REPORT OF THE SYSTEMS RECOGNITION ASSESSMENT OF CANADA

Executive Summary

The Canadian Food Inspection Agency (CFIA), Health Canada, and the United States Food and Drug Administration (U.S. FDA) have a long history of cooperation and coordination on food safety issues. Consistent with this history of collaboration, CFIA participated in an *ex officio capacity* in the FDA working group that developed FDA's approach to systems recognition in 2009 and 2010. CFIA and FDA expressed a commitment to do a reciprocal assessment of their respective food control systems. The U.S.-Canada Regulatory Cooperation Council (RCC), established in 2011 with the objective to create increased regulatory cooperation between the United States and Canada, provided a framework for this activity. An element of the RCC work plan is to conduct systems recognition assessments of the respective food safety systems.

Systems recognition is one of a variety of tools that the U.S. Food and Drug Administration (FDA) has developed to better target and manage food safety risks associated with imported food. The scope of the systems recognition assessment conducted by the FDA of the Canadian food safety system includes all human food under FDA jurisdiction, excluding dietary supplements and certain commodities covered under U.S. State cooperative programs (i.e., raw molluscan shellfish and Grade "A" dairy). Note that the systems recognition exercise described here was a bilateral activity, with Canada concurrently conducting a reciprocal assessment of the components of the U.S. food safety system that are under the purview of the FDA.

The systems recognition review process may be used to determine whether a foreign food safety system is comparable to the U.S. food safety system in that it provides (1) a similar, though not necessarily identical, system of protection (e.g., legal authorities and responsibilities) as the U.S. food safety system, and (2) the food safety authority or authorities provide(s) similar oversight and monitoring activities for food produced under its jurisdiction. At the core of the assessment is the question: Are Canada's food safety authorities, policies and programs implemented as designed and do they provide a comparable level of food safety protection as the corresponding authorities, policies and programs of the FDA?

An in depth review of relevant Canadian food safety authorities, laws, procedures, and policies, based on Canada's submission of documentation, was conducted by FDA subject matter experts.

This review was conducted using the International Comparability Assessment Tool (ICAT), which was developed to objectively assess the robustness of a trading partner's overall food safety system and determine whether the system has similar elements and similar levels of oversight as the FDA's system. The ICAT is composed of ten standards, which 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.

After completion of the initial review of documentation submitted by Canada, four FDA teams conducted in-country evaluations for one to two weeks in June 2013, to verify the implementation and effectiveness of the Canadian food safety system.

Overall, each of the FDA teams recommends a positive finding of systems recognition, for the programs that fall within the scope of the systems recognition assessment conducted of Canada's food safety system. The FDA teams found that, based on their assessments, the Canadian food safety system appears to provide a level of oversight comparable to that of the FDA, as summarized below.

- Onsite evaluations of Canada's training, inspections, audits, compliance and enforcement, and illness and outbreak response programs, as well as a review of resources allocated for the aforementioned programs resulted in no major concerns with the Canadian food safety system as implemented.

- Canadian Food Inspection Agency (CFIA) inspectors followed appropriate inspection protocols and displayed competency through technical knowledge, training, preparing and implementing inspectional protocols, recognizing and evaluating deficiencies based on Canada's requirements and regulations, and communicating appropriately with the manufacturing facilities' personnel during inspections.

- The implementation of requisite elements of laboratory operations are consistent with documentation submitted by CFIA, and the overall laboratory system was found to be in keeping with CFIA's requirements and procedures for laboratory operations.

The assessment of the Canadian food safety system occurred in 2012 and 2013. Since this time, both countries have made changes to their legal and regulatory structure. Once a foreign country's inspection system is recognized through a Systems Recognition Arrangement, the U.S. FDA and the foreign government will continue, through ongoing bilateral communication and periodic review, to examine the performance of each country's regulatory systems to ensure that they continue to provide the appropriate level of protection. This continuing process will assure further alignment of the two systems as each country adopts new food safety approaches.

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Part I: Introduction

The United States (U.S.) and Canada are in the process of modernizing their respective food safety systems, through the FDA Food Safety Modernization Act and the Safe Food for Canadians Act, respectively. The U.S. and Canada have a long history of food safety collaboration as we strive to improve our respective regulatory systems. Furthering these efforts, the U.S.-Canada Regulatory Cooperation Council (RCC[1]), was established in 2011 with the objective to create increased regulatory cooperation between the U.S. and Canada. The objectives under one of the work plans developed by the RCC, titled *Common Approach to Food Safety*, include the following: increase collaboration between the U.S. Food and Drug Administration (FDA), Canadian Food Inspection Agency (CFIA), and Health Canada (HC) to better align regulatory systems; reduce unnecessary duplication of effort; enhance sharing of information; and to the extent feasible, better leverage resources to help the agencies meet their public health missions. One action item under this work plan is to conduct systems recognition assessments (initially called comparability reviews) of our respective food safety systems.

Understanding that the current systems recognition reviews are taking place as the U.S. and Canada are each working to improve our respective food safety systems, we believe that a systems recognition arrangement, once established, will be, by definition, a "living" arrangement, where we will continue to work collaboratively to ensure that our food safety systems remain comparable, making adjustments as needed.

The U.S. and Canada systems recognition assessments of the food safety control systems under the jurisdiction of the FDA, CFIA and HC, were conducted to determine if our respective systems provide a similar, though not identical, level of oversight and monitoring that result in comparable public health and consumer protection outcomes. Federal food safety responsibilities are structured differently in the U.S. and Canada; the scope of the systems recognition assessments conducted was defined to reflect these differences. Canada's assessment included review of FDA's oversight and monitoring of the federal food safety system for foods under FDA's jurisdiction, including oversight of inspection programs delegated to the States.

[1] http://trade.gov/RCC/

More specifically, food, for the purposes of these systems recognition assessments, includes food for humans, but excludes:

- Meat, poultry, processed eggs and farmed catfish[2] as regulated by CFIA and the U. S. Department of Agriculture (USDA);
- Dietary supplements, regulated as food by FDA and as natural health products by HC;
- Dinnerware, which is regulated as a food contact surface by FDA and as consumer products by HC; and
- Raw molluscan shellfish; and Grade "A" milk which are covered in the U.S. under State cooperative programs.

Certain country-specific requirements such as labeling requirements, food additive approvals, and maximum residue levels for pesticide and veterinary drug residues in food were agreed to fall outside the scope of the systems recognition assessments. Exporters and importers of food traded between the U.S. and Canada must ensure that these and other requirements of importing countries are met as a matter of compliance, as has always been their responsibility.

Canada and the FDA did agree that raw molluscan shellfish and animal feed programs may be assessed in the future under the systems recognition rubric.

The systems recognition assessment conducted by the FDA of the Canadian food safety system, as outlined in this document, involved both an initial assessment of documents submitted by Canada outlining the relevant Canadian food safety laws, procedures, and policies, via the International Comparability Assessment Tool (ICAT), and in-country audits to verify implementation of the Canadian food safety system. FDA teams, locations and assessment activities performed during the in-country reviews are outlined in Text box 1. FDA team assignments and biographies are available in Appendix 1 and 2.

This report provides an overview of the systems recognition review of the Canadian food safety system as conducted by the multi-sectorial team of FDA experts, and their recommendations. Part II provides background on systems recognition and the systems recognition review process. Part III summarizes the results of the in-country assessment and final recommendations from the FDA review teams. Part IV provides a summary and conclusions.

[2] Primary responsibility for the regulation of catfish in the U.S. will be transferred to the USDA and will not be covered by the systems recognition agreement between the FDA and Canada.

Table 1. Four teams of FDA subject matter experts traveled to Canada to complete verification activities in support of FDA's review of Canada's food safety system.

FDA Team	Location	Assessment activities performed
ICAT Team	Ottawa, Toronto	Documentation assessment at CFIA Headquarters (HQ) in Ottawa and at a CFIA Regional Office in Toronto to review the implementation of national food safety programs. The ICAT team examined operational records pertaining to inspection, work planning, training, compliance and enforcement and gathered information to clarify remaining questions that had been raised during the initial documentation assessment.
FDA West Coast Field Team	British Columbia	Observation of CFIA inspectors performing inspections in four processing facilities (non-Grade "A" milk products, seafood products, processed fruit and vegetable products, and cookie dough and muffin batter production) to verify implementation of CFIA's inspection program.
FDA East Coast Field Team	New Brunswick, Nova Scotia, Ontario	Observation of CFIA inspectors performing inspections in seven processing facilities (frozen French-fried potatoes, peanut and nut butters, seafood, yogurt, confections, and apple juice) to verify implementation of CFIA's inspection program.
Laboratory Team	Ottawa, Toronto	Observations of the implementation of CFIA's laboratory system as related to sampling and testing of foods.

Part II: Background on Systems Recognition and the International Comparability Assessment Tool (ICAT)

Systems Recognition

The 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. U.S. consumers expect that all foods sold in U.S. markets will be safe for themselves and their families.

To help ensure the safety of the increasing volume of imported food, FDA's new, preventive approach shifts from using inspection and testing of imported foods at U.S. ports of entry to try to identify adulterated or misbranded products to focusing on the implementation of adequate hazard controls in the foreign food production environment and supply chain to prevent the shipment of unsafe and noncompliant food products to the U.S. in the first place. While

inspection and testing of imported foods at U.S. ports of entry will continue to inform FDA's risk-based food safety program, FDA's shift to a preventive approach, which will include systems recognition as one of several tools, 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 (FSMA) reflects this new paradigm and provides FDA with many of the legal authorities and tools needed to address the challenges presented by our increasingly global food supply.

Prior to FSMA, systems recognition was developed by FDA as a tool to assist the agency in ensuring the safety of imported food. Systems recognition 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. Systems recognition is based on the conclusion that food safety systems with similar elements and similar levels of oversight lead to similar food safety outcomes.

The systems recognition review process may be used to determine whether a foreign food safety system is comparable to the U.S. food safety system in that it provides (1) a similar, though not necessarily identical, system of protection (e.g., legal authorities and responsibilities) as the U.S. food safety system, and (2) the food safety authority or authorities provide similar oversight and monitoring activities for food produced under its jurisdiction.

Systems recognition is currently being piloted by the FDA with the goal of finalizing a protocol that can be objectively and consistently applied. The first pilot was conducted with New Zealand, resulting in a systems recognition arrangement signed in December of 2012. The second pilot, with Canada, is described in this report.

The systems recognition assessment process, as piloted, provides a country that exports food to the U.S. with the opportunity to demonstrate that its food safety system is science-based; comprised of similar key elements to that of the FDA's food safety system; has ongoing processes to ensure the sustainability of preventive controls; provides competent oversight; and has a similar public health focus. The systems recognition process consists of two steps. First, an assessment tool, the ICAT, is completed by the country interested in being assessed to provide information on legal authorities, responsibilities, structures, procedures, and the overall

foundation of its food safety system. Next, after the FDA completes an initial review of the documentation submitted by the country, an in-country assessment by one or more FDA teams takes place. The in-country assessment includes (1) a review of documentation to verify that the country has implemented the various components of its food safety program, and (2) a review of relevant documentation to verify that the government's inspection programs are being implemented as defined and onsite audits of inspectors conducting inspections that cover a variety of food commodities and processing operations in different regions of the country.

Certain product specific regulatory requirements and food safety standards are not included in the scope of systems recognition assessments, such as labeling requirements, food additive approvals, and maximum residue levels for pesticide and veterinary drug residues in food. Countries may have food safety systems that are comparable to that of the U.S. yet include specific requirements and food safety standards that differ from those of the U.S. In these cases, exporters and importers of food to and from the U.S. must ensure that the requirements of importing countries are met as a matter of compliance.

ICAT

The ICAT was created as an objective tool for assessing the robustness of trading partners' overall food safety system(s) and for determining whether the system(s) has similar elements and levels of oversight as the FDA system. The ICAT is based on the Manufactured Food Regulatory Program Standards (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 facilities[3]. The draft ICAT, while based on the Manufactured Foods Regulatory Program Standards, has been modified to identify food safety systems in other countries that may differ from the U.S. system but offer the same level of public health protection. FDA will update the draft ICAT as we continue our pilot systems recognition activities, in order to improve the clarity and ease of use of this tool.

Format of the ICAT

The ICAT is composed of ten standards, which include: Regulatory Foundation; Training Program; Inspection Program; Program Assessment and Inspection Audit Program; Food-related

[3] http://www.fda.gov/forfederalstateandlocalofficials/partnershipscontracts/overview/default.htm

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 country's food safety authority interested in systems recognition.

The Canadian ICAT submission was reviewed by a team of FDA subject matter experts, who determined that the Canadian food safety system, on paper, appeared to be comparable to that of the FDA. The FDA team that reviewed the ICAT submission identified areas, including specific programs and practices that required further clarification and/or verification during the FDA in-country assessment.

Part III: Results from In-Country Assessments

Based on findings from the ICAT review of Canadian laws, regulations and other submissions from Canada that the food safety system appears to be comparable, four FDA teams conducted in-country assessments in June 2013 to verify the implementation and effectiveness of specific components of the Canadian food safety system. The FDA ICAT Team further reviewed and assessed documentation at CFIA HQ in Ottawa and at the CFIA Regional Office in Toronto.

Two FDA Field Teams observed CFIA inspectors conducting inspections at a variety of food processing facilities; one Field Team conducted audits in British Columbia and the other Field Team conducted audits in New Brunswick, Nova Scotia and Ontario. The fourth team, the FDA Laboratory Team, reviewed and assessed CFIA's laboratory system. More specifically, the Laboratory Team, in part, verified and evaluated the implementation of CFIA laboratory protocols through on-site observations made at CFIA laboratories in Ontario (Ottawa and Toronto) and assessed laboratory resources.

In-Country ICAT Assessment of Program Components

The In-Country ICAT Assessment is not an inspection, which focuses more narrowly on food safety activities at a facility level. Rather, the objective of the ICAT Team was to assess the implementation of specific components of the Canadian food safety system and verify that the components were implemented as described in the Canadian ICAT submission. The ICAT Team focused its assessment and review on questions and items flagged for follow-up during FDA's ICAT documentation review. The questions and items flagged for follow-up were shared with Canada prior to the in-country assessment.

At CFIA offices in Ottawa, staff from the CFIA, Public Health Agency of Canada (PHAC), and HC provided an overview of the Canadian food safety system, including the oversight responsibilities of each of the aforementioned three Canadian agencies and described how the three communicated with one another. The three Canadian agencies also provided additional information on Canada's programs and policies regarding the following topic areas flagged by FDA for in-country review, which included:

- Personnel training
- Activities related to outbreaks and recalls

- Inspection systems
- Process user fees
- Compliance and enforcement operational policy
- Business work planning process
- Quality management systems
- Values and ethics program/Conflict of interest

The ICAT Team then traveled to the CFIA Toronto Regional Office to review operational records pertaining to inspections, work planning, training, compliance and enforcement.

The results of the ICAT Team assessment are summarized below. Each section first lists the topics for review or verification, followed by a summary of the assessment and overall conclusions of the ICAT Team.

ICAT Standard 2: Training Program

Areas for Review

The ICAT Team reviewed in more detail the training available to food safety investigators, laboratory personnel, risk assessment professionals and others, from newly hired employees through established professionals with advanced credentials. Also of interest were classroom-based coursework offerings and joint inspections and/or field training available for staff. Other areas of interest and further dialogue included:

- Learning portal website; Online Learning Catalogue – Agricat;
- Overview of Individual Learning Plan development and implementation
- Examples of training course outlines and materials;
    - How often courses are offered
    - List of courses that must be completed as a condition of different position descriptions
- Individual training records for field staff and report reviewers;
- Agency recordkeeping and oversight; tracking of required training and completion of training, including post training requirements, if any; and
- Programs in place for remedial training, if available.

In Country Observations and Conclusions

The ICAT Team reviewed the overall training programs for inspectors and laboratory personnel. The Team reviewed the curricula for the 6-week new inspector training and was provided a demonstration of on-line courses. Team findings are described below.

The CFIA uses a combination of online and classroom training. Some of the online modules are based on FDA Office of Regulatory Affair's training courses. New inspectors attend a 6 week on-site program in Rigaud (a municipality in Quebec between Ottawa and Montreal). The 6 week new inspector core training is limited to 15-20 employees at a time, and it is conducted when there is a critical mass of new hires to attend. While there is no formal certification program, the CFIA does have a process to demonstrate competency before new inspectors are sent to conduct solo inspections. Core training is followed by developmental programs to gain more specific expertise. Classroom training is offered as needed and may be requested by a region(s.)

Training is tracked at a national level. Individual training records are also maintained at the Regional Offices. At the Toronto Regional Office, the ICAT Team reviewed training records for a new inspector, a senior inspector, and a dairy inspector. A review of job descriptions indicated the requirement for appropriate technical background as a condition of employment. The need for remedial training may be identified through the Quality Management System (QMS), complaints, or other means. Re-training is conducted as needed.

The ICAT Team had no overall concerns with the training program as implemented by CFIA.

ICAT Standard 3: Inspection Program

Areas for Review

- Documents of registration (registered facilities);
- Walk-through of work planning process; criteria used;
- Review of Client Management System (CMS), Multi Commodity Activity Program (MCAP), and Laboratory Sample Tracking System (LSTS);
- Review of Issues Management System (IMS) for tracking complaints, investigation and recall information;

- Review of inspection reports – including whether or not inspectors make sure that facilities are implementing Hazard Analysis and Critical Control Points (HACCP) plans; and
- Review of specific components of inspections.

In Country Observations and Conclusions

The ICAT Team reviewed the overall inspection program including the review of inspection related IT systems, which could only be accomplished in-country. The Team observed real-time utilization of CMS, MCAP, and the LSTS. CMS is the database that contains facility information used to maintain lists of registered and non-registered facilities. Non-registered facility lists are often maintained for specific inspection, compliance, or monitoring projects. The Team observed the utilization of Cognos®, which is a reporting program used to produce queries and summary reports from the data systems.

In the Toronto Regional Office, the ICAT Team reviewed inspection reports and facility audit reports and verified that inspectors were reviewing the implementation of HACCP plans at food facilities. The Team also observed the utilization of the data systems with respect to the implementation of regional inspection activities.

The ICAT Team reviewed CFIA's work planning process, at CFIA HQ in Ottawa, including the risk based criteria used to determine inspection priorities and schedules and the operations planning IT tool. At the Toronto Regional Office, the Team reviewed the regional work planning process from the standpoint of implementation at the inspector level.

The Team had no overall concerns with the inspection program as implemented by CFIA or with CFIA's work planning process.

ICAT Standard 4: Program Assessment and Inspection Audit Program

Areas for Review

- Examples of audit protocols and audit sheets, and
- Review of completed audit reports.

In Country Observations and Conclusions

In Ottawa and Toronto, the ICAT Team reviewed the overall QMS, including a review of the QMS IT database. In Toronto, the Team reviewed QMS quarterly reports and audit results for reviews of inspectors conducted by their supervisors. The Team reviewed the "criteria verification checklist" for on-site reviews and reviews of inspector activities, such as label compliance reviews. The Team reviewed the supervisory notes for corrective actions taken in response to deviations noted during the inspector review. The Team felt that the QMS system was of sufficient rigor and scope to be effective at improving performance.

The ICAT Team had no overall concerns with the QMS audit program as implemented by CFIA.

ICAT Standard 6: Compliance and Enforcement Program

Areas for Review

- Non-public documentation (via Merlin, the CFIA's Intranet system), illustrating implementation of compliance and enforcement programs;
- Documentation of compliance assessment programs that have taken place;
- Documentation of corrective action plan programs that have been implemented;
- Documentation of progressive enforcement actions that have been taken and follow-up corrective actions, including two administrative and two regulatory examples, and associated database tracking;
- Case studies describing a range of activities, from administrative actions through seizures, injunctions and criminal cases; and
- Databases, including:
    - IMS,
    - National Enforcement Tracking System (NETS), and
    - Database utilization in implementing compliance programs.

In Country Observations and Conclusions

In Ottawa, CFIA presented to the ICAT Team with an overview of CFIA's compliance and enforcement programs, including a discussion of food safety-related criminal prosecutions. The overview included a discussion of the NETS, which has restricted access to the Enforcement and Investigative Services (EIS) and is used to track investigational activities. EIS is the branch of

CFIA that plans, develops, and implements CFIA's enforcement activities. Area EIS staff conduct investigations and recommend the issuance of monetary penalties or prosecution.

At the CFIA Toronto Regional Office, the ICAT Team reviewed a number of case studies that covered compliance assessments by CFIA inspectors, documentation and verification of corrective action by the facilities, and that demonstrated the use of progressive enforcement actions. A case study involving criminal prosecution for adulterated olive oil was included in the review. The Team reviewed original facility and case files to verify information presented during the case study discussions.

The ICAT Team had no overall concerns with the CFIA's food safety-related compliance and enforcement programs as implemented.

ICAT Standard 5: Food-Related Illnesses and Outbreaks

Areas for Review

- A variety of cases, including those of simple to moderate complexity and more challenging cases, e.g., multi-regional, multi-food/component, international, to get a sense of how the Foodborne Illness Outbreak Response Protocol (FIORP) and the Food-borne Illness Emergency Response Plan are implemented during food safety incidents and emergencies;
- Interagency communications protocols to see how they function in practice;
- IMS and specifics on Canada's trace back system; and
- Examples of trace back/trace forward incidents and case studies.

In- Country Observations and Conclusions

Canadian officials presented to the ICAT Team an overview of Canada's foodborne illness and outbreak response activities, including an explanation of the roles and responsibilities of CFIA, PHAC, and HC. They also presented several case studies of food outbreaks which demonstrated all aspects of the process, from identification of emerging issues through investigation and recall. Almost all food recalls are voluntarily carried out by the responsible firm. Should a firm choose not to recall a product that poses a health risk, the Minister responsible for the CFIA has mandatory recall authority, and has exercised this authority on seven occasions since the establishment of the Agency in 1997. The case studies presented illustrated the mechanisms

through which the various Canadian agencies work together to coordinate activities. PHAC is the lead agency for coordinating the investigation and response to all multi-jurisdictional food – borne illness outbreaks. The CFIA is responsible for conducting food safety investigation and recall activities.

The ICAT Team received a live demonstration of the CFIA's IMS which is used to organize information and to assign tasks to relevant geographical regions as needed. The IMS contains complete information relating to food safety investigations managed at national and area levels. The IMS contains very detailed information about the activities associated with a particular event. One of the case studies reviewed in the IMS was the Mexican mango outbreak from 2012, with which FDA is very familiar.

In the Toronto Regional Office, the Team reviewed a case study demonstrating how CFIA Regional Offices participate in outbreak and illness investigations, and their role within Canada's national outbreak response system. In this context, the Team reviewed the operation and usage of the IMS in a Regional Office, as representation of implementation in a field location.

After a review of national and regional illness investigation and outbreak response programs, the ICAT Team had no overall concerns with the implementation of these programs by Canadian authorities.

ICAT Standard 8: Program Resources

Areas for Review

- The Canadian ICAT submission indicated that during FDA's in-country assessment, the teams could review CFIA's IT operations planning tool, the Management Resources and Results Structure – Operations Planning Module (MRRS-OPM) and its work planning process.

In-Country Observations and Conclusions

As discussed in the Inspection section (page 11), the ICAT Team reviewed CFIA's work planning process, including the risk based criteria used to determine inspection priorities and schedules, at both the national and regional levels. The Team reviewed the MRRS-OPM operations planning IT tool as well as implementation of the program at the inspector level. The

Team also reviewed CFIA's user fee cost recovery program. The team noted that the business systems used by CFIA provided adequate feedback to prioritize program activities on a rational, systematic basis, while allowing for unexpected events. No overall concerns were noted by the ICAT Team related to CFIA's program resources and implementation of work planning programs.

In-Country Assessment of Processing Facility Inspection Programs

Two FDA Field Teams traveled to Canada to conduct on-site audits and verification of the implementation of Canada's food safety inspection system by CFIA. The West Coast Team traveled to British Columbia, and the East Coast Team traveled to New Brunswick, Nova Scotia, and Ontario, to observe and assess on-site implementation of CFIA's inspection program in a variety of food processing facilities.

Each FDA Field Team consisted of three members (two subject matter experts from the Center for Food Safety and Applied Nutrition and one national food expert from the Office of Regulatory Affairs) who observed CFIA inspections in a variety of food processing facilities. The FDA West Coast Team spent one week performing on-site audits of CFIA inspectors conducting inspections in four food manufacturing facilities; the facilities manufactured non-Grade "A" milk products, seafood products, processed fruit and vegetable products and cookie dough and muffin batter. The FDA East Coast Team observed CFIA inspections at seven food processing facilities over the course of two weeks. Facilities included processors of frozen French-fried potatoes, peanut and nut butters, seafood (cooked lobster meat, scallops), yogurt, confections (chocolate covered nuts) and apple juice.

The goal of the on-site, in-plant audits conducted by each of the FDA Field Teams was to verify the knowledge and ability of CFIA food safety inspectors to implement Canada's regulations and food inspection programs.

The immediate goals of the on-site audits conducted by the Field Teams were to:

- Verify CFIA inspectors' knowledge and ability to implement the Canadian food safety regulations during in-plant inspections;

- Assess and verify the ability of CFIA inspection staff to implement Canadian food inspection programs and protocols as outlined in the ICAT; and
- Clarify certain information provided in ICAT submission relative to CFIA's inspection programs.

Through interviews and observations, the FDA Field Teams assessed whether CFIA inspectors had appropriate training, technical knowledge, and ability to recognize and evaluate deficiencies, based on CFIA's requirements. The FDA Field Teams observed CFIA inspections of processing facilities under various commodity-specific regulatory compliance programs. The on-site audits, interviews and observations were not intended to evaluate whether CFIA inspection program elements met FDA requirements. However, FDA Field Teams did evaluate the CFIA inspectors' abilities to recognize food safety and sanitation concerns.

In order to ensure that evaluations by the two FDA Field Teams were consistent, each Team used the same protocols for conducting the evaluations and based their assessments on draft criteria found on FDA Office of Regulatory Affairs program evaluation worksheets, with an emphasis on a systems review approach. The draft criteria covered key concepts, applicable across commodities, including sanitation, inspection performance, communication skills, and documentation of findings.

FDA Field Team Results

Each of the FDA Field Teams' verification activities included meetings at local CFIA offices to review aspects of the particular commodity to be inspected, review inspector training records, and to discuss how the inspector prepared for the inspection. In the facilities, the FDA Field Teams observed the CFIA inspectors' discussion of the scope of the inspection with facility management, processing operations review, the interaction of CFIA inspectors with key facility employees, records review and the close out with facility management.

Verification activities took place in a variety of food processing facilities; inspections therefore covered multiple CFIA program standards and protocols and food safety Acts (laws) and regulations. Program standards and protocols and relevant Acts and regulations covered during the on-site audits of CFIA inspectors include:

- *Canada Agricultural Products Act*
    - *Dairy Products Regulations*
        - Dairy Establishment Inspection Manual for the dairy processing facility.
        - Dairy Establishment Program Inspection Manual, Chapter 9 Good Manufacturing Practice Inspections
    - *Processed Products Regulations*
        - Processed Products Establishment Inspection Manual (PPEIM) applied to processed fruits and vegetables

- *Consumer Packaging and Labelling Act* (as it relates to food)
    - *Consumer Packaging and Labelling Regulations*

- *Fish Inspection Act*
    - *Fish Inspection Regulations*
        - Quality Management Program (QMP)
        - Fish Inspection Program Facilities Inspection Manual
        - Fish Products Standards and Methods Manual
        - Fish Inspection Program's Corrective Action Process Standard
        - Quality Management Program Reference Standard for Fish

- *Food and Drugs Act* (as it relates to food)
    - *Food and Drug Regulations,* Imported and Manufactured Food Program (IMFP) guidelines applied across the board as the overarching instruction provided to CFIA inspectors, including:

        - IMFP Work Specification – Nuts (Peanuts, Tree nuts, Peanut Butter and Tree nut butter)
        - IMFP National Sampling Plan and Criteria
        - IMFP Work Specification – Confectionery

- General Principles of Food Hygiene, Composition and Labeling (GPFHCL) applied to non-registered facilities (in this case – cookie dough, muffin batter, peanut and nut butters and confections).

The FDA Field Teams were informed that CFIA is in the process of consolidating its different inspection manuals for the different commodity groups into one manual.

The FDA Field Teams observed and interviewed CFIA inspectors with respect to their technical knowledge, training, implementation of inspection protocols, ability to recognize and evaluate deficiencies based on Canada's requirements and regulations, and ability to recognize food safety and sanitation concerns identified within their programs.

CFIA inspections of food manufacturers are conducted at various frequencies, based on risk and as indicated in commodity specific protocols. Frequencies vary from a minimum annual inspection to more often depending on risk, program requirements and inspection findings. Follow-up on previously identified deficiencies is conducted each quarter or during the subsequent inspection if the operation is under a lower inspection frequency.

Computer databases (e.g., MCAP) are used by CFIA staff to track inspectional focus and follow up on corrective actions. CFIA inspectors use these databases to review topics covered during the previous inspection in preparation for an inspection and also use the databases to document inspectional outcomes. These systems are in place to assure that all aspects of the inspection protocols are covered within the timeframe specified by CFIA compliance programs.

FDA Field Team Conclusions

CFIA inspectors were observed by the FDA Field Teams during on-site audits to perform their duties in a competent manner, be thorough in their preparation for inspections and in the execution of inspection protocols and to effectively communicate with plant personnel during the course of inspections. The FDA Field Teams also observed that CFIA inspectors possessed appropriate technical knowledge, were adequately trained, and competent in recognizing and evaluating deficiencies based on Canadian requirements and regulations.

Identification and classification of deficiencies by CFIA inspectors were consistent with FDA Field Team observations, indicating that, when implemented, CFIA's inspection program is

likely to result in outcomes similar to FDA inspection results. While every inspector had their own individual style, the overall implementation of field inspection protocols was consistent among the various inspectors observed and the execution of the CFIA inspection programs can be recommended as comparable to that of the FDA.

Based on the observations made during this assessment of CFIA's inspection programs, the FDA Field Teams conclude that Canada's food safety inspection program can be recommended as comparable to that of the FDA.

ICAT Standard 10: Laboratory Support

ICAT Standard 10, 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 private laboratories, if applicable.

The Laboratory Team spent one week in Canada reviewing laboratory function, role, and accreditation at HQ; operations and systems implementation at two CFIA laboratories (Ottawa and Toronto, ON); and use of laboratory data for case support at the CFIA Regional Office in Toronto. The Laboratory Team focused on assessing that the implementation of the laboratory system is in keeping with the CFIA's standards and that the CFIA's laboratory system is robust and effective.

ICAT Elements Review

A presentation of the CFIA's laboratory support system by CFIA during the initial introductory session was provided to the ICAT and Laboratory Teams.

There are thirteen laboratories currently operated by CFIA, located in four regions. The laboratories have dedicated capabilities in broad areas, such as food, animal health, and plant health. Nine of the laboratories provide food testing services, and each of these labs is further specialized, with some system redundancy for analytical capabilities (e.g., two labs can perform allergen testing).

In addition, approximately 100 private laboratories are accredited for food analysis in Canada. These labs are eligible to perform routine work for established programs under contract to the Canadian government. All private laboratories performing this work are accredited to the International Organization for Standardization (ISO) 17025 standards for laboratory operations and technical competence in food analysis. The contracts go through a competitive bid process; each contract specifically states the analysis required, expected sample volumes, sample collection responsibilities, and timelines for analysis and reporting, as well as all other information as necessitated by the contract process.

CFIA officials perform the technical auditor role in the ISO 17025 accreditation audits for private and public food-analysis laboratories in Canada. All accreditation audit reports are submitted to CFIA for accredited private labs and CFIA labs. As a result, the CFIA has a high level of assurance that these private labs can perform the contracted sample collection and analysis.

The Laboratory Team reviewed documentation at CFIA HQ and reviewed processes and procedures in the field related to the following topic areas:

Laboratory Accreditation

All CFIA food analysis laboratories are ISO 17025 accredited. In addition, accreditation is required for private labs that want to contract or conduct lab work for CFIA. Canada recognizes two laboratory accreditation bodies for accrediting CFIA and private food testing laboratories that do work for CFIA under contract: the Standards Council of Canada (SCC) and the Canada Association for Laboratory Accreditation (CALA). Both accreditation bodies are signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). This status indicates that these accreditation bodies operate in accordance with ISO 17011, the standard for accreditation bodies, and that they are internationally recognized as competent to accredit laboratories in accordance with ILAC rules and procedures.

The SCC is a governmental agency which oversees the development and use of national and international standards and accreditation services. All CFIA labs are accredited by the SCC. Additionally, the SCC accredits about 90 of the approximately 100 private labs accredited for food testing in Canada.

CALA is a private not for profit corporation. CALA was originally part of the SCC but formed a separate legal entity for laboratory accreditation. Originally CALA was focused on environmental analyses; CALA has expanded to food laboratory accreditation recently and was recognized in Q1 2012 for food accreditation. CALA has accredited about 10 private labs for food testing in Canada.

All food laboratory accreditation teams are accompanied by technical assessors from CFIA, except for the accreditation of the CFIA laboratories. The accreditation body selects assessors based on technical capability for the analytical scope under review, in accordance with ISO 17011 and ILAC requirements. The lab under review can reject the proposed auditor, but must be reasonable when rejecting auditors. Examples of reasonable rationale for rejecting an auditor were described as conflict of interest or lack of appropriate technical expertise. For accreditation audits of CFIA labs, technical assessors are selected from other federal labs, provincial labs, city labs, or industry if no other options are available. For example, extraneous material (filth) accreditation required a private lab technical assessor.

All accreditation audit reports for food laboratories are forwarded to CFIA HQ for review. Some trending of results has been performed by CFIA to identify differences in audit findings between public and private labs. CFIA is working to determine how best to address trends and to improve laboratory accreditation findings.

Contracts with Private Laboratories

Non-CFIA laboratories may support CFIA laboratory functions through a defined contract establishment and fulfillment process. The majority of these contracts are fulfilled by private labs. The contract process also allows for other laboratories, such as university or other governmental laboratories, to provide support for developing, emerging or unusual situations.

Private laboratories are utilized in a different capacity than CFIA laboratories. Private laboratories conduct analyses as specified in a contract using an established method as defined under an existing program, typically for data collection exercises or other defined surveillance activities. CFIA laboratories are used to analyze samples collected for surveillance and monitoring, directed sampling and compliance testing; analyses related to emergency response;

methods development and validation; in support of emerging issues; and to analyze samples to support legal actions[4].

Work planning is integral to determining when private laboratories will be needed to meet CFIA operational goals. The work planning process takes into account CFIA laboratory capacity, maintenance of analytical expertise, work flow, and an allowance for responding to emergencies. Analytical needs are determined through the work planning process, including the need to contract with private laboratories to accomplish work plan targets and goals.

Those analyses that are determined to be amenable to private laboratory analysis are put out for competitive bid. This generally involves the collection of samples at retail, while CFIA laboratory analysis is generally focused on samples of imported foods, and samples collected from processors and distributors.

A contract was reviewed for natural toxin analysis, with the following observations:

- The contract specifically described how samples will be collected, that the private lab will collect them, the number of samples to be collected, documentation requirements, analysis to be performed, reporting frequency, historical positive rate, and costs.
- The contract required that positive results be reported to CFIA within two hours to one day and that all results are summarized and submitted to CFIA monthly. This reporting is done via a specialized CFIA IT system for private labs. Worksheets are submitted by the private labs after such reporting, and sometimes much later than the reporting of the results, and are audited as noted below.
- Contracts are audited for financial issues by the Public Works and Government Services Canada. The private laboratory's financial reliability and business stability is assessed as well.
- Contracts are audited for compliance with the technical requirements by CFIA. Worksheets are audited by CFIA's Food Safety Science Directorate. The contract stated that CFIA reserves the right to send blanks to the lab. Results are also trended.
    - One example of data trending was reviewed. A private lab was submitting results significantly different from other labs performing the same analysis. CFIA went

[4] Compliance samples are collected by inspectors and can support civil actions. Legal samples are collected by Canada's criminal investigators to support a criminal case.

on site to audit analysts conducting the analysis. Technical issues were found and corrected, and the private lab subsequently submitted results that were within the expected variability for the analysis.

- It was also stated in the contract that CFIA can use the data provided by the private lab to take action.
    - The actions taken are case-by-case, and depend on the analysis, the product, and risk.
    - Actions may include additional targeted sampling, investigation, recall (voluntary or not, though voluntary is by far the most common result), or other as determined via discussion between HC and CFIA.

CFIA's National and Local Laboratory QMS

CFIA has established national procedures and policies for specific needs, such as cross-lab functions, communications with CFIA HQ and laboratory interactions with field operations. Individual CFIA laboratories have implemented QMS locally and independently, with the national level procedures functioning to fill in any gaps and ensure smooth operations for the system as a whole.

CFIA Lab Reporting to HQ and the LSTS

The LSTS is the CFIA IT system exclusively for CFIA sample collections and analyses. Private laboratory analysis is reported via a distinct system completely separate from LSTS.

Sample collection information is entered into LSTS by the CFIA inspector. A hard copy report is printed and included with the samples. On arrival at the CFIA lab, the sample condition is logged into LSTS. Analytical results are entered and approved by the supervisor. Data refreshes every 20 minutes. Email subscriber lists can be set up by users to receive notifications whenever the requested results are available.

User privileges are set so that each government user has appropriate access capabilities. Each CFIA lab has a "super user" with greater access to function in a more administrative role.

To correct errors, entries have to be unlocked with a reason given for the change. Data is not released until approved by a user with those privileges, usually a supervisor.

Laboratory Field Visits

The FDA Laboratory Team reviewed laboratory operations directly via site visits to two CFIA laboratories and a district location. The review included both QMS documentation and analytical worksheet trace-back for microbiological and chemical analysis. Systems reviewed include:

- Laboratory Quality Management
- Internal audits and management review
- Document Control
- Sample receipt and handling
- Facilities
- Instrumentation
- Calibration
- Equipment
- Training
- Corrective and preventative actions
- Method selection
- Method validation and verification

All of the above systems were found to be consistent with documentation submitted by CFIA and to be in keeping with CFIA's requirements and procedures for laboratory operations.

Legal and routine sample standard operating procedures were reviewed for both the Ottawa and Toronto laboratory locations. The Laboratory Team found that there are additional sample handing and documentation requirements for samples classified as legal samples (intended to be used in civil court action or criminal prosecution). Legal samples require a single pre-assigned analyst, access controls to prevent possibility of tampering, and additional documentation (e.g., photographs of the package to document integrity). An attestation of chain of custody certification and analysis were included as part of a legal sample case file reviewed at the Toronto District Office by the ICAT Team. As they are rare, legal samples were not reviewed as part of the trace-back on-site at the laboratories.

In contrast, routine samples are tracked by a Sample Submission Form and assigned a laboratory identification number after log-in. Routine samples can be used in support of administrative actions, e.g., recalls, condemnation of lots, administrative fines. Actions that may require a court order in the U.S., such as condemnation or seizure, can be conducted by CFIA personnel without court involvement. If routine sampling indicates a violation for which CFIA may seek court action, a new set of samples may be taken under the legal-sample procedures. On site at both laboratory locations, the routine samples that were reviewed via trace back were confirmed to have procedures in place for sample security, receipt, and traceability for analysis.

At the Toronto District Office, the FDA Laboratory Team reviewed several cases where laboratory analysis was used as case documentation, including one case with a legal sample as noted above.

Laboratory Team Conclusions

The Laboratory Team reviewed the laboratory support capability of the CFIA. The Team reviewed the controls and capabilities of the CFIA laboratory system, including the ICAT standard, the implementation of the system, and the process for CFIA to contract work to external private laboratories. The team found evidence that the systems are consistent with documentation submitted by CFIA, are in keeping with CFIA's requirements and procedures for laboratory operations, and support a finding of systems recognition with respect to CFIA's laboratory resources.

Part IV: Summary and Conclusions

A systems recognition exercise was conducted by FDA personnel to evaluate if Canada's food safety authorities, policies and programs are implemented as designed and if they provide a comparable level of food safety protection as the corresponding authorities, policies and programs of the FDA. The scope of the systems recognition assessments conducted by FDA includes all foods under FDA jurisdiction, excluding certain commodities regulated under U.S. state cooperative programs (i.e., raw molluscan shellfish and Grade "A" dairy).

An initial review of relevant Canadian food safety authorities, laws, procedures, and policies, based on Canada's submission of documentation, was conducted by FDA subject matter experts using the FDA-developed ICAT.

The FDA reviewers found that although the Canadian authorities, laws, procedures and policies concerning food safety are structured in some respects differently than those of the U.S., CFIA has authorities and capabilities to manage food safety that are similar to those of the FDA.

After completion of the initial review of documentation submitted by CFIA, four FDA teams conducted in-country evaluations for one to two weeks in June 2013 to verify the implementation and effectiveness of the Canadian food safety system. The ICAT Team performed documentation reviews at CFIA HQ in Ottawa and at a CFIA Regional Office in Toronto. Two Field Teams traveled to Canada to observe CFIA inspectors during inspections of a variety of types of food processing facilities. More specifically, these Field Teams observed CFIA inspections at 11 food processing facilities. The Laboratory Team evaluated the implementation of CFIA laboratory programs, resources and procedures at two CFIA laboratory facilities (Ottawa and Toronto, ON), as well as CFIA HQ in Ottawa and at a CFIA Regional Office in Toronto.

A summary of findings and conclusions follows.

1. The in-country FDA ICAT Team found no major concerns with the Canadian food safety system as implemented.

2. Each of the FDA Field Teams concluded that the CFIA inspectors followed the appropriate inspection protocols and demonstrated competency in technical knowledge,

training, preparing and implementing inspectional protocols, recognizing and evaluating deficiencies based on CFIA requirements and regulations, and communicating appropriately with the manufacturing facilities' personnel during inspections.

3. The FDA Laboratory Team found the implementation of requisite elements of laboratory operations to be consistent with documentation submitted by CFIA and found the overall laboratory system to be in keeping with CFIA's requirements and procedures for laboratory operations.

Overall, based on observations made during their evaluations, each of the FDA Teams recommends a positive finding of systems recognition, for the programs within the scope of the assessment of Canada's food safety system and supports recognition of the Canadian system.

Glossary of Acronyms

CALA	Canada Association for Laboratory Accreditation
CFIA	Canadian Food Inspection Agency
CMS	Client Management System
EIS	Enforcement and Investigative Services
FDA	United States Food and Drug Administration
FIORP	Foodborne Illness Outbreak Response Protocol
GPFHCL	General Principles of Food Hygiene, Composition and Labeling
HACCP	Hazard Analysis and Critical Control Points
HC	Health Canada
HQ	Headquarters
ICAT	International Comparability Assessment Tool
ILAC	International Laboratory Accreditation Cooperation
IMFP	Imported and Manufactured Food Program
IMS	Issues Management System
ISO	International Organization for Standardization
LSTS	Laboratory Sample Tracking System
MCAP	Multi-Commodity Activity Program
MFRPS	Manufactured Food Regulatory Program Standards
MRA	Mutual Recognition Arrangement
MRRS-OPM	Management Resources and Results Structure– Operations Planning Module

NETS	National Enforcement Tracking System
PHAC	Public Health Agency of Canada
PPEIM	Processed Products Establishment Inspection Manual
QMP	Quality Management Program
QMS	Quality Management System
RCC	U.S.-Canada Regulatory Cooperation Council
SCC	Standards Council of Canada
U.S.	United States
USDA	U.S. Department of Agriculture

Appendix 1

Table 2.FDA personnel identifying their involvement during the review, indicating the location and length of time for each activity.

Name[§]	Affiliation	Ottawa	Toronto	West Coast	East Coast	Lab Review
Julie Callahan	OIP/OSPA					
Jane Cluster	CFSAN/OFS					
Debra DeVlieger	ORA/OFFO			X		
Ken Hinga*	CFSAN/IAS	X	X			
Beverly Kent	CFSAN/OFS					
Rachel Lange	OC/OPL					
Cynthia Leonard	CFSAN/OFS				X	
David LeRay	ORA/OFFO				X	
Jennifer Letts	CFSAN/OFS					X
Jack Mowbray*	CFAN/OFS	X	X	X		
Michael Roosevelt	CFSAN/OC	X	X			
John Sakowski	ORA/DIO					
Michelle Smith	CFAN/OFS			X		
Miriam Stuckey	ORA/OFFO					
Karen Swajian	CFAN/OFS				X	

[§] All participants worked on the review of the ICAT as submitted by the Canadians' Competent Authorities. This documentation review started on February 2012 and lasted until June 2012.

*Retired

Appendix 2

Short biographies of the FDA personnel that participated on the Canada ICAT review

Julie Callahan, PhD,
Currently Acting Director FDA/OIP/ Office of Strategy, Partnerships, and Analytics
Previously International Policy Manager, FDA/CFSAN/International Affairs Staff

Before coming to the Office of Strategy, Partnerships, and Analytics, OIP, as Deputy Director, Dr. Julie Callahan was an International Policy Manager in CFSAN' s International Affairs Staff, specializing in international food safety systems assessments and other policies and programs that ensure the safety of imported. Dr. Callahan also served as a AAAS S&T Diplomacy Fellow as an International Trade Specialist with the USDA Foreign Agricultural Service (FAS) Office of Scientific and Technical Affairs. At FAS her work focused on chemicals-related international food safety issues and their impacts on international trade, including extensive work at the US Embassy in Beijing on issues related to pesticide and veterinary drug residues in foods. Dr. Callahan also worked as the American Chemical Society's (ACS) Global Content Development Manager in the ACS Office of International Activities, developing programs to foster international scientific collaboration in the areas of sustainable agriculture, clean energy and water. Her academic background is in atmospheric and marine chemistry, including a bachelor of science from Massachusetts Institute of Technology in Earth, Atmospheric and Planetary Science and a PhD from the University of Massachusetts in Marine Chemistry.

Jane A. Cluster, Consumer Safety Officer
FDA/CFSAN/OFS/DSS/Seafood Processing and Technology Policy Branch

Ms. Jane Cluster has worked as a Consumer Safety Officer with the Division of Seafood Safety (DSS) since September 1999 and has developed expertise in application of FDA's regulations, training, and evaluation of food safety programs. She has developed an extensive knowledge of FDA regulatory requirements, seafood HACCP food safety controls, CFSAN compliance policy, and ORA field investigation procedures. Ms. Cluster has participated in over 60 FDA foreign facility inspections providing technical support to FDA investigators, observing processing

operations, and evaluating both seafood-HACCP and GMP compliance. She currently provides technical support to ORA, CFSAN staff, and CFSAN management. She is a board member for the Seafood Certification Board which develops certification and training criteria for FDA investigators and participates as a trainer for investigators in conducting seafood HACCP inspections. She has assisted in developing prioritization criteria for the FDA PREDICT automated import screening project, and participated in writing the protocols, standards, and guidance for 3rd Party Certification of Foods and Feed in 2008 and the International Comparability Assessment Tool (ICAT). Prior to employment with FDA, Ms. Cluster worked for 13 years as an inspector for the National Marine Fisheries Service (NMFS), Seafood Inspection Program. Ms. Cluster holds a BS on Biological Sciences from the University of Tampa, Florida.

Debra DeVlieger, Consumer Safety Officer, National Food Expert
FDA/ORA/Office of Food and Feed Operations

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

Kenneth R. Hinga, PhD, Consumer Safety Officer (Retired)
Previously FDA/CFSAN/International Affairs Staff

Before his retirement, Dr. Kenneth Hinga joined FDA in 2013 as an International Policy Analyst, International Affairs Staff. Previously, he was at the USDA Foreign Agricultural Service's (FAS) International Standards and Regulations Division. He provided technical and science support standards being developed by the *Codex Alimentarius Commission* and to the resolution of technical sanitary issues relating to US exports of agricultural products. Dr. Hinga drafted the dossier which led to the first EU approval of a pathogen reduction treatments for meats. Prior to working on food safety issues for USDA, he represented USDA in a variety of international environmental agreements and forums. Dr. Hinga spent his earlier career as an academic marine research scientist. His research included open ocean studies, totaling a year of time at sea, radiotracer work in large marine enclosures, and data mining projects. Immediately prior to his move to USDA in 2003, Dr. Hinga was the Assistant Dean of the University of Rhode Island's Graduate School of Oceanography. Dr. Hinga earned his Ph.D. in Chemical Oceanography and a M.S. in Biological Oceanography from the University of Rhode Island. He received a Bachelor's degree in biology from Purdue University.

Beverly Kent, Senior Federal-State Programs Specialist (Retired)
Previously ORA/Office of Partnerships

Ms. Beverly Kent has worked in the FDA's Office of Regulatory Affairs (ORA) for 36 years. For more than ten years, she has been the Senior Federal-State Programs Specialist in ORA and the project manager for several high-level FDA programs and projects including the development and implementation of the Manufactured Food Regulatory Program Standards (MFRPS) and the Animal Feed Regulatory Program Standards (AFRPS). The MFRPS and the AFRPS are assessment tools ensuring effective food safety programs at the state level. Ms. Kent also developed the audit criteria to determine a state's implementation of the MFRPS and was the first lead auditor for the MFRPS program. She is the FDA's subject matter expert on the procedures for auditing state contract inspections. She has been the project manager for the expansion and oversight of the state contract inspection program and the lead instructor for the

state contract inspection audit training course for 15 years. She also helped develop the International Comparability Assessment Tool (ICAT), which is based on the Manufactured Food Regulatory Program Standard (MFRPS). Ms. Kent is currently the project manager for the development and implementation of a new state training program within the ORA/Office of Partnerships that will improve the process for allocating training slots in FDA's manufactured food courses to states. Ms. Kent holds a M.A. in international trade from the State University of New York, The University at Buffalo.

Rachel Lange, Ph.D., Economist
FDA/OC/OPL/Economics Staff

Dr. Rachel Lange is an economist who joined FDA in 2003 and received her PhD from the University of Kentucky. Since joining the agency, she has worked on a variety of food-related issues, including irradiation labeling, infant formula good manufacturing practices, and produce safety. She's currently working on food transportation issues, and is involved in a project that looks at FDA's international presence.

Cynthia (Cindy) Leonard, M.S., Consumer Safety Officer
FDA/ CFSAN/OFS/DDEMP/Milk and Milk Products Branch

Ms. Cindy Leonard is a Consumer Safety Officer and FDA's subject matter expert for Food Safety of Dairy Foods in the Division of Dairy, Egg and Meat Products, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S Food and Drug Administration in College Park, Maryland. Ms. Leonard's responsibilities for FDA include science, policy and regulatory review of dairy products, including cheese, produced in the U.S. and imported. She participates as a dairy food safety expert for foreign inspections and the international systems recognition program. Her work includes food safety risks of raw milk, raw milk products and cheeses, advising management on issues related to dairy product safety, and conducting research on legislative documents, legal precedents, and FDA enforcement history related to raw milk, raw milk products, and dairy product safety. As a dairy and food technologist and microbiologist, Ms. Leonard has extensive experience in the dairy and food industry in technical and

management positions. Prior to working with the U.S. Food and Drug Administration, she owned a consulting company and laboratory in Atlanta, Georgia. In June 2013, she participated as an auditor for the interdisciplinary audit ICAT team to Canada's East Coast for the in-country evaluation of the U.S. audit of the food safety inspection system by Canadian Food Inspection Agency (CFIA) which is Canada's competent authority for food safety inspections. Ms. Leonard's educational degrees are M.S. Dairy and Food Science/Microbiology and B.S. Environmental Health Science/Microbiology, University of Georgia, U.S.A.

David J. LeRay, Consumer Safety Officer, National Food Expert
FDA/ORA/Office of Food and Feed

Mr. David LeRay is a National Food Expert in FDA's Office of Regulatory Affairs, Office of Food and Feed Operations, where he provides technical expertise for development and implementation of national and international programs, develops and instructs at national training courses, and conducts complex inspections of food processors. He began his career with FDA in 1990 as a Consumer Safety Officer (CSO) at the New Orleans District Office (NOL-DO). He became NOL-DO's Seafood/Food Specialist in 1993. Mr. LeRay became a Supervisory CSO in 2006. He was selected as a charter member of FDA's Foreign Food Inspection Cadre in 2009 for which he performed food inspections internationally for three years. His specialties include seafood, low-acid canned foods, and acidified foods. He has conducted over 140 inspections of foreign food processors in 19 countries in North and South America, Asia and Europe. Mr. LeRay has conducted more than 600 domestic inspections of regulated industries including food firms, biologics firms, and medical gas firms. He has collected over 400 physical samples of food products. Mr. LeRay holds a Bachelor of Science Degree from Louisiana College.

Jennifer Letts, Consumer Safety Officer
FDA/CFSAN/OFS/DSS/Seafood Processing and Technology Policy Branch

Ms. Jennifer Letts has been involved in many FDA programs and projects to develop the Laboratory Support section of the ICAT, including piloting the ICAT and the precursor in

multiple countries by performing laboratory program reviews and direct laboratory assessments. Prior to joining CFSAN, she spent 5 years in the FDA Office of Regulatory Affairs, working with FDA laboratories to respond to outbreaks and develop and implement laboratory metrics. Before joining FDA, she worked in various FDA-regulated industries, performing and supervising microbiological quality control analysis to detect objectionable organisms and pathogens in products and environments, investigating laboratory deviations and developing corrective actions, and performing internal audits for ISO and FDA requirements. Now with CFSAN, Ms. Letts continues to apply her microbiology background to Seafood HACCP. Ms. Letts holds a MS in Biotechnology from Johns Hopkins University and a BS in Biological Sciences from California State University, Fullerton.

John C. Mowbray, Consumer Safety Officer (Retired)
Previously FDA/CFSAN/OFS/ Division of Plant and Dairy Food Safety

Before his retirement, Mr. John Mowbray was a Senior Policy Adviser, at the Division of Plant and Dairy Food Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration. His responsibilities included dairy foods regulatory policy development, dairy import and export matters, international standards development, foreign inspection programs and dairy products-related equivalence work. He previously served as Alternate U.S. Delegate to the Codex Committee on Food Hygiene and Alternate U.S. Delegate to the Codex Committee on Milk and Milk Products. He was the lead drafter of the Codex Code of Hygienic Practice for Milk and Milk Products. Prior to FDA, he held a number of management positions in the dairy industry (production and quality control) including ice cream, fluid milk, cheese, butter and powder manufacturing. Mr. Mowbray holds a B.S. and an M.S. in Food Science, from the University of Maryland.

Michael W. Roosevelt, Deputy Director
FDA/CFSAN/Office of Compliance

Mr. Michael Roosevelt is the Deputy Director, Office of Compliance, in FDA’s Center for Food Safety and Applied Nutrition (CFSAN). In this capacity, he provides leadership for food

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

John P. Sakoski, Consumer Safety Officer
FDA/ORA/OEIO/Division of Imports Operations

Mr. John Sakoski has been a Consumer Safety Officer for the Import Operations & Maintenance Branch (IOMB), Division of Import Operations, for about six years. He was hired as a CSO in FDA's Port Elizabeth Resident Post, Elizabeth NJ in April 2012 where he worked in Import Operations before transferring to FDA's New York District HQ in Jamaica, Queens, NY. Prior to being employed at FDA, Mr. Sakoski worked in product R&D and product quality control in several food processing facilities producing spices, sauces, and other products. Mr Sakoski holds a B.S. in Food Science & Nutrition from the University of Maryland and a certificate in Culinary Arts from the New York Restaurant School.

Michelle Annette Smith, PhD
FDA/CFSAN/OFS/Division of Produce Safety

Dr. Michelle Smith is a Senior Policy Analyst for FDA's Office of Food Safety. She has worked at FDA/CFSAN since 1991, and on produce safety specifically, since 1997. She is a nationally and internationally recognized expert. Dr. Smith led development of FDA's "*Guide to Minimize*

Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs guide). She assisted in developing the FDA's international GAPs training program, and provides assistance to the national GAPs program and other public and private programs in developing materials for education, outreach, guidance, and standards. In 2009, Dr. Smith received the United Fresh Award for Technical Assistance. Dr. Smith provides policy and technical support to FDA's response to foodborne illness outbreaks and interfaces with U.S. and international partners on safety issues in fresh produce. Dr. Smith led development of FDA's Produce Safety Action Plan and continues to play a leadership role in implementing guidance, education, outreach, and research components of the plan. She is currently working on select provisions of a proposed regulation to establish preventive controls for the growing and packing of fresh produce consumed in the U.S. and providing technical and policy assistance to the Produce Safety and Sprout Alliances to support education and outreach. Dr. Smith has a Ph.D. in Food Science & Technology, an M.S. in Crop Physiology, and a B.S. in Soil Science.

Miriam Stuckey, Supervisory Consumer Safety Officer
FDA/ORA/OO/OFFO/DFFPOI/Food and Feed Inspections Branch

Ms. Miriam Stuckey is the first line supervisor for the Food and Drug Administration's Dedicated Foreign Food Cadre (DFFC), a position she established in 2009. The DFFC is composed of 15 highly trained and qualified investigators who conduct foreign inspections in food facilities. In this capacity; Ms. Stuckey is responsible to manage, organize, and direct all of the inspectional activities of foreign food inspections. Ms. Stuckey has served in a wide variety of FDA regulatory programs and conducted inspections of several FDA regulated products. Many of the inspections resulted in FDA taken regulatory actions. Ms. Stuckey is a graduate of the Inter American University (IAU), Hato Rey, Puerto Rico. She holds a bachelor's degree in natural science with a minor in Chemistry. Ms. Stuckey has post graduate studies in Medical Microbiology and Marine Science.

Karen A. Swajian, Consumer Safety Officer

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

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