June 19, 2012 Public Meeting to seek input on FDA's International Capacity-Building Plan under the FDA Food Safety Modernization Act (FSMA)

Background

The June 19, 2012 public meeting will provide interested persons an opportunity to discuss FDA's comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States (the "capacity-building plan"). FDA is developing this plan pursuant to section 305 of the Food Safety Modernization Act (FSMA), and is publishing this document to provide the public with an opportunity to view---and comment on---the draft recommendations that FDA is considering for inclusion in the plan. In developing these draft recommendations, FDA has kept in mind the challenges posed by the increasingly globalized food supply system, as well as opportunities for addressing these challenges through targeted, sustainable food safety improvements and by using enhanced risk assessment techniques to prioritize agency efforts. As the recommendations are in draft form only, the public is also welcome to provide comments on whether FDA's eventual plan should address any additional issues related to building food safety capacity.

In addition to putting forth draft recommendations, this document poses numerous questions. Interested persons (both those in attendance at the meeting, as well as those who are unable to be present) can share their answers to these questions. Interested persons can provide feedback on all matters related to FDA's plan for food safety capacity building, and need not be limited by the questions posted in this document.

Any comments that FDA receives will inform the agency's development of the final version of the capacity-building plan. Comments may be submitted in electronic or written form to FDA's Division of Dockets Management. Comments should include docket number FDA-2012-N-0437. The deadline for submitting comments is July 20, 2012.

Finally, the recommendations and questions included in this document reflect the six elements that Congress included in section 305. Congress provided that the plan must include these six elements, as appropriate:

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.
(2) Provisions for secure electronic data sharing.
(3) Provisions for mutual recognition of inspection reports.
(4) Training of foreign governments and food producers on U.S. requirements for safe food.
(5) Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.
(6) Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.

Provided below are draft recommendations and questions related to each of these elements in turn.

Element 1: Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.

In considering how to incorporate Element 1 into the plan, FDA reviewed a number of current arrangements and agreements related to food safety, including ones focused on information sharing and collaboration. Based on this review, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

- In pursuing new arrangements, and in re-evaluating existing agreements, FDA should seek opportunities with exporting countries and with other federal government agencies that optimize FDA's ability to leverage resources, rely on the findings of other government entities, and support joint capacity-building activities.
- To ensure effective arrangements, FDA should seek arrangements and agreements that are specific, goal-oriented and offer a gain for all parties.
- In developing new arrangements, FDA should focus on anticipated U.S. public health outcomes.
- FDA should also seek informal arrangements, which can be highly effective in promoting collaboration and technical exchange. Formal agreements and arrangements are not always necessary (though may sometimes be required by counterparts).
- FDA should prioritize the role of arrangements to ensure the safety of food imports.

Questions for public input:

- Are there instances where cooperation and information sharing efforts have been particularly effective?
- How can models of effective arrangements and agreements best support capacity building, and how can arrangements and agreements allow parties to leverage each others' resources?
- What are the anticipated goals and gains FDA should seek in these types of arrangements?
- Do you find informal or formal agreements/arrangements to be more effective?

Element 2: Provisions for secure electronic data sharing.

In drafting the recommendations for Element 2, FDA reviewed successful electronic information sharing models, both domestic and global. Based on this review, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

The agency would benefit by sharing key information with regulatory counterparts and with multilateral organizations, as appropriate, to:

- Support scientific and technical exchange of information (e.g., outbreak data, audit reports, inspection findings, etc.),
- Facilitate regulatory follow up (e.g. foreign inspections and recall actions), and
- Communicate rapidly during an emergency.

As FDA implements the import-related sections of FSMA, the agency should continue to analyze the capacity of current IT systems and determine whether any needs exist for system integration or the development of new systems to facilitate and enhance data sharing.

Questions for public input:

- What factors should FDA consider in providing for secure electronic data sharing? Are there any technological or other challenges related to data sharing, such as challenges related to inter-operability and system compatibility?
- What kinds of information should be shared in a secure electronic data sharing system?
- What factors would enable greater information sharing?

Element 3: Provisions for mutual recognition of inspection reports.

In considering the draft recommendations for Element 3, FDA reviewed its involvement in a number of harmonization and mutual recognition efforts, including several that address inspections. Based on this review, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

- FDA should continue exploring the issues surrounding mutual recognition of inspection reports with the intent of expanding reliance on inspection reports from other countries that have demonstrated strong inspectional programs.

Questions for public input:

- What are some examples of effective models for mutual recognition of inspection reports?
- What preconditions must exist to ensure that a system for mutual recognition of inspection reports ensures confidence?
- How should a system for mutual recognition of inspection reports assign responsibility for regulatory follow-up actions, where an inspection report indicates the need for such follow-up?

Element 4: Training of foreign governments and food producers on United States requirements for safe food.

In drafting the recommendations for Element 4, FDA considered the need for training efforts to be effective and sustainable, as well as the need for such efforts to have maximum reach. Based on these needs, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

- As resources are available, FDA should facilitate the provision of technical assistance and should participate in capacity-building activities focused on preventive controls, produce and seafood safety, and U.S. food safety requirements.
- FDA should prioritize its training and capacity-building activities according to risk assessments and the needs of identified countries, as appropriate.
- FDA should continue to develop materials (i.e., web, classroom) about U.S. food safety requirements, including material about FSMA. Similarly, FDA should refine existing material on U.S. food safety requirements.

Questions for public input:

- What are the best ways to ensure that developing countries are engaged with any training efforts?
- What training methods, modalities and models are effective, and why have they proven effective?
- What are potential obstacles to the effectiveness of training efforts, and why?
- How should FDA ensure that its training efforts are sustainable?
- How should FDA's training plan be designed in order to ensure the multiplier effect (e.g., train-the-trainer)?

Element 5: Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.

In considering the draft recommendations for Element 5, FDA took stock of its relationship with the Codex Alimentarius Commission---a relationship that dates back to 1963, when Codex was inaugurated. Through FDA's participation in Codex, FDA has contributed to the development of science-based international food safety, labeling standards and other pertinent issues that provide a level of consumer protection, labeling information and prevention of economic fraud and deception. Based on this experience, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

- FDA should continue its active participation in Codex, assisting in developing science-based standards where appropriate.
- FDA should provide continued support to the U.S. Codex Office and support the development and implementation of Codex-based capacity-building programs.
- FDA should support the Codex Trust Fund and active participation by other countries.

- FDA should seek to harmonize its requirements with Codex standards where appropriate.

Question for public input:

- What are your thoughts on Codex engagement (e.g., mentoring) and how can U.S. Codex (with FDA participation) help other countries?

Element 6: Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.

In drafting the recommendations for Element 6, FDA considered its participation in a host of domestic and international laboratory networks and reviewed the laboratory training efforts of counterpart agencies. Based on this analysis, FDA is considering the following recommendations. For each of these recommendations, FDA seeks public input.

Recommendations:

- FDA should encourage the adoption of laboratory methods based on performance criteria for a given outcome (such as for screening purposes or for regulatory action) and validating appropriately for their intended use (e.g., for contaminants above or below a limit; or the need to actually quantify the contaminant).
- FDA should have methods available that are not only fit-for-purpose (e.g., to select methods based on performance criteria for a given outcome), but also usable in various sectors within a country. International food and feed safety testing laboratories, including government laboratories, must offer a range of access to appropriate technologies (i.e., only basic analytical technologies versus state-of-the-art technologies).
- FDA should partner with training institutions and domestic and international laboratory networks to conduct outreach and education about fit-for-purpose laboratory methods, with a goal of increasing the multilateral acceptance and use of fit-for-purpose/acceptable current best practices by the international community.
- FDA should continue to be transparent and share its methods for compliance purposes.

Questions for public input:

- What are the needs for multilateral acceptance of laboratory methods?
- What role should industry laboratories have, and how should FDA coordinate with such laboratories?
- What role should multilateral organizations (e.g., WHO, ISSO) have in multilateral acceptance laboratory methods, testing, and detection techniques?

<u>Additional Considerations</u>

In addition to charging FDA to include the six elements as appropriate in the capacity-building plan, Congress directed that the plan be “comprehensive”---a charge that FDA

interprets to mean that the plan can go beyond the six elements listed in the legislation. Thus, FDA is considering incorporating additional themes into the plan. Specifically, FDA is considering incorporating themes associated with evidence based decision-making, partnerships, and assessment analysis. In considering these themes, FDA has given thought to the importance of partnerships between players in the global food safety system. FDA has also given thought to the importance of assessing the effectiveness of capacity-building activities.

Evidence Based Decision Making

Recommendations:

- FDA's capacity-building plan should focus on preventing unsafe food from entering the U.S. market.
- FDA should gather and obtain information that is country-and-product specific. Such information should help set the agency's capacity-building priorities, along with additional information FDA obtains.
- FDA should use data from multiple types of self-assessments (formal and informal) to inform its planning process. FDA will seek assessment results of other countries and encourage discussion about the identified adequacies and inadequacies of those countries' food safety systems. These results should inform FDA decision making.
- FDA's approach to capacity building should account for the interest of individual countries in collaborating with FDA, their ownership of such undertakings, and their willingness to address the needs identified through assessment tools.

Questions for public input:

- What data should FDA consider in setting capacity-building priorities?
- How should FDA assess a country's food safety system, and what tools should FDA use in doing so?
- Are there other considerations for prioritization that FDA should consider?

Establishing Partnerships

Recommendations:

- FDA should seek greater coordination with other all global food safety actors in pursuing global and regional food safety capacity-building efforts.
- FDA should encourage development agencies to invest in food safety systems as part of agricultural and economic development efforts. A model is the newly established Global Food Safety Partnership managed by the World Bank.

Questions for public input

- Who should FDA partner with and why?
- Are there partnership models that FDA should consider?
- How should FDA engage development agencies?

Designed for Effectiveness

Recommendations:

- FDA should develop strategic results frameworks for partner countries and high risk commodities with the aim of preventing food safety problems in the foreign food supply chain. This strategy will be used to inform decision making in FDA about strategic programming.

Questions for public input:

- What types of data should FDA consider for measuring public health outcomes?
- What are effective strategic planning models?
- What are effective strategic planning models that link to public health outcomes?
- What are effective ways to measure or evaluate capacity building programs?

FDA welcomes comments, suggestions, additional recommendations, and specific examples of best practices on any of the areas discussed above.