

Agricultural Outlook Forum 2001

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REDUCING THE RISK OF FOODBORNE ILLNESS: A STATE PERSPECTIVE

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This afternoon's panel discussion is focused on the area of risk analysis as it pertains to reducing the risk of foodborne illness. The three components of risk analysis; risk assessment, risk management and risk communication, all play equally important roles in how states approach food safety and the reduction of foodborne illness. Therefore, in keeping with this afternoon's focus on the three components of risk analysis, I would like to share with you a look at the current relationship of these components within a state food safety program, and some ideas on improvements that can significantly enhance the nation's food safety system.

RISK ASSESSMENT

In most cases, state food safety agencies' predominant focus can probably be most accurately classified as risk management, since most of these agencies do very little of what would normally be considered as formal risk assessment. However, from the standpoint of typical activities, our inspection staffs conduct thousands of field risk assessments every day during the performance of food establishment inspections. As a matter of fact, state and local food safety programs conduct 80 to 90 percent of food establishment inspections performed in the United States. In order to effectively conduct these inspections, these inspectors must know and be able to recognize and assess the likelihood and severity of food safety risks related to food products, processes and operator performance. In most cases, these traditional inspections focus on every aspect of the food establishment that can negatively impact the safety of the food products handled by that establishment. Such traditional inspections are based largely on state laws that mirror the Federal Food, Drug and Cosmetic Act, good manufacturing practice regulations and retail and food service codes developed from earlier versions of U.S. Food and Drug Administration (FDA) models. These inspections, although thorough and comprehensive, can be labor intensive and time consuming.

States are currently in the beginning stages of a shift away from these traditional inspections towards risk-based, or HACCP inspections. Under such a system, the responsibility to recognize and eliminate or mitigate food safety risk becomes the primary responsibility of the food establishment operator. The role of the regulator in this system is to assure that the food establishment has a plan to effectively identify, monitor and control food safety risks, or more simply, that the establishment is operating in accordance with their HACCP plan to minimize food safety risks. However, the transition to such a system is enormous, is as much cultural as it is procedural, and at this point in time is largely incomplete in the non-meat food arena. Currently, the only industries with HACCP systems in place are the meat and poultry and seafood industries (although the FDA just recently published a final rule requiring the use of HACCP principles for fruit and vegetable juices).

The transition to a HACCP system is enormous and difficult from a cultural standpoint both for regulators and food establishment operators. Regulators need an improved understanding of underlying food safety principles, improved food-processing knowledge, and improved interpersonal skills. Food establishment operators need more or different knowledge and the will and ability to identify, monitor and manage food safety risks. Even in areas where this transition has been formalized (meat and poultry and seafood), the transition is occurring at an evolutionary, rather than a revolutionary, pace. This slow pace is dictated, in part, by the fact that state food safety programs must make large investments in time, training and consultation to assure that both regulators and food business operators have a clear understanding of redefined roles, and the knowledge and skills necessary to effectively operate a risk-based food safety system.

In all areas other than meat, poultry and seafood, the movement to risk-based inspections is uneven and uncoordinated. States are looking to partner with local and federal food safety agencies and the food industry to incrementally, steadily and systematically move the entire food safety system to a risk-based foundation.

RISK MANAGEMENT

Many are unaware of the level of risk management activities that are currently undertaken by the States. In addition to conducting 80 to 90 percent of all inspections, nearly all foodborne illness investigations are handled at the state level. The states maintain major and extensive food sampling databases, covering a broad variety of food products that have been tested for an equally broad variety of analytes. The states initiate numerous recalls of food products and in many cases have more authority in this area than federal food safety agencies. The states also are leaders in the areas of enforcement, compliance activities and educational efforts with food industries.

Within the past two and one half years, there have been significant efforts taking place focused on managing food safety risks in the most effective and efficient manner possible. These efforts are based on the vision of a nationwide, seamless, fully-integrated food safety system that incorporates all food safety resources at the federal, state and local levels and involves all food safety stakeholders including industry, academia, consumers and other interested parties. Such a system would eliminate overlaps and gaps that currently exist among federal, state and local food safety programs and would utilize all available food safety resources nationwide to further enhance the safety of the nation's food supply and significantly reduce the incidence of foodborne illness. This activity, which has become known as the National Food Safety System project (NFSS), has been focused on development of a system having the following properties:

- ◆ **A common vision among all stakeholders**
- ◆ **National uniform standards**
- ◆ **Uniform inspections and enforcement**
- ◆ **Uniform laboratory practices**
- ◆ **Adequate training**
- ◆ **Enhanced communications**
- ◆ **Federal oversight**

Work products that have developed out of the efforts of five NFSS workgroups include:

- ◆ **Development of a template identifying all roles and responsibilities of each federal, state and local agency in the area of food safety;**
- ◆ **Development of consensus support and a conceptual design for a “virtual” National Food Safety Training Center, currently known as the “Food Safety University”;**
- ◆ **Development of a draft model food safety partnership agreement for FDA and state food safety agencies;**
- ◆ **Development of a draft oversight model based on capacity and performance for FDA to use to audit state inspections conducted under partnerships and contracts;**
- ◆ **Development of draft guidelines for coordination of multi-state foodborne outbreaks, which include consideration of federal, state and local needs;**
- ◆ **A pilot project, sponsored and funded by the U.S. Department Agriculture/Food Safety and Inspection Service (USDA-FSIS), that utilizes eight federal, state and local laboratories to develop standards for E. coli O157:H7 sampling and testing methods;**
- ◆ **An Information sharing pilot, known as eLEXNET, jointly sponsored and funded by FDA and FSIS, to demonstrate how an internet based system can be used by federal, state and local food safety laboratories to exchange laboratory data;**
- ◆ **Development of uniform criteria that can be used to evaluate local, state and federal food safety programs in the areas of retail foods, meat and poultry, seafood and manufactured foods, by building on the FDA retail food standards as a basic template.**

Also as a result of NFSS activities, many states have recently, within the past year, formed State food safety task forces which provide a forum for people from a broad cross-section of disciplines to identify, discuss and design real life improvements with respect to food safety. One of the objectives of these task forces is to provide a mechanism to route food safety information to and from the NFSS project. These task forces often include representatives from federal, state and local food safety agencies, food industries, academia and legislative and consumer groups. Subjects of meetings often deal with gaining knowledge, developing skills or designing and implementing systems to monitor and manage risks. However, the wide open forum of these meetings allows these groups to tackle topics related to practical risk assessment and risk communication if it is a need in their environment. Additionally, these task forces are invaluable to state regulators in raising the level of comfort, trust and communication among the participants; this may not be risk communication, but its product is more open and honest communication about risks.

The recently released Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors, often referred to as the “Baseline Study” is an excellent example of useful information now available to states and retail food businesses to assist them in targeted management of food safety risks. This report is an assessment within institutional food service establishments, restaurants and retail food stores of the occurrence of the following foodborne illness risk factors:

- ◆ **Food from unsafe sources;**
- ◆ **Inadequate cooking;**
- ◆ **Improper holding temperature;**
- ◆ **Contaminated equipment; and**
- ◆ **Poor personal hygiene**

In addition to providing the states and retail food businesses with a tool to target resources, information presented in this report will also allow them to measure progress in decreasing critical food safety risks against the now-established baseline.

RISK COMMUNICATION

Much of what I have already presented has a direct or overlapping link to risk communication. Risk communication may arguably be the most important component of current risk analysis efforts. Currently, State and local governments are actively seeking ways to partner with others to provide regulatory staff and food businesses the information that is necessary to understand, monitor, manage and communicate food safety risks. Examples of current partnering or leveraging activities include the following:

- ◆ **Working with federal agencies in the development of the virtual “Food Safety University” as part of the NFSS project;**
- ◆ **Working with other states to help in the implementation of the U.S. Centers for Disease Control and Prevention’s (CDC) “States Helping States” initiative;**
- ◆ **Interacting with the University Extension System and other agricultural organizations to develop and communicate “Good Agricultural Practices” and “Good Management Practices” that deal with food safety issues at the production, or farm level;**
- ◆ **Developing effective liaisons between professional organizations such as the Association of Food and Drug Officials, the United States Animal Health Association, the National Association of City and County Health Officials, the Council for State and Territorial Epidemiologists, and many others.**

States are also enthusiastically involved in activities designed to provide consumers with the appropriate information about identifying and managing risks in their purchasing, transporting, handling, preparing and serving food to their families and friends. State regulators are willing and able to assist with the content of consumer communications, but are looking to access the capacity and expertise of others in packaging and distributing behavior-altering information to consumers.

In conclusion, the bottom line for states is summarized in the adage “think globally but act locally.” State, and local, food safety agencies need to have the conceptual knowledge about risk assessment, management and communication for the primary purpose of converting that knowledge to concrete, risk-lowering food safety improvements in their states, cities, counties and towns.

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RISK ASSESSMENT

- vs. RISK MANAGEMENT
- FORMAL RISK ASSESSMENT - VERY LITTLE
- 1000's OF RISK ASSESSMENTS EACH DAY
- 80 - 90% OF FOOD ESTABLISHMENT INSPECTIONS

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BASIS FOR INSPECTIONS

- STATE LAWS BASED ON FD&C ACT
- CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS
- EARLY VERSIONS OF FDA MODEL RETAIL & FOOD SERVICE CODES

SHIFT TOWARDS RISK-BASED (HACCP) INSPECTIONS

- RESPONSIBILITY OF FOOD ESTABLISHMENT OPERATOR - MITIGATING RISK
- ROLE OF REGULATOR - ASSURE THERE IS A PLAN TO EFFECTIVELY IDENTIFY, MONITOR & CONTROL FOOD SAFETY RISKS & ESTABLISHMENT IS OPERATING ACCORDING TO PLAN

TRANSITION FROM TRADITIONAL TO RISK-BASED

- ENORMOUS
- CULTURAL AND PROCEDURAL
- LARGELY INCOMPLETE IN NON-MEAT
FOOD AREAS

HACCP SYSTEM - REGULATOR'S NEEDS

- IMPROVED UNDERSTANDING OF UNDERLYING FOOD SAFETY PRINCIPLES
- IMPROVED FOOD-PROCESSING KNOWLEDGE
- IMPROVED INTERPERSONAL SKILLS

HACCP SYSTEM - ESTABLISHMENT OPERATOR'S NEEDS

- MORE KNOWLEDGE
- DIFFERENT KNOWLEDGE
- WILL AND ABILITY TO IDENTIFY,
MONITOR AND MANAGE FOOD SAFETY
RISKS

TRANSITION

- EVOLUTIONARY RATHER THAN REVOLUTIONARY
- DICTATED BY LARGE INVESTMENTS IN TIME, TRAINING AND CONSULTATION
- NECESSARY FOR CLEAR UNDERSTANDING OF REDEFINED ROLES, KNOWLEDGE AND SKILLS

MOVEMENT - UNEVEN AND UNCOORDINATED

- STATES LOOKING TO DEVELOP PARTNERSHIPS
- MOVE ENTIRE FOOD SAFETY SYSTEM TO RISK BASED FOUNDATION
 - INCREMENTALLY
 - STEADILY
 - SYSTEMATICALLY

RISK MANAGEMENT BY STATES

- 80 - 90% OF ALL INSPECTIONS
- FOODBORNE ILLNESS INVESTIGATIONS
- MAJOR FOOD SAMPLING DATABASES
- RECALLS OF VIOLATIVE FOOD PRODUCTS
- ENFORCEMENT, COMPLIANCE AND EDUCATIONAL ACTIVITIES

VISION

- NATIONWIDE, SEAMLESS, FULLY-INTEGRATED FOOD SAFETY SYSTEM
- INCORPORATE ALL FOOD SAFETY RESOURCES
- INVOLVE ALL STAKEHOLDERS
- ELIMINATE OVERLAPS AND GAPS
- SIGNIFICANTLY REDUCE INCIDENCE OF FOODBORNE ILLNESS

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NATIONAL FOOD SAFETY SYSTEM (NFSS) PROPERTIES

- COMMON VISION
- NATIONAL UNIFORM STANDARDS
- UNIFORM INSPECTIONS & ENFORCEMENT
- UNIFORM LABORATORY PRACTICES
- ADEQUATE TRAINING
- ENHANCED COMMUNICATIONS
- FEDERAL OVERSIGHT

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NFSS WORK PRODUCTS

- TEMPLATE OF ALL ROLES/RESPONSIBILITIES
- "FOOD SAFETY UNIVERSITY"
- MODEL FOOD SAFETY PARTNERSHIP
- OVERSIGHT MODEL TO AUDIT STATE INSPECTIONS
- GUIDELINES FOR COORDINATION OF MULTI-STATE/FOODBORNE OUTBREAKS

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NFSS WORK PRODUCTS (cont.)

- PILOT TO DEVELOP STANDARDS FOR E. coli O157:H7 SAMPLING/TESTING METHODS
- INFORMATION SHARING PILOT (eLEXNET)
- UNIFORM CRITERIA TO EVALUATE FOOD SAFETY PROGRAMS

STATE FOOD SAFETY TASK FORCES

- IDENTIFY, DISCUSS AND DESIGN REAL LIFE IMPROVEMENTS
- PROVIDE MECHANISM TO ROUTE INFORMATION TO AND FROM NFSS
- BROAD CROSS SECTION OF REPRESENTATION
- RAISE THE LEVEL OF COMFORT, TRUST & COMMUNICATION

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"BASELINE STUDY" OF FOODBORNE ILLNESS RISK FACTORS

- FOOD FROM UNSAFE SOURCES
- INADEQUATE COOKING
- IMPROPER HOLDING TEMPERATURES
- CONTAMINATED EQUIPMENT
- POOR PERSONAL HYGIENE

RISK COMMUNICATION

- DEVELOPMENT OF THE "FOOD SAFETY UNIVERSITY"
- "STATE HELPING STATES" INITIATIVE
- "GOOD AGRICULTURAL PRACTICES"
- "GOOD MANAGEMENT PRACTICES"
- DEVELOPMENT OF EFFECTIVE LIAISONS

CONCLUSION

"THINK GLOBALLY, BUT ACT LOCALLY"

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