

COLLABORATIVE FOOD SAFETY FORUM
Imports and Third-Party Certification Workshop
November 16, 2011

The Pew Charitable Trusts
901 E St. NW
Washington, DC 20004

Workshop Summary

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the Collaborative Food Safety Forum (Forum). On November 16, 2011, they invited representatives from industry, consumer advocacy groups, academia, state regulatory bodies, the international community, and other key organizations to Washington, DC to engage in a workshop focused on the imports and third-party certification provisions of the Food Safety Modernization Act (FSMA). In addition to the stakeholder groups, individuals from the US Food and Drug Administration (FDA) were invited to observe the workshop and the discussions. This meeting continued deliberations begun during the July 20-21, 2011 session focused on the overall imports program developed under the FSMA. The goals and outcomes proposed for the session were the following:

Goals:

- Identify important principles underlying a successful third-party certification program
- Discuss key issues related to implementation of the third-party certification provisions in the FSMA
- Determine any next steps

Outcomes:

- A shared understanding of the different third-party certification systems
- Through dialogue and exchange of ideas among stakeholders and policy makers, explore opportunities and challenges posed by key issues in implementing third-party certification in the FSMA import program, and identify where there are common views among participants on these issues;
- Develop ideas and possible recommendations for implementing third-party certification as part of FDA's import oversight program

A detailed summary of the workshop deliberations follows. In addition, a shorter document highlighting key themes was developed. For copies of the presentations, visit <http://www.resolv.org/site-foodsafety/imports-forum/certification-workshop/>. A glossary of terms, excerpted from Mike Robach's presentation, is included in [Appendix A](#).

I. Welcome

Eric Olson, the Pew Health Group, welcomed the workshop participants. He affirmed Pew's belief in the importance of third-party certification for FSMA implementation and expressed confidence in the ability of the group to find common ground on some of the issues. Mr. Olson also noted the possibility of continuing the discussion if there was interest around particular topics. While he did not expect this meeting to answer all the questions around implementation of the third-party certification provisions in

FSMA, Mr. Olson encouraged the group to identify the key issues that would be amenable to further dialogue and potential agreement.

II. Overview of the Collaborative Food Safety Forum

Abby Dilley, one of the meeting facilitators from RESOLVE, provided some background on the Forum. RESOLVE has been organizing, managing, and facilitating the Collaborative Food Safety Forum under the auspices of Pew and RWJF. The Forum is designed to build on the community and collaborative processes that helped get FSMA passed, holding a series of meetings focusing on implementation among stakeholder groups. During the planning stage, RESOLVE consulted with a number of stakeholders to determine what issues would be best suited to collaborative dialogue, and on which issues the Forum could add value. Based on those discussions, the Forum is focusing on 1) the imports program and 2) the surveillance provisions of FSMA. The first Forum workshop in July 2011 concerned the imports program as a whole, with this meeting focusing on third-party certification as a follow-up to that session. The first surveillance workshop was held in early November, and an additional workshop focusing on food attribution is planned for February 2012.

Ms. Dilley listed the objectives of the workshop, which were to (1) identify common areas of interest, (2) narrow the differences among different stakeholder groups, and (3) discuss how third-party certification can meet the intent of FSMA's imports program.

III. FSMA Imports Program and Third-Party Certification

To inform the discussion, three panelists – one from FDA, one from industry, and one from a consumer advocacy organization – provided background on the FSMA import requirements, third-party certification schemes, and their perspectives on how such schemes could work in the context of FSMA.

Charlotte Christin, US Food and Drug Administration

Ms. Christin provided some background information on the FSMA import requirements, noting the “paradigm shift” the Title III import provisions entail with regard to FDA's authority and importers' responsibility. She highlighted the third-party components, which require FDA to establish a program to accredit certifying bodies (CB) to conduct food safety audits of foreign entities and to issue food and facility certifications. She noted that FDA can also recognize accreditation bodies (AB) that accredit CBs; furthermore, if there are too few CBs able to meet the demand for review of programs after two years, FDA can directly accredit CBs. FDA must issue implementing regulations and model accreditation standards for third-party certifiers (including accreditation and reporting requirements, conflict-of-interest provisions, and user fees) by July 2012, with the program entering into effect by January 2013.

In addition, the voluntary qualified importer program (VQIP) allows for expedited review for participating importers and entry for food from certified facilities. The process should be consistent with the third-party certification program. Finally, if FDA determines that a food import qualifies as high-risk, certification is required. FDA can accredit third-party certification bodies or designate country governments where the food originates to carry out the certification.

A short discussion session followed Ms. Christin's presentation. Several participants focused on different aspects of oversight involved in third-party certification, both by FDA and others. Ms. Christin noted there will be a feedback mechanism in the accreditation and certification process. The International Accreditation Forum (IAF) has peer-review agreements among its members, which the Agency is taking into consideration as the rule-making progresses. Ms. Christin invited members of IAF and the

International Laboratory Accreditation Cooperation (ILAC) to contact FDA to explore how the Agency could use their peer-review and evaluation methods to ensure the competency of CBs and ABs.

In response to a question, Ms. Christin listed some lessons learned from FDA's previous experiences with third-party roles and systems. From the third-party certification pilot for shrimp produced in aquaculture, FDA learned there is a large administrative and logistical burden associated with direct accreditation, even in one discrete sector.

The group also discussed the definitions of "audits" and "inspections," and several participants noted that the meanings of these terms are slightly different outside of the United States.

One participant informed the group of a consensus document, "United States Conformity Assessment Principles," which is published by the American National Standards Institute (ANSI).¹ The document contains definitions related to conformity assessments and standards and explains the principles of the World Trade Organization Agreement on Technical Barriers to Trade. The committee that put the document together was comprised of representatives from government agencies, consumer groups, non-governmental organizations, and academia.

Caroline Smith DeWaal, Center for Science in the Public Interest

Ms. Smith DeWaal presented to the group the history of the third-party provision in FSMA and the thinking behind it. She briefly reviewed how other organizations – specifically, the U.S. Department of Agriculture (USDA) and the Codex Alimentarius (Codex) – used certification. USDA relies on foreign governments to help inspect foreign plants processing meat and poultry products for export to the United States. Codex has adopted provisions addressing the recognition of certification systems in international trade. Ms. Smith DeWaal then summarized how certification had been used within FDA before FSMA, focusing on at-the-border inspections. She also noted that two approaches represented by – Hazard Analysis & Critical Control Points (HACCP) and Organic Standards – were both initially industry-driven and later evolved into governmental programs.

Noting that some stakeholders have expressed concern with third-party certification, she listed some of the concerns raised in a 2009 United Nations' Food and Agricultural Organization (FAO) white paper, including: the burden of multiple standards, the legitimacy and transparency of standards, and assurance that standards are protective of public health

In response to a question, Ms. Smith DeWaal elaborated on a public health concern raised by the FAO on whether third-party systems could attain the Codex standards. The FAO worried that such systems would be widely adopted but use lower standards than those set by international bodies and by governments. One participant noted that, given his experience, third-party certifications are based on the Codex standards and have improved public health in developing countries.

Mike Robach, Cargill

Mr. Robach laid out some of his thoughts on third-party certification, listing four key messages which were developed by studying FDA's prior experience with third-party certification:

- (1) Certification is an effective tool to assess food safety and an important component of several FSMA mandates and programs.

¹ This document is available online on the ANSI website at <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/USCAP%202011.pdf>.

- (2) FDA should establish a system to recognize ABs rather than directly accrediting third-party auditors, and recognize the role of ABs operating under IAF oversight play in accrediting third-party certifiers.
- (3) Certification should be carried by an independent organization accredited by a non-profit AB that is a signatory to the IAF Multilateral Recognition Arrangement.
- (4) This model is currently in place for the most widely-used food safety schemes (e.g., those recognized by the Global Food Safety Initiative (GFSI)).

He reviewed some of the terms and definitions associated with accredited third-party certification (see [Appendix A](#)) and recommended elements for FDA's accreditation program. He explained the benefits of an accredited third-party certification system with IAF oversight and noted that FDA could insert itself into such a model relatively easily and ensure harmonization with the existing system.

A discussion session followed Mr. Robach's presentation focusing on the governance of accredited third-party certification and how it differs from non-accredited third-party certification. Given that CBs play many different roles at different levels of inspection or certification, the public is easily confused about third-party certification, particularly when an outbreak occurs at a plant that was inspected. Mr. Robach noted that audits, which are just snapshots of the state of a facility at a given point in time, are not failsafe. Outbreaks will be reduced, but not down to zero, and thus will continue to occur even with the best of systems. However, the inspection is intended to increase assurance of compliance with best practices and, consequently, reduce outbreaks. A participant stated that audits and inspections are just one part of the food safety system, and that companies should have robust and comprehensive systems and interventions in place that the certifying body can verify.

One participant explained that because every CB is different, oversight by the IAF is vitally important. Checks and balances are necessary to ensure that the CBs are operating and training their reviewers, as well as conducting their reviews of facilities with integrity. The participant clarified that concerns regarding third-party certification relate to unaccredited CBs, which would not have an oversight body.

A few participants expressed concerns with CBs that perform multiple types of activities, which could be perceived as a conflict of interest (e.g., performing internal inspections for a facility, as well as conducting a formal audit of that facility). To explain how one organization could take on these multiple roles, one participant gave the example of AIB International, a CB which has internal divisions in place to allow different types of activities to take place within the organization. This participant noted that different activities have different goals and objectives, and that each does not necessarily carry the same weight as an "audit."

One participant shared data from a study that looked at the effectiveness of GFSI as a certification scheme. The results showed significant reduction in recalls, and the study concluded that adopting a GFSI scheme played a large part in that reduction.

In response to questions, Mr. Robach made the following additional points:

- FDA could recognize ABs as a means of facilitating imports into the country. There are issues with transparency and information-sharing that still need to be worked out.
- The industry wants harmonized food safety standards and will work with FDA to ensure that their standards and requirements are included in certification schemes.

IV. The Role of Foreign Governments/Agencies/Cooperatives

The group moved to a more focused look at how foreign entities could play a role in implementing the third-party provisions of FSMA. To inform the discussion, two representatives from foreign food safety agencies provided their perspectives on third-party certification.

Mary Ann Green, Canadian Food Inspection Agency (CFIA)

Ms. Green discussed the Canadian government's perspective on certification and accreditation. She emphasized that the two were tools to be applied to a task and were not a panacea. Ms. Green then explained these tools in more detail and discussed how the Canadian government uses both to increase efficiency in managing food safety systems. She emphasized that Canada would only consent to accreditation via a government-to-government relationship, rather than by an independent AB.

A short discussion session followed Ms. Green's presentation. In response to participants' questions, Ms. Green made the following points:

- CFIA inspects food and food systems and will not certify a product if it does not meet its requirements. Approximately 90 to 95 percent of all inspections are carried out by the government, but CFIA is starting to experiment with a system of third-party inspection with government oversight.
- A company that is working within the scope of CFIA's duties is covered by the government's liability provisions. If it is not working within CFIA's scope, it is not covered.
- Third-party auditors would be partially liable under normal processes for the performance of the companies they audit.
- The safety of imports entering Canada has to be assured by the exporting country's government. There is a continuum in the assurance CFIA accepts based on risk. Higher-risk products must meet standards equivalent to Canadian safety standards. For lower-risk products, there is the concept of "systems recognition" when the exporting country has a comparable food safety system to Canada's. Finally, there are plants operating in countries where CFIA does not have much confidence in the government's ability to provide assurance, which may be an area for third parties to provide the necessary assurance.
- Risk is calculated based on a combination of the actual food product and the level of oversight. For example, a low-risk product produced with low oversight may have a higher risk level than a high-risk product with high oversight.
- CFIA inspects high-risk seafood facilities three times a year and low-risk facilities twice a year. However, some plants operate for a very limited amount of time because the season for a particular product is short and may only receive one inspection a year.

Bill Jolly, New Zealand Ministry of Agriculture and Forestry

Dr. Jolly presented New Zealand's approach to third parties. He reviewed some "reality checks" that need to be taken into account in designing an effective and efficient food safety management system. He then explained the role of government in the system, noting that government-to-government agreements between "comparable competent authorities" provide the most food safety assurance. He reviewed New Zealand's regulatory model of third-party certification and the role of government in that model. Speaking to the topic third-party certification in particular, he defined the term and the requirements, as well as differentiated certification from audits.

Dr. Jolly explained the system of comparability assessment New Zealand uses to achieve food safety assurance. He listed the following elements of comparability, which include elements such as regular review; continual improvement; science-based assessments and standards; and transparency.

In response to questions from participants, Dr. Jolly made the following points:

- While New Zealand does some in-country audits and audits for high-risk products, it relies on comparability analyses to assure food safety. If an exporting country can trade with a country with a comparable system to New Zealand's, then New Zealand will likely trade with them.
- As a sovereign nation, New Zealand will not be subject to accreditation by a private body. Dr. Jolly further noted concerns with the variability found in third-party accreditation.
- New Zealand recognizes the International Organization for Standardization (ISO) 17999 and 17929 standards for auditing and certification, but also requires a facility to fulfill New Zealand's requirements.
- The New Zealand system has user fees and targeted taxes for licensing, inspections, and other services (not just for food safety and production), which are deposited into a central fund. Audited companies and facilities must report back to the government, which then owns the reports.
- New Zealand accepts third-party certifications for due diligence, but does not have agreements with those companies, only with governments.

During the discussion, the group talked about comparability. Ms. Green noted that comparability is based on the domestic system, and that CFIA looks at the exporting country's own standards for health and food safety. If a country has the same standards for both export and import, that country is considered to have a stronger system than one with different standards for export and import. Dr. Jolly suggested that some countries could be considered comparable for specific industries, even if their system is not comparable on the whole. New Zealand considers the U.S. a comparable system and will accept their imports.

In response to a point Dr. Jolly made about potential fraud, one participant identified a situation where a company had to withdraw from a country because of fraudulent food safety practices. GFSI and other international programs aim to help small companies that might be barred from market entry because of their governments' food safety record. By helping individual companies achieve certification, these programs have a long-term objective of improving the entire country's food safety standards.

V. Identification of Important Principles for a Successful Third-Party Certification System for the Imports Program

Informed by the presentations, the group discussed principles of a successful third-party certification system. In order to start the discussion, the facilitators presented three potential principles for the group to consider: (1) effectiveness, (2) efficiency and accountability, and (3) transparency. In addition, the group identified the governance structure as integral to determining how these three principles are carried out. With regard to the principle of effectiveness, the group discussed the need to build capacity among small producers and farms, as well as within the auditing community, in order to meet FSMA requirements. The group also identified the need for incentives for producers to participate in third-party certification.

Effectiveness

The group discussed two aspects of effectiveness –first, how to ensure that third-party certification is effective; and second, how to demonstrate its effectiveness. Several participants emphasized the need

for metrics and benchmarks to show that third-party certification can effectively improve food safety. One participant informed the group of a leading indicator study that revealed the adoption of GFSI correlated with an increased trust in the food produced by the suppliers, as well as a significant reduction in recalls. The study results might be published in the *Journal of Food Protection*. Another participant mentioned research by Michael Toffel from Harvard, which showed improvements in food safety related to adoption of ISO standards.

Another participant identified the availability of a facility's compliance and audit history as one reason why third-party accredited audits are more effective than unaccredited audits. By having this history, an auditor can determine a facility's willingness to comply or its ability to solve problems. This can inform a decision to revoke a facility's certification, if necessary.

Several participants emphasized that it was in the industry's best interest to ensure safety of their brands, and that industry leaders believe third-party certification to be an effective tool to do so.

Capacity Building

Many participants spoke to the need to build adequate capacity, both lower down the supply chain and at the small producer level, as well as within the auditing community.

One participant identified the need to address capacity at the farm level. Most of the certification schemes, such as GFSI, focus on the processor level. This leaves a significant gap because the rest of the production system relies on the products from the farm. In addition, the industry needs to work with small producers to increase their participation in certification programs. One individual observed that the GFSI guidance includes many of the same elements as FSMA; therefore, if small producers have trouble meeting GFSI standards, they will also have difficulty meeting FSMA regulations. The GFSI Global Markets Program was developed with the idea of helping small producers to eventually meet the certification standards and increase their access to markets. Several participants identified instances when a particular company, once it has achieved the standards, recognizes the value in it and begins requiring its suppliers to meet those standards as well.

Much of the discussion focused on the need to build and assure capacity of the CBs to carry out the third-party certifications under FSMA. Much of this is related to the number of trained, experienced, and competent auditors. One participant noted that while there is not currently enough capacity, CBs are working to increase the number of skilled auditors. Currently, many auditors enter the field as a second career, and the CBs are working on encouraging this as a first career choice. One participant identified several possibilities currently being considered, such as scholarship funds, apprenticeships, and including auditing skills in food science curriculums. In addition to being trained and familiar with the standards at, auditors must also be familiar with the systems they are auditing. Participants also identified barriers to implementing standards overseas. One issue is developing capacity in emerging markets. Some countries, such as China, require a certain number of auditors to be Chinese nationals. There is also the need for auditors to understand the local language. Implementation can also be delayed because of the need to train auditors in new standards.

One participant identified a need to build capacity on the part of the small importers to learn about certification and be able to demand it from their suppliers.

Efficiency and Accountability

The group identified components of a third-party certification system that would increase efficiency and enhance accountability. Much of the discussion focused on varying levels of oversight. Several participants described a “nesting doll” model, in which each level is responsible for overseeing the level beneath it. The auditors are overseen by the CBs, which are overseen by the ABs. Under FSMA, FDA would have oversight over the entire system. There are bi-directional feedback mechanisms throughout the system, used to analyze the performance of the auditor and the third-party system as a whole.

Another component to accountability is notification by the facility to the CB if there is a public health incident. One participant informed the group that suppliers certified under the Safe Quality Food Institute (SQFI) are required to report an incident to the CB within 72 hours; the CB will then work with the supplier to address the issue. The CB later performs a follow-up assessment. If the supplier does not notify the CB, the CB can withdraw its certification, and the supplier’s buyers are notified.

Certifications can also be suspended if a facility does not pass an inspection. If the issues are not corrected, then the facility has its certification withdrawn. If it wants to be certified again, it has to start over from the beginning of the process.

Transparency

The group discussed access to information throughout the supply chain and the implications for ownership of the information and confidentiality. It is important for FDA to have access to the information it needs to oversee the system. However, information provided to FDA often becomes available via the Freedom of Information Act, which limits the type of information the industry may be willing to provide to the FDA.

During the discussion, several participants identified types of information that FDA should be able to have access to without concern from industry. These included:

- Certifications
- Audit reports
- Non-conformance logs
- Actions taken to address non-conformance

FDA can use all of the above to help perform their risk analyses of different facilities and better target their own inspections and resources. One industry representative noted that his company would never request information from a supplier that it would not be comfortable passing along. Given the sheer volume of data being collected, however, it is important to focus on the important elements needed to identify gaps and ensure those are addressed adequately.

Several participants noted that more discussion is needed to determine the specifics to transparency in the system, and there were several outstanding questions that need to be answered, such as:

- What should be appropriate triggers to share certain information?
- Who owns the information being collected and shared?

One participant argued that consumers cannot demand a higher level of transparency in the third-party system than is provided by the government. A second participant pointed out that transparency is linked to the credibility of the system and that there should be assurance that transparency is occurring.

Incentives

The group also discussed the issue of incentives for companies to provide higher levels of assurance to the safety of their products and to notify the government if there are any issues. Ms. Green related that one of CFIA's programs includes an incentive for increased due diligence and a higher level of assurance. Participating companies' products are not held for inspection, but CFIA must be notified of any issues within the production system and the company must demonstrate that they are meeting food safety standards. Dr. Jolly noted that if a company reports a problem, rather than reacting punitively, the New Zealand government will work cooperatively with the company to solve the problem. One participant argued that incentives must incorporate behavioral science and that positive reinforcement should outweigh negative consequences. The group identified a number of possible incentives for companies, including:

- Faster inspection at the border
- Access to markets
- Business efficiencies (e.g., removing redundancies in the system)

In addition, the group also discussed incentives to participate in certification and accreditation schemes. Participants identified the main incentive is increased access to markets. Companies also have a vested interest in increasing the standards in their facilities internationally to protect their product and their brand.

The group then discussed incentives for ABs and CBs to participate in FDA's regulatory system. One participant pointed out that the ABs has a mission to safeguard the international standards, which are developed in partnership with all the stakeholders, including FDA. The representatives from certification and accreditation bodies expressed a willingness to accredit to FDA requirements in addition to their own standards. One participant suggested that once FDA is comfortable with the third-party model, it could be adopted domestically.

VI. FDA's Role in Overseeing Third-Party Certification

Informed by the previous discussions, the group turned to FDA's potential role in overseeing third-party certification. One participant suggested looking at other models in which the government partnered with industry to achieve certifications and standards. These included the EPA safe drinking water program, the EPA EnergyStar program, the Federal Communications Commission, and the Nuclear Regulatory Commission.

One participant noted that FDA is looking establish standards by next June and encouraged the group to let the Agency know of any systems or standards that may be helpful in developing the regulations. There will also be a comment period following the release of the draft regulations.

A few participants suggested FDA should not draft regulations based on the current capacity within industry and government, as that capacity will change. CBs are actively working on increasing the number of competent, experienced auditors, the economic situation will likely improve; at that point, FDA will have increased resources to carry out its responsibilities under FSMA.

VII. Next Steps

In the discussion, participants identified potential topics for further discussion. These included:

- The conflict-of-interest issue, in order to respond to consumer groups' concerns with third-party certification

- The domestic use of third-party certification
- Food safety in foreign countries of concern (in particular, lessons learned, necessary safeguards, and what an effective food safety system would look like)

Ms. Dilley thanked the workshop attendees for their participation. She informed them that the facilitators will prepare a short themes document to share with the group.

Ms. Eskin also thanked the group and expressed the hope that the discussion was helpful to both the participants and FDA. She encouraged participants to contact the meeting facilitators with any suggestions for additional issues that can be included in a continued dialogue. The facilitators and the meeting conveners will consult and determine any next steps.

Appendix A Terms and Definitions

(Excerpted from Mike Robach's presentation)

International Accreditation Forum (IAF): Through the IAF Multilateral Recognition Arrangement (MLA), IAF helps ensure that all accreditation bodies are following the rules of accreditation and applying the standards to affirm consistent delivery of certification schemes. Members (national accreditation bodies) perform verification activities by peer review using ISO 17011 to ensure conformance to IAF membership rules.

Accreditation Body (AB): An authoritative body that gives formal recognition of the competence of a certification body to provide certification services against a scheme or a standard. ABs ensure that certification bodies are subject to oversight using ISO 17021 or ISO Guide 65 (to be replaced by ISO 17065 in 2012).

Certification Body (CB): An independent (third party) organization that conducts certification audits and provides written assurance of an audited food company's conformance to a certain scheme or standard. A CB is accredited (by an AB) for its ability to certify a food facility's conformance to a defined scheme or standard.

Standard: Auditable and certifiable food safety requirements.

Scheme: A standard plus a governance and management system to assure the integrity of the standard's delivery.

Appendix B

COLLABORATIVE FOOD SAFETY FORUM *Third-Party Certification and Imports Session*

November 16, 2011

The Pew Charitable Trusts
European Union Conference Room
901 E Street, NW
Washington, DC

Proposed Agenda

Goals:

- Identify important principles underlying a successful third-party certification program;
- Discuss key issues related to implementation of the third-party certification provisions in the Food Safety Modernization Act (FSMA); and
- Determine any next steps.

Outcomes:

- A shared understanding of the different third-party certification systems;
- Through dialogue and exchange of ideas among stakeholders and policymakers, explore opportunities and challenges posed by key issues in implementing third-party certification in the FSMA import program, and identify where there are common views among participants on these issues; and
- Develop ideas and possible recommendations for implementing third-party certification as part of FDA's import oversight program.

7:45 am **Coffee and Light Breakfast**

8:30 am **Welcome and Introductions**

- *Erik Olson, Director of Food Programs, The Pew Charitable Trusts*
- *The Robert Wood Johnson Foundation (TBA)*

8:45 am **Overview of the Collaborative Food Safety Forum; Goals and Outcomes of This Session and Future Sessions; Agenda; and Ground Rules**

- Objectives:* Brief all participants on the goals and objectives of the session, review and adjust agenda to meet the goals and objectives, and establish ground rules to support a productive dialogue.
- *RESOLVE*

9:00 am **FSMA Imports Program and Third-Party Certification: An Overview of the FSMA Requirements, the Development of Third-Party Certification Systems and Insights from Other Examples, and Key Issues and Questions**

Objectives: Reach a shared understanding of key aspects of the FSMA import requirements, the development of third-party certification schemes, and the existing system of third-party certification.

- FSMA Imports Program Requirements and Third-Party Certification - *Charlotte Christin, Senior Policy Advisor, U.S. Food and Drug Administration Office of Policy*
- Import Certification in Historical Context and Insights from Other Examples - *Caroline Smith DeWaal, Director, Center for Science in the Public Interest*
- Overview of the Existing System of Accredited Third-Party Certification - *Mike Robach, Vice President, Corporate Food Safety and Regulatory Affairs, Cargill*

10:30 **Break**

10:45 am **Identification of Important Principles for a Successful Third-Party Certification System for the Imports Program**

Objectives: Develop principles that could guide the successful development of the third-party certification program and its role in the FSMA import system. Each principle identified will include a discussion of how that principle could be most effectively realized. We will consider each of these principles in our subsequent discussion of specific aspects of the program.

Potential principles could include:

- Effectiveness:
 - What are key elements of an *effective* third-party certification program?
 - Is capacity an issue and how can it be addressed?
 - What can we learn from the instances when the system has not worked as planned?
 - What training and qualifications of auditors are necessary to ensure an effective system
 - Evaluated how, by whom, and with what criteria?
- Efficiency and Accountability:
 - What is most important for an efficient and accountable third-party certification program?
 - What are the various stakeholders' views on this: FDA (so the agency is not diverting resources from other important functions)?
 - Importers and foreign food companies?
 - Accrediting bodies -- both public (foreign governments) and private entities?
 - Auditors?

- Consumers?
 - Concerns about conflict of interest protections
- Transparency
 - What are the collective expectations regarding transparency, and how can these expectations be met most effectively?
 - What are consumer groups' expectations for transparency of audit reports and other related information?
 - What is industry's view, recognizing that FSMA requires submission of certain information to FDA—even though this information would, under current circumstances, be shared only by the parties?
 - Other interested parties?
 - What is an appropriate level of transparency of audit reports, recognizing the resource implications (particularly in the field) for redaction and disclosure?

12:00 pm **Lunch**

12:45 pm **Discussion on Specific Topics of Interest: The Role of Foreign Governments /Agencies/Cooperatives**

- What role is envisioned for foreign governments?
- How can foreign governments best serve as certification bodies (CBs)?
- Should foreign governments also serve as accreditation bodies (ABs)?
 - If so, could they accredit certification bodies beyond their borders?
 - Could they accredit public and private certification bodies?
 - Would foreign governments wishing to seek accreditation be willing to go to a recognized AB to seek accreditation?
 - Does it matter to them whether the AB is public (i.e., government-to-government), private, or quasi-governmental?
- What is the most effective role of foreign cooperatives?

Presenters:

- *Mary Ann Green, Senior Advisor, Canadian Food Inspection Agency*
- *Bill Jolly, Manager Import & Export Food, New Zealand Ministry of Agriculture and Forestry*

2:15 pm **FDA's Role in Overseeing Third-Party Certification**

- Is there a need for direct accreditation and, if so, why?
- If so, what degree of oversight of directly accredited CBs would be conducted by FDA or is there an opening for direct accreditation by FDA with some but not all aspects of oversight by a recognized AB? For example, is a "hybrid role" feasible and desirable?

- Is FDA oversight of CBs and ABs always the same regardless of type of entity (i.e., public, private, domestic or non-domestic)? If there are expectations for different oversight, why, based on what criteria, and what are the potential implications?

3:30 pm **Break**

3:45 pm **Assessing Progress**

- On what issues/principles is there agreement?
- On what issues/principles is there disagreement, why and what possible options might address or narrow different points of view?
- What summary document might be most useful to produce?
- Are there any other outcomes to capture or highlight?

4:45 pm **Wrap-Up and Next Steps**

5:00 pm **Adjourn**

**Appendix C
Attendee List****PARTICIPANTS****Rance Baker**

Program Administrator, Entrepreneurial Zone
National Environmental Health Association

Leon Bruner

Senior Vice President for Scientific and
Regulatory Affairs and Chief Science Officer
Grocery Manufacturers Association

Nancy Donley

Board President
Stop Foodborne Illness

Sandy Eskin

Project Director, Food Safety Campaign
Pew Health Group

Bob Garfield

Senior Vice President, SQFI
Food Marketing Institute

Donna Garren

Vice President, Regulatory and Technical Affairs
American Frozen Foods Institute

Albert "Skip" Greenaway

President/CEO
EAGLE Registrations Inc.

Lane Hallenbeck

Vice President, Accreditation Services
ANSI

Stan Hazan

Senior Director, Regulatory Affairs
NSF International

Mike Liewen

Vice President, Global Quality Assurance
YUM Brands

Joan Menke-Schaenzer

Global Chief Quality Officer
ConAgra Foods, Inc.

Maureen Olewnik

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