

Meeting Report:

Gateway to Food Protection

Federal, State and Local Partners National Meeting

St. Louis 2008



A MESSAGE FROM THE CONFERENCE CHAIR

On behalf of the Food and Drug Administration, I want to take this opportunity to thank you for your participation in the "Gateway to Food Protection" meeting in St. Louis. Your work during those three days with other state, local, tribal and territorial stakeholders was invaluable in bringing all of us closer to making the goals of the Food Protection Plan reality -- as we build a national food protection system to address the global challenges in food safety.

Within the enclosed CD you will find the report of the meeting, including the recommendations of each of the four work groups: Recalls, Outbreak Investigations, Risk-Based Inspection and Sampling, and Roles and Responsibilities. In addition, we have included a participant list, the agenda, and copies of all the presentations. By the end of November, we will:

- Identify the top recommendations that FDA suggests for immediate follow-up action
- Hold conference calls with the Council of Association Presidents and St. Louis meeting participants to share our plans to move forward
- Develop an implementation process for the top recommendations (including identifying federal, state and local volunteers to participate in workgroups and a proposed timeline for next steps for these projects).

Currently, we are reviewing the outcomes and recommendations from the workgroups and finalizing a strategy to continue our integrated approach in protecting the nation's food supply.

During the months ahead, I look forward to your continued enthusiasm, knowledge, and dedication as we continue on the course we set in August: To create a global food safety system that includes all of our partners, at all levels of food safety, from farm to table. As I said in my closing remarks at the meeting, it is up to us to power this wave and ride it to success. I have no doubt that I can count on you to keep us on course, whether through direct action in workgroups, or supporting the goals of the Food Protection Plan in your own jurisdiction.

Once again, thank you for your hard work and commitment that made the Gateway to Food Protection meeting such a success. Let's keep the momentum going!

David W.K. Acheson, M.D., F.R.C.P.
Associate Commissioner for Foods
U.S. Food and Drug Administration

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EXECUTIVE SUMMARY

In August, 2008, in the shadow of the Gateway Arch, a tribute to Thomas Jefferson's vision of westward expansion and the pioneers who charted the route, another group came together in St. Louis to chart a historic course of its own. The "Gateway to Food Protection" meeting August 12-14, 2008, brought federal, state, local, territorial, and tribal partners together to address challenges and opportunities to ensure the safety and security of the food supply Americans enjoy and demand.

Participants included health department staff, epidemiologists, program managers, veterinarians, microbiologists, consumer safety officers, state officials responsible for the safety of animal feed, and others. Representatives from 49 states participated, as did representatives from American Samoa, the U.S. Virgin Islands, and Guam. The National Congress of American Indians was represented for the first time at such a large national meeting. The meeting plan: To help plot the course of a new framework for food protection efforts on a truly global scale.

This working meeting was a major step in the Food and Drug Administration's (FDA's) efforts to implement the strategy to strengthen the food system outlined in the Agency's 2007 Food Protection Plan (FPP). The FPP provides a framework for FDA's efforts to prevent problems before they become problems; to employ risk-based measures to identify potential hazards and counter them before they cause harm; and to provide for a rapid, coordinated response if contaminated food or feed is detected and harm to animals or humans could result. The FPP focuses on safety measures at every point in a food or feed's life cycle – from the time it is produced to the time it is consumed. Its integrated approach of prevention, intervention, and response relies on the collaboration and integration of all stakeholders in order for the Plan to succeed and has the goal of having an integrated national food protection system in the face of a global food supply.

One of the goals of the 2008 *Gateway to Food Protection* meeting was to lay the foundation for that success by recognizing, mobilizing, and empowering the strengths and expertise of the attendees and the segments of the greater stakeholder community each represented. An optimistic goal was set to at the end of the meeting develop short- and long-term action items based on workgroup exercises that were the main focus of the participants' time.

Although several federal agencies, including the U.S. Department of Agriculture (USDA), FDA, U.S. Department of Homeland Security (DHS), and the Centers for Disease Control and Prevention (CDC) were represented, their primary roles were to *listen* and to *provide technical assistance*. The meeting was designed to provide a setting for the state, local, tribal, and territorial stakeholders to apply their expertise across the board to address the challenges of a growing global food supply. The participants – not the FDA – were tasked with identifying and

developing a series of action items and recommendations designed to better coordinate and align with FDA's objectives and programs outlined in the Food Protection Plan.

MEETING OVERVIEW

The St. Louis meeting provided a convenient benchmark to reflect on the progress of a 50-state food safety meeting that was held in 1998 in Kansas City, framed around what was then the Food Safety Initiative. **Janice Oliver**, Deputy Director of FDA's Center for Food Safety and Applied Nutrition, kicked off the meeting with a historical perspective, "10 Years of Success: Accomplishments Since the 50-State Meeting in 1998."

Ms. Oliver chaired the steering committee from that 1998 meeting, and directed several workgroups that were formed to study various issues. From 1998 to 2001, there were workgroups that focused on laboratory operations, information sharing, outbreak coordination and investigations, national uniform criteria and clarifying roles and responsibilities. "There was a recognition then that food safety is not just the federal government's business," said Ms. Oliver. "We recognized that the states, the local governments, we all needed each other. Then, as now, we weren't trying to re-invent the system, but to improve the system we had, and to work better together doing it." One of the significant accomplishments that came out of those workgroups was the electronic Laboratory Exchange Network (or eLEXNET) project. What began as a pilot with 8 laboratories to demonstrate how an internet-based system could be used to exchange data now includes 135 laboratories representing multiple government agencies and all 50 states contributing data into the system. This allows eLEXNET to successfully populate its database with valuable information that can be used in threat detection, risk assessment, inspection planning, and traceback analysis during outbreaks and recalls.

Ms. Oliver commented that what began as a series of specific concerns from federal, state or local sectors became more of a cooperative atmosphere – that they began working together to tackle issues that were vital to all. Some unique relationships developed during that period, and partnerships began to form. These stronger relationships were invaluable when we were challenged with implementing the Bioterrorism Act of 2002 (BTA), to put food defense on par with national security for the first time.

Following the terrorist attacks of 9/11/2001, the possibility of deliberate contamination of our food supply was on the minds of Americans – for many, for the first time. Some of the elements of the BTA, Ms. Oliver explained, led to FDA's successful Food Defense program and signaled the beginning of coordinated risk assessment approaches that continue today. She commented that the BTA may not have been possible were it not for the cooperative efforts that came out of the 1998 meeting and its workgroups. She went on to say that many of the obstacles she saw 10 years ago have either been eliminated or reduced. During the 1998 meeting, she recalled, the states and the federal government weren't communicating very well – although they acknowledged the need to do so. Fast-forward 10 years to St. Louis. One of the most observed changes, even in the first few hours of the meeting, she noted, was an increased level of trust and collaboration among state, local, and federal government agencies. People felt it

and expressed it to her and to each other. This was a change for the better, she concluded, a move forward in continuing the partnerships which have become essential in today's food safety efforts.

Dr. David Acheson, Associate Commissioner for Foods at FDA, welcomed the participants and asked that everyone start on the same page – of the Food Protection Plan. The three key elements of the Plan: Prevention, Intervention, and Response, he said, need to be on the minds of all participants throughout their actions during this meeting. Dr. Acheson went on to outline some of societal and other issues that led to the Plan, including changes in consumer behavior, industry practices, and the need for all segments of the system to think and act globally. “It’s time for a new approach,” said Acheson, “a more proactive one to deal with new challenges in food safety.” He discussed some of the high profile outbreaks, including the *E. coli* O157:H7 outbreak traced back to spinach in 2006, and highlighted some new threats involving the deliberate adulteration of food or feed for economic gain, brought to the forefront with the melamine found in pet food in 2007.

Dr. Acheson spoke about a key shift at FDA to a greater risk-based focus in all areas, and the need to establish an inspection presence in other countries if prevention is to succeed. “No one, no two of us can do this alone,” he concluded. “Times have changed since 1998 – now, the partnerships and the trust that have been built need to work even better. We need to integrate knowledge and efforts and cooperate to make it happen. This meeting is the start of how we get there.”

The 2008 meeting was coincidentally held in the shadow of the largest food-borne outbreak in the United States during the past 10 years – when more than 1,400 cases of *Salmonella* Saintpaul spread across 43 states, the District of Columbia, and Canada. Although the outbreak was considered to be “winding down” during the time of the meeting, lessons learned during the more than 10 weeks of the outbreak remained fresh in everyone’s mind, and participants freely expressed their views on how things had worked between all the entities involved at both the state and local levels. Labeled as one of the most complex outbreaks in recent years, the *Salmonella* Saintpaul outbreak revealed gaps in the food safety system that needed to be addressed.

“When I look around and realize the diverse expertise in this room, I am reminded that food safety really is an integrated system – without that, we have nothing.”

Dr. David Acheson

FDA Commissioner Andrew von Eschenbach outlined FDA initiatives in food protection currently underway and reiterated the FDA commitment at all levels

to make changes, revitalize infrastructure, increase staff, and provide better tools for staff. He then responded to a series of questions and comments in an informal, town hall meeting format.

Faye Feldstein, Director of FDA's Center for Food Safety and Applied Nutrition's Office of Food Defense, Communication and Emergency Response, detailed the history and successes of the Food Defense program and outlined several new communication and training tools that are under development. She asked for volunteers at the state and local level to test some of these tools and to identify ways to make them more visible and more accessible to those who need them. Finally, she directed the group to include intentional contamination of the food supply as part of their discussions and workgroup activities over the remainder of their time together.

Other speakers included **Michael Taylor**, of George Washington University and **Joe Corby**, Executive Director, Association of Food and Drug Officials. Taylor outlined a project underway that is funded by the Robert Wood Johnson Foundation. Based at The George Washington University School of Public Health and Health Services, the project is being pursued jointly with the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and the Emerging Pathogens Institute at the University of Florida. In early 2009, the project will produce a report with recommendations based on the analysis and policy ideas generated through a series of meetings, workshops and other outreach to state and local officials, federal officials, the food industry and consumers. The report aims to complement ongoing efforts by FDA and USDA to improve collaboration with state and local agencies. The report will be used to educate policymakers and will provide a fact-based platform for advocacy to strengthen the roles state and local food safety agencies must play as part of the national food safety system.

"I don't want us to leave this meeting and just read a report on a shelf. We've got it started – what will sustain it is success and our continued interdependence. "

Commissioner Andrew von Eschenbach

WORKGROUP EXERCISES

From the call to order, it was evident that this was not just “another meeting.” Certainly, there were speakers and slide presentations, but it was clear that the bulk of the participants’ time would be spent in workgroups – working.

This was not designed to be a public meeting. The FDA invited state, local, tribal and other stakeholders and participants were nominated by their various departments and agencies to attend. Although many topics were discussed among the meeting organizers around which to frame the workgroup activities, four emerged as those the participants would focus on: **Recalls; Outbreak (Food-borne and Feed-borne) Investigations; Risk-Based Inspections and Sampling; and Roles and Responsibilities.** Participants were asked to make their workgroup selection in advance. Two facilitators and two notetakers or “scribes” were assigned to each of the four workgroup topics. Another indication that this was truly a working meeting: the required deliverable for each workgroup topic was a 20 minute presentation (plus 10 minutes allowed for questions) – to be ready for presentation by 7:45 a.m. on Day 3 of the meeting.

To better facilitate discussion and exchange of ideas, the four large groups were broken down into eight; two groups each working on one of the four topics. By late afternoon on Day 1, the workshop participants were given their charge:

1. It’s 2013. What is your vision of what an effective/efficient recall, outbreak investigation, or risk-based inspection/sampling program looks like to ensure safe and secure food and feed?
2. What is in place in 2008 that you can build on?
3. What challenges/barriers exist to achieve the 2013 goal?
4. How do you overcome current and perceived challenges/obstacles to achieving your 2013 goal (e.g., projects and actions)?

Further, the participants were given some “ground rules” under which to operate:

- Listen to each other – but don’t be quiet
- There is a role for every single one of you in the group
- You must think more broadly than at any time in the past
- Work outside your “silos”
- We are all part of this system, and we need to work through it and across it
- Speak up – share your knowledge, your vision, your ideas

The eight small groups spent the remainder of Day 1 brainstorming ideas they felt might fit into their particular areas (recalls; outbreak investigations; risk-based inspections and sampling; and roles and responsibilities). The first three groups were able to follow the charge outline pretty closely by identifying specific projects or other activities that could be pursued to reach the 2013 goal. However, the Roles and Responsibilities workgroup, because of its unique focus, chose to tackle the assignment by identifying and then categorizing the roles currently in place, specifying where they felt the largest gaps were, and suggesting how to close those gaps.

On the morning of Day 2, the workgroup exercises continued. By now, each group had lots of ideas, thousands of words written on flip charts or on 5x8 cards and tacked to the walls. Now the sorting began. The facilitators tasked each group to look at all those ideas and sort them into the following categories: training/certification; communication/information sharing; resources; research; and coordination. Each workgroup handled this task a little differently.

All the cards, all the ideas were gathered and the groups decided where those ideas might fit, or if they fit. Some of the groups further broke down categories into the “who” and the “how.” For example, communication/information sharing was grouped into sharing information with: (the “who”) government, industry, the medical community, the public and (the “how”) Web-based vehicles, including chat rooms, and internet search engines. All the materials used in every workgroup were saved and the information captured to share later with participants. Cards were moved around and reassigned as themes and thoughts emerged from the groups. The next step was prioritizing or ranking the “cards” or ideas. This was not a judgment of the value of the ideas – only whether this was a priority item with which the group felt it could move forward. Participants were asked to “vote” for various ideas and a ranking system was identified to come up with priorities.

“Every food should be traceable within 10 years. Farm to fork, boat to the throat.”

Meeting Participant

At 1 p.m. on Day 2, the conference room walls were opened between the two groups working on the same topic; they merged and began to compare notes. For some, this process went smoothly – they were on the same path; they had arrived at their destinations in pretty much the same way. For others, the merge prompted more discussion. With the deadline looming to get recommendations ready to present early the next day and choose someone from the group to present them, all the workgroups did a remarkable job in coming together on the priority ideas or items they could all agree upon.

By 6 p.m. on Day 2, most of the flip charts were being collected; the note takers were polishing up their notes, and presentations for the next day had been completed.

THE FOLLOWING REPORTS REPRESENT THE RECOMMENDATIONS OF THE FOUR WORKGROUPS:

I. ROLES AND RESPONSIBILITIES WORKGROUP

The goal of this group was to identify who would play which roles in the nation's food protection system in 2013 and to identify the barriers and gaps that might prevent the establishment of such a system.

Roles were identified first. This was further broken down by industry (domestic and international,) federal participants, states, local, international/foreign, academia, NGOs (non-governmental organizations,) consumers, other, and legislative (government/authority.).

The next categorization was that of "responsibilities." This consisted of the production system (growing, harvesting, etc.), emergency management, over-arching administration (i.e. auditing, registration, funding), education/training, inspection/enforcement, surveillance/investigation, research, and consumer.

The group recognized what was already in place to build upon: the Food Protection Plan, industry standards, partnerships, contracts/grants, associations, ORA University, EPI-X, Food Shield and FERN.

The next exercise for this group was to identify the biggest gaps to achieving the ideal 2013 system. This resulted in six items: **(1) sharing information/better communication/confidentiality; (2) funding and capacity; (3) qualified staff; (4) uniformity; (5) establish who's in charge, and (6) length of time to change laws.**

The first gap of sharing information/communication had the goal of developing an interactive information system allowing for communication and data sharing by all stakeholders for food protection. Legislative authority may be required in order to create a national system and to use this resulting system as an international model.

The next gap of funding and capacity was the need to make the public aware that there is a cost associated with providing safe food; a need to have more coordination between agencies and the need for increased training and education of staff.

The gap of qualified staff entailed the possible creation of an international food protection training academy, where there would be specific and uniform standards across the board.

Uniformity as a gap was discussed as being global the goal is to specifically recognize outcome-based standards, science-based best practices and to have a standard collection of data.

The element of who's in charge was included to emphasize that a particular person should be responsible for each element of the Food Protection Plan across all levels (federal, state and local.) Those elements are prevention, intervention and response.

The last gap on the length of time needed to change laws consisted of recognition of the problem, that there should be more emphasis on collaboration with state and local partners, and the need for re-evaluation and prioritization of internal processes. There was a basic awareness of the time it takes for laws to change and the resulting need for everyone to work together to make it happen.

The Workgroup produced four key recommendations:

Short-Term:

1. Establish a point person (coordinating element/agency) for each element of the food protection plan. The workgroup indicated that each element of the plan -- prevention, intervention and response -- needs federal leadership, guidelines and standards. Cross-cutting issues need to be coordinated. Elements from farm to fork should be identified under these roles and then coordinated with the states and others. We think it would be helpful to have guidelines and standards in place for what would trigger a response. Funding should be available for food safety and defense, perhaps a tap into funds through federal, state, private entities or industry. A suggestion of using a reciprocal agreement with resource training programs or a non-profit that already has models built was offered.
2. Establish an international food protection training center (both short- and long- term.) The training would encompass all stakeholders, all elements of food protection (animal and human), training to specific standards, span a professional's entire career, and serve as an umbrella to incorporate existing training programs. The workgroup suggested soliciting grants for sources of funding; that the training center would build upon Office of Regulatory Affairs U and Centers of Excellence, and stakeholders should be solicited for input on curriculum and the developmental process. Upon completion, attendees would be credentialed. Also cited was the need to make the public aware of the cost of this, and that there is indeed a cost associated with providing safe food. Public education as well as education of the staff was noted, as well as coordination between the agencies on all different levels.

Long-Term:

1. Create a food protection council to oversee the development, application and management of quality systems, standards, and metric systems. The discussion was based on experiences from other existing councils, such as Conference for Food Protection, CIFOR, NCIMS, and shellfish. These groups include representatives from federal and state agencies, state associations, industry trade associations (representing specific industry constituencies), and some include consumer advocates. The workgroup also discussed the opportunity to build on the audience framework from the St. Louis meeting to decide upon representation within this new council

The workgroup recommended in order to ensure global uniformity, there should be outcome-based standards, science-based best practices, credentials and accrediting certification, data-standard collection and data-interoperable IT systems. There needs to be recognition that outcomes-based standards are already in place; if a set standard is exceeded, the product is adulterated. For credentialing, it was suggested every person at the beginning of his or her career in food safety should know how to collect samples, complete affidavits and submit appropriate paperwork, resulting in level one certification. Trained and experienced quality control professionals should be recruited and performance measures should be established to determine whether a quality control system is working (metrics) SMART, i.e. specific, measurable, achievable, reproducible and timely.

2. Develop and adopt/create an interactive information system for communication and data sharing. The workgroup's designated goal here was to develop an interactive information system that allows for communication and data sharing by all stakeholders for food protection. Legislative authority may be required in order to create a national system, funding, and the removal of the legal barriers to confidential information exchange. In turn this system could be used as an international model. Stakeholders would have to commit to the design and governance of this, as well as the IT construction and maintenance of such a system. Examples already in place include FoodShield and Epi-x.

II. OUTBREAKS/FOOD-BORNE AND FEED-BORNE INVESTIGATIONS WORKGROUP

In determining what the food safety system should look like in 2013, this group cited steps that could be taken in three distinct areas: traceback/traceability; adequate resources for food-borne and feed-borne illness investigations; and an early warning system to report disease outbreaks in companion animals or contamination incidents concerning pet food or animal feed, which they named PetNet.

For traceback/traceability, five short-term goals were identified, which could be accomplished in 12-18 months:

1. The use of state or local staff commissioned by FDA for multi-state outbreak tracebacks. This policy change can be implemented quickly by FDA.
2. FDA and the U.S. Department of Agriculture to define standardized fields essential to tracebacks for high risk (to be defined later) commodities. This goal would involve developing a standard form that could be used by state and local as well as federal investigators to collect traceback information, which could then be presented in a standard format and could be shared.
3. Review existing FDA traceback procedure guidelines. If it leads to a rewrite of the guidelines, it could be a resource-intensive task.
4. Develop a Web-based traceback data sharing system that would allow state and local commissioned staff in states involved in a traceback to see that data at the same time as FDA headquarters staff.
5. Review existing Investigation Procedures guidelines and potential new techniques. FDA could work with high tech firms such as ArcView, Microsoft, forensic accounting firms, Google, and others to develop new methods of data analysis and visualization. (This goal might be combined with number 4.)

The following long-term goals were identified:

The 10-year goal is mandatory traceability for all foods and food ingredients, from farm to table, using standardized data fields. Barriers to this include industry resistance, a lack of funding, a lack of defined standards, international constraints, and legislative requirements or obstacles. Other long-term goals are to:

1. Share with stakeholders any lessons learned from outbreaks to prevent future outbreaks.

2. Expand the number of industry firms and food producers that are complying with GMPs and GAPs. Congress is considering legislation that would make compliance to GMPs and GAPs mandatory.

3. Develop a legal mandate to make all commodities traceable. Congress is considering legislation that would make it mandatory that some commodities are traceable.

To address adequate resources, three short-term action items were identified:

1. Define minimal standards and best practices for food-borne outbreak investigations and the resources to accomplish both. The CIFOR (Council for Improvement of Food-borne Outbreak Response) group (of which FDA is a part) has already done some work in this area.

2. Review the needs of state and local departments of health. This step could involve surveying local departments to see what resources they lack.

3. Provide needed resources (money, personnel, and equipment) to state, local, and tribal agencies to support core food production work.

An Early Warning System to Report Outbreaks or Incidents in Companion Animals, Pet Food or Feed:

In this subgroup, veterinarians, animal feed regulators, and others involved with animal health issues developed a proposal called the “Pet Event Tracking Network,” or “Pet Net,” to report disease outbreaks in companion animals or contamination incidents concerning pet food or animal feed. The proponents said the United States has no organized system for early reporting of food or feed problems, and no system for investigating companion animal disease outbreaks. The system they envision would be supported by adequate laboratory facilities, including toxicology laboratories, and an established mechanism for conducting national epidemiological investigations of food-borne outbreaks and other disease outbreaks involving companion animals.

To develop Pet Net, the short-term deliverables would be:

- A meeting involving multiple stakeholders, called to develop a database and to develop models for incident reporting and investigation.
- Identification of the appropriate location for the database.

The long-term deliverable for PetNet:

- A multi-state pilot program, leading to recommendations for nationwide implementation of the program.

III. Risk-Based Inspections and Sampling Workgroup

This workgroup recommended action in four specific topic areas, and recommended the use of a pilot program using a national cooperative work plan model as the first step in establishing a national food protection surveillance system.

Recommended Actions in Topic Areas:

1. **Defining and classifying risk.** The workgroup recommended that FDA assess groups and mechanisms already in place for ranking types of products based on the risk they posed to public health. If no group or mechanism is in place, the workgroup recommended that FDA assemble a group of experts to rank products according to public health risk. The expert group would evaluate scientific studies and databases, review food-borne illness data, surveillance data, risk vulnerability assessments, and compliance history for food companies. A short-term goal would be the ranking of relative risk from products of food processors.
2. **Development of a “National Integrated Risk Management Strategy” work plan.** The work plan would integrate inspection and sampling systems based on defined risk criteria and classifications. The work plan would include a central, uniform electronic system; uniform program standards; training, data collection; mitigation strategies; uniform inspection forms (which will ensure the collection of the same type of information across jurisdictions, and permit population of a database to track trends); a tracking system for food and feed inspections; and regular review and evaluation.
3. **Development of a national training and certification program that reflects a risk-based inspection and sampling approach.** FDA can assemble a team to determine what training and certification programs are currently available, such as the Web (for distance learning) and centralized and regionalized training courses so FDA could take advantage of them. It could use internal and external resources. The program would have to be audited to make sure it was performing as planned. A board would have to manage the certification program. Industry as well as government personnel could be trained through this program.
4. **Development of a vibrant, continuing educational campaign** to raise consumer awareness and promote behavioral change on risk and methods of risk mitigation. The campaign would educate members of the public about how to protect themselves from food risks, noting that individuals have some responsibilities for mitigating risk. The campaign would also explain what government at the state, local, and federal levels are doing to improve food safety. The campaign would target health care professionals and the general public. A short-term goal within this topic is the establishment of a “dialogue” between Agency risk communicators and representatives of a national health educators group. The health educators could review the strengths and

weaknesses of the way FDA communicates food safety risks to consumers and suggest strategies to improve that form of risk communication.

Pilot Program Toward Establishment of a National Surveillance System:

The workgroup recommended a short-term goal of a pilot program using the national cooperative work plan model as the first step toward establishing a national food protection surveillance system. The pilot would take 12-18 months to complete and could be implemented while simultaneously addressing some of the recommended actions the workgroup identified for further work.

The pilot would focus on a single product and industry so that it could touch as many points in the farm-to-table continuum as possible. The goal of the pilot project would be to test a system-wide approach to establish a viable, effective risk intervention strategy to address an identified problem or risk.

The pilot program would have five components:

1. Conduct a risk assessment and develop a system relative risk ranking. It would assess and rank risks from farm to table. Farms, firms, products, and processes would be included.
2. Develop a risk management strategy: The strategy would depend on the product and the hazard. The highest risk hazards (including biological, chemical, and physical) and commodities would be addressed first. Inspections and sampling would be targeted at the greatest risks.
3. Develop a national cooperative work plan model that would be used to coordinate inspections and sample collections to maximize effectiveness and eliminate duplication of efforts. A limited number of states would participate. All participating agencies within those states would provide a portion of their resources to fund the model pilot plan. Laboratory capacity would be made available to all who need it. Inspectors would be trained and certified so that inspections and sample collections would be standardized. The standardized data could be fed into a national system that would be available to all participants. The workgroup recommended that the pilot focus on one product to test the model. *Soybeans were suggested as a product to use because soybeans are in both animal and human food and would allow both food and feed programs to participate in the pilot program.*
4. Develop a risk communication strategy: It would involve the development of an educational awareness campaign explaining to consumers what actions federal, state, and local government are taking to improve food safety and what the consumers themselves must do to mitigate risks inherent in the food they eat.

5. Assess the performance of the pilot: It would show whether the pilot's goals were accomplished and determine whether the pilot should be expanded to other products.

The workgroup identified the following action items:

- Rank relative risks of products from food processors
- Develop a national cooperative work plan model under a pilot program as the first step in establishing a national food protection surveillance system.
- Establish a team to determine what training and certification programs are available.
- Establish a dialogue for an educational awareness campaign with health educators

IV. RECALLS WORKGROUP

The initial exercise of brainstorming among this workgroup resulted in some 66 ideas presented. Some of those included: the need for movement toward mandatory recalls; the verification and documentation of the supply chain integrity; the need for tracking/tracing of food commodities; the need to determine the disposal of the recalled material; the need for a comprehensive communications strategy to announce the recall; the use of one single real time data network; the possibility of coding products and the need to keep electronic records for tracing to preclude the purchase of recalled foods; and the emphasis to develop a model/standardized recall procedure that the states can use.

The groups identified three existing items that were in place that could be built upon: current Incident Command System (ICS); existing recall classification system; and current relationships with regulators and industry.

The long list of initial thoughts was broken down into major categories: **(1) training/certification; (2) communication/information sharing; (3) resources; (4) research/innovation, and (5) coordination/authority/standards.**

For **training and certification**, the recommendation was to provide integrated and ICS training for regulators and industry.

The goal of **communications and information sharing** was the development and implementation of a comprehensive communications strategy that would include all levels of government, consumers, the media, and industry.

Resources, encompassing people, equipment and money, focused on identifying recall audit checks and creating a national standard which would include having state teams in place using the ICS model to handle recalls and coordination between states.

In addressing **research and innovation**, the workgroup identified the need to not always be in a response mode but rather to put a testing program in place and to develop a national surveillance system using state labs. In addition, to develop a more rapid methodology for testing, and develop a framework to foster companies to use technology to notify customers of recalls.

Under **coordination of efforts**, the group advocated creating an ICS/NIMS structure to expedite communication and coordination, for manufacturers, growers and distributors to require electronic recordkeeping in a standardized format, and for government to develop procedures for a model recall system including an overhaul of the current Recall Class (I, II, III) class system.

The action items for the Recalls group were identified as long-term:

- Develop and implement a comprehensive communication strategy that includes federal, state, local and tribal governments, consumers, media and industry;
- Provide an integrated and ICS-based interdisciplinary recall training to stakeholders involved in responses including industry, federal, state and local governments, emergency response preparedness and response personnel;
- Provide legal authority for mandatory recalls including authority to issue monetary penalties, jail time and seizures and enjoining companies, both domestic and foreign;
- Exclude distribution information from inclusion in proprietary confidential information;
- Capture/maintain recall effectiveness data in one system available to all involved in the recall and analyze data in real time and provide situational awareness action taken if the recall is ineffective.

Day 3 – PANEL DISCUSSION

Following the presentations and question and answer portions of each workgroup, the final day of the “Gateway to Food Protection” meeting concluded with a roundtable discussion featuring an FDA panel: **Dr. David Acheson**; **Dr. Stephen Sundlof**, Director, Center for Food Safety and Applied Nutrition; **Dr. Bernadette Dunham**, Director, Center for Veterinary Medicine; and **Dr. Steve Solomon**, Deputy Associate Commissioner for Compliance Policy, Office of Regulatory Affairs.

The panel members voiced their reactions to the meeting and to the presentations they had just witnessed. **Dr. Sundlof** told the group that the meeting had given him valuable input to the strategic planning that is underway at CFSAN. **Dr. Dunham** said she was energized by the presentation and that she wants to “build a bridge between the health of people and animals; food and feed.”

“People should not have to second guess safety when they take a food item off the shelf. We need the people in this room to make that a true reality.”

*Dr. Bernadette
Dunham*

Dr. Steve Solomon called the dynamics of the workgroups “outstanding” and noted that there was so much meaningful dialogue and discussion, and not a lot of dissonance.

Dr. Acheson reiterated the commitment that FDA has to work more closely with state and local partners to develop a truly integrated national food safety system to address the global food supply. He encouraged all participants to keep the momentum going from this meeting. “We’re in a perfect storm,” he told the group. “We’ve got new funding, new legislation that is supported, massive interest in food safety, and then the worst food-borne outbreak in 10 years...we need to build a strong surfboard to keep this thing going – not sink or crash on a reef. We need to make sure we are in a position to be unstoppable, that we have some solid action items we can get in place as soon as possible.”

“This is a place to start – to build on. We should leverage what we’ve done here to draw a circle wider until everyone’s inside it.”

Meeting Participant

Where Do We Go From Here?

After thanking the participants, the planners, and everyone else involved in the meeting, Dr. Acheson outlined what he thought were the next steps once we left the room:

- The final report of the meeting will be published as soon as possible.
- FDA will identify the top 6 to 10 issues recommended by the workgroups that the Agency can move forward with. FDA will propose specific deliverables and solicit help through small workgroups to address them.
- Follow-up conference calls with all participants: October, November, 2008 and January, 2009.
- A series of regional meetings in 2009 to further drive deliverables.
- A planned 50-state/tribal/local partners meeting in 2010.

Dr. Acheson outlined some common themes he and the panel heard across the groups:

- Working with industry, with each other/partnerships
- Training (perhaps a national center)
- Uniformity (in procedures, in forms, other areas)
- Data Sharing (especially of commercial/confidential data needed during outbreaks and recalls)
- Making inspections count – use a risk-based process to focus on problem areas
- Improve communication with each other, with all stakeholders
- More legislative authority needed for FDA to mandate recalls, levy civil penalties

Hundreds more comments and ideas were discussed during the short time the participants had in St. Louis. The food safety system is comprised of thousands of individuals from state, local, and tribal governments, the food industry, academia, public health and consumer groups, and, increasingly, the international community. All create and collect food safety information. Each has a vital role in prevention,

intervention and response to food safety issues. However, as we've learned, each connects to and depends upon each other –or, as someone said more than once during the meeting in St. Louis, “The chain is only as strong as the weakest link.” Cohesive, integrated thinking and incorporating that integrated thinking into our actions remain at the core of the many challenges to building a food safety program that really works.

FDA is proud of the hard work on the part of everyone involved in the “Gateway to Food Protection” meeting in St. Louis. The charge now is to continue to harness the energy that was shown in those workgroups, build on those ideas, and move forward. Even though things are more complex than in the past, in the end, our biggest challenge is to find practical solutions that can really make a difference. And, although we have made progress, much remains to be done. With the essential, ongoing cooperation and collaboration with our partners, FDA will continue to execute the action steps laid out by the Food Protection Plan and act upon the recommendations of the workgroups from this year’s “Gateway to Food Protection” to ensure that U.S. consumers continue to have a safe food supply.

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