Testimony of

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I. Introduction - Integrated Proactive System

I would like to thank Chairman Tom Harkin, Ranking Member Michael Enzi, and Distinguished Members of the Subcommittee for the opportunity to offer this testimony. We are faced with the challenging task of protecting the safety and economic viability of our nation's food supply system. Americans are fortunate to enjoy one of the safest food supplies in the world. However, we are still faced with multi-state foodborne illness outbreaks that result in deaths and life-changing illnesses. Americans are beginning to question the safety of our food supply and are calling upon all of us to implement stronger food safety measures.

We can achieve our shared vision for a safer food supply only if we concentrate on true integration and collaboration. Over 3,000 Federal, state, and local regulatory and public health agencies have a role in protecting the food supply. FDA provides guidance, model codes and other technical assistance to state, territorial, tribal and local regulatory partners to assist them in carrying-out their regulatory responsibilities. Since 1972, FDA has also contracted or entered into partnership agreements with many state regulatory agencies to perform inspections and investigations. In fact, more than half of all FDA inspections are performed under contract by states. As a result states perform approximately 90% of all food safety inspections conducted at food manufacturing and distribution establishments.

Within the last two weeks the NC Department of Agriculture & Consumer Services initiated a recall of sandwiches due to the potential for the contamination of *Listeria monocytogenes*. Listeriosis is a bacterial infection that can result in stillbirths or miscarriages in pregnant women or cause serious illness in elderly or immunocompromised populations. This year FDA began funding environmental sampling as part of the contract with state regulatory programs. Our in-depth inspection of the subject food manufacturer was a firm under contract inspection with the FDA. Our laboratory testing initially identified *Listeria monocytogenes* only in the processing environment, which led us to conduct additional finished product testing. Testing determined sandwiches distributed by the firm may also be contaminated and a voluntary recall by the firm was initiated.

An effective response to any food incident requires the collaboration of Federal, state, and local agencies. Our partnership with FDA allowed us to initiate a voluntary recall of a potentially hazardous food and prevent future illnesses in multiple states. We collaborated with the NC Department of Environment and Natural Resources and our 86 local health departments to notify the public and firms not under our regulatory jurisdiction, such as schools and other institutions, of the recall. In addition, we used technology referred to as reverse 911 to call thousands of firms in less than one hour that had received the recalled product.

North Carolina hosted a listening session for FDA and USDA to allow the concerns of small and medium farmers to be expressed concerning upcoming food safety legislation. The farmers were committed to ensuring the safety of their produce. However, two themes that were clearly heard were scalability and there needs to be indemnification for farmers damaged by fresh-produce linked outbreaks. For example, the Salmonella St.

Paul outbreak was initially linked to tomatoes. Further investigation linked the outbreak to a farm in Mexico. Unfortunately, for tomato farmers in the United States the economic damage was irreversible.

We must continue to implement sensible measures which lead to the early identification of food safety issues and prevent foodborne illnesses from occurring. Food safety must be built into the entire lifecycle of a food, from production to consumption. We must not rely only upon epidemiological data alone, after illnesses and deaths have occurred, to alert us to food safety issues. Similarly, we will never be able to realistically maintain a system which relies solely upon testing to verify the safety of the American food supply.

The food supply system is extremely complex. It includes more than 150,000 registered domestic food manufacturers, over 1 million supermarkets, restaurants, and other foodservice establishments, and more than 2 million farms.

Regulators must promote corporate responsibility for food safety. Firms should identify and evaluate hazards, implement preventive measures, and monitor the effectiveness of risk-based preventive controls. As new risks are identified or controls are found to be ineffective, industry must establish corrective actions. Regulatory agencies can then conduct risk-based inspections and testing to verify preventive controls were effective.

Establishing the metrics for measuring our success will allow us to direct our resources most effectively. Of equal importance, regulatory agencies must have the authority and resources to protect the consumers when preventive measures fail.

Trust must also be built between the regulatory agencies and the food industry. Last week, the NC Department of Agriculture & Consumer Services was notified by one of our firms of a positive Salmonella testing result. The firm had not shipped the product and had no mandatory requirement to report the positive finding to a regulatory agency. However, our relationship with the firm prompted them to immediately notify us of the issue. The Department, in collaboration with the FDA, is now verifying the firm's restoration plan through systematic inspections including environmental and finished product sampling. Like other states, North Carolina is committed to helping our firms quickly identify and respond to a food safety issue so they can safely resume production.

II. Standards

Legislation under review by Congress will undoubtedly give the FDA new authority and tools and resources to comprehensively reform the nation's food safety systems. Some proposals specifically address issues surrounding the recall of unsafe product by increasing the frequency of inspections at all food facilities, giving the FDA expanded access to records and testing results, and allowing the FDA to recall dangerous food products in the event a company fails to recall a product at the FDA's request. Increased inspection frequencies and mandatory recalls can only be achieved by leveraging the resources of state regulatory programs. Also, many state and local agencies currently have broader regulatory authorities than the FDA. The collaboration of all agencies allows us to rapidly and effectively minimize the public health impact of a food incident.

Furthermore, rapid containment is necessary to minimize the economic impact of a food incident and to maintain consumer confidence.

Leveraging Existing Resources

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Throughout the years, numerous reports point out that the FDA does not take full advantage of the inspectional and surveillance capabilities of our state, territorial, tribal and local regulatory and public health partners. This situation is due in large part to the varied standards and laws in each state as compared with the federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

Equivalency

A fundamental concept to be found in a nationally integrated plan is the development of uniform standards and programs with demonstrated equivalency. The concept of equivalency allows states to use different approaches yet achieve the same level of public health protection. The demonstration of equivalency will allow the FDA and states to make greater use of each other's laboratory analytical and inspection data in pursing advisory, administrative, or judicial actions. North Carolina was one of the first pilot states for the Manufactured Food Regulatory Program Standards (MFRPS). MFRPS is a continuous improvement program developed by FDA for state and local food regulatory agencies to ensure equivalency in regulatory programs including inspections, sample analysis, compliance, training, and emergency response. While originally designed for food programs, North Carolina is now piloting MFRPS in our animal feed regulatory program. The interconnectivity of the food supply makes it necessary for us to demonstrate equivalency in both food and animal feed programs. In addition, the Retail Food Standards are another important tool in the standardization and continuous improvement of retail food regulatory programs.

Oversight and Accountability

System integrity and credibility should be maintained through regular program oversight and accountability at all levels. The FDA conducts audits of state inspectors who perform inspections under contract. Also, many states have trained auditors to ensure inspections conducted under the authority of the FDA and state meet the same high standards. Maintaining the credibility of the regulatory program is a key feature of the MFRPS program through auditing all aspects of the inspection.

National Risk-based Planning

Federal and state inspections should be conducted in accordance with a public health risk driven national work plan. Multiple risk factors should drive the inspection frequency including the type of food being produced, population being served, and the compliance history of the firm. An integrated system will result in more coordinated response efforts to prevent food incidents from occurring and enhance our response to multi-state outbreaks when they do occur.

Laboratory Accreditation

Regulatory programs must be supported by accurate and defensible laboratory results. Many states such as North Carolina are either ISO 17025 accredited or in the process of receiving accreditation. ISO 17025 accreditation allows for laboratory data to be accepted by Federal, state, and even international partners. Currently, the lack of laboratory accreditation hinders the capability of FDA to accept data from state regulatory partners. By providing the FDA the confidence to initiate regulatory actions based on state results can exponentially increase the nation's capacity to detect and respond to food safety problems.

III. Training

Uniform standards are worthless if regulatory officials and industry partners do not know how to implement, meet, and exceed them. An integrated food safety system can only be accomplished through an integrated and standardized training program for both regulatory officials and industry.

International Training Food Protection Training Institute

The International Food Protection Training Institute in Battle Creek, Michigan provides the foundation for the certification of food regulatory specialists. In partnership with the Association of Food and Drug Officials (AFDO) and FDA, the Institute is committed to providing food regulatory specialists with continuous training through a network of university-affiliated centers and the use of multiple innovative instructional methods. The training of food regulatory specialists should be career-spanning as new food safety challenges emerge, inspection and investigation strategies evolve, and regulatory authorities change. The training provided by the Institute will complement the courses offered by FDA.

North Carolina has demonstrated our commitment to training our staff by being the first state to modify and teach the ADFO-developed "Applications of Basics of Inspection and Investigation" to our food regulatory specialists. Just last week we provided our modified course and sent our training coordinator to Battle Creek to teach inspectors from other agencies from around the country.

Industry Training

The United States food industry will have greater responsibility for complying with increasing food safety regulations. State and federal regulatory agencies have traditionally relied upon land-grant colleges and universities to deliver education and training programs that address the food industry's needs. Food safety experts agree the time has come to establish a measurable matrix to evaluate our industry partners. Without a concerted effort to educate, train and re-tool industry partners, legislation which is intended to improve the safety our nation's food supply will not meet that objective. An urgent need exists to increase both the regulatory community and industry's capacity to prevent food safety problems, detect and respond to food-borne illness outbreaks, and protect our food supply from natural and deliberate contamination.

IV. Response and Recovery

Traceability

An integrated, proactive system should decrease the number of major food borne illness events. However, when an event occurs, states need the tools to provide timely traceability, rapid recall and to facilitate market recovery. Recent multi-state outbreaks linked to fresh produce and ingredients, such as the peanut recall earlier this year, have magnified our inability to rapidly trace and remove potentially contaminated foods from the market. Delays in market removal result in additional illnesses, deaths, and economic loss. "Rolling" recalls only serve to undermine consumer confidence in the food supply and government. While the Bioterrorism Act of 2002 requires one step trace back and trace forward, current record keeping systems often do not provide investigators the information necessary to rapidly identify the source of a foodborne illness outbreak. FDA should provide guidance for uniform traceability requirements and systems for food manufacturers and distributors. Such guidance should be scalable and meet the needs of the entire industry.

Market Recovery

National food safety scares, food illness outbreaks, and recalls have a direct economic impact on the specific entity at the center of the action, but they also have an economic impact that ripples throughout industries, into processing facilities, farms, and communities across the country. Put differently, when a foodborne illness outbreak occurs, that outbreak and any accompanying recall efforts, media notifications, and regulatory actions can devastate entire commodity markets and the farmers and processors involved with that particular market. For example, many North Carolina farmers who grow peanuts were just coming off their best crop year ever when the Peanut Corporation of America-based salmonella outbreak occurred. Many of those farmers were not able to secure contracts for the peanuts they harvested and many have lowered their planting projections as a result of weak demand in the market.

Securing the safety of America's food supply simply cannot occur if some system is not put into place to "re-establish" markets damaged by a food-illness or outbreak and offer indemnification for the farmers, lest we limit the number of individuals involved in food production and become even more dependent on foreign sources for our food. Comprehensive food safety legislation must include market recovery assistance for industries battered by food safety scares, consumer advisories, recalls, and peripheral events. Such assistance may include provisions for state Departments of Agriculture, commodity associations, or others to access funds for market recovery efforts which can be narrowly tailored to the scale of the market disruption and which are targeted to audiences who can take actions to minimize that disruption.

Unified Rapid Response

The use of the Incident Command System (ICS) has allowed North Carolina to engage all of our partners for a unified and rapid response to a food incident. During the Castleberry recall, the use of ICS allowed us to coordinate the efforts of over 700 regulatory officials to conduct more than 16,000 recall effectiveness checks. We

continue to implement ICS and utilize rapid response teams to respond to any significant food safety event. As noted earlier, the PCA-based salmonella outbreak affected the entire food industry, including one major snack manufacturer in North Carolina. The use of ICS allowed us to efficiently coordinate recall effectiveness checks with our Federal, state, and local partners in addition to overseeing the restoration of a major snack manufacturer and conducting in-depth inspections of our peanut processors to restore consumer confidence.

V. Information Sharing

As the nation moves towards integration of the food safety system, real-time sharing of information must occur. Multiple surveillance activities for early detection of food safety issues and illnesses are in place yet the information is not systematically mined. Surveillance activities include conducting risk-based inspections, risk-based retail survey programs, recall effectiveness checks, and responding to consumer complaints.

Real-time Information Sharing

Accurate and standardized data should be collected from all levels of government and systematically mined for early detection of food incidents. Real-time data sharing systems must be in place and accessible to all Federal, state, and local food protection agencies to provide for seamless sharing of all data. By combining the multiple layers of data we are collecting, we can begin to detect food safety issues before multi-state outbreaks occur and thousands of consumers become ill.

North Carolina and other states are now piloting a project to share all manufactured foods inspection data with the FDA by interfacing with eSAF. We have also developed a real-time system for collecting recall effectiveness data that we have shared with all of our state and local regulatory partners. During the cookie dough recall initiated for E. coli O157:H7, we piloted the system with other states. The result was the ability to determine nationally the effectiveness of the recall and provide a platform for targeting resources during a response. Also, many states participate in eLEXNET, an electronic system of the Food Emergency Response Network (FERN) to store sample data results and allow users to identify trends.

Removal of Legal Barriers

Currently, only a fraction of the data being collected is accessible to all food protection agencies. The legal barriers to sharing information must also be eliminated. The FDA currently requires all firms subject to their regulation to be registered underneath the Bioterrorism Act of 2002. However, states do not have access to this database. Conversely, many states are aware of firms that are not registered with FDA. The result is not one agency contains a complete and accurate inventory of food manufacturers, distributors, and retailers. The same is also true of the newest initiative of FDA, the Reportable Food Registry. While the FDA has committed to share information with the states as appropriate, having real-time access to all of the information collected can help all regulatory partners develop appropriate risk-based responses and implement preventive measures.

VI. Funding

A commitment from both the FDA and the states is necessary for the successful integration of a proactive and prevention-based food safety system. The states have demonstrated their commitment through the participation of multiple initiatives to build equivalent regulatory, laboratory, and emergency response programs. We have also demonstrated our commitment to share our data in real-time. An equal commitment from the federal government is necessary for full integration of the nation's food safety system. Funding to state agencies must hinge upon measurable objectives and deliverables.

The FDA contracts with state regulatory programs to conduct inspections and sample analysis, which contracts are generally renegotiated annually. The annual renewal of Federal funding prevents states from building the foundation for long-term success. However, to be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. It must be sustained through multi-year funding that will be provided to state and local regulatory and public health partners to build the necessary state and local infrastructures, contain adequate legislative authorities to facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and reduces time to detect and respond to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

Congress should provide dedicated, line-item funding from the Federal level to state and local programs. A current model for assessment and funding may be the USDA Talmadge-Aiken meat inspection program. Pursuant to the Talmadge-Aiken Act, states may enter a cooperative agreement with USDA, pursuant to which state plants receive "federal inspection" performed by federally licensed state employees. The T/A program provides funding to state programs that are uniform and consistent with USDA-FSIS standards based on the regulatory responsibilities (e.g., number and size of firms) of the state agency.

Direction should be given for the Secretary of HHS to develop timelines for all states to be compliant with MFRPS and to demonstrate, at minimum, equivalency to FDA. Full implementation of MFRPS in all states will require greater funding to acquire the staff, training, and data management systems necessary. Funding should be based on regulatory responsibilities and meeting benchmarks for full compliance with MFRPS. While $5,000 was provided for pilot states to conduct a self-assessment and to create an operational plan for self improvement, this amount of limited financial support does not provide the states the capability to fully meet the requirements of MFRPS. Furthermore, funding for the International Training Institute for Food Protection and its affiliated universities is another key component for states to be in compliance with MFRPS.

Congress should also increase funding for the food protection training institutes affiliated with land-grant colleges and universities for the development and delivery of a

measurable comprehensive food safety education and training program that addresses the needs of industry in meeting the new food safety modernization act reforms. Similar to the training program for food regulators, the training program for industry should include a certification component.

Funding is not only necessary to identify food safety issues, but to facilitate the recovery of the food industry following a major food incident. The restoration of a major food manufacturer is costly to both the government and industry. State regulatory agencies are committed to assisting our industry in recovering from a major food incident, however, the financial resources must be provided. Also, to no fault of their own, the entire farm to fork food continuum suffers when a significant food incident occurs. We must build a food safety system which promotes prevention, early identification, rapid response, and swift recovery to any type of food incident.

VII. Conclusion

I would like to thank the Committee for this opportunity for North Carolina to present our perspective on the resources and commitment required for an integrated food safety system to be successful. Nothing is more important to the quality of our lives than the food we eat. We can no longer take the safety of our food supply for granted. State and local regulatory agencies are currently conducting 80% of the food safety and defense work in the United States including inspections, emergency response, consumer complaints, and laboratory testing. By investing in state and local regulatory program we can build the capacity necessary to protect the food supply and fulfill our obligation to the American public. I will be happy to answer any questions the Committee may have.