the NZFSA is comparable to that of the FDA. Additionally, with respect to dairy and seafood (including molluscan shellfish), the review team concluded that the food safety systems employed by FDA and the NZFSA for these two commodity areas are comparable.

Organization of this Document

This document is arranged in such a way as to describe fully the pilot comparability assessment of the food safety component of the NZ Ministry for Primary Industries (known as the NZFSA at the time of the comparability assessment), including all relevant information gathered, documentation reviewed, follow-up meetings that took place between the FDA and NZFSA and subsequent in-country reviews, as well as the comprehensive analysis performed by FDA of all information gathered.

The sections of this document provide an overview of the information gathered and reviewed over the course of the pilot comparability assessment of NZ at different levels of detail.

Part I, *Introduction*, provides a brief introduction to the report on the comparability determination of the NZFSA, including the rationale as to why NZ was chosen to take part in this pilot.

Part II, *Background*, explains the comparability process that was employed and the scope of the assessment. This section fully describes the International Comparability Assessment Tool (ICAT), which was used to gather information on overall systems controls for this pilot study, the process of the comparability determinations and the scope of the assessment. The ICAT, which was used in draft form for the purposes of this assessment, is made up of ten standards, each consisting of individual elements, which when reviewed as a whole reveals the level of robustness of a country's overall food safety system. These standards and elements form the basis for the comparability review.

Part III, *Findings*, provides the findings and consists of narrative reviews of each of the ten ICAT standards, with commentary provided by the ICAT Team as well as Dairy, Seafood and Laboratory Teams (as relevant), outlining results of the in-country review of NZ's food safety system with respect to assessed standards.

Part IV, *Summary of Reports and Recommendations*, provides a higher-level assessment of NZ's overall food safety system, summarizing briefly the outcomes from in-country reviews and providing recommendations with respect to comparability.

Appendices are attached to provide the greatest level of detail, which cover: NZ's ICAT submission; information gathered during the paper assessment and in-country ICAT team review, with detail at the level of individual elements; and detailed information gathered by the Shellfish Team on the NZ shellfish sanitation program for growing area classification and related controls. Individual team member notes and confidential documentation provided by NZFSA have been retained for internal use, in accordance with confidentiality agreements.

REPORT OF THE COMPARABILITY DETERMINATION OF THE FOOD SAFETY COMPONENT OF THE NEW ZEALAND MINISTRY OF AGRICULTURE AND FORESTRY

Part I: Introduction

The U.S. and NZ have a mutually beneficial, longstanding trade relationship, which includes several Memoranda of Understanding, Cooperative Arrangements and other agreements. Likewise, NZ foods exported to the US have a well-established history of compliance with U.S. food safety requirements.

In order to facilitate the renewal and strengthen the underpinning of existing cooperative arrangements between the U.S. and NZ, the food component of the NZ Ministry for Primary Industries (known as the NZFSA at the time of the assessment and termed the NZFSA throughout this report) agreed to participate in a comparability assessment. This assessment was to serve as a pilot of the comparability assessment approach, *allowing FDA to evaluate the concept of comparability while at the same time enabling a facilitated cooperative program with the NZFSA which addresses specific commodities*. Both parties were of the understanding that a positive outcome would provide formal recognition to NZ's food safety program through appropriate cooperative agreements.

After an initial meeting to discuss the concept of comparability and the scope of assessment, NZFSA completed the ICAT and submitted materials and references to the FDA.

After completing a review of materials submitted by NZFSA, FDA participated in a follow-up meeting with NZFSA in the U.S, in order to clarify information and discuss next steps. Based on the information received and the clarifications provided by NZFSA in the follow-up meeting FDA determined that sufficient and adequate information had been gathered to justify the next portion of the comparability assessment, an in-country verification visit by FDA to NZ.

Implementation of NZFSA's written programs, policies, and associated documentation, were reviewed during that visit. This report contains the summary of the complete comparability determination, including information gathered throughout the determination process as well as conclusions drawn from the comparability assessment as a whole.

Part II: Background

The following sections are included to provide context regarding the comparability determination carried out with NZFSA.

Comparability

The United States (U.S.) trades with over 200 countries and territories and imports food products through over 300 U.S. ports. Imports of food to the U.S. have increased by 300% in the past decade. This active international trade has allowed U.S. consumers to enjoy a wide variety of foods year-round, and U.S. consumers expect that all foods sold in U.S. markets will be safe for themselves and their families.

To ensure the safety of this increasing volume of imports into the U.S. FDA's new, preventive approach shifts from testing and reaction to focusing on the foreign food production environment and supply chain. While inspection and testing of foods will continue to inform FDA's risk-based food safety program, FDA's shift to a preventative approach, which will include comparability as one of several programs, will hold those that produce, process, and import foods responsible and accountable for ensuring the safety of their products. The FDA Food Safety Modernization Act reflects this new paradigm and provides FDA with many of the legal authorities and tools needed to address the challenges presented by today's globally based food supply.

The concept of comparability offers an opportunity for FDA to identify countries that are most able to provide meaningful assurances of the safety of their exports and to leverage the work of these comparable national competent authorities to avoid duplication of effort. Establishing comparability will help FDA to better allocate its resources efficiently and transparently, concentrating resources on countries and country-commodity combinations that have a higher risk profile. FDA has carried out extensive work to develop the concept of comparability, an effort that is on-going. The pilot program completed with NZ is one aspect of this work. Additionally, FDA has conducted a public meeting to present the concept of comparability and to obtain input from stakeholders including the consumers and the food industry².

The comparability assessment process, as piloted, provides a country that exports food to the U.S. the opportunity to demonstrate that its food safety system: is science-based; comprised of similar key elements to that of FDA; has ongoing processes to ensure the sustainability of preventive controls; provides competent oversight; and has a similar public health focus. FDA may take comparability into account when determining whether physical examination and/or sampling of particular imported foods are necessary. This may result in expediting entry for food products from comparable countries.

International Comparability Assessment Tool (ICAT)

² See "Transcript: FDA Public Meeting on Ensuring the Safety of Imported Food and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries," <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm254816.htm>

The International Comparability Assessment Tool (ICAT) was created as an objective framework for assessing the robustness of trading partners' overall food safety systems and determining whether those systems appear comparable to the FDA's system. The ICAT is based on the Manufactured Food Regulatory Program Standard (MFRPS), which is an assessment tool that FDA utilizes to provide a uniform foundation for the design and management of state programs responsible for the regulatory oversight of food plants. The MFRPS and ICAT are each composed of ten sections corresponding to ten food safety program standards. However, the ICAT has been customized to ensure that the tool is suitable for international use and to examine the oversight systems used by international competent food safety authorities from a broader scale. This allows for the assessment and identification of food safety systems in other countries that may differ from the U.S. system but offer the same level of public health protection.

Format of the ICAT

As mentioned in the previous section, the ICAT is composed of ten sections, with each section corresponding to a specific food safety program standard. Standards include: Regulatory Foundation; Training Program; Inspection Program; Program Assessment and Inspection Audit Program; Food-related Illness and Outbreaks; Compliance and Enforcement Program; Industry and Community Relations; Program Resources; International Communication and Harmonization; and Laboratory Support.

Each ICAT standard includes a narrative that describes the purpose and requirements of the standard as well as the program elements that FDA considers necessary to satisfy the basic requirements. Following each narrative is a self-assessment worksheet, to be completed by the trading partners' Competent Food Safety Authority(ies) which are used to illustrate that the program element has been met.

The self-assessment worksheets are organized in tabular form, with column one listing the food safety program elements, and column two listing descriptions and links to FDA programs and measures that satisfy the element. Columns three to five provide space for the Competent Food Safety Authority to outline the comparable measures that they have in place, provide web links to references (if available) and explain how measures may differ from those of the FDA.

Process of Comparability Determinations

The comparability assessment, as piloted, involves a multiple step process, beginning with a determination of whether a country meets a threshold level of food safety systems development. Prior to initiating a full ICAT assessment, a consultation meeting (by teleconference or digital video conference) will take place, where the threshold for a positive comparability determination will be outlined. After this consultation meeting, countries may choose to pursue a comparability determination, in which case they will complete the ICAT, may seek recognition as a certification body (through the Third Party program), may pursue training or capacity building to strengthen their food safety systems, and/or may continue trading with the U.S. as usual, understanding the need to comply with FDA regulations when shipping product to the U.S.

After a country submits a completed ICAT, an FDA review of the materials submitted will take place, including a thorough review of the country's domestic food safety system, as well as its systems for export food safety, where appropriate. Additionally, FDA will review the compliance history of products exported from the country to the U.S., including data such as volume of trade, number of refusals of admission, types of refusals, import alerts directly affecting products or processors within that country, products subject to import alerts, country reports (including information from the U.S. Department of Agriculture's Global Agricultural Information Network (GAIN)), and other available information.

If the ICAT and compliance history reviews indicate that a country is likely to receive a positive comparability assessment, FDA will arrange an in-country assessment. During the in-country assessment visit, a team of FDA reviewers will conduct interviews and review records to verify the implementation of programs and measures outlined in the ICAT response. This will include visiting associated government agencies as well as selected field sites as appropriate. Particular emphasis during in-country review will be placed on observing the implementation of written policies.

The comparability assessment process involves open dialogue at each step of the way between FDA and the country under review, to ensure efficient use of resources for both countries.

Scope of the Assessment

The scope of the assessment involved a determination of comparability of the food safety control system of the New Zealand Ministry for Primary Industries (MPI) and the United States Food and Drug Administration (FDA) as applicable to all foods regulated by FDA. An on-site audit was carried out to verify the implementation of New Zealand's overall food control system. Additionally, for seafood and dairy products, because these products may present a somewhat higher public health risk, a simultaneous on-site audit to verify New Zealand's implementation of its specific controls for these products was carried out. The audit included a review to verify that New Zealand's molluscan shellfish food safety control measures were consistent with those of the United States' National Shellfish Sanitation Program. The audit did not include all measures required under the United States' Grade "A" Pasteurized Milk Ordinance and, hence, the comparability determination does not include products classified by the FDA as Grade "A" dairy products.

In-Country Review Teams

The in-country review trip of the FDA to NZ took place in September, 2010. Five teams participated in the in-country review, each focusing on a specific area of the assessment.

The NZFSA has the authority and mandate to ensure the safety of domestic and internationally traded foods and animal feed in NZ. NZFSA accomplishes its mission

through agreements and partnerships within and outside of the NZ government. Third party oversight and certification plays a central role in the food safety system in NZ, with NZFSA maintaining oversight of each component of the system, including the certification and auditing of inspectors (“verifiers”) and inspection (“verification”) agencies. FDA teams that participated in site visits in NZ reviewed the implementation of the NZFSA system to determine whether the implementation of this system of governmental and non-governmental food safety oversight, inspection and enforcement is comparable to FDA’s food safety control system.

ICAT Team

The ICAT Team spent one week in NZ reviewing documentation at NZFSA headquarters as well as at two recognized auditing agencies that conduct field audits (inspections) of food manufacturing facilities: NZFSA Verification Agency (VA) in Wellington and AsureQuality in Auckland. The ICAT Team’s goal was to verify documentation covering the implementation of programs and policies that had been reviewed as part of the paper review of ICAT materials submitted by NZFSA.

Following the paper review of NZFSA’s complete ICAT submission, the in-country review focused specifically on implementation documents such as: documentation of consumer complaints and follow-up; training records of food safety personnel; specific examples of food safety issues and incidents and the NZFSA response, including surveillance data collection, investigations, recalls, communication and associated follow-up activities (including but not limited to court proceedings). The in-country review also included the review of individual inspection reports, including documentation of follow-up compliance activities; accreditation documentation for recognized persons and recognized agencies; and other types of documentation showing the implementation of NZFSA’s food safety control system.

The ICAT Team’s main goal during the in-country review was to answer the question: does the NZFSA, through its written policies, procedures and authorities, as well as through implementation of programs, offer the same level of food safety protection for consumers as does FDA’s food safety system?

Commodity-Specific Audits:

Seafood Team and Dairy Team

The Seafood and Dairy teams each spent two weeks in-country, conducting performance audits of NZ’s food safety auditors within firms that process foods associated with those specific commodities. The mission of the commodity teams was not focused on assessing the adequacy of NZ’s regulations (which were reviewed during the FDA paper review prior to the trip) or on the regulatory compliance of the individual firms that they visited. Rather the goal of the commodity teams was to assess the ability of the NZ food safety inspectors to verify the implementation of NZ’s regulations and procedures during the in-plant assessments.

Through the completion of site visits, the commodity teams addressed the question: are NZ's inspection and audit programs implemented and do they provide a comparable level of food safety protection as the inspection program of the U.S. FDA?

Shellfish Team

The goal of the in-country review of the NZ shellfish sanitation program was to answer the question: Is NZ's shellfish sanitation program implemented and does it offer a comparable level of protection as the U.S. Shellfish Sanitation Program?

Shellfish specialists spent two weeks in NZ performing a thorough review of the NZ shellfish sanitation program for growing area classification and related controls, including a thorough review of:

- Program administration
- Legal authorities
- Staffing
- Training
- Shellfish growing area reviews
- Comprehensive sanitation surveys

The team also reviewed records and observed field operations related to:

- Marine biotoxin contingency plan
- Surveillance of growing areas
- *Vibrio parahaemolyticus* (Vp) risk assessment and control plan: (Completion of this part of the review will be finalized pending additional information from NZ.)

The comprehensive report supplied by the Shellfish team can be found in an Annex at the end of this document.

Laboratory Team

The Laboratory Team spent one week in NZ reviewing laboratory accreditation documentation and accompanying laboratory auditors on their inspections of accredited laboratories. The Laboratory Team, like the commodity teams, focused not on conducting their own inspections of individual laboratories but rather on assessing NZ's ability to ensure that their laboratory system is in compliance with NZFSA's standards and that the accreditation system is robust and effective.

Part III: Findings Narrative

Standard 1 - Regulatory Foundation

The Regulatory Foundation Standard describes the laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food safety control system, which are used by competent food safety authorities to define and ensure compliance with food safety regulations. In order to meet the basic requirements of the standard, the competent food safety authority must demonstrate that they have the legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect and analyze samples, and take enforcement actions to protect the public health by ensuring the safety and security of the food supply.

ICAT

Standard 1 is the most extensive of the NZFSA ICAT submittals, covering twenty-five elements related to the legal and legislative authority of government agencies in NZ to ensure the safety of foods and animal feed in NZ.

The submission from NZFSA for Standard 1 was complete, in that each of the elements was addressed and relevant regulatory authority was cited. The ICAT team reviewed the documentation provided and determined from a paper-review standpoint that the submission was complete; that is, for each of the elements, NZFSA provided the appropriate proof of legal/legislative authority and documentation outlining policies and procedures in place related to each element.

The goal of the ICAT Team during the in-country review was to verify the implementation of information provided in the ICAT. However, most of the “implementation” relates to standards 2 through 10 rather than Standard 1 (which covers specifically legal authorities and regulatory foundation). Documentation and paperwork related to Standard 1 elements were reviewed while performing the in-country assessment. However, verification of implementation focused more closely on elements under standards 2 through 10.

Primary legislation that forms the food safety regulatory foundation for NZ is the Animal Products Act 1999 (APA); the Food Act 1981; and the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM). The NZ food safety system is legislated and implemented as follows:

- Acts of Parliament - *enabling legislation and framework that provides some flexibility to manage regulatory issues*
- Regulations - *sets outcomes such as the requirement for Risk Management Programs*
- Tertiary Notices - *provides the technical details that give effect to the outcomes such as specifications (i.e., Specifications for Products Intended for Human Consumption – Notice 2004, which covers GMPs)*
- Guidances (i.e., *Seafood Code of Practice*)

- Importing country specifications (*i.e.*, *U.S. Overseas Market Access Requirement (OMAR)*).

Included in the APA is authority to permit non-government agencies and individuals to perform functions for the NZFSA. Third party certifiers known as Recognized Agencies (RA) and individuals known as verifiers (auditors) or signatories perform the routine verification (inspection) functions for the food safety program. These third parties and individuals act as recognized agents for the government and have legal duties set forth by law. Third parties cannot apply sanctions and must report issues to the NZFSA.

All processing and packing facilities in NZ operating under the APA 1999 are required by law to operate under a written and registered Risk Management Program (RMP), which is based on a preventive control approach to food safety and sanitation. Facilities must meet the requirements in their RMP and are routinely audited against their RMP. Operators processing and selling food in NZ and to export markets hold the primary responsibility for food safety, suitability and meeting any market access requirements. The NZFSA approves and audits RMPs, RAs, individuals and laboratories, and recognition is updated each business evening on the NZFSA website.

The NZFSA sets food standards. Standards are developed utilizing the Code of Regulatory Practice, are risk-based and are science-based. Many standards are outcome based rather than prescriptive. Approval of a standard is generally a short process (three to four months), which allows for rapid response to emerging issues. Export requirements can be changed within a day if required. Export requirements for animal products (includes seafood) are mandatory and have a full legal status. At a minimum, all food (including foods for domestic consumption as well as foods for export and import) must meet NZ requirements. Foods for export must also meet any special overseas market access requirements (OMAR) of the importing country.

Certain food standards in NZ, primarily in the areas of labeling, composition and irradiation, are set jointly with Australia under the Food Standards Australia NZ (FSANZ) Agreement. Additionally, the NZFSA is required by law (APA Section 167) to consult with stakeholders when developing standards. The NZFSA works with various consultative committees and the Regulatory Review Committee (for regulation setting) to review proposed standards.

Chemical residue standards are set by the NZFSA and follow three types of authorization: Registration, Provisional Registration, and Exemption from Registration (either exempt under APA Section 75(1) (a) or listed as Generally Recognized As Safe). Animal feeds are not exempt from regulation; but are exempt from registration under the Agricultural Compounds and Veterinary Medicine Act. However, any animal-based ingredients must come from establishments operating under an approved and registered RMP. Additionally, all feed mills which process ruminant protein must be registered and operate in accordance with the Ruminant Protein Control Regulations. Maximum Residue Levels (MRLs) are set by NZFSA. While the legislation defaults to Codex Alimentarius standards for imports, tighter MRLs may be set for domestic producers

where good agricultural practice does not justify a high level or where a key export enforces lower levels. For MRLs that have not yet been established and where there is no safety concern, NZFSA uses a default value of 100 parts per billion (ppb).

At the time of review the NZFSA had recently merged back with the Ministry of Agriculture and Forestry (MAF) and has since changed name to Ministry for Primary Industries (MPI). While the NZFSA name is being used in this report, the legal name of the new Ministry is the Ministry for Primary Industries.

ICAT Conclusions

Documents reviewed under Standard 1 were complete and in support of the recommendation for comparability of NZ's regulatory foundations as related to the NZ Food Safety Authority's legal authority to implement its food safety control program.

Standard 2 - Training Program

The Training Program Standard defines the essential elements of a competent food safety authority's training program for food safety personnel. In order to meet the basic requirements of the Training Program standard, the competent food safety authority must have a training plan in place that ensures all inspectors receive the training required to adequately perform their work assignments. The plan should provide for basic and advanced food inspection training as well as continued training for professional development and documentation of staff training must be maintained.

ICAT

The ICAT team reviewed records associated with training programs within the NZFSA as well as those in recognized agencies. Reports included:

- Individual training records for NZFSA staff, recognized persons and reviewers
- Records tracking the completion of required training
- Examples of training course outlines and materials
- Documents outlining job descriptions and competencies

In addition to the above mentioned training documentation, during presentations by the Joint Accreditation System of Australia and NZ (JAS-ANZ), information was provided on the training requirements and records reviews involved in the accreditation of both recognized persons and recognized agencies. Managers from the NZFSA Verification Agency as well as AsureQuality, the state-owned recognized agency, provided information on job descriptions and competencies of their staff as well as the requirements (in terms of both training and experience) for various positions in their agencies. Documentation was provided as evidence of implementation of training policies.

Individual auditors or verifiers must pass a performance based assessment. An auditor or verifier must meet ISO 17020 (Inspection Bodies) requirements; which covers conflict of interest issues. An accreditation body, JAS-ANZ, conducts a "witness assessment" of each auditor annually, or once every two years if the individual had received an

exceptional rating during the previous assessment. A “witness assessment team” includes a JAS-ANZ representative, a NZFSA Compliance and Investigation Group (CIG) technical expert and a Recognized Agency representative. Training and qualification records were reviewed for several AsureQuality individuals; and records were found to meet the requirements.

Minimum qualifications for a new auditor at AsureQuality (AQ) (though not a specific NFSA requirement for a recognized person) include a degree in a relevant field of study, and preference is given to applicants who have experience in the product category they will be working in, either in industry or compliance. New auditors must also pass a criminal background check. Training for new hires is conducted on the job, with 100% supervision. Once training is complete all auditors must be recognized by NZFSA, which involves an on-site verification (audit) by JAS-ANZ and CIG, plus passing a technical interview to ensure that they understand legislative requirements, market access requirements and specific issues related to the commodities that they cover.

AQ auditors are shadow audited, and have an internal peer review at least annually. Training courses are routinely provided. However, there is no annual on-going education requirement. Annual meetings are held for all auditors, and information sharing team meetings and calibration meetings are held approximately once a month. Weekly phone call meetings are conducted with the dairy team auditors.

The NZFSA Verification Agency (VA) provides training that includes Induction Training, E-Learning, Sector Training, and National Conferences. Criminal background checks are required for all VA signatories (authorized persons) and psychometric profiling is required for all new applicants to inform hiring decisions. Induction training for new hires involves a six week program, followed by a six month warranting plan, which includes participation in a JAS-ANZ audit course, HACCP training, etc. (“Warranting” is the term used for the process that gives final approval to a VA signatory, and is similar to the FDA term “credentialed”).

Under current business practice, new applicants for positions at the NZFSA VA are required, to have a degree in a field relevant to the position sought. Existing staff (hired prior to this policy taking effect) without a degree are required to complete a two year “associate degree” program customized for VA. An on-going training program consisting of continuing education courses is delivered via a web-based E-learning system. Individuals are required to achieve a certain number of training “points” in order to maintain competency, and spreadsheets documenting the individual training plans of each employee are maintained by the agency. In addition to individual training plans, a one week national training conference is held annually, with sessions repeated so that all individuals are able to attend.

ICAT Conclusions

An effective training and certification program which can assure qualified staff appears to be in place. Training of NZFSA is well documented, complete and comprehensive.

Adequate oversight of the qualifications and certification of recognized agencies also appears to be in place. Based on information provided in the NZ ICAT submission and records reviewed on-site that demonstrated the implementation of training policies, the ICAT team can recommend that training programs in the NZFSA food safety system are comparable to those employed by the FDA.

Standard 3 - Inspection Program

The Inspection Program Standard describes the key elements of an effective food safety inspection program. In order to meet the basic requirements of this standard the competent food safety authority must have an inspection program in place that reduces the likelihood of the occurrence of food borne illness, injury, or allergic reaction by:

- maintaining basic surveillance of the entire food safety system, from production to manufacturing and transportation;
- focusing inspection resources on high risk plants, products, and processes. The criteria for classification of risk for food processors includes: type of processing, type of food, volume of product manufactured/distributed, target population, and compliance history;
- obtaining immediate corrections and long-term improvements by manufactured food processors; and
- responding efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food system.

Individual elements that must be in place include a risk-based inspection program, written inspection protocols, the ability to address consumer complaints, industry inspection complaints and food recalls, and a system in place to document these activities.

ICAT

Documentation that was reviewed over the course of the ICAT review of Standard 3 included:

- Certification documentation (including initial accreditation and periodic reviews) of recognized agencies and individuals
- Copies of audit reports submitted to NZFSA
- Documentation showing that verifications (i.e., inspections) are being conducted on time and to appropriate standards (e.g., shellfish)
- Inspection guidelines that are provided to individual field staff (seafood and dairy)
- Information on the implementation of inspection and compliance programs. (e.g., the make-up of an inspection team and the roles of each participant such as the technical manager)
- Inspection schedules (allocated vs. unallocated) for seafood and dairy and inspection reports submitted by various recognized agencies

NZFSA's inspection program is comprehensive, and documentation reviewed by the ICAT team supports the finding that the program is implemented fully and consistently.

Inspections of firms in NZ are conducted as Performance Based Verifications (PBV) with frequency of inspection varying based on compliance history. Firms are categorized into six levels of performance. Levels 1 – 3 involve increased verifier oversight, while Levels 4 – 6 have decreasing verifier involvement. Inspection frequencies are dependent on firms' compliance history, which is used to determine the level at which a site is performing. If a firm does not meet inspectional expectations, the facility will drop one or more levels, depending on the severity of the issue(s). Premises at Levels 1 or 2 require a written Management Plan to be created and implemented. Unacceptable inspection results in the bottom three performance levels require three acceptable audits in sequence before the facility can move up one level. Unacceptable inspection results in the top three performance levels require two acceptable results in sequence before the site can move up one level. It is the operator's responsibility to make sure that the RMP is "Correct to Run" and that it is "Run Correctly".

After completing the paper review of materials submitted by the NZFSA on NZ's inspection program, the ICAT team had some remaining questions on the specific interaction between the NZFSA (a government agency), recognized agencies (such as AsureQuality) and private "recognized persons" who perform inspections for the government. An important element of the ICAT team's review of NZFSA's programs focused on how the agency addresses potential conflicts of interest in the fee-for-service operations of the food safety system and how the government maintains control of the different sectors involved in the process.

During meetings with NZFSA staff as well as officials from governmental and non-governmental recognized agencies (which perform inspections), the ICAT Team discovered that NZ's fee-for-service system in fact provides incentives for firms to remain in compliance with NZ's regulations, and potential conflicts of interest are addressed systematically. Food processors in NZ must pay all costs associated with regulatory activities, including inspections of their facilities. Firms that are deemed out of compliance during an inspection are required to undergo inspections at increased frequency (and therefore increased cost). If non-compliance issues continue, frequency of inspections will continue to increase and in serious cases a firm could be forced to cease operations (by NZFSA) until such time as corrective actions are implemented.

ICAT Review of AsureQuality

AsureQuality (AQ) is a recognized agency (RA) that was established in 1998. AQ is operated as a commercial enterprise and is owned by the NZ government, conducting business primarily in NZ and Australia and also has a laboratory in Singapore. Auditors are qualified for various specialties (for example Heat Treatment & Premises Evaluators; Evaluators; and Verifiers). As a certification body AQ adheres to a number of requirements to avoid conflicts of interest and ensure a reputation of impartiality. The policies and practices at AQ regarding conflict of interest are consistent with those of the NZFSA. Documentation reviewed at AQ revealed that conflict of interest policies are implemented consistently and effectively.

Audit scheduling at AsureQuality is managed through a database at headquarters. AQ provides standard checklists to auditors to be covered over the course of the audit. A plan is created annually with some flexibility to meet additional needs as necessary. Most audits conducted by AQ are “announced”, with facility notification approximately 12 months in advance. AQ conducts routine audits of dairy processors. Heat treatment for dairy facilities is audited quarterly, which includes records, operator’s logs and operator interviews. Calibration records are checked annually. One out of ten scheduled audits is unannounced (defined as a zero to forty-eight hours notification).

If a major compliance issue is discovered during an AQ audit, the auditor could make a recommendation to the facility to stop production, or in cases where the RMP provides AQ auditors the authority to stop production, they may do so. If the operator were to refuse to stop production, the auditor would immediately report this to AQ, and AQ would in turn report the incident to CIG for follow-up. Depending on the severity of the situation CIG may mobilize staff to shut down the facility. NZFSA may also administratively determine any or all product from the premises to be non-conforming on the basis of it not being produced in compliance with the approved RMP. Non-conforming product must remain on hold and cannot be sold without a specific product disposition approval from NZFSA. At the audit exit meeting, the facility is left with a “site report” listing any non-conformances that had been identified over the course of the audit. A corrective action (CA) and completion date is assigned to each non-conformance.

AQ implements an internal peer review system to review audit reports, after which some final reports are reviewed by NZFSA CIG. Final audit reports must be completed and sent back to the site within ten working days of the audit.

Corrective actions are tracked at AQ headquarters. Defined escalation procedures are in place for cases where facilities do not complete CAs. An audit appeal process is also in place, including internal appeal with AQ, appeal to NZFSA, and finally the possibility of an appeal to the Minister.

“Exception reports” must be issued by facilities for any critical event and/or event involving non-conforming product. By law, an operator is required to verbally report critical events or non-conforming product issues within 24 hours to AQ, with follow-up written documentation submitted within 72 hours (a requirement for all recognized agencies). AQ must in turn report critical events immediately to NZFSA CIG and the Manager Export Eligibility. All critical non-compliances where product is deemed to be affected are required to be reported by AQ to the Manager Export Eligibility. These are then logged into the Interim Verification Database (IVDB) which links with NZFSA’s certification system. A monthly report of all non-conforming product events (critical or non-critical) is sent to NZFSA. Non-conforming product is required to remain on hold and can only be sold in compliance with product disposition approval criteria set by NZFSA.

Review of AssureQuality records by the ICAT team showed one critical exception in 2010 that required reporting to NZFSA. Other documentation of non-conforming product reported to AQ involved cases where the operator or the export broker maintained control and addressed the issue. The ICAT team also reviewed the August 2010 AQ Exception Report Tracking spreadsheet.

ICAT Team Conclusions

The ICAT team was allowed full access to all documentation requested and was satisfied with the completeness of documentation sufficient for a recommendation of comparability of NZ's inspection program with that of the FDA. From a program management standpoint, NZFSA has implemented the elements of Standard 3 and, based on the team's review of AQ, it appears that NZFSA provides suitable oversight of recognized agencies to assure that recognized agencies implement the same elements in their inspection programs. However, the ICAT Team review was limited to documentation at headquarters only. The full review of Standard 3, therefore, will be based on ICAT Team findings as well as the findings of each of the commodity teams that reviewed inspection programs in the field.

Commodity Specific Audits:

Seafood and Dairy Teams

Background

The purpose of the on-site observation of inspection program implementation was to assess the performance of verifiers conducting audits of manufacturers on behalf of NZFSA with regards to the technical knowledge, their implementation of inspection protocols, and their ability to recognize and evaluate deficiencies based on their own requirements. FDA observed NZFSA Verification Agency's (VA) audits of processing facilities' Risk Management Programs (RMP) and the implementation of the RMPs approved by NZFSA. The on-site observation was not intended to evaluate whether NZFSA's inspection program elements met FDA's requirements. However, it did evaluate the verifier's abilities to recognize food safety and sanitation concerns.

Each FDA seafood team consisted of two members who observed VA verifiers and CIG auditors performing eight audits in eight facilities of various sizes processing different commodities. Six of the audits were performed by VA and two of the audits were CIG's audits of the VA verifier's performance. Facilities that were visited processed various products including: ready-to-eat molluscan shellfish, aquacultured salmon products, breaded seafood, and wild caught finfish.

The FDA dairy team consisted of two members who observed Recognized Agency (RA) verifiers performing audits in five processing facilities and NZFSA Compliance and Investigation Group (CIG) auditors in two processing facilities. The types of products manufactured in the facilities visited ranged from milk or milk component powders, butter, cheese and ice cream.

In order to ensure that evaluations by individual teams covered uniform and common points, the seafood and dairy teams used the same premise for conducting evaluations, basing their assessments on criteria from the FDA Office of Regulatory Affairs (ORA) Level II Seafood HACCP Certification program evaluation worksheet. The criteria was modified to cover key safety concepts, applicable across commodities, including sanitation, audit performance, communication skills, and documentation of findings.

Raw molluscan shellfish processors included in the observed audits were operating under standards which reflected the outcomes required by the U.S. National Shellfish Sanitation Program (NSSP) requirements. Shellfish processors in NZ are audited by NZFSA under dual controls, receiving quarterly inspections for compliance with NSSP-based requirements in addition to periodic Performance Based Verification (PBV) inspections for compliance with NZ national standards. FDA observed PBV audits rather than NSSP verifications due to the fact that the proposed comparability agreement between FDA and NZFSA is intended to include molluscan shellfish as part of that program.

Seafood Team

NZFSA VA assumes primary responsibility for verification of seafood processors who are exporters. The NZFSA VA utilizes a sophisticated computer system called VA OnLine that links inspectional resources with inspection histories and assigns to each facility's RMP key inspection points based on their process and their RMP. The system then assigns a required number of components to be covered during each PBV. VA verifiers can use the system to review topics covered during the last inspection or previous inspections and topic outcomes. The system assures that all key inspection points will be covered on an annual basis. The minimum inspection frequency is twice annually, though inspections can occur more frequently based on the compliance history of the processor.

The facility audits observed by FDA consisted of several components. First, in preparation for the audit, the VA verifier reviewed previous inspection reports and developed a general approach to the inspection, including the use of an audit template that outlined areas that would be covered during the audit. Although the audit templates varied from plant to plant, the performance of the VA verifiers in meeting their verification goals was consistent. Next, the verifiers completed on-site review of records that processors are required to maintain, including documentation of the implementation of their RMP. Verifiers referred to RMP manuals, which were provided by the firms, during all audits to assure that records accurately reflected the written program. They reviewed documents for completeness and accuracy and were meticulous in their records reviews, viewing multiple documents and cross-checking those records. The verifiers spent a reasonable portion of their time to complete this process. Facility employees were questioned during these paper reviews. In addition to direct communication that takes place during inspections, VA and the processing facilities are in direct communication to ensure compliance and implementation of the corrective actions between inspections.

The facility walk-through inspection (called a "reality check") is the third component of an NZFSA audit. The facility inspections include comprehensive sanitation inspection and also cover specific areas under the RMP that are specified by the VA online program. During the observed audits this included the entire facility and storage areas. The VA verifiers targeted key "high risk potential" processing steps and assessed overall sanitation and GMPs. Verifiers spent a significant portion of time assessing structural defects and sanitation issues. Each inspection is conducted in a single day. During the inspection the VA verifies compliance with new and updated regulations/ guidances where applicable.

Differences were observed between the PBV protocols and components covered during an FDA HACCP inspection. Processors in NZ utilize RMPs that are developed by the processors or a qualified third party. As mentioned previously, RMPs are approved by "recognized" technical experts. Outlines of the approved RMPs are forwarded to NZFSA for a compliance review, acceptance, and registration. RMP safety controls are accomplished through a combination of HACCP plans and RMP written SOPs. As a rule, the VA verifiers do not evaluate the content of RMP's during their inspections, since content has already been approved by NZFSA as part of the RMP approval process. However RMP documentation and the facility's implementation of the RMP are evaluated to determine the firm's compliance with NZ regulations. Unlike an FDA investigator, the VA verifier does not conduct a hazard analysis, flow diagram, or evaluate the processor's HACCP plan to determine completeness of the RMP, because these are evaluated and approved by NZFSA as a condition of approval for facility start-up.

FDA observed that hazard analyses excluded what FDA would normally consider hazards and critical control points that would be identified in a HACCP plan, but rather covered them under different standard operating procedures (SOPs) or codes of practice within the RMP. Additionally, certain deficiencies were observed by FDA but the occurrence of deficiencies is often the case in inspections, and corrective actions were identified by NZ to be put into place by the firms.

Part of FDA's performance audit criteria was to assess the quality of the audit reports for accuracy and content. FDA received some copies of completed VA audit reports prior to departure from NZ and others, including the CIG audit reports, upon return to the U.S. The reviewed reports were well written, appeared to meet NZFSA criteria, and accurately reflected conditions and observations.

Dairy Team

As with seafood, the RMPs of dairy facilities are verified over multiple site visits over the course of each year, with a rotating quarterly focus on various aspects of the RMP. Certain aspects such as traceability and follow up on previous deficiencies are covered each quarter (or more frequently if the operation is under more frequent performance-based verification protocols). Software used by RAs allows verifiers to review topics covered during the last inspection or previous inspections as well as topic outcomes. The software system appears to provide controls to assure that all topic listings are covered

within a given year. The minimum inspection frequency is quarterly, but may increase based on the compliance history of the processor.

The overall system observed by the dairy team was consistent with that observed by the seafood team, in terms of preparation of checklists and the functioning of the system overall.

One component of the verification activity conducted by the dairy team included a review of records, in particular records associated with traceability of products. Dairy processors in NZ are required to self verify and maintain documentation of the implementation of the different components of their RMP, including HACCP plans. In all cases, pasteurization was identified as a Critical Control Point (CCP). NZFSA requires that the RMP manual is maintained by the firm, and the dairy team noted that the manual was available and referred to during all audits to assure that records accurately reflected the written program. Verifiers reviewed documents for completeness and accuracy. Verifiers were meticulous in their records reviews, viewing multiple documents and cross-checking those records. The verifiers spent a reasonable portion of their time to complete this process. Facility employees were questioned during these paper reviews.

The dairy team noted that the ISO systems-based approach used in NZ (i.e., the requirement that firms develop and submit their RMP for prior approval) that uses HACCP principles at its core, is above and beyond the minimum regulatory requirements for dairy in the United States (i.e., GMP requirements contained in 21 CFR 110 and the pasteurization requirement contained in 21 CFR 1240.61).

The RA verifiers from SGS and CIG assessors verbally reviewed findings with the facility personnel during the audits. Significant findings (“key topics”) were discussed at the end of the seafood and dairy inspections. All RA verifiers and CIG assessors were competent, articulate and communicated well with the facility staff.

As with seafood, dairy processors are required to develop and implement RMPs that are reviewed and approved by the RA technical experts, who are not members of the field verification staff. Safety controls are accomplished through a combination of HACCP plans and RMP written Standard Operating Procedures (SOPs). During the dairy audits, RA verifiers did not necessarily evaluate the content of an RMP during their inspections, instead evaluating the firms’ implementation of their own RMP.

FDA observations during the dairy audits were mostly limited to Good Manufacturing Practices and sanitation deficiencies. In all cases, the NZ verifier/assessor noted the same things observed by FDA observers, all of the items relating to housekeeping and facility maintenance issues typically observed in domestic dairy manufacturing operations.

Conclusions

RA verifiers and CIG assessors appeared competent, completing effective and accurate evaluations of audited processors’ implemented RMP programs. Verifiers and auditors were familiar with the food safety issues and necessary controls associated with their

respective commodities. Their identification and classification of deficiencies was consistent with FDA's observations, which implies that the overall inspection program is likely to result in outcomes similar to FDA's inspection evaluations. The third-party certification (recognition) approach used by NZ for the direct oversight of firms, in addition to the NZFSA audit program, effectively results in compliance with NZ food safety standards. Overall, the implementation of the field audit program was consistent among various auditors and between agencies and the inspection program can be recommended to be comparable to that of FDA.

Standard 4 - Program Assessment/ Inspection Audit Program

The Program Assessment and Inspection Audit Program Standard describes the basic quality assurance reviews necessary to: (1) evaluate the effectiveness of the food safety and inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections and to protect the public health by ensuring a safe food supply.

In order to meet the basic requirement of this standard the competent food safety authority (CA) must provide documentation demonstrating how they conduct periodic self-assessments and quality assurance reviews of the food safety and inspection program that are designed to identify the strengths and weaknesses of the program. The CA should then demonstrate how the results of the self-assessments are used to determine areas or functions of the food safety program that need improvement, to develop improvement plans and to establish timelines for implementing improvements.

ICAT

Upon completion of the review of materials submitted by NZFSA regarding Standard 4, Program Assessment/ Inspection Audit Program, and finding the submission to be complete, the ICAT Team's goal during the in-country review was limited to verification of materials that were submitted.

Documents reviewed related to this standard included:

- CIG audit protocols and audit sheets
- Audit reports completed by CIG (located on CIG Information Leader database)
- Documentation outlining the procedures in place for auditing contractors

The NZFSA has agreements with two accreditation bodies that perform audits of recognized agencies (including NZFSA VA, AsureQuality and SGS) and laboratories: the International Accreditation NZ (IANZ); and the Joint Accreditation System of Australia and NZ (JAS-ANZ). NZFSA requires that the accreditation bodies must be accredited to ISO 17011 (General requirements for accreditation bodies).

Recognized Agencies

Recognized Agencies (RA) in NZ are required to be accredited to ISO 17020 (General criteria for the operation of various types of bodies performing inspection) and must have quality assurance plans. Accreditation audits of Recognized Agencies (RA) are based on

the following performance measures: documented regular review of verification reports; results of audits by the NZFSA Compliance and Investigations Group (CIG); meeting reporting requirements; and demonstrating compliance with ISO 17020 and NZFSA requirements. AsureQuality, one of several recognized agencies, and recognized for dairy audits, is accredited by JAS-ANZ against ISO 17020, ISO 17025 (General requirements for the competence of testing and calibration laboratories) and ISO 17021 (Requirements for bodies providing audit and certification of management systems).

During the in-country review, the ICAT team met with a representative from JAS-ANZ, a nonprofit agency that reports to governmental departments in both NZ and Australia. JAS-ANZ provides performance based audits of recognized agencies and individual auditors, primarily focusing on the dairy program. (JAS-ANZ is not involved with meat or seafood.) Information obtained from JAS-ANZ includes the following:

- Recognized Agencies (RA) must be visited at least annually per NZFSA requirement. However, JAS-ANZ requires reviews every 6 months.
- A JAS-ANZ assessment team includes one JAS-ANZ assessor and one CIG technical expert. The CIG participant provides immediate feedback to the assessor or agency under review.
- The official JAS-ANZ report is provided to the assessor or agency after internal review (within 5 days), after which the assessor or agency has 15 days to review the document. Concurrence or non-concurrence by the client is evaluated before the report is finalized.
- JAS-ANZ assessors receive quarterly training, and their work is peer reviewed.
- JAS-ANZ participates in and is reviewed by the International Accreditation Forum (IAF) and the Pacific Accreditation Cooperation.

The NZFSA Verification Agency (VA) performs system verification audits of Risk Management Programs. The VA has been accredited to ISO 17020 by IANZ, with re-accreditation taking place every 3 years and annual audits of paperwork only. Accreditation includes office review of documentation as well as audits of field activities. The VA also conducts its own self-assessment audits on an annual basis.

The ICAT team reviewed the most recent IANZ accreditation audit of the VA while in country. Twenty-five recommendations were made with no major issues noted.

ICAT Team Conclusions

NZFSA program files and documentation requested by FDA were made available to the ICAT team for review. Files reviewed included Letters of Recognition of Recognized Agencies, Accreditation Assessment Reports, Certificates of Accreditation, Corrective Action Plans, Certificates of Approval for Risk Management Plans, Laboratory Approval Schemes (LAS)/Program Manager Assessment Reviews, documents showing additions/deletions/approved test changes sent to the LAS Administrator and NZFSA, Risk Management Programs and associated registrations, letters showing changes to another Recognized Agency, Accreditation Schedules, NSSP Standardized Shellfish

Processing Plant Inspection Forms, documentation of an Internal Audit of the NZFSA Verification Agency completed by the NZFSA CIG, and others. After a thorough review of documentation related to Program Assessment and Inspection Audit Programs, the ICAT team found that NZFSA had an effective, implemented program in place and can be recommended to meet all comparability requirements for this standard.

Seafood and Dairy Teams

The purpose of the on-site observation of performance audits was to evaluate the implementation of NZFSA Compliance Investigation Group (CIG) assessments of the performance of NZFSA Verification Agency (VA) and Recognized Agency (RA) verifiers. These assessments are intended to verify that an acceptable level of performance and consistency in performance within the VA and RA field inspection programs is in place. CIG performance audits assess the VA verifier's ability to follow established standards, to determine the accuracy of their observations, observe the verifier's inspection, and the verifier's performance of corrective action follow-ups. The goal of FDA's audit was to confirm and evaluate the implementation of these internal control activities.

CIG has 'read only' access to VA records through VAOnline. In preparation for audits involving VA, CIG assessors obtain background information on the verifier and facility to be audited through VAOnline. This plus information from previous CIG audits of the facility (reports are held in CIG's Information Leader) help, along with CIG procedures and checklists, to generate a list of topics to be covered. As the terms of reference for the audit are being created in Information Leader, each assessment/audit is assigned a unique audit number by Information Leader.

As part of each audit, the CIG assessor reviews the verifier's training records and "recognition" records/documentation, which assures their qualification to perform audits. Audits include interviews with the verifier, which cover conflict of interest and technical knowledge, documentation reviews of both NZFSA VA records and of facility records, and observation of the performance of the verifier.

Seafood and Dairy Team Observations of CIG Audits

Each team observed two NZFSA CIG assessors as each performed an assessment of the performance of recognized verifiers from different recognized agencies. The recognized verifiers who were audited worked in separate regions and were reviewed at facilities that were on their list of assigned firms.

The performance audits were interactive and appeared to be used, in part, as a teaching tool. It was clear during each of the audits that the CIG assessor was considered the lead. CIG provided the closing observations to the firm. Each of the verifiers was rated as acceptable by the CIG assessors.

The recognized verifiers and CIG assessors verbally reviewed findings with facility personnel during the audits. Significant findings ("key topics") were discussed at the end of the inspections. All verifiers and CIG assessors were articulate and communicated

well with the facility staff. CIG's verifier assessment reports are subject to internal peer-review by other CIG assessors.

Seafood Conclusions

CIG oversight of the performance of the VA audit program appeared comprehensive, encompassing preparation for inspection and on-site performance, including both facility inspections and records reviews. The CIG assessors exhibited high levels of expertise and were qualified to assess the abilities of the VA verifiers. Observed audits demonstrated that the NZFSA self-assessment of their implemented inspection protocols appears effective.

Dairy Conclusions

The implementation of the internal RA review and oversight appeared to be more comprehensive in one RA than the other. CIG indicated that they are working closely with the lesser performing RA to assist them in making improvements. CIG oversight of the performance of the RA verification program appeared comprehensive, encompassing preparation for inspection and on-site performance, including both facility inspections and records reviews. The CIG auditors exhibited a high level of expertise and were well qualified to assess the activities of the RA verifiers. Observations made by FDA affirmed the effectiveness of NZFSA oversight of the RAs.

Overall Conclusions

Overall, the implementation of this standard by the NZFSA can be recommended as being comparable with FDA.

Standard 5 - Food-related Illness and Outbreaks

The Food-Related Illness and Outbreaks Standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies that may result in illness, injury, and outbreaks. The standard also applies to the collection, analysis, and dissemination of information that may prevent illness and outbreak recurrence. In order to satisfy the basic requirement of this standard the competent food safety authority must have a system for surveillance, investigation, response, documentation, analysis, communication and follow-up of alleged food-related illnesses, injuries, and unintentional or deliberate food contamination.

ICAT

Written documentation provided in NZ's ICAT submission covered the system that NZFSA has in place to handle food safety events, from surveillance and reporting through investigation, follow-up and communication. Communication tools are viewable on the NZFSA website.

While in-country the ICAT team was able to view documentation describing an actual food safety event, including specific procedures undertaken for trace-back / trace-forward. All records and documentation were located within the Information Leader database.

The case history that the ICAT team reviewed involved the investigation of a *Salmonella* outbreak that resulted in a recall of finished product. The investigation and follow-up activities appeared to have been conducted in an efficient and responsible manner. The NZFSA Crisis Incident Management System (CIMS) and sections of the NZFSA CIMS operations manual were reviewed. An overview of the agency activities related to the recent earthquake in Christchurch was also provided, as well as sharing of information and “lessons learned” related to the international melamine incident.

ICAT Conclusions

After a full review of records from the database the team was satisfied that NZ has implemented a robust system of trace back and trace forward and is well equipped to handle food safety emergencies and events. Based on records review and discussion with NZFSA officials, the system in place to investigate food-related illness and outbreaks can be recommended to be comparable to that of the US.

Standard 6 - Compliance and Enforcement

The Compliance and Enforcement Program Standard describes the competent food safety authority’s strategies, procedures and actions to enforce food safety laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program. In order to satisfy the basic requirement of this standard the competent food safety authority must have a compliance and enforcement program that provides procedures to ensure that policies are supported by sound judgment, adequate evidence, and appropriate documentation.

ICAT

In their ICAT submission, the NZFSA provided a complete view of the compliance and enforcement mechanisms that are in place in NZ. Mechanisms include the implementation of a risk-based enforcement and compliance system which incorporates corrective action plans and progressive enforcement actions that include seizures and other mechanisms to prevent adulterated foods from entering the marketplace. When warranted, criminal prosecution and other sanctions are also available options.

The ICAT team reviewed key documentation in order to assess the implementation of compliance and enforcement. This documentation included:

- Certificates and/or contracts of recognized agencies/individuals
- Copies of audit reports submitted to NZFSA
- Verifications being conducted on time and to appropriate standard (i.e. shellfish)
- Inspection guidelines provided to individual field staff (seafood vs. dairy)
- Examples and documentation of compliance assessments, including:
 - Case(s) where the verification agency and a recognized agency required corrective action, with follow-up documentation
 - Case(s) where the VA and a recognized agency notified CIG of high-risk violation(s) and follow-up actions taken.

ICAT Review of CIG

During the on-site review of CIG the ICAT team reviewed a report of all CIG activity for the period July 1, 2009 to June 30, 2010. Over this time period 306 audits had been conducted, and 48 of those audits showed issues needing correction. The ICAT team also reviewed specific files involving consumer complaints and regulatory investigations that precipitated formal warning letters, regulatory sanctions and court cases.

The ICAT review of CIG included the following:

- Overview of CIG's system, including risk classification system and determination of a critical violation
- Examples of RMP outlines and/or FSPs filed at NZFSA
- Documentation of compliance assessments (verifications) that have taken place
- NZFSA's annual review report of CIG audits
- Documentation of a corrective action plan that has been implemented
- Documentation of progressive enforcement actions, follow-up corrective actions that have been taken (including ~2 administrative and 2 regulatory) and tracking via the Information Leader system
- Records indicating how CIG maintains consistency between recognized agencies (i.e. periodic reviews and calibrations)

CIG is comprised of three teams: Compliance (audit), Response (Investigation, Recalls, Prosecution, etc.) and Business Services (Admin support). A specialist advisor is also on staff to assist with mitigations. CIG primarily performs audits of verifiers and industry systems as a whole, rather than specific facilities.

CIG utilizes the previously referenced Information Leader database to organize and document CIG activities, from the scheduling of audits (complete with eight types of audit or assessment templates) to the storage and documentation of data and other files and more. The database can generate a "Location Findings Report", which is sent with a cover letter (similar to a FDA untitled warning letter) to firms that have compliance issues. Depending on the type of audit, serious issues are followed up on by the NZFSA VA (e.g., if found during a NZFSA VA internal audit), with a follow-up letter to the firm.

Information Leader allows for all investigation documents to stay "attached" to the electronic summary file. The system also has the capability to trend data fields for an analysis of systems audits, a very useful self-auditing tool. A quarterly trending report is sent to CIG upper management, and a toll free phone number is available for consumers to report issues directly to CIG. Approximately 2000 consumer contacts per year require CIG involvement.

In terms of authority to take action in response to non-compliance, members of the NZFSA VA field staff have immediate legal authority to detain product and suspend processing operations in cases where issues are identified that may pose a threat to public health. Additionally, a primary enforcement tool and administrative sanction available to food safety officials in NZ is a Notice of Direction – similar to a US injunction.

According to NZ law, the operator must prove that the CIG acted improperly in order for

the operator to get a favorable injunction ruling. In cases of technical non-compliance issues (i.e. labeling), a “template” cautionary letter may be generated by NZFSA, which is primarily advisory in nature.

While on site, a facility’s Risk Management Program (RMP) may allow the auditor to “stop production” if a major compliance issue is discovered. Generally, however, in such cases the auditor would make a recommendation to the facility to stop production. If the operator were to refuse to stop production, the auditor would immediately report this to the RA’s head office, and the RA would in turn report the incident to CIG for follow-up. Depending on the severity of the situation CIG may mobilize staff to shut down the facility or direct the product be detained, subject to further treatment, downgraded to a non-human consumption status or destroyed.

ICAT Conclusions

NZFSA has a system in place to document and track non-compliance and corrective actions. There are procedures in place to assure appropriate regulatory action when necessary. The agency has the ability to track trends to aid in the assessment of their industry and programs.

The compliance and enforcement system as reviewed on paper and in-country can be recommended to be comparable to that of the FDA.

Standard 7 - Industry and Community Relations

The Industry and Community Relations Standard describes the elements of industry and community outreach activities developed and accomplished by the competent food safety authority. In order to satisfy the basic requirements of this standard, the competent food safety authority must participate in activities that foster communication and information exchange among regulators, industry, academia and consumer representatives, and use outreach and educational activities to inform the varied populations about food safety-related issues.

ICAT

Through documentation provided by the NZFSA in their ICAT submission, the FDA reviewers noted that the NZFSA provides outreach to industry and the community through its website as well as other traditional media outlets. Outreach materials are developed for food safety officials, inspectors, consumers and industry. NZFSA utilizes extensive web-based communication tools, including quarterly publications, press releases and other electronic communication tools to disseminate information. Monthly industry calls and other activities are also initiated as needed.

ICAT Conclusions

The materials and links provided in the NZFSA ICAT submission demonstrate that the NZFSA has a robust public and industry outreach program that provides comprehensive information to both consumers and industry. The system can be recommended to be comparable to that of the FDA for this standard.

Standard 8 - Program Resources

The Program Resources Standard describes the elements for assessing the adequacy of the resources (staff, equipment, and funding) available to support a food safety regulatory program. In order to satisfy the basic requirements of the standard the competent authority must have adequate resources to support a comprehensive food safety program.

ICAT

Through documentation provided by the NZFSA in their ICAT submission, the FDA reviewers were satisfied that the competent authority has adequate staff, equipment and funding available to support the food safety programming. In-country review revealed a system that was running efficiently and with adequate staffing and equipment, including new web-based systems for documenting and tracking activities and outcomes of work conducted by NZFSA, compliance histories of firms and other aspects of the food safety control system.

Funding of inspection and enforcement activities in NZ is provided through fee-for-service operations, including the use of third parties to conduct inspection activities. NZFSA has implemented programs and policies to address potential conflict of interest issues, through the establishment of ethics guidelines, accreditation audits and audit programming to ensure impartiality. Conflict of interest is addressed more fully in this document under Standards 3 and 4.

ICAT Conclusions

NZFSA has a system in place that assures that adequate funding and resources are available to accomplish their food safety mission. Based on records reviews, adequate staffing and resources are in place. In terms of program resources, NZ can be recommended to be comparable to the US.

Standard 9 - International Communication and Harmonization

The International Communication and Harmonization standard describes interaction between the competent food safety authority and the international community. In order to meet the basic requirements of this standard the competent food safety authority should have mechanisms in place to interact with the international community regarding international food safety standards as well as communication mechanisms in place to be used during food safety events of international concern.

ICAT

Through documentation provided by the NZFSA in their ICAT submission, the FDA reviewers were satisfied that the NZFSA's international communication and harmonization policies and their implementation are comparable to those of the United States. NZ is extremely active in international venues, including the Codex Alimentarius Commission, the World Trade Organization, the United Nations Food and Agriculture Organization and World Health Organization. In addition to NZ's active participation in the multilateral arena, NZFSA participates extensively in bilateral meetings and activities on an ongoing basis.

ICAT Conclusions

Because of NZ's high level of activity in bilateral and multilateral venues as well as their strong history of close communication with trading partners, no additional in-country review was necessary, and the ICAT team concludes that NZ can be recommended to be comparable with respect to this standard.

Standard 10 - Laboratory Support

The Laboratory Support Standard describes the elements of laboratory support necessary for a comparable food safety regulatory program. In order to meet the basic requirements of this standard the competent food safety authority must have access to the laboratory services needed to support program functions and must document its laboratory capabilities, including written agreements with external laboratories where applicable.

ICAT

The ICAT team participated in the verification of the NZFSA laboratory support documentation only from the perspective of the records available at the NZFSA headquarters. The actual laboratory visits were performed by the Laboratory Assessment team.

Requirements for NZ laboratories are covered under the APA 1999. Laboratories that perform food safety testing must be recognized by the NZFSA, be ISO 17025 accredited and analytical methods must be approved by NZFSA. Specific supplemental requirements are in place for laboratories that test specific commodities. For instance, dairy labs must go through a commodity-specific recognition process and meat, poultry and seafood laboratories must operate under a Laboratory Approval Scheme (LAS). Additionally, AsureQuality (the third party recognized verification agency described in detail in previous sections of this report also operates laboratories utilized in testing dairy, meat and seafood product) offers an Inter-laboratory Comparison Program (ILCP). The AQ laboratory offering the ILCP provides standardized samples and result assessment of the program. The ILCP ensures compliance with regulatory and laboratory accreditation requirements (including ISO 17025). There are 44 laboratories in NZ currently approved by NZFSA.

Laboratory Site Visits

The FDA Laboratory Assessment Team (LAT) reviewed oversight and regulation of laboratories via site visits to NZFSA, the NZFSA Compliance and Inspection Group (CIG), and International Accreditation NZ (IANZ). IANZ is NZ's national authority for the accreditation of testing and calibration laboratories, inspection bodies and radiology services. Additionally, LAT visited four laboratories to review implementation of oversight and regulation of laboratory support. LAT also observed a simultaneous abbreviated visit by NZFSA CIG personnel to the laboratory, conducted per NZFSA program requirements.

Review of NZFSA Records

The NZFSA Laboratory Approval Scheme (LAS) program specifies standards and requirements for NZFSA approved laboratories that carry out microbiological, chemical, or other specified laboratory tests for market access requirements. NZFSA considers LAS to be an integral part of NZFSA official assurance for market access. As part of the in-country verification of information provided by NZFSA in their ICAT submission, the laboratory team reviewed records for LAS laboratories to verify NZFSA implementation of laboratory controls. LAT reviewed documentation related to NZFSA laboratory audits and NZFSA communication with IANZ regarding laboratories. Additionally, LAT verified that the listing of accredited laboratories on the NZFSA website is up to date and is updated regularly.

During the records review, LAT verified that NZFSA has accreditation and audit documentation on file, communications with IANZ were documented, and that the NZFSA website listing was current.

International Accreditation New Zealand (IANZ)

As mentioned previously, IANZ is the national authority in NZ for the accreditation of testing and calibration laboratories, inspection bodies and radiology services. IANZ is signatory to the International Laboratory Accreditation Cooperative mutual recognition agreement (ILAC MRA) This status indicates that IANZ operates in accordance with ISO 17011 and is internationally recognized as competent to accredit laboratories in accordance with ILAC rules and procedures.

IANZ performs laboratory accreditation for food laboratories in NZ following the International Organization for Standardization's (ISO) standard ISO 17025. The ISO standard includes general requirements for the competence of testing and calibration laboratories. In addition, standards published by NZFSA specific to a particular laboratory's scope and business are reviewed as part of the accreditation scope. During the in-country review of NZ's laboratory resources LAT reviewed in detail the IANZ accreditation and record review process.

CIG Oversight of Laboratories

CIG audits are complementary to accreditation by IANZ. Accreditation by IANZ ensures that an operating quality management system is in place; CIG ensures that the labs follow applicable regulations, guidance, and laws. By necessity, there is overlap in review areas, but the goal of each auditing organization is unique. The focus of CIG audits is not detailed procedural auditing, because verification of implementation of procedures is performed by IANZ as part of laboratory accreditation. Instead, the CIG audits have a systems focus, emphasizing the ability of the lab to provide accurate and reliable laboratory results. Examples of CIG audit documentation and performance were reviewed during FDA onsite visits at laboratories.

Laboratory Support: Summary and Conclusions

The FDA Laboratory Assessment Team (LAT) visited multiple locations in NZ to facilitate the review of laboratory support capability of the NZFSA. The team reviewed the oversight and regulation of laboratories through site visits to NZFSA, the NZFSA

Compliance and Inspection Group (CIG), and the laboratory accreditation body, IANZ. Additionally, LAT visited four laboratories to review the implementation of oversight and regulation of laboratory support. While at lab sites, LAT reviewed laboratory operations, as well as observation of a simultaneous abbreviated visit by NZFSA CIG personnel to the laboratory, per NZFSA program requirements.

Several aspects of the NZFSA laboratory support system, as verified by LAT, provide evidence of NZFSA's comparability with the US in terms of laboratory support. These include:

1. Direct governmental oversight of laboratory operations takes place via NZFSA CIG audits.
2. NZFSA approval requires external third party accreditation of laboratory operations, including accreditation to ISO laboratory standard (ISO 17025) and NZFSA supplemental requirements.
3. NZFSA publishes and maintains supplemental standards and specific methods for exported products.
4. NZFSA approval is required for a laboratory to operate as a testing lab for exported products.
5. Laboratories undergo additional laboratory system reviews by destination countries (*e.g.* EU), which are tracked and overseen by NZFSA.
6. NZFSA ensures transparency in the publication of laboratory results, laboratory approvals, and key technical personnel.

In summary, the laboratory system oversight provided by NZFSA has multiple groups reviewing laboratory operations, with information centralized in NZFSA. NZFSA approval is required for laboratories to perform testing of products for export. These factors provide evidence that the system can generate laboratory results that are reliable, and which can be used to make regulatory and enforcement decisions. It can be recommended that the NZFSA laboratory system is comparable to that of FDA.

Part IV: Summary Reports and Recommendations

ICAT Team

The ICAT Team spent one week in NZ reviewing documentation at NZFSA headquarters as well as at two recognized agencies: NZFSA Verification Agency in Wellington and AsureQuality in Auckland. The ICAT Team reviewed detailed documentation relating to the implementation of programs and policies that had been reviewed during the FDA paper review of ICAT materials previously submitted by NZFSA. Over the course of the week, NZFSA provided all documentation that was requested, and the ICAT team found the information to be complete and in support of a positive comparability finding.

Seafood Team and Dairy Team

The seafood and dairy teams each spent two weeks in-country, performing systems audits within firms that process foods associated with their specific commodities. The mission of the commodity teams was not focused on assessing the adequacy of NZ's regulations (which were already reviewed in the US prior to the trip) or on the regulatory compliance of the individual firms that they visited. Rather the goal of the commodity teams was to assess the ability of the NZ food safety auditors to implement NZ's inspection and audit programs to ensure that firms comply with NZFSA regulations. Each of the team's reports provides a favorable review of NZ's inspection and audit programs within the NZFSA food safety system and supports a positive comparability assessment outcome.

Shellfish Team

Shellfish specialists spent two weeks in NZ performing a thorough review of the implementation of the NZ shellfish sanitation program for growing area classification and related controls. The shellfish team was satisfied with NZ's current system of shellfish safety, and their report supports a positive outcome from this comparability exercise.

Laboratory Team

The laboratory team spent one week in NZ reviewing laboratory accreditation documentation and accompanying laboratory auditors on their inspections of accredited laboratories. The laboratory team, like the commodity teams, focused not on inspections of individual laboratories but rather on assessing NZ's ability to ensure that their laboratory system is in compliance with NZFSA's standards and that the accreditation system is robust and effective. The laboratory team report provides a positive assessment of NZ's laboratory support resources, supporting a positive comparability assessment outcome.

Summary

Based on the team findings outlined above, a positive comparability determination appears justified with respect to NZ's food safety system, pertaining to seafood (including molluscan shellfish) and dairy products (exclusive of Grade "A" products as these were outside the scope of this determination).

Overall Conclusion and Recommendation

The overall findings and recommendation to the Agency from all teams is that the food safety system implemented by the NZFSA is comparable to that of the FDA. Additionally, with respect to dairy and seafood (including molluscan shellfish), the review team concluded that the food safety systems employed by FDA and the NZFSA for these two commodity areas are comparable.

Part V: Annex

Report of the Comparability of the New Zealand Food Safety Authority's (NZFSA) Molluscan Shellfish Safety Program to the US Shellfish Safety Program for the Classification of Shellfish Growing Areas and Related Control

Background

This report presents the findings of the US Food and Drug Administration's (FDA) audit of the New Zealand Shellfish Sanitation Program (NZSSP) conducted 11 October to 22 October, 2010. The audit was conducted in a manner significantly different from the usual and customary FDA evaluation process historically mandated by the 1980 Molluscan Shellfish Memorandum of Understanding (MOU) between the FDA and the New Zealand Ministry of Agriculture and Forestry (MAF), now with the New Zealand Food Safety Authority (NZFSA). Under the MOU, strict compliance with the guidelines of the US National Shellfish Sanitation Program (NSSP) was mandated. Additionally, the requirements of the US Food, Drug, and Cosmetic Act (FDCA) and the general authority of the US Public Health Service Act (PHSA) were required for all food entering the United States. While the overarching food safety and public health requirements of the FDCA and the PHSA stand as basic requirements for food entering United State commerce, the activities and findings of this audit and presented herein are consistent with the agreed upon process to examine comparability between the US and the NZ shellfish safety programs. As such, the audit excluded any effort to look for strict compliance with the NSSP and instead broadly examined the ability of the NZFSA to implement a shellfish program fit for purpose and offering a high level of safety for bivalve molluscan shellfish products. In other words, does the NZSSP provide a high level of food safety protection commensurate with that of the US program for bivalve molluscan shellfish without necessary implementation of identical controls.

For a foreign country, comparability is determined through a paper and onsite audit process that demonstrates whether or not the country has the ability to make and support favorable food admissibility decisions for safe entry into US markets. Through this process, FDA provides a country that exports food to the US the opportunity to demonstrate that its food safety system is science-based, comprised of similar key elements as that of the United States, has ongoing processes to ensure sustainability of preventive controls, provides competent oversight, and has a similar public health focus.

Activities carried out during this audit are part of a comprehensive effort by the FDA and the NZFSA to enter into a seafood agreement that recognizes the comparability of each others' seafood safety programs, including molluscan shellfish. Via a comparability assessment, the regulatory authority of each country recognizes the other as providing a high degree of safety for fish and fishery products built upon a system of science based controls that may or may not be the same. Recognizing comparability as the determining factor for safeguarding public health as it relates to bivalve molluscan shellfish, this audit examined the Growing Area Classification Element and the Control of Harvest (Surveillance) Element of NZ's existing bivalve molluscan shellfish safety program. Examination of these elements included a review of program staffing and training,

pollution source survey and analysis, sanitary surveys and reports, growing area classification and maintenance, relaying, wet storage, and depuration. The shellfish processing and shipping element and the laboratory element of the NZSSP were examined using the FDA International Comparability Assessment Tool (ICAT) in conjunction with onsite audits of laboratories, seafood processing facilities, and evaluation of inspection activities as performed by NZ program personnel. The ICAT is a self-assessment tool that is completed by a country requesting a comparability determination. The ICAT, in conjunction with in-country program assessment and analyses of imported product compliance information enables the FDA to determine whether or not a foreign country's food safety system provides a comparable level of public health protection.

Organization of the Report

This document summarizes the findings and recommendations of the FDA audit of the NZSSP's Shellfish Growing Area Classification and Control of Harvest (Surveillance) Programs. The review focused on existing NZSSP controls and how well they were being implemented by NZFSA program personnel and non-NZFSA personnel officially recognized to carry out program functions.

Key areas reviewed included program administration, legal authority, staffing, training, classification of bivalve molluscan shellfish (BMS) growing areas, marine biotoxin control, control of harvest (surveillance), and *Vibrio parahaemolyticus* (Vp) risk assessment and management.

Findings

Program Administration

In July 2002, the New Zealand government established the New Zealand Food Safety Authority (NZFSA). This was a semi autonomous food safety control agency under the NZ Ministry of Agriculture and Forestry (MAF) whose purpose was to provide an integrated approach to food safety by providing an effective regulatory program covering food produced and consumed in New Zealand as well as food imports and exports. The NZFSA had four main sector groups, Animal Products, Processed Foods and Retail Sale, Dairy and Plant Products, and Agricultural Compounds and Veterinary Medicines. For bivalve molluscan shellfish the NZFSA controlled product safety in accordance with the NZ Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations of 2006 and the NZ Animal Products (Specification for Bivalve Molluscan Shellfish) Notice 2006. In June, 2010 the NZFSA was concluded as a government department with its functions to be integrated back into MAF. Complete restructuring is scheduled for completion in 2011. The FDA team was informed that the restructuring will not impact the existing shellfish safety program, its existing responsibilities or its program personnel. There will be no difference in functions or services to external stakeholders and the working program will continue unchanged. As such, the NZSSP will continue to operate in accordance with the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 and Animal Products (Specification for Bivalve Molluscan Shellfish) Notice 2006.

Shellfish program field work is coordinated through the Shellfish Quality Assurance Delivery Centers under direction of the MAF's Verification Agency (VA). One Regional Shellfish Specialist, where two (2) previously existed, currently provides technical support, guidance and direction to the Delivery Centers under statutory delegation. Recognizing that this has placed significant responsibility on the single Regional Shellfish Specialist, the NZFSA is in the process of training a second individual, currently serving as a Technical Coordinator (Sectors and Verification Programs) with the VA, to become a Regional Shellfish Specialist. This will bring the program back to its previous contingent of two Regional Shellfish Specialists, one serving the south island and one the north island. Responsibilities for conducting NZSSP sanitary surveys, annual reports and recommendations for classification and management of shellfish growing areas is held by NZFSA Animal Products Officers (APO) who conduct these activities with assistance from District Health Board Health Protection Officers, Health Technicians, Environmental Health Officers, Technical Coordinators, and an ex-Health Protection Officer. The ex-Health Protection Officer conducts numerous activities associated with the classification and management of shellfish growing areas on the south island including the Marlborough Sound under contract with the shellfish industry. This individual and the associated program functions are officially recognized under a NZFSA legal agreement. Technical support staff falls under the direction and guidance of the NZFSA's eleven (11) APOs. The Regional Shellfish Specialist is responsible for final review and approval of all growing area classification reports and supporting data. The review process used by NZ provides a multi-layered system of checks to ensure that growing areas are properly classified and managed.

The NZFSA Compliance and Investigation Group (CIG) is an internal auditing unit. Its function is to carry out random compliance audits of both the industry and regulatory sectors of the NZSSP. CIG Assessors conduct detailed audits of program reports, data collection and analysis, personnel competencies, program personnel interviews (industry and regulatory), field observations, recommendations for additional program needs and assessments, as well as other activities directed at ensuring that the competencies of program personnel and the basic components of the shellfish program are being met.

Legal Authority

The NZFSA Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 and Animal Products (Specification for Bivalve Molluscan Shellfish) Notice 2006 lay down the regulations for implementing and administering the NZSSP.

The Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 sets forth a “regulated control scheme” for shellfish intended for human consumption. The primary purpose of the scheme is to identify, monitor, evaluate, and manage the risks associated with the commercial production of bivalve molluscan shellfish. This includes the commercial growing, harvesting, sorting, transportation, and other activities or conditions affecting the suitability and fitness for the intended purpose of BMS. Part 29 of the regulation provides for the Director General or an Animal Products Officer to classify growing areas. While the BMS Regulation sets forth the basic tenants for managing the risks of bivalve shellfish, the BMS Notice establishes the detailed requirements

incumbent upon persons involved in, and activities involving BMS; on marine farms; in land based aquaculture facilities; and in the wild. Detailed requirements for controlling the safety of bivalve shellfish in the Notice include those components of the NZSSP which were the focus of this audit, i.e. growing area classification and management and control of harvest (surveillance).

FDA's thorough review of the BMS Regulation and Notice demonstrated a system of controls which when fully implemented will achieve a high level of public health safety. Historically the NZSSP has been based on development and implementation of a program fully compliant with the US NSSP. While efforts to examine the safety of the NZSSP from a comparability perspective did not look at compliance with the NSSP, nor was it intended to do so, the fact that the NZ program has historically been one of NSSP compliance and the fact that there is no intent to change the regulatory mandates of the program made efforts to examine the NZSSP for comparability very transparent. As a whole, the audit found the NZSSP to be comparable to the US program, ensuring the production and harvest of bivalve shellfish safe for human consumption.

Staffing

NZ has in place a shellfish safety program adequately staffed to carry-out the mandated food safety control measures as set forth in the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 and Animal Products (Specification for Bivalve Molluscan Shellfish) Notice 2006. For molluscan shellfish the program includes a cadre of trained and well seasoned personnel including a Regional Shellfish Specialist, Animal Products Officers, and other technical staff including Health Technicians, Environmental Health Officers, Health Protection Officers, Technical Coordinators, and one ex-Health Protection Officer. In addition to staff under the NZFSA and local health agencies, there are approximately 80 individuals involved in routine sample collection and growing area surveillance. These individuals are contracted by industry and officially recognized by the NZFSA.

Overall, the level of staffing associated with implementation of New Zealand's shellfish growing area classification and surveillance programs is adequate. The audit found staffing levels to be comparable to those under the US program.

Training

Training functions as a critical component of a well founded BMS safety program. An established training program ensures that program personnel are thoroughly versed and knowledgeable regarding the regulatory requirements, the public health reasons for the regulatory requirements, the principles and conduct of program evaluation, and the basic constructs of program management necessary to ensure continuation of a comprehensive and effective BMS safety program. Training serves as the foundation for a high degree of consistency over time and across program personnel.

The NZFSA was found to provide a significant level of training to all personnel having responsibility for the conduct and administration of the various aspects of the NZSSP. The agency provides an array of training through online instruction, classroom

instruction, in-field instruction and competency evaluation, and one-on-one mentoring. All shellfish program personnel are required to complete training commensurate with their level of involvement and responsibility within the NZSSP. Each individual is required to complete a 5-6 week induction course that covers auditing, legislation and regulation, industry standards, HACCP, chemical contaminants, and certification authority. Personnel also go through a detailed warranting (certification) program designed by senior program management to provide each individual with proficiency in areas of specific responsibility. Continued education and training above and beyond induction and warranting includes participation in technical seminars and conferences (domestic and international), industry sector training, university graduate certification in food science for circuit staff (staff whose responsibilities extend to multiple food categories and public health programs), as well as specific sector/course training in areas such as marine biotoxins and wastewater treatment.

The NZFSA utilizes a detailed electronic training management data base called Verification Agency Online (VAonline) to track training completed by program personnel and identify additional (required and recommended) training needs. VAonline provides access to general online courses as well. In addition to agency personnel, the NZFSA utilizes industry contracted personnel for conducting growing area water, shellfish and phytoplankton sample collection. These individuals operate under two year contracts with the shellfish industry. Approximately 80 individuals are associated with monitoring activities. Each is required to complete classroom training and pass an in-field competency review for recognition by the NZFSA as a collection agent. Once recognized as a collection agent their work has legal standing and can be used for enforcement purposes.

Based on the audit findings FDA found the NZFSA’s training program to provide a high level of competency among BMS program personnel. Discussion with personnel at all levels during both office and field activities demonstrated a degree of proficiency commensurate with the level of training and proficiency found among shellfish program personnel in the US, at state and federal levels. Shellfish personnel at all levels demonstrated a sound understanding of the reasons and science associated with the public health and regulatory requirements of the NZSSP.

BMS Growing Area Review

New Zealand had 93 officially classified shellfish growing areas at the time of FDA’s 2010 comparability audit. The majority, approximately 90%, are classified as conditionally approved. Thirteen (13) conditionally approved growing areas were reviewed during the audit. File reviews were conducted for each of the thirteen (13) growing areas selected. Field visits were conducted for eight (8) of the thirteen (13) growing area selected. Areas reviewed are listed below.

Growing Area	Designation
Waikeke	411
Kauri Bay	502
Te Kouma Harbor	612

Moturua Island	613
Firth of Thames – Outer	619-1
Hikapu	1501
Hallam	1503
Port Underwood	1505
Upper Kenepuru	1510
Stafford	1511
Tawhitinui	1518
McGregors Bay	6101
Preece Point	6102

Comprehensive Sanitary Surveys

Comprehensive sanitary survey reports (12 year surveys) were current for all growing areas reviewed. The surveys met all NZSSP requirements and included a thorough shoreline survey assessment, an evaluation of the effects of meteorological, hydrographic, and geographic effects on the growing area, an analysis of bacteriological data (water and shellfish), a summary of the findings and classification recommendations. Potential pollution sources that may impact the growing areas are classified as indirect or direct and included individual residences with onsite waste disposal, domestic animals (sheep and cows), wildlife, storm water runoff, effluent from WWTPs, and marinas. NZ has identified domestic animals as a major contributor of bacteriological contamination in many areas. The fact that many of the areas surrounding the growing areas are steeply sloped can have an increased impact on water quality. During rainfall events, associated runoff contributes fecal coliforms to surrounding shellfish growing areas, thus the conditional management of most growing area based on rainfall.

NZSSP utilizes both adverse pollution condition sampling (APC) and systematic random sampling (SRS) for classifying growing areas. During the review of sanitary surveys and discussion with program personnel it was recognized that conditions representative of APC have not been clearly defined. For example, sanitary survey reports identified multiple adverse conditions including, “heavy rainfall, consecutive days of light rainfall, long periods without rain, unusually hot temperatures and spring tides”. It was questioned whether some of these conditions constituted adverse conditions. Discussion with program personnel clarified that rainfall at levels below conditional area closure amounts represent the true APC. Nonetheless, there was a level of confusion that warranted further discussion and clarification in survey reports and among shellfish program personnel.

Annual Reevaluations

In accordance with program requirements annual assessments growing areas, for purposes of ensuring compliance of existing classification, are conducted. Reports are well written and effectively document pollution sources, up-to-date bacteriological sample data and analysis, and other important classification review information. Field visits to growing areas did not indicate any classification concerns and demonstrated consistency with information included in written reports. NZFSA personnel, including Regional Shellfish Specialist,

APOs, etc. demonstrated considerable expertise and proved knowledgeable regarding growing areas under their supervision. Technical questions were addressed with relative ease and authority.

Shoreline Survey

Shoreline survey is a significant and critical component of NZ's classification of shellfish growing areas. Comprehensive pollution source surveys to identify and assess actual and potential pollution sources are conducted every twelve (12) years in accordance with NZSSP requirements. Pollution source information is continually evaluated as part of efforts to conduct routine water and flesh sampling as well as during marine biotoxin monitoring activities. Pollution source information gathered throughout the year is fully incorporated into comprehensive sanitary surveys and annual reports for each growing area. Shoreline survey areas are clearly delineated and described and all information and data collected during surveys is well documented.

During the comparability audit it was evident to the FDA auditors that program personnel are well trained in identification and assessment of pollution sources and their incorporation into decisions regarding final growing area classification. Here too, New Zealand's efforts to conduct, document, and assess shoreline surveys is comparable to similar programs conducted in the US by state shellfish programs.

Growing Area Classification

Based on comprehensive sanitary survey reports, annual reports, field observations and discussion with program personnel, FDA's audit determined classification of shellfish harvesting areas meet the requirements of New Zealand's Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 and the NZ Animal Products (Specification for Bivalve Molluscan Shellfish) Notice 2006. FDA's audit has determined that the New Zealand shellfish program provides a level of product safety and growing area management that is comparable to that of the US program.

Marine Biotoxins

The NZSSP Biotoxin Contingency Plan was examined and found to be satisfactory, fully complying with the requirements of Part 6 of the 2006 Animal Products Notice for BMS. New Zealand has a well established science based and supported management program for marine biotoxins. Currently six marine biotoxin groups are monitored. These include, brevetoxins, domoic acid, okadaic acid, pectenotoxins, saxitoxins, and yessotoxins. Shellfish samples are collected weekly, bi-monthly or monthly as determined necessary by the Regional Shellfish Specialist and based on the historical information regarding the occurrence of toxic blooms. Samples are analyzed for each of the respective toxin groups depending on the toxin's history in the particular growing area. Phytoplankton sampling is performed weekly or at a frequency determined by the Regional Shellfish Specialist. However, the tissue sampling component of the biotoxin monitoring program must stand on its own, with phytoplankton testing being a supportive function of the toxin control system. Levels of concern for phytoplankton densities are

established at levels low enough to ensure that the risk of allowing toxic product into the market is extremely unlikely. All closures and openings are based on toxicity levels in shellfish tissue, although phytoplankton levels can be used to institute precautionary closures while additional tissue samples are collected and analyzed. Acceptable levels for toxins and phytoplankton cell counts have been established and are generally consistent with levels recognized as safe under the US program.

Surveillance of Growing Areas (Control of Harvest)

New Zealand's shellfish industry is based almost entirely on farm raised aquacultured shellstock. This type of operation affords tight controls on illegal harvesting for both the shellfish industry and the NZFSA. New Zealand has very few natural sets of viable shellfish. There is little advantage for closed area harvesting since the risk exceeds the reward with penalties for illegal harvest being high. Furthermore, given the competitive nature of the industry, it is almost impossible for harvesting to occur in closed aquaculture areas as industry members maintain a keen eye on activities of other growers and harvesters. Each shipment of shellstock arriving at a certified dealer has to be accompanied by a harvesting declaration. The declaration is completed by the harvester and attests to the harvest time, harvest date, type and quantity of the shellstock. The declaration also identifies the harvest area and the harvester responsible for the activities on that harvest day.

The NZFSA uses the term "surveillance" throughout their program with the same meaning as "patrol" under the US program. Surveillance is completed by three primary groups of individuals. First, the contracted water and flesh quality sample collectors and NZFSA officials who perform activities associated with sanitary surveys monitor harvesting areas for unusual activity. Second, the NZFSA Verification staff, who conduct plant audits, routinely conduct reconnaissance in their travels along growing areas, again looking for boats in unapproved areas. Third, as mentioned above, industry members themselves are constantly policing each other to ensure that unsafe product is not harvested and to make sure that no one industry member has an unfair advantage over another.

The NZFSA conducts patrol training as required. The training targets individuals responsible for conducting surveillance activities. New Zealand also has an on-going harvester and vessel operator education program, including an Annual Conference. The training includes the impact and management of pollution including overboard discharge, the need to properly control and dispose of human waste and the potential for improper disposal to result in contaminated shellfish and consumer illness. Harvest vessels are annually inspected and registered, thus offering another opportunity to provide additional guidance and training to the industry. Harvesting declarations and identifying tags contain such information as the Harvester's Name, Lease Number, Date and Time of Harvest.

Some New Zealand District Health Boards in key shellfish growing regions have similar education programs. Recreational vessels are also boarded from time to time for inspection and to provide information, including brochures, regarding the impact of

overboard fecal discharges, oil and fuel and other wastes on water quality. Also a 24-hour/day hotline is in place to report any pollution events noted in the coastal zones.

Vibrio parahaemolyticus (Vp) Risk Assessment and Control Plan

A June 11, 2009 letter to FDA from the New Zealand Market Access Counselor stated that “...the NZFSA determined that the risk of illness from the consumption of pacific oyster[s] is not reasonable[y] likely to occur.” This determination was based on a review of existing data for *Vp* and information relative to factors to be used in the risk evaluation identified in the NSSP, i.e. *Vp* illnesses, levels of total and tdh+ *Vp*, water temperature, air temperature, salinity, harvesting techniques, and harvest quantity and use.

In order for the NZFSA to conduct a more thorough risk evaluation and better define the potential risk of *Vp* illness from oyster consumption, the NZFSA coordinated with FDA’s Gulf Coast Seafood Laboratory (GCSL) to conduct a joint *Vibrio* project. The aim of the project was to determine *Vp* levels present in oysters harvested from the northern island where conditions were most favorable for its presence and proliferation. The study was to further determine the proportion of pathogenic (tdh+ and trh+) *Vp* to total *Vp*. While the FDA has not received the final risk assessment and control plan needs assessment, preliminary indications suggest that the percentage of pathogenic *Vp* in New Zealand oysters is similar to that estimated for the US Atlantic and Gulf regions.

In the audit close-out meeting the NZFSA informed the FDA that it will forward to FDA the complete 2009 *Vp* risk evaluation and control plan needs assessment as well as the 2010 follow-up risk evaluation and control plan needs assessment. The 2010 risk evaluation will include an analysis of the data collected in 2008/2009 under the above mentioned joint *Vibrio* project.

Prior to a final decision regarding comparability of the New Zealand shellfish safety program to the US shellfish safety program the FDA will need to obtain and review the final NZFSA *Vp* risk evaluation and control plan needs assessment.

Flesh versus Water Quality Monitoring

In accordance with New Zealand’s 2006 Animal Products Notice for BMS both water and flesh samples are routinely collected for bacteriological analysis. Sample results from both are used to verify compliance of existing growing area classifications with water and flesh quality standards. However, the NZFSA has informed the FDA of its intent to shift solely to a flesh based shellfish safety program. Presently the FDA has not recognized a flesh quality based program as comparable to the water quality based system used in the US for classifying and managing shellfish growing areas. Discussion is currently underway by experts within the FDA and the NZFSA to coordinate efforts to examine whether or not use of flesh quality standards offer a comparable alternative to water quality standards. The fact that NZFSA has implemented a comprehensive growing area classification program with strong emphasis on pollution source identification and analysis poses itself as a significant factor in determining comparability between the two. Examination of paired water and flesh quality data during the audit suggests a strong relationship between the two, particularly in those areas used for the

farming of mussels. This relationship does not appear to be as strong in areas where oysters are farmed and relayed, at least for the limited oyster areas reviewed during the audit.

The NZFSA informed FDA that it would be conducting an analysis of its paired water and shellfish data using the model developed by FDA. That model and other supportive information was provided by FDA via email to NZFSA at the time of the audit. During the audit close-out meeting FDA offered its assistance to the NZFSA in this regard, including an offer to conduct the analysis if the NZFSA wished to provide the raw data to FDA. FDA made a similar offer prior to the audit mission during a pre-audit teleconference with the NZFSA. Of course, FDA would maintain the confidentiality of such data in accordance with the FDA Confidentiality Commitment Statement of 2004 regarding information sharing by the NZFSA.

Prior to moving to a flesh only classification system the flesh vs. water comparability issue will have to be resolved. Until such time, it is expected that the NZFSA will continue to conduct routine water quality monitoring in accordance with existing requirements under the 2006 Animal Products Notice for BMS.