

COLLABORATIVE FOOD SAFETY FORUM***Imports Session*****July 20-21, 2011****The Pew Charitable Trusts****901 E Street, NW****Washington, DC****Workshop Summary****Goals:**

- *Discuss key components of the imports provisions under the FDA Food Safety Modernization Act (FSMA) and identify and explore approaches to implementing these measures to enhance food safety;*
- *Discuss models for importer or foreign supplier verification to gain insights for the development of the U.S. Food and Drug Administration's (FDA) approach to the Foreign Supplier Verification Program; and*
- *Determine any next steps.*

Outcomes:

- *Through rigorous dialogue and exchange of ideas among stakeholders and policymakers, identify the opportunities and challenges in implementing the FSMA import requirements and where there are common views among participants on key issues;*
- *Develop ideas and possible recommendations for implementing the import program; and*
- *Derive a work plan for continued dialogue.*

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the Collaborative Food Safety Forum. On July 20-21, 2011, they invited representatives from industry, consumer advocacy groups, academia, state regulatory bodies, the international community, and other key stakeholders to Washington, DC to engage in a workshop focused on the import provisions of the Food Safety Modernization Act (FSMA). In addition to the stakeholder groups, individuals from the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the US Government Accountability Office, and the US Department of Agriculture were invited to observe the workshop and the discussions.

I. Welcome and Introductions

Erik Olson, The Pew Charitable Trusts, welcomed the workshop attendees and provided some background information about the Collaborative Food Safety Forum. The Pew Charitable Trusts makes their interest in food safety a priority, was active in advocating for legislation, wants to support productive implementation of FSMA, and hopes the Forum will provide opportunities for constructive dialogue. He further mentioned that the conveners heard from the stakeholders consulted during the Forum development phase that there was a lot of interest in holding multi-stakeholder discussions around some important FSMA implementation issues, including imports. He therefore was looking forward to the discussion over the next two days.

Angela McGowan, RWJF, echoed Mr. Olson's appreciation of the meeting attendees' participation. She emphasized the public health importance of building a safe food system, and the usefulness of

including all the partners in discussions around building such a system. RWJF believes food safety to be an important health issue with great impact, and also hopes the Forum will be an effective vehicle for information and productive dialogue.

II. Overview of the Collaborative Food Safety Forum; Goals and Outcomes of This Session and Future Sessions

Abby Dilley, one of the meeting facilitators from RESOLVE, acknowledged there are multiple activities addressing the implementation of FSMA, including on the topic of imports, which several of the meeting participants have also attended. During the development phase of the Collaborative Food Safety Forum, RESOLVE discussed with stakeholders ideas for structuring the Forum to take advantage of its structure, i.e., smaller, multi-stakeholder, idea-generating sessions. They also considered how best to add value to (rather than be redundant with) other efforts already underway to implement FSMA. Regarding substantive topics, stakeholders consistently suggested imports and surveillance; therefore, those two topics will be the subject of the first two Forum sessions.

For this session on imports, RESOLVE heard from stakeholders that a discussion around the imports program as a system would be a unique and useful approach. While several other meetings addressing FSMA imported foods have taken place, most have looked at particular elements of the imports program as separate or individual pieces. While stakeholders all believe the various components are part of a larger system, to date there has been less discussion about the larger vision and how each of the components or programs could contribute to a holistic system, near and long term.

Ms. Dilley informed the group that the Forum could provide a platform for continued conversation, if there is interest, and that possible future sessions would be discussed before the close of the meeting.

The meeting agenda, meeting materials, background reading, and presentation slides are available online at <http://www.resolv.org/site-foodsafety/workshop-1-imports/>.

III. Remarks from FDA

Mike Taylor, the Deputy Commissioner for Foods at FDA, thanked Pew and RWJF for organizing the meeting, and acknowledged the importance of dialogue among stakeholders as an essential aspect of FSMA implementation. The FDA is still in the pre-proposal stage for implementing FSMA regulations, and ensuring that the imports provisions are designed effectively is crucial to the overall success of FSMA.

Mr. Taylor noted that FDA was working on a number of regulations and that the agency is looking at food safety as a systems challenge that involves oversight of domestic and imported foods. It is vital all the different pieces of the system fit and work together effectively. He emphasized how critical ongoing stakeholder dialogue, sometimes with FDA as an observer, is during rule development. When a proposed rule is out, then FDA will continue to be very involved in dialogue during the public comment period.

Mr. Taylor stated that the FDA considers the implementation of FSMA as developing an overall risk-based prevention system, including, but not exclusively concerning, the imports portion of the Act.

Mr. Taylor outlined the following rules under development:

- The Preventive Control Rule, for which the agency anticipates promulgating final rules by summer 2012.
- The Produce Safety Rule, which has a January proposed rule deadline, with the final rule to be promulgated one year following the close of the public comment period.
- Foreign Supplier Verification Program (FSVP) Rule, which has a statutory deadline of one year from FSMA enactment. The agency will not make that deadline, and will take the time necessary to interact with stakeholders and to develop a rule that accounts for a prevention framework.

Mr. Taylor emphasized the fundamental paradigm shift underway and precipitated by FSMA, giving FDA increased authority over imports and holds importers accountable for managing their supply chains to ensure compliance with food safety requirements. While many companies are already managing their supply chains, FDA is also aware there are many supply chains not being managed. While FSMA provides FDA with very powerful tools for increasing food safety, the agency also is cognizant that these tools must be implemented in a practical way. Therefore, an effective implementation strategy for FSMA is one that has practical near-term steps that also establish the correct course for achieving the longer-term vision.

Mr. Taylor acknowledged that many companies already comply with multiple certifications, verification systems, and audits. The agency is working on integrating with the existing systems so as to avoid duplicating efforts and deploying agency resources where most needed for improving food safety. He noted that while the agency is focusing on implementing FSMA, it is also looking at how to build the system long-term so it works for everyone.

Following Mr. Taylor's comments, meeting participants were given the opportunity to ask questions. In response to questions, Mr. Taylor made the following additional points:

- Although the deadlines established in FSMA are somewhat out of sync, FDA is working to release the proposed rule for the FSVP to coordinate with the release of the proposed Preventive Control Rule, given their inter-connectedness.
- Coordination among different agencies and authorities is essential and FDA has established dialogues with principal trade agencies, such as the US Trade Representative and the Department of Commerce, and expects those discussions to continue through the rulemaking process. There will also be an interagency review process for the import provisions.
- The timeframe for the third-party certification program is flexible. As it is a completely new program, and has many different components, including as a part of the imports system, it is important that the framework be successful.

IV. Overview of the Food Imports Landscape and Discussion of a Systems Approach

To begin the meeting, participants heard three presentations discussing the food imports program from a systems approach at a macro level – how the various FSMA requirements and associated components (Foreign Supplier Verification Program, Voluntary Qualified Importer Program, 3rd Party certification, and inspection) fit together to form an overall imports program. Later presentations would focus on various attributes of an overall program, including how to prioritize high-risk imported foods, at what junctures coordination among different entities is critical,

where capacity building is essential for a robust and effective program, and what data and information are needed to implement and evaluate the imports program.

The three panel presenters outlined the requirements in FSMA, the implementation of the various requirements over time and how they shape the overall program, and the role of the private sector in meeting the requirements and conducting activities to enhance the safety of imported foods.

Dave Elder, US FDA

Mr. Elder, the chair of the FSMA Imports Team at FDA, provided an overview of the FSMA import requirements and FDA's current thinking about FSMA implementation.¹ He noted that there are three parties involved with the import provisions: the importer, the foreign manufacturer, and the accreditation body. He provided the diagram in slide 6 to illustrate how this system is envisioned to work.

- FDA is given authority over US-based *importers*, who must assure that the preventive controls placed on the product overseas are the same or similar to those required domestically. Importers have to comply with the provisions of the FSVP and will sometimes be required to produce certification. Importers will also have the opportunity to participate in the Voluntary Qualified Importers Program (VQIP) which would allow expedited entry for eligible products from certified facilities.
- *Foreign manufacturers* are expected to produce food for import using either US or comparable preventive control standards.
- FDA-recognized *accreditation bodies* will accredit third-party entities to certify that facilities are using the appropriate preventive controls. FSMA also allows for foreign governments to take on the role of a third-party certification entity.

Caroline Smith DeWaal, Center for Science in the Public Interest

Ms. Smith DeWaal gave an overview of the timeline for FSMA implementation for imports, and the associated components of the food safety system as they come on line with progression of implementation.² In the first year, FDA is required to register foreign food facilities, carry out inspections of 600 facilities (with that number doubling every year in the subsequent five years), establish foreign offices, and make changes to border inspections. She noted that the inspections will prove the most difficult of FDA's mandates to implement, and that the annual doubling is unachievable given current resources. She also delineated the different timelines for large companies, for whom the process control system becomes mandatory by 2012 even without any further FDA intervention, and small companies, for whom FDA must issue regulations.

Ms. Smith DeWaal then provided a summary of FSVP and VQIP. She explained that FSVP is a mechanism that allows companies to look back along their food chain for opportunities for improved practices that can enhance food safety. She expressed the opinion that the program would provide a lot of consumer protection, while providing enough flexibility for the importers to meet requirements efficiently. FSVP is a mandatory requirement for all importers, regardless of risk. FSMA requires FDA to have VQIP in operation eighteen months from FSMA enactment. VQIP is a voluntary program that relies on certification – however, Ms. Smith DeWaal pointed out that as

¹ A copy of Mr. Elder's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Elder-Presentation.pdf>.

² A copy of Ms. Smith De Waal's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Smith-DeWaal-Presentation-Intro.pdf>.

certification is on a two-year rulemaking timeframe, companies will have to wait until the certification system is developed before entering into VQIP.

She also provided an overview of the certification provisions of FSMA, noting that a foreign government or a qualified third-party auditor may issue certification. FDA may also require certification if the food itself, the country or origin, or some other characteristic qualifies the food as high-risk.

Mike Robach, Cargill

Mr. Robach presented the following guiding principles that Cargill developed regarding FSMA implementation:³

- 1) Flexibility optimizes food safety outcomes.
- 2) Harmonization with global standards and principles.
- 3) Utilize a holistic food safety *systems* approach.
- 4) Food safety facilitates global trade.
- 5) Role of third-party accredited certification.
- 6) Food safety applies to all foods.
- 7) Testing as a tool to verify food safety systems are preventing hazards.

He noted that industry does food safety every day and that flexibility and harmonization with existing standards is extremely important. He laid out the four components of a food safety system, and presented a diagram reflecting the integration of these components:

- International governance;
- Science-based standards;
- Guidelines and recommendations; and
- Business initiatives.

Mr. Robach then noted where existing international entities and standards, industry best practices, and initiatives may fit within that framework, and be integrated with FSMA programs. He also described the Global Food Safety Initiative (GFSI) as a model for third-party certification to be considered as a component of the imports program. GFSI is a private sector initiated program that emerged in Europe. It combines multi-stakeholder benchmarking of food safety systems with capacity building and incentives for participation through access to markets.

Questions and Discussion

A short session for questions, answers and discussion followed the presentations.

There was a brief discussion on foreign inspections. Mr. Elder clarified that his current understanding is that FSMA does not allow third-party inspections to count towards FDA's mandatory inspections required under the law. He added that conducting more than 1,200 inspections annually, which is required after year two of implementation, will be extremely difficult for FDA, given current resources. While FDA acknowledges the importance of inspections, given limited resources the agency will plan to put those resources towards efforts that would result in the greatest public health protection, and the agency will perform the most inspections possible while targeting them based on risk.

³ A copy of Mr. Robach's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Robach-PEW-Import-Session.pdf>

Participants also discussed the question of confidence in verification activities. One meeting participant expressed concern with the frequency of inspections, even if FDA reaches its mandated 19,200 inspections in 2016, noting that number would mean only one in every twenty facilities are inspected. Referring to cases where third-party auditors failed to protect consumers, the participant also expressed a lack of confidence in third-party auditors, whether private entities or foreign governments. A few others acknowledged the importance of inspections, but noted that inspections are only one component of the food safety program. A few participants described the oversight in place for existing third-party auditors. The auditors are not paid directly by food companies, but through a body that certifies the auditor. FDA's role would be to ensure the accreditation bodies are operating correctly, and the accreditation bodies in turn would be monitoring the auditors.

Several participants emphasized the importance of the auditors being familiar with the particular industry they are auditing, so they can identify potential hazards and the appropriate actions to address those hazards.

During the discussion, presenters made the following additional points:

- The FDA is still determining a definition for "importer" and thus those entities included, and is considering whether to define the term in two different ways: one for FSVP and one for VQIP.
- The Global Food Safety Initiative (GFSI) was created to solve the problem of multiple redundant audits. Once a facility is certified under a GFSI benchmark scheme, that certification is accepted throughout the supply chain. Companies purchasing from that facility still reserve the right to do a site visit if the risk warrants.
- FSMA does allow FDA to recognize third-party accreditation and certification systems to play a role in managing food safety risks posed by foreign facilities importing to the US. Facilities that are accredited are considered to adhere to US or equivalent guidelines for food safety. International Organization for Standardization (ISO) standards can be an appropriate model for a food safety management system.

V. Risk Prioritization for Imports

As mentioned in the earlier presentations and discussion, FSMA is focused on establishing a risk-based, prevention-driven system. A key component of such a system, including for imported foods, is to focus on the greatest risks. Meeting participants heard three presentations that focused on risk prioritization from different perspectives.

Glenn Morris, Emerging Pathogens Institute, University of Florida

Dr. Morris reviewed the approach to risk prioritization outlined in *Enhancing Food Safety: The Role of the Food and Drug Administration* from the Institute of Medicine and the National Research Council.⁴ The report noted that in order to develop and enhance our food safety system, it is essential that the US move to a risk-based approach. The FDA must first understand the underlying system and Dr. Morris pointed out that arriving at that understanding requires data. He then outlined the steps of a risk-based approach, noting it is an iterative process (*see slide 3 in Dr. Morris' presentation*).

⁴ A copy of Dr. Morris's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Glenn-Morris-Presentation.pdf>.

Dr. Morris emphasized the two main components of a risk-based food safety system are to 1) identify the major problems from a public health perspective and target the interventions accordingly, and 2) get the data. The data need to be accurate, reliable, secure, timely, comprehensive, integrated, and collected specifically for developing a risk-based approach. Dr. Morris discussed FoodNet as an example. The CDC created FoodNet to monitor the impact of the USDA HACCP rule. The data collected showed a drop in the frequency of key pathogens, with some of them eventually leveling off. The FoodNet data are pathogen-specific, however, and given that intervention actions are all food-based, it is important to be able to provide food attribution information and trends. In another example, the Emerging Pathogens Institute released a report identifying the top ten food-pathogen combinations; it ranked them using public-health metrics in order to begin identifying where the problems are and to use that information to develop appropriate interventions. Dr. Morris emphasized the data-intensive nature of developing a risk-based approach to food safety.

Lorna Zach, Independent Consultant (Systems Solutions for the Food Industry) and University of Wisconsin – Madison

Dr. Zach provided an overview of a three-year collaborative study that evaluated the hazards in supply systems along the food chain.⁵ She explained what risk assessment entails and how it can aid public health decision making. She identified some of the specific risks associated with imported food, including unintentional contamination, intentional contamination, sourcing issues, and country-specific issues.

Dr. Zach then listed the recommendations coming out of the project to improve import safety:

- 1) Improve communication and resource sharing in federal oversight.
- 2) Improve consignment inspection rate at the border and improve the ability to identify high-risk shipments using PREDICT, with a unique firm identifier.
- 3) Build an EU-style rapid alert system for food and feed.
- 4) Intelligent, cost-effective forms of public-private cooperation.
- 5) Private strategies, such as supplier qualification programs from brand protection.
- 6) Expand global governance to include an organization for food protection.

Domenic Veneziano, FDA

Capt. Veneziano provided an overview of the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) application that FDA is further developing to improve import screening and targeting for investigation.⁶ PREDICT is intended to improve import screening by identifying potentially “adulterated, misbranded or other violative goods” and expedite non-violative goods. PREDICT is combined with MARCS (Mission Accomplishment and Regulatory Services Compliance Services) to prioritize investigations. He noted that PREDICT prioritizes based on entry lines. A line entry is defined as a portion of an import entry that is listed as a separate item on an entry document and is assigned a score based on risk and surveillance requirements. Each FDA-regulated commodity must be listed separately if there is any variation in the required data elements, such as foreign manufacturer, product code, country of origin, or consignee.

Capt. Veneziano emphasized the dynamic nature of PREDICT, noting that changes can be made quickly.

⁵ A copy of Dr. Zach’s presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/ZACHRisk-in-food-imports.pdf>.

⁶ A copy of Capt. Veneziano’s presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Veneziano-Presentation.pdf>.

The Division of Import Operations is working with the FDA workgroups to provide information for the development of the imports provisions. The division is also working with other agencies to incorporate information from their voluntary programs into PREDICT in order to continue to reduce risk.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations. In response to individual questions, presenters made the following points:

- PREDICT aggregates data from multiple sources, including from the states and the Reportable Food Registry.
- PREDICT will feed back into FSVP. If violative products are found, FDA can investigate. It can also prioritize investigations based on repeated issues.
- Those who are advocating for increased global food safety governance would like the system to address preventive aspects all along the supply chain, not just the point of outbreak.
- FDA has outreach events every year and will continue to hold them as FSMA provisions are promulgated. It is building a website to identify points of contact and procedures for each U.S. port, as well as to link various affirmation and compliance codes to product codes. FDA is actively working to improve communication with industry.

One participant raised the issue of how to act in the context of imperfect data. An FDA observer noted that the agency plans to draw on available data and evaluate risk in order to best allocate resources, while acknowledging that the data is not perfect. FDA will build the system to incorporate continued analysis and data collection. Dr. Morris added that data will always be changing, so the system must be designed with flexibility in order to take new data into account.

During the discussion, several participants made specific suggestions. These include:

- Identify high-risk situations in the source regions, such as outbreaks and illnesses, which could affect the safety of imported food from those regions. The Center for Science in the Public Interest has started collecting data identifying pathogens of interest by region. This information is available on its website.
- PREDICT should, in determining risk, consider whether the intended use of the imported product would reduce the risk before it reaches the end consumer (e.g., if a raw material is being imported for further processing).
- FDA can learn from models for environmental exposure to chemicals in developing their risk- assessment models.

VI. Coordination

Coordination at multiple levels will be important for effective implementation of FSMA and necessary for efficient deployment of resources. FDA will need to coordinate with foreign governments and other international entities, with other federal agencies, as well as with state and local health departments. Meeting participants heard three presentations that focused on coordination.

Julie Moss, US FDA

Ms. Moss informed the group about the FDA's activities related to coordination. Since FSMA was signed into law, the agency has focused on outreach: the agency informed all US trading partners of the basic aspects of the law; did embassy briefings and question-and-answer sessions; cabled US

foreign posts so they could do further outreach and collaboration abroad; opened a dedicated email address for FSMA-related questions, comments, and suggestions; held bilateral meetings; hosted foreign visitors; and held open public meetings to collect comments. Ms. Moss noted that all these avenues were not simply for outreach, but also to initiate dialogue and collaboration with all the interested parties.

Dave Covell, Cuyahoga County Board of Health, Representing NACCHO

Mr. Covell provided the local perspective on an integrated food safety system.⁷ He summarized the current system in which federal agencies, states, and local health departments operate at various levels and with various amounts of coordination and overlap. He provided examples of effective coordination, and noted ongoing domestic efforts that FDA can leverage towards investigating imports. For example, state and local agencies can investigate international foods appearing in local markets and help to identify gaps in the system. He provided suggestions of ways for FDA to better utilize and enhance existing domestic partnerships: utilize the current system; beef up the system where needed; and standardize wherever possible.⁸

Carol Tucker-Foreman, Consumer Federation of America

Ms. Tucker-Foreman stated that FSMA's passage was indicative of the political will of the American public to address food safety, including the safety of imported food. She noted that as a consequence of the increased authority the law gives FDA, the American public is investing more expectations and confidence in the agency to assure food safety. It is therefore important that FDA continue to carry out its responsibilities for inspections and audits to ensure compliance. In her opinion, if the US government cannot carry out all those activities, then a foreign government would be the next most trustworthy entity to do so. Ms. Tucker-Foreman listed a "hierarchy of trust" with FDA personnel at the top, followed by other US federal agencies sworn to protect public health (e.g., FSIS), and then by countries that FDA is confident are committed to public health and food safety. She noted, however, that she does not believe FDA should accept one country's certification of another country without its own separate analysis.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations. In response to individual questions, presenters made the following points:

- In order to improve the current system, it is necessary to first determine what exists now. There needs to be a comprehensive assessment of the resources and manpower on the ground.
- Better and continued food attribution data would be helpful for those working on the ground to identify and address outbreaks caused by unexpected sources. For example, prior to the occurrence of outbreaks, *E. coli* and *Salmonella* would not have been associated with fresh produce.
- In Ohio, industry pays a licensing fee that is determined by risk. This funds the inspecting sanitarians.
- In order for states to contract to perform FDA and USDA inspections, states must demonstrate they can meet the standards.
- More states are adopting the FDA food code. FDA can set the bar for states, and industry's voluntary standards can help states move towards a harmonization of standards. It was

⁷ A copy of Mr. Covell's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Covell-Presentation.pdf>.

⁸ Please see Mr. Covell's presentation slides for more detail.

suggested that FDA coordinate with FSIS personnel to help inspect plants where there is dual jurisdiction (e.g., pizza).

VII. Capacity

Capacity is a significant issue for the effective implementation of FSMA and was mentioned several times in the previous session regarding coordination. Capacity is important for FDA in building its programs and relationships with other entities conducting various activities and tasks critical to meeting the goals of FSMA, and it is a significant issue for those in the private sector working to comply with FSMA.

Meeting participants heard three presentations that focused on capacity building.

Julie Moss, US FDA

Ms. Moss provided an overview of FDA activities related to helping build foreign capacity.⁹ Prior to FSMA, the International Capacity Workgroup of the FDA Imports Team gathered information on what other groups and agencies were doing regarding capacity building and their lessons learned and applied that knowledge to the FSMA directives. Ms. Moss reviewed the mandates for FDA in Section 305 that direct FDA to develop an international capacity building plan and how that section overlapped with other sections of FSMA. Section 305 directs FDA to consult with various stakeholders in developing the plan and Ms. Moss noted that this meeting is an opportunity to receive such input. She noted that the plan is in progress and the Workgroup is keeping in mind the need for flexibility.

Mike Cherry, Griffith Laboratories

Mr. Cherry described his company's current verification activities and how they might comply with FSMA import provisions.¹⁰ Griffith Laboratories contracts with a third party to audit its high-risk suppliers and their supply chains. He highlighted four main components of Griffith Laboratories' verification system:

- Knowing the supplier and the supply chain
- Utilizing a third-party auditor to monitor foreign suppliers
- Validating test results at a defined frequency
- Centralizing key records for rapid accessibility

Bob Bauer, Association of Food Industries

Mr. Bauer informed the group of some of the questions AFI – an international trade association fostering international trade of food products – is hearing from its members regarding FSMA that can inform FDA's continuing education and outreach activities. Some of these questions include:

- What are the benefits to participating in VQIP? FDA needs to be very clear on the benefits, and assure that there are no penalties for participating in the program.
- What is the definition of an "agent"?
- If a company buys a product from an importer, what are the responsibilities of the buyer in verifying information supplied by the importer?

⁹ A copy of Ms. Moss's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Moss-Presentation.pdf>.

¹⁰ A copy of Mr. Cherry's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Cherry-Presentation.pdf>.

- How long is the process to certify a foreign government as a third party? How is the certification order determined? Would those who are certified first have a competitive advantage?
- If a country's certification is revoked, is there a way for exemplary companies within that country to still export to the US?
- What about infrequent importers? How can FDA reach out to them?
- How can FDA ensure that inspectors are interpreting the standards consistently?
- Is there a way for the US to adopt *Codex Alimentarius* (CODEX)?

Questions and Discussion

A short question-and-answer and discussion session followed the presentations. In response to individual questions, presenters made the following points:

- The FDA International Capacity Workgroup discussed GFSI and would like to hear more details on that program in order to consider how it may inform food safety assessment, prioritization, and capacity-building activities.
- FSMA directs FDA to help build capacity within industry and in foreign governments.
- Griffith Laboratories determined what to test for based on a risk assessment. Internally, the company determines the key and non-key attributes that contribute to risk.
- FDA is working with Asia-Pacific Economic Cooperation (APEC) and the Food Safety Cooperation Forum Partnership Training Institute Network (FSCF PTIN) on further outreach and education efforts. PTIN is mandated to focus specifically on government, academia, and industry.
- CODEX is focused on trade, but also on food safety through quality and hygiene standards.

The group briefly discussed how to manage risk, given imperfect and incomplete information. A number of participants explored the possibility of looking at events internationally to predict what could happen within the US.

The group also discussed how far back in the supply chain to take verification activities. A few meeting participants noted that some businesses will ensure verification and traceability throughout the supply chain in order to protect their brands. McDonald's, for example, requires its suppliers to have verification programs in place to check on their suppliers, and "one-step-forward plus one-step-backward" traceability is required throughout the entire supply chain. For high-risk products such as fresh produce, beef, and eggs, additional oversight is carried out down to the farm, where producers are trained and tested on good agricultural practices (GAPs). In addition, one meeting attendee raised the issue of products being sold to another party once inside the US.

During the discussion, individual meeting participants made the following additional points:

- Auditors must be trained in the specific industry systems they would be inspecting in order to adequately perform hazard analyses.
- GFSI may have tools available for industry training.

During the discussion, several participants made specific suggestions for FDA to consider. These include:

- Holding joint training with industry. Such joint training has been shown to be effective, and will lead to more long-term and effective results.
- Consider the Global Markets Program's step-wise approach to help foreign industry build capacity. The program has had great results.

- It is best to avoid requiring a particular technology in the regulation because technology is always changing. Instead, the regulation should be focused on the outcome, and individual companies can best determine how each can meet that outcome.

VIII. Data and Metrics

Information and evaluation are important components of the FSMA imports program and are essential for determining risk-based priorities. Meeting participants heard three presentations that focused on data and metrics.

Dale Morse, Centers for Disease Control and Prevention

Dr. Morse summarized the current data on US foodborne illness due to imports,¹¹ noting that while there have been outbreaks linked to imports, that data are incomplete. He provided several examples of outbreaks that were linked to imported produce, and one example of an outbreak linked to a domestic product that used a contaminated imported ingredient. He emphasized the difficulty involved in tracking implicated imported food items to their source, and noted that the investigations are extremely labor intensive and involve multiple agencies working in collaboration. He also acknowledged the increased challenge of tracking outbreaks to the source given limited resources at the state and local levels. Dr. Morse provided some recommendations on how to collect better import outbreak data.¹²

David Plunkett, Center for Science in the Public Interest

Mr. Plunkett provided an overview of CSPI's efforts to collect data and develop metrics.¹³ CSPI has two main initiatives that collect foodborne-illness data: Outbreak Alert!, a database of domestic outbreaks, and through Safe Food International, which collects information on foodborne illness outbreaks in other countries. These databases use CDC data to develop food attribution categories and food types and to track the number of solved outbreaks both nationally and by state. Safe Food International attempts to track risk by region, based on various international information and news sources. This initiative identifies the top five pathogens reported by region.

With regard to metrics, CSPI has gleaned data on FDA activities based on publicly available information. Mr. Plunkett reviewed data that showed how the number of inspections correlated with funding, and observed that the variation is indicative of the need for mandated inspection frequencies and appropriate funding levels. He also reviewed how FDA staff activities have shifted from 2001 to 2009, the reported reasons for refusing imported produce, and the types of imported food frequently refused.

Mr. Plunkett noted the difficulties in collecting the data and in using available data to determine appropriate metrics. He also offered suggestions for how FDA can develop more accessible metrics.¹⁴

Bob Reinhard, Sarah Lee

Mr. Reinhard explained how industry approaches metrics.¹⁵ The goals of metrics are to:

¹¹ A copy of Dr. Morse's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Morse-Presentation.pdf>.

¹² Please see Dr. Morse's presentation slides for more details.

¹³ A copy of Mr. Plunkett's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Plunkett-Presentation.pdf>.

¹⁴ Please see Mr. Plunkett's presentation slides for more details.

- Identify the public health opportunity,
- Establish a framework for resources to be applied based on risk, and
- Measure the outcomes of activities.

How one sets up metrics is important, and the results drive further action. Mr. Reinhard noted that the most important metric for industry is consumer confidence in the safety of the product and overall food supply.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations. In response to individual questions, presenters made the following points:

- Local agencies appreciate seeing how the data they provide feed into national data and decision making.
- Imports can be refused entry based solely on appearance. “Filth” refers to dirt or other similar material found co-mingled with the product. “Insanitary” refers to the manufacturing conditions. A refusal of entry does not mean there was a violation.

During the discussion, several participants made specific suggestions. These include:

- The agencies (FDA and CDC) should consider capturing data on single cases of illnesses related to allergic reactions or chemical sensitivities. These data are captured in recalls. Allergens do not affect many people, but have serious consequences in a few individuals. In addition, chemicals can have both short-term and cumulative effects.
- The agencies should consider how they can better follow up with isolated cases, as those may link to larger outbreaks once identified.
- Based on a study by Pew and the Consumers Union in which small samples of bagged lettuce were tested for pathogens or contaminants, larger scale testing is needed to give a sense of the incidence of contamination and exposure.
- The agencies should encourage more testing of patients who seek medical care with symptoms consistent with foodborne illness.
- FDA should develop a metric around Import Alerts, as it is an extremely valuable tool for the agency to stop imports at the border.
- FDA should mandate a verification step that requires importers to search the Import Alerts for companies they are considering importing from.

The session on data and metrics concluded the first day of discussions and a broad overview of the components of a systems approach, with a focus on particular components of a systems approach, such as risk prioritization, coordination, capacity-building, and data, and determination of risk.

The second day focused more specifically on a particular aspect of the FSMA imports program – foreign supplier or importer verification and provided an opportunity to review other models involving verification and its role in enhancing food safety.

IX. Current Approaches for Importer/Foreign Supplier Verification

¹⁵ A copy of Mr. Reinhard’s presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Reinhard-Food-Safety-Metrics-July-2011.pdf>.

The series of presentations and discussions during the second day began with an overview of the requirements in FSMA for a foreign supplier verification program, followed by different points of view as to how this requirement could be met.

Dominic Veneziano, US FDA

Capt. Veneziano summarized the FSVP requirements in FSMA – noting that FDA has to implement the program as it is codified in law in a practical manner. He informed the group that there are many aspects of the FSVP still to be determined and developed, and that the agency welcomes any input. Some of the issues still in development include:

- Definition of importer – should it include the importer of record, consignee, bondholder, individual initiating the import, other?
- Verification of programs for the defined group of importers.
- Activities or requirements to ensure the programs are risk based.
- Appropriate treatment of imported foods that may be adulterated but are destined for further processing.
- Enforcement mechanisms with clear delineations of responsible parties.

Joan Menke-Schaenzer, ConAgra

Ms. Menke-Schaenzer provided an overview of an approach for FSVP.¹⁶ She expressed the belief that the guiding principles for FSVP are the same as those for FSMA as presented by Mr. Robach earlier in the day. She noted that industry already has systems and tools in place to manage food safety of both imports and domestic suppliers, and that those same systems and tools could be applied to the FSVP. Ms. Menke-Schaenzer then turned the remainder of her presentation time to Mark Overland for an overview of auditing and certification, including the Global Food Safety Initiative as a model to consider.

Mark Overland, Cargill

Mr. Overland provided the group an overview of the auditing process.¹⁷ He described auditing as a three-legged stool in which one leg is the criteria, the second leg is how the process works, and the third leg is personnel to carry out the work. These three components are the same for any auditing program.

He explained the earlier days of auditing food production in the US in the private sector involved multiple audit companies. The system was cheap, quick, and flexible, but there were concerns with the lack of external oversight, transparency, and competition. Then a proliferation of auditing requirements began, and in reviewing the key criteria for the most common auditing systems and elements of CODEX related to safe food production, the industry found that 91 percent of the criteria were the same.

Mr. Overland summarized the GFSI model of accredited third-party certification, noting that GFSI has a number of rules that focus on the accountability of the accreditation system and the accredited third party. He suggested that the advantages of this system include a multi-stakeholder approach, benchmarking of schemes, requirements for schemes and auditors, accountability for

¹⁶ A copy of Ms. Menke-Schaenzer's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Menke-PEW-Import-Session-FSVP.pdf>.

¹⁷ A copy of Mr. Overland's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Overland-Accredited-Certification.pdf>.

scheme delivery, and acceptance by industry. The disadvantages are higher costs and challenging standards to meet for emerging markets.

Cindy Jiang, McDonald's

Ms. Jiang provided an overview of the GFSI Global Markets capacity-building tool.¹⁸ She explained the program was designed to help small and/or less sophisticated businesses develop effective food safety management systems through a continuous improvement process. The Global Markets program employs a three-step approach in which companies are required to meet increasing numbers of the key elements of the GFSI Guidance Document within a given timeframe, eventually achieving 100 percent compliance within three years. The scope of the program includes the manufacturing, distribution, and storage of the food, and is designed to help local companies. Ms. Jiang suggested that pilot projects around the world have demonstrated the Global Markets program to be effective and helpful to the industry.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations.

Participants discussed how FSMA would affect small businesses and options for reducing the burden on those businesses. Some individuals noted that the step-wise framework in the GFSI Global Markets Program allows for small businesses to incrementally achieve full compliance with GFSI Guidance. Customers are asking businesses to meet improved standards through GFSI, and small businesses have shown they can meet those standards. The GFSI benchmark scheme also allows for cost savings, as its audit system is accepted broadly throughout the industry.

One individual observed that there has been pushback on GFSI from the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO), and others who believe that GFSI is adversely affecting the ability of small producers and holders in Africa to access markets. Another participant responded that the GFSI has incorporated CODEX and World Organisation for Animal Health (OIE) standards into private sector systems, and that GFSI is not intended to restrict trade. There is ongoing dialogue between industry, CODEX, and OIE on this topic.

One participant expressed concern with third-party auditing and pointed to FSIS's sampling program as an example of a regulatory process that uses industry standards and that some stakeholders view as flawed. Another participant noted that there is no competitor to GFSI in terms of benchmarking to spur continuous improvement. In response, it was stated that GFSI is a collaborative effort amongst industry members that has the goal of serving safe food to customers.

An additional question was raised in terms of the access to information regarding standards and compliance with those standards.

During the discussion, several participants made specific suggestions. These include:

- As the GFSI Global Markets program is designed for evolving businesses in developing countries, FDA may want to consider incorporating elements of the program into its training regimen.
- FDA should review the GFSI benchmark scheme fully, carefully, and with additional input if it is considering incorporating it into the FSMA imports provisions.

¹⁸ A copy of Ms. Jiang's presentation slides is available online at http://www.resolv.org/site-foodsafety/files/2011/07/Global_Markets_Presentation.pdf.

- The agency should simplify the regulations to allow for the flexibility to change standards and schemes without going through the rulemaking process.

X. Other FDA Food Safety Programs: Seafood HACCP

Meeting participants heard three presentations on FDA's Seafood HACCP program.

Lisa Weddig, National Fisheries Institute

Ms. Weddig gave an overview of the Seafood HACCP program, its history and its implementation.¹⁹ The Fish and Fishery Products Hazards and Controls Guidance has become de facto regulation for the industry, as it is the benchmark for inspections. Firms are required to have written HACCP plans demonstrating compliance with the guidance. She listed various categories of seafood prioritized by risk, provided example language from warning letters to a foreign supplier and to an importer, and gave examples of import alerts. She laid out some parallels between Seafood HACCP and FSMA, noting that the Seafood HACCP's written importer verification procedures and the options for affirmative steps are similar to those set out by FSMA.

Caroline Smith DeWaal, Center for Science in the Public Interest

Ms. Smith DeWaal provided some lessons from the implementation of the Seafood HACCP.²⁰ She outlined the Seafood HACCP rulemaking and compliance timeline and provided the available data on compliance. Although there are some issues with the data, she noted that the available data give her cause for concern with the effectiveness of implementation of the Seafood HACCP Rule. She pointed to the high number of warning letters for missing or inadequate seafood HACCP plans, the incidences of repeat violations, and that Seafood HACCP has not been implemented in one hundred percent of the industry. Ms. Smith DeWaal also identified other weaknesses in the program including the lack of a baseline for measuring progress, the current lack of data from FoodNet in tracking most common food hazards except for *vibrio*, and verification is optional. She then provided some lessons learned from the implementation of the Seafood HACCP Rule that FDA can take into consideration during FSMA implementation, including the establishment of metrics and collecting data to evaluate progress, follow-up to increase compliance, effective coordination and enforcement.

David Moreno, US Government Accountability Office (GAO)

Mr. Moreno provided an overview of the GAO report "*FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*," released in April 2011.²¹ The report had been requested by the Senate Commerce Committee as a follow-up to an early report on seafood fraud. GAO had two main objectives with this report: 1) to determine the extent to which FDA ensured the safety of imported seafood products against veterinary drugs; and 2) to determine the status of a Memorandum of Understanding between FDA and the National Marine Fisheries Service (NMFS) to leverage each other's resources to enhance seafood safety. Mr. Moreno explained that the GAO decided to focus on imported seafood given the rising amount of imported seafood consumed in the US, which is increasingly produced via aquaculture. He noted that aquaculture is associated with veterinary drugs, which is particularly potentially hazardous because those drugs cannot be processed or cooked out.

¹⁹ A copy of Ms. Weddig's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Weddig-Seafood-HACCP-and-FSMA.pdf>.

²⁰ A copy of Ms. Smith De Waal's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Smith-DeWaal-Presentation-Seafood.pdf>.

²¹ This report can be accessed online at <http://www.gao.gov/new.items/d11286.pdf>.

In its review, the GAO examined the following elements: countries of origin for imported seafood, the frequency of facility inspections, the frequency of inspections of the importers, and the frequency of sampling at the port of entry. The GAO found limitations in the oversight of imported seafood. HACCP regulations are unique to the processor and do not carry back through the supply chain to the farm. The authors also found limitations in the importers' oversight of their suppliers because importers relied on documentation provided by the companies.

The GAO also found limited collaboration between FDA and NMFS to lessen FDA's workload. GAO has been recommending that FDA use NMFS's inspection results and/or reports for years.

Mr. Moreno listed several recommendations for FDA related to seafood safety. These included:

- Communicate requirements to the rest of the world more effectively.
- Improve the sampling program to determine what drugs other countries are using and determine what is high risk.
- Collaborate with NMFS to more effectively use resources.
- Require more substantive verification of the companies selling to importers.

Discussion and Questions

A short question, answer, and discussion session followed the presentations.

Ms. Wedding expressed the belief that industry has an overreliance on the guidance. While the guidance can be flexible, it has become the *de facto* industry standard for inspections. If a firm does not follow the guidance, it has to spend significant resources to prove their system is equivalent to the guidance. Ms. Smith DeWaal expressed the belief that industry is not overusing the guidance because the guidance allowed industry to innovate. She noted that the guidance allowed for faster incorporation of new science than regulations might do. One meeting participant expressed a concern with the guidance becoming a "safe harbor" for industry, as it eliminates industry's responsibility to be aware of their own systems and the appropriate measures for their systems.

During the discussion, individual participants made the following additional points:

- FDA had issued a countrywide import alert for China and only allowed entry for seafood from an approved list. This action allowed FDA to focus its resources elsewhere, rather than on in-country inspections.
- Adherence to HACCP has to be verified on-site. There are many countries in Asia in which the documentation is used to gain entry in to a market, but the processing of the actual seafood does not reflect the documentation.

During the discussion, one participant recommended that FDA develop better metrics to evaluate the Seafood HACCP program.

XI. Other Verification Models – International

Meeting participants heard two presentations on international verification models.

Carlos Alvarez Antolinez, Delegation of the European Union

Mr. Alvarez Antolinez explained the European Union's system of controlling food imports.²² He provided a basic overview of Europe's governance structure and the EU's role as an importer. He covered the legal framework that the EU uses to govern food imports, noting that the EU makes a clear distinction between food of animal origin and food of non-animal origin, and that the former is considered higher risk and therefore subject to more prescriptive regulation and requirements. Mr. Alvarez Antolinez then summarized the specific requirements and the procedures that importers must follow in order for both categories of products to enter the EU. He also explained the verification and audit systems in place to ensure the effectiveness of the various import controls. He added that until the recent *E. coli* outbreak in Germany, there has been no outbreak associated with legally imported foods. This outbreak will affect how the EU will think about and address imports in the future.

Ron Doering, Gowlings

Mr. Doering, former president of the Canadian Food Inspection agency (CFIA), provided meeting participants with an overview of the Canadian import safety system. The Canadian food inspection system was overhauled in 2007 to put all enforcement authority of the food chain – including seed, feed, and fertilizer – within one agency, although Health Canada still has a small role with high-level risk assessments. Since the overhaul, overlapping and multiple inspections have been eliminated, and there has been improved coordination with the provinces and international agencies, and improved focus on market access. The agency is funded by fees from industry, which allows for flexibility for agency decision making. Mr. Doering explained that the CFIA allocates resources based on risk and focuses its efforts on products considered high risk, such as food of animal origin and low acid canned food. New legislation requires that all importers be licensed, and CFIA has the authority to seize, search, and control products without getting court authorization.

He then went into greater detail on Canada's fish import system, the first mandatory HACCP system for seafood. At the moment, all fish products are subject to inspection and importers must be certified. CFIA requires pre-notification and documentation of the product's risk profile, and inspections for new importers, any importer who has not been importing for two years, and for any high-risk products. Canada has implemented an e-certification program for fish imports in which the CFIA Import Control and Tracking System (ICTS) recommends inspecting a product based on inspection and compliance history.

Mr. Doering then briefly touched on perceived risk, noting that most of the recalls have been for completely safe food, and that very few outbreaks trace back to an imported product. He also raised some concerns with inspections and audits, which are resource-intensive and only provide snapshots of what is happening within facilities. The CFIA focuses much of its efforts on traceability, which is demanded by the market. In terms of risk, Mr. Doering expressed the opinion that imports may not be the most effective place to allocate resources for improving the safety of a nation's food supply. Rather, he believes a food safety agency should be very good at being reactive, given limited resources.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations. In response to individual questions, presenters made the following points:

- Canada has ten to twelve ports of entry for food, with four or five main ones.

²² A copy of Mr. Alvarez Antolinez's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Carlos-Alvarez-Antolinez-Controls-of-Imported-Food.pdf>.

- The Canadian Seafood HACCP program requires facilities to develop quality management programs (QMP). Once a QMP is developed, industry pays an inspection fee and every plant is inspected; the frequency of inspection depends on what is found in the plant. Once the QMPs are in place and the initial inspections are completed, there is little continued inspection unless there is a problem. After the initial inspection, every twentieth import is inspected.
- Canada does not recognize third-party certification, though all the big companies are using it themselves. All the audits pertaining to food of animal origin are carried out by the government.
- Canada defines food of animal origin to include meat, poultry, dairy, eggs, seafood, and honey. All of these have mandatory HACCP and whole-system inspection requirements.
- The EU does not officially recognize third-party certification as a tool to replace the role of official authority, but that does not preclude third-party certification. The EU system is based on governments and guarantees from the official authorities.
- After the bovine spongiform encephalopathy (BSE) crisis, there was public support for the separation of the responsibilities for the promotion of agricultural markets and for food safety into different agencies. The Food Safety Authority was then created as a completely independent agency. The FSA is responsible for risk assessment and providing scientific advice, but has no decision-making authority.
- The EU considers meat, poultry, dairy, eggs and honey – both processed and not – to be foods of animal origin. Fish is regulated separately.
- For the EU, an audit is an independent and systematic examination of the system. An inspection is an examination to verify that aspects of the system comply with legal requirements. The EU will audit authorities, not facilities.

XII. Other Verification Program Models – Domestic

Meeting participants heard two presentations on domestic verification models, including one state program and the US Department of Agriculture's Food Safety Inspection Service's program.

Steve Stich, New York State Department of Agriculture and Markets (NYSDA&M)

Mr. Stich informed the group of his agency's expanding role with imports, and provided data on where imports enter the state as well as the frequency of recalls.²³ In 2004, NYSDA&M collaborated with FDA to address imported foods, and Mr. Stich provided some background information on this initiative and described some of the outcomes. He then showed examples of food products that were found on the market shelves and were recalled for various reasons. He also noted that NYSDA&M and USDA worked together in "Operation Year of the Tiger" to address increased imports due to the Lunar New Year in 2010. The NYSDA&M also undertakes outreach and educational efforts to the different ethnic communities in the state.

Daniel Englejohn, USDA FSIS

Dr. Englejohn presented the USDA FSIS's approach to ensuring the safety of imported meat, poultry, and egg products.²⁴ He reviewed the FSIS mission, authority, and jurisdiction, and noted FSIS must approve a product before it can move into commerce. FSIS has developed food safety goals for four

²³ A copy of Mr. Stich's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Stich-RESOLVE-Workgroup.pdf>.

²⁴ A copy of Dr. Englejohn's presentation slides is available online at <http://www.resolv.org/site-foodsafety/files/2011/07/Englejohn-Presentation.pdf>.

main pathogens: *Campylobacter*, *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*. All, except for *Salmonella*, have seen reductions in causing human illness cases.

Dr. Englejohn then reviewed FSIS's equivalence standard, in which a foreign country must demonstrate the same level of food safety before its products can be approved for import. A country must have government inspections and daily inspections in order to be eligible. He summarized the process through which a country can be determined to be equivalent.

After going through US Customs and Border Protection and APHIS, all imports must be re-inspected and verified at a FSIS facility prior to release into commerce. Approximately five to ten percent of imports are subjected to a more thorough inspection. FSIS has dedicated officers focused on enforcement at ports of entry.

Questions and Discussion

A short question-and-answer and discussion session followed the presentations.

During the discussion, participants made the following additional points:

- The system was a success in New York because of two individuals who led the effort – suggesting that leadership is a key component to any successful program.
- New York forwards on information about Class I and Class II recalls to the New York District office.
- NYSA&M has held voluntary trainings for Chinese and Russian importers because of the large amount of recalls related to ethnic foods. It is hard to gauge outcomes from those meetings. While recall numbers have dropped, so has the amount of sampling due to funding cuts.
- About two years ago, FSIS moved from doing annual verification audits to a quality control system in which it reviews documentation annually, and determines if an in-country audit is necessary based on risk and volume. FSIS has also moved the focus towards the system in place within a country
- The border inspections provide a feedback mechanism to FSIS. If a violation is identified at the port of entry, FSIS sends the originating country a letter asking for corrective action. That country will then send documentation back to FSIS, which can choose to accept the action undertaken or not.
- FSIS is using all available data on food attribution to better target its efforts. Both FDA and FSIS have identified *Salmonella* as a pathogen of concern, and FDA has adopted part of FSIS's methodology to target effort to address *Salmonella* risk and exposure.
- FSIS must provide notice in the *Federal Register* if it plans to designate a country eligible to export to the US, and must go through a public comment and review process prior to the final determination. Equivalency determinations have been published in the *Federal Register* in the past, but the agency plans to publish them online in the future and provide opportunity for public comment.
- FSIS deals with individual countries. If there is a common authority (e.g., the EU), then the agency will work through the competent authority to make the determination on how its member countries equate to the US system.

During the discussion, individual participants made the following additional points:

- FDA focuses inspections at the facility level, both domestically and internationally. FDA comparability assessments are similar to FSIS's equivalency determinations, and consider at the entire country's system.

- It would be difficult for FSIS and other agencies to help FDA perform inspections without training and developing the expertise needed.
- The products Mr. Stitch showed in his presentation are easy to spot as adulterated or a food safety risk. There are also products that may be an issue that are harder to identify, such as a case in which the quality of the product received by an importer changes without notice.

During the discussion, a participant recommended that FDA determine state and local agencies it already has good communication and coordination with, and then focus efforts to build networks and partnerships in areas that are lacking.

XIII. Components of an Importer/Foreign Supplier Verification Program

Over the course of the two-day meeting, the participants discussed various components of an importer and foreign supplier verification program. RESOLVE staff identified some key themes that emerged during the sessions. This summary of themes was not discussed in detail nor is it intended to reflect any consensus of the group.

Some components and attributes of a successful imports program identified included:

- Adopting a systems approach
- Data collection
- Developing metrics
- Building in flexibility
- Allocating resources and effort based on risk
- Using third-party auditors

Adopting a Systems Approach

Looking at food safety from the perspective of a systems approach was a theme heard throughout the meeting. FDA acknowledges the need to meet the statutory requirements of FSMA, while thinking long-term of how to modify the system to more effectively manage imports safety, and within the context of an overall effective, risk-based food safety program. Meeting participants discussed how the different parts of the imports provisions could fit together, and how they could complement existing institutions and practices, such as GFSI and HACCP.

Data Collection and Developing Metrics

A number of meeting participants spoke of the need for better data collection, and transparency and accessibility of that data. Specifically, the need for food attribution data was mentioned repeatedly during the meeting, as that data would inform where FDA should focus efforts to protect public health.

Individual participants identified additional information to be collected, including more data on outbreaks and isolated cases; information on activities throughout the food chain; more pathogen-related data; data on recalls and facility inspections; data on pesticides and allergens in food products; and data on importers and importer compliance.

Data can then be used to determine risk and develop metrics to assess the effectiveness of FSMA implementation. The FDA should determine the appropriate metrics to track. Some stakeholders emphasized the need for the metrics to be accessible and transparent.

Building in Flexibility

A number of meeting participants emphasized the need for flexibility in the regulations to take into account industry's existing practices and the differences between facilities, as well as to incorporate new data and science in the future. The system should include a feedback loop so that it can continually improve.

Allocating Resources and Effort Based on Risk

Given limited resources not only at FDA, but also at the local and state levels, meeting participants discussed the need to allocate available resources where they would have the most public health value. Several participants suggested that FDA enhance collaboration with other federal agencies, as well as with local public health departments.

Stakeholders also talked about how to balance the statutory mandates with limited resources. For example, FDA acknowledged that the eventual mandated number of annual foreign inspections is unreachable given resource constraints, and therefore it will target the inspections towards high-risk facilities.

Inspections

The issue of inspections was a theme throughout the meeting – how frequent should they be? Who should do them? How can FDA reach its mandated number of foreign inspections? Some meeting participants expressed the opinion that inspections were extremely important to food safety and should be a priority for the federal government to carry out. Other meeting participants expressed the belief that there were other activities FDA can focus on to achieve greater public health benefit in addition to inspections.

There are differing interpretations of FSMA regarding whether third-party inspections could count towards FDA's mandatory inspections. A few meeting participants expressed the view that if allowed, third-party inspections would greatly reduce FDA's inspection burden.

Third-party auditors

Much of the discussion over the two days circled back to the role third-party auditors can play under FSMA. Some meeting participants voiced concern with the idea of relying on third parties, while others expressed the view that third-party auditors could help relieve FDA's burden and help protect the safety of food imports.

The group had a discussion about liability in the case of the failure of a third-party audit, when a product is found to be in violation of US import standards. Several industry participants noted that the importers would have the ultimate liability if something goes wrong. The importer is the one responsible and accountable for the product, no matter who carries out the audits or inspections.

Under the current GFSI system, there is auditor oversight in place. GFSI accredits the certifying body and can investigate that body if there are concerns with an auditor. Audit reports, while the property of the supplier, can be subpoenaed if necessary. If there is a problem with a supplier, it is the supplier's responsibility to notify the regulatory authorities, and buyers would be notified by the certifying body that the supplier has lost its certification. Certification is not reinstated until after the non-conformance is corrected.

Transparency and Enforcement

While FSMA does not explicitly provide for penalties for non-compliant importers, several meeting participants suggested ways to impose penalties on importers if necessary. One participant

suggested that FDA could write penalties into the rule. A few other participants noted that companies are protective of their brand and FDA could use transparency of information as a way to publicize when an importer is non-compliant. Finally, FDA could de-list repeat offenders and not allow them to import into the US. FDA also has the authority to bar from entry any import with an appearance of a violation; PREDICT will help the agency target inspections to high-risk entries.

Several meeting participants noted that of the thousands of US-based importers, the infrequent importers need more attention to ensure they are compliant with FSVP.

XIV. Next Steps

Ms. Dilley thanked all the participants and observers for attending the meeting and for providing their thoughts to the dialogue. She informed the group that the facilitators will prepare a summary of the meeting, which will be distributed to the group for feedback. Meeting attendees were also invited to provide additional thoughts on the imports provisions after the meeting.

Sandy Eskin from the Pew Health Group and Angela McGowan from the Robert Wood Johnson Foundation expressed their appreciation for the attendees' participation and adjourned the meeting.