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President's Food Safety Working Group Listening Session
May 13, 2009

Expand Risk Based Inspection and Enforcement
Breakout Listening Session Notes

Note: These meeting notes do not represent the views of the United States government, and are only intended to capture the various views of participants, including non-government participants, during the listening session. The points listed below describe these views and do not necessarily represent a consensus opinion of the group.

Moderators:
Dr. Carol Maczka, Assistant Administrator, Office of Data Integration and Food Protection, United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS)
Dr. Stephen Sundlof, Director, Center for Food Safety and Applied Nutrition, United States Department of Health and Human Service (HHS), Food and Drug Administration (FDA)

Participants: Tony Corbo, Food and Water Watch; William Fisher, Institute of Food Technologists; Jessica Frederick, U.S. Senate; Chandler Goule, U.S. House of Representatives; Jennifer Greiner, National Pork Producers Council; Ferd Hoefner, Sustainable Agriculture Coalition; Heather Klinkhamer, Safe Tables Our Priority; Peter Kyriacopoulos, Assoc. of Public Health Laboratories; Joel Newman, American Feed Industry Assoc.; Rod Nilsesteun, Wisconsin Department of Agriculture; Adela Ramos, U.S. Senate; Craig Reed, National Academies; Brian Ronholm, U.S. House of Representatives; Michael Rybolt, National Turkey Federation; Caroline Smith DeWaal, Center for Science in the Public Interest; Thomas Stenzel, United Fresh; Mary Catherine Toker, General Mills, Inc.; Todd Tucker, Public Citizen's Global Trade Watch

Question 1: Do you agree that this Principle should be a priority area of focus for the Obama Administration and that the Principle is framed properly?

- A risk-based approach is the right path. Many illnesses can be tracked to a few products, and time and resources need to be focused on where the risk is.
- As the risks change, the risk-based system also must allow for flexibility and fluidity to change in response to events. Inspectors cannot become stuck in a routine if that routine does not allow for changing risks.
- A risk-based system exposes some issues, but it must be built on high quality data before it can proceed. Even in cases of products that are highly regulated, there is often insufficient data on prevalence of foodborne illness attributable to that product to assess its relative risk. The concept of a risk-based approach sounds great, but it is very complex in the implementation phase.
- This data must not just be from the past; it must also be on-going with stakeholders constantly adding real-time data to assess the current risks.

- It is important that decision-making across the food industry, including at FSIS and FDA, is standardized so that the data can be applied regardless of which agency is regulating a specific product.
- Some questions that need to be addressed: How is risk defined? What is acceptable risk and what is unacceptable risk? Who defines "high-risk" and how does that process work?

Question 2: What should be the roles and responsibilities of the federal government, state and local governments, industry, and consumers, individually and in relation to each other?

- Should the food safety agencies (FSIS and FDA) have the authority to do their own research and data collection? FSIS is prohibited from conducting research and must rely on USDA's Agriculture Research Service/Cooperative States Research Education and Extension Service. The FDA's food safety research is an integral component of its operation. If some agencies are already in plants collecting data, then that should be shared with other agencies, not duplicated.
- For example, industries that have their own internal data should make it available in a useful format to the government agencies.
- State and local partners are heavily relied upon by federal agencies for resources, such as laboratories, but they are under funded. Congress should appropriate more funding for these state and local partners.
- All data should be communicated and shared effectively and efficiently. Data should be used by FSIS and FDA in a holistic approach from the farm to the consumer.
- Information also must flow back. In other words, all stakeholders – whether Federal, State, local, industry, or consumer group –, should share data interchangeably in both directions.
- The data and data systems need to be standardized across local, county, State and Federal governments.
- There should be a National Work Plan defined by the federal government that would coordinate state and local food safety programs and ensure that all the laboratories adhere to the same standards.
- The Federal role must be to provide a framework and benchmarks so that all states are working with the same methods and meet defined quality standards.
- States also have different expertise, and a comprehensive data system would allow states with one area of expertise to share that knowledge with other states.
- Currently, there is a huge difference between how FSIS and the FDA share information with industry and consumer groups. This needs to be the same for both agencies and should be funded at the same levels.
- When legislators consider funding for laboratories, they should consider that improving data collection systems is not simply a one-year process and cannot be allocated for a specific fiscal year. Sometimes states cannot spend all the money within that year and lose it. Sometimes the process needs to take place over many years. It is difficult to have a plan to build these new data systems when it is unknown whether an initiative will be funded from year to year. It also is difficult

to attract the experts needed because of a lack of job security. Funding must be multi-year.
- Quality assurance is expensive, and it is often the first thing that gets cut with funding is tight.
- When legislators grant new authorities, it is important that funding is authorized for those new authorities. Otherwise budgets from other areas have to be cut to fund these new authorities.
- To ensure that inspectors are certified in equivalent ways, audits must occur at the State and local levels.

Question 3: What new or expanded authorities, if any, should the federal government have?

- Some participants believe Congress should develop a statutory framework that includes risk categories, the approach currently advanced by some in Congress.
- Each product is different and has different risks. A statute should flexible so that risk categories can be changed as risks change.
- However, some participants believe regulation might be the best place to do this.
- If the legislative approach is followed, the language must provide for flexibility. Both performance and the nature of the product should be considered. This, in turn, will encourage plants to control their own fate by adopting safety measures.
- Some participants believe lawmakers should define a framework which in turn provides the agencies (FSIS and FDA) with guidance on how to proceed with defining more specific details.
- Defining this framework in a statute also strengthens enforcement and gives the agencies support. However, there might be some resistance from industry groups.
- Statutes can be difficult to change. While it might make something stronger now, it might make it weaker in the future because it becomes antiquated and has an inability to adapt.
- Some participants believe that U.S. standards for safety should be applied uniformly to domestic and foreign plants.
- Resistance from elements of Congress is possible.
- When assigning risk, participants urged that one must be careful not to overlook anything.
- Some participants believe there should be a minimum frequency for inspections of plants by FDA. Additionally, inspections may have to occur more frequently to assess changing conditions.
- For future meetings of the Food Safety Working Group, the actual inspectors should be invited to participate. The people who are actually involved in the day-to-day operations have a unique knowledge. This must include state and local personnel, as well as the Federal inspection workforce, and all different categories (for example inspectors at HIMP and non-HIMP plants).
- Intentional adulteration of imported products should not be excluded from the discussion. They should be included in this risk-based approach.
- There are ways to include intentional adulteration in a risk-based method through vulnerability assessments.

- Some participants believe the Federal Government should have expanded authorities with regard to enforcement, including mandatory recall authority and imposition of civil monetary penalties.
- If there is mandatory recall authority, some participants believe there needs to be a requirement for better recordkeeping to create a system of traceability. There is no need to recall a whole class of product, when it is traceable to a single source.
- If mandatory recall authority is granted to federal agencies, there may be concerns about court intervention. Also what are the repercussions if an agency recalls a product that is later found to not be the fault product?
- Legislation for mandatory recall authority should include a provision for voluntarily recalling the product first and if a company does not cooperate, mandatory authority can proceed similar to the current process for seizing a product.

Question 4: What current federal government food safety activities should be expanded, scaled back, or stopped?

- Some practices are out-dated, too rigid, and do not properly allocate resources. Resources are going to fulfilling these rigid practices when they could be reallocated to higher priority areas.
- Animal Identification is not a food safety issue. Instead, it is a disease surveillance issue. It can be used as a tool in traceability, but the distinction must be made that pathogens in animals on the farm are not necessarily the same pathogens as those found in meat.
- Within FDA, the Director for Food Safety should have a direct line to the Secretary of HHS.
- The Centers for Disease Control and Prevention should stay outside of the regulatory agencies to maintain its independence as a science organization.
- The Food Safety Working Group should conduct a survey of traceability systems already in place in the federal government, for example, the Perishable Agricultural Commodities Act (PACA), which is managed by USDA's Agricultural Marketing Service.
- Historically, an affected industry does not go to the regulatory agency already responsible for its product to implement a change. Instead the industry goes to a different agency to accomplish its goal.
- The public health agency must set the framework. Other partners might enforce aspects of it (state and local partners or other agencies within in the federal government). Some participants believe any new approach cannot be based on a self-regulatory aspect (industry regulating itself or being the catalyst to drive a change).
- There may need to be more follow-up audits on importing countries.
- The full impact of any changes to the U.S. food safety system should be considered in an international context.
- Some participants believe the industry has been doing innovative things and the Federal Government should consider adopting these innovations.

Question 5: What actions should be taken, alone or in collaboration with others, by a) the federal government, b) industry, c) state and local governments, d) foreign governments, and e) others?

- There is no need to duplicate work in the Federal Government. If industry already has the information, use it.
- Assess what is done well at the state and local levels and leverage those assets; but also ensure that all data are compatible.
- Some participants believe that State and local government should not be making export agreements with governments.
- There is an opportunity for industry and consumer groups to share data in the times of public health emergencies. Tomatoes were incorrectly identified as the source of a foodborne illness last summer, even though industry data showed no common link. This information should be more readily shared and there should be a method to share it with regulatory agencies.
- Something needs to be done to expedite the movement of clinical samples from health care providers to laboratories. This will shorten the timeframe from when people get sick to when the illness can be traced back to a source.
- Members of the health care provider community need to be a part of this discussion. They spend a lot of time taking care of sick people, and in order to facilitate the movement of samples to laboratories, their input is needed.
- Food attribution data needs to be available sooner from the CDC. Data from 2007 is still unavailable so trends over the last two years cannot be identified.
- Systems currently in use at the international level need to be evaluated. For example, some industries use third-party certifiers. This should be studied as a potential model and perhaps integrated into the regulatory system.
- When designing a new system, we should reach out to the Centers for Excellence, and other science-based entities.
- There needs to be more research for new technologies that can eventually lead to more real-time data in the plants.

Question 6: What are the obstacles to and opportunities for success?

- Some participants believe the Obama Administration needs to reach out to foreign governments.
- Some participants believe there should be an assessment of global best practices.
- Any reform needs to focus on how to reduce the risk of pathogens across the farm-to-fork continuum.
- Public confidence in the food safety system needs to continually be improved. But, at the same time, all outbreaks cannot be prevented. This is not a time of crisis; instead data and science are making it possible to relate foodborne illnesses to distinct food sources. There needs to be realistic idea of how much improvement is possible.
- Technologies are underutilized. For example, there are temperature monitors that are automated and they should be used.
- Politics is an obstacle.

- The Food Safety Working Group cannot let this window of opportunity pass, and the Obama Administration must maintain focus on the issue.