As a regulatory official, I would like to address the topic of assessing and controlling food safety risks from this perspective. In other words, how do regulatory agencies translate new scientific information into regulatory strategies?

This is not an easy task, because regulatory agencies must weigh many factors before setting new requirements. These include legislative authority to change requirements, the benefits to the public health of any changes, the feasibility of implementing new requirements in a regulatory setting, and the economic burden new requirements pose to industry. In addition, regulatory agencies must fully explain the process they follow in making such decisions and must provide the opportunity for public input before finalizing any regulations.

This regulatory process sometimes appears at odds with the pace of scientific discovery. The challenge now and in the future is to ensure that regulatory agencies are able to incorporate the newest scientific information into their programs in a timely manner while at the same time ensuring the integrity of the regulatory process.

I represent the Food Safety and Inspection Service (FSIS), which is the federal agency within the U.S. Department of Agriculture responsible for ensuring the safety of meat, poultry, and processed egg products. For those of you who are not familiar with FSIS, the Agency has undergone significant transformation since the early 1990’s to enhance its focus on public health protection.

This transformation was sparked by a 1994 outbreak of foodborne illness attributed to E. coli O157:H7 from undercooked ground beef patties served at a fast food restaurant chain on the west coast. The outbreak emphasized the need for FSIS, as well as other agencies with food safety responsibilities, to better address the hazards associated with microbial pathogens and in general, to be ready to address emerging hazards in food.

Following the outbreak, FSIS worked with other federal agencies with food safety responsibilities, such as the Food and Drug Administration and the Environmental Protection Agency, to chart a direction for the future. Six areas were identified as being essential to this process—coordination, surveillance, inspections, research, risk assessment, and education.

For FSIS, the most significant change made was the implementation of the Pathogen Reduction and HACCP rule because it was the cornerstone of our food safety strategy. In 1996, FSIS published this final rule, which set new requirements for plants that slaughter and process meat and poultry.

The rule has four provisions. First, it requires that each plant develop and implement standard operating procedures for sanitation. Second, it requires regular microbial testing by slaughter establishments to verify the adequacy of process control for preventing and removing fecal contamination. Third, it established pathogen reduction performance standards for Salmonella that slaughter and grinding plants must meet. Fourth, it requires that all meat and poultry plants develop and implement HACCP systems to prevent food safety problems by addressing microbial, chemical, and physical hazards that are reasonably likely to occur.

The rule was very significant for a number of reasons. First, it signaled a change in FSIS’ approach to inspection. The Agency recognized that it was not enough to rely on “after-the-fact” detection of defects. To ensure food safety, it was necessary for plants to monitor their processes to ensure that they were working and for FSIS to verify the effectiveness of these processes and accompanying process controls.

Second, HACCP provides a framework for continual food safety improvements because as new food safety hazards are identified within a plant, HACCP systems can be easily adjusted to address them. HACCP systems don’t go out of date as long as they are reassessed by industry at appropriate intervals.

And third, the rule further established the importance of food safety performance standards, which provide objective, measurable standards that can be incorporated into industry HACCP systems. Translating science into regulatory performance standards is a challenging area, and one that FSIS continues to address. In the Pathogen Reduction and HACCP rule, the Agency established pathogen reduction performance standards for Salmonella based on prevalence studies on meat.

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and poultry. In other words, we based the standards on what the industry was achieving at that time, with the expectation that the standards would be tightened as industry made progress in reducing levels of Salmonella. This is because we did not have enough information on dose-response for the pathogen. It is our ultimate goal to be able to base performance standards on such dose-response data; however, this is not a goal we expect to reach in the near future due to the challenges of obtaining such data.

Basing the Salmonella performance standards on prevalence data certainly has worked from a public health standpoint, because data from the first several years of HACCP implementation show significant reductions in Salmonella prevalence across product categories (2). We’ve also seen reductions in foodborne illness data from the Centers for Disease Control and Prevention for a number of key pathogens (3). Despite these good results, the standards have been challenged in court by industry, and two studies are ongoing to evaluate the role of performance standards in regulatory programs.

FSIS now has the benefit of about six years of implementing food safety changes such as HACCP and performance standards, so I would like to talk about where we are headed. As I mentioned, the Pathogen Reduction and HACCP rule was a significant development, but it is a foundation that must be built on as we learn more about hazards in food and how to address them. Being an effective public health regulatory agency means being ready to adapt to emerging food safety concerns.

We are making significant changes in our Agency’s infrastructure and resources as one way of ensuring we can respond when needed in a timely fashion. Changes in infrastructure do not mean we are rearranging boxes on the organizational chart. We are asking hard questions of ourselves and critically considering how we deploy our personnel to support achievement of our public health goals.

FSIS has not always been perceived as a public health regulatory agency because it wasn’t staffed like one. It has been easier for the Food and Drug Administration, our sister food safety agency, to be perceived in this manner because it is formally part of the U. S. Public Health Service. FSIS has had to work to highlight its visibility as a public health agency and has made a number of changes to enhance its public health focus. For example, we now have an agreement with the Surgeon General to place U.S. Public Health Service Commissioned Corps officers in FSIS. In addition, we have underway a “Workforce of the Future Initiative” to ensure that the Agency has in place an interdisciplinary workforce that can meet future needs.

The Agency must also be equipped with the right tools to analyze and integrate its scientific, policy, inspection, and enforcement functions. The Pathogen Reduction and HACCP approach demands good data quality and sharing of that data. FSIS must be able to integrate information across the Agency’s data systems. Right now, we have a lot of databases that are unconnected silos—to use an agriculture analogy—and we need to break down these walls to build one database.

We also need to better use the data we collect to help us design better approaches to pathogen control and reduction. This requires analyzing the data in order to convert it to useful information—in other words, what do the data really mean and how can we use them to reach our public health goals?

FSIS also is taking advantage of advances in risk assessment—particularly in the area of risk assessment for microbial pathogens—as it plans for the future. Risk assessments must become part of the standard process of setting priorities and developing risk management strategies.

FSIS has conducted a number of risk assessments on its own. FSIS broke new ground in 1998 when it conducted, in cooperation with others inside and outside USDA, the first farm-to-table quantitative microbial risk assessment, which focused on Salmonella Enteritidis (SE) in eggs and egg products (4). That risk assessment was a significant milestone in our ability to quantify the risks associated with specific pathogens and specific foods. The risk assessment was useful in pointing us in new research directions and in identifying points in the farm-to-table chain at which pathogen reduction control interventions could be put in place. The risk assessment has helped in developing with FDA the Egg Safety Action Plan (5), which includes a variety of farm-to-table strategies designed to reduce foodborne illnesses associated with SE in eggs by 50 percent in 2005, and eliminate egg-associated SE illnesses by 2010.

FSIS also worked with FDA on a risk comparison for Listeria monocytogenes and is developing a risk assessment for E. coli 0157:H7 in ground beef. FSIS is now in the process of establishing a formal Risk Assessment Center, which will significantly enhance our technical risk assessment capabilities to support the increased importance of risk assessments in FSIS.

As we rely increasingly on risk assessments, I want to make it clear that risk management decisions can be made without formal risk assessments. The best assessment is the one that most directly addresses risk manager’s needs. That is why as we proceed with risk assessments to informed risk management decisions, you will see risk assessment in all shapes and sizes.

A challenge for the future will be to further integrate risk assessments with risk management and risk communication activities. As you know, once a risk assessment is completed, risk managers consider the results along with other information to make policy decisions. These decisions can range from new directions for research to educational strategies to new regulations. We are taking baby steps in this area. As I mentioned, the SE risk assessment has been used to help develop an Egg Safety Action Plan. A risk assessment on Bovine Spongiform Encephalopathy (BSE), underway by Harvard University under contract to USDA, will help us to evaluate the controls already in place to prevent BSE from entering U.S. cattle herds and the U.S. food supply.

With this greater focus on risk assessments, our risk management strategies will become more risk-based. FSIS is a regulatory agency, but that does not mean every action it takes must be regulatory in nature. Thus, risk management strate-
gies include research and education as well. I will give you an example of non-regulatory approaches when I talk about our farm-to-table strategy in a few moments.

As I mentioned, it is important to note that risk management decisions can be made with or without formal risk assessments. That is why you will often hear the term “risk-based” used in describing changes made in FSIS.

One of our more visible risk management strategies is setting performance standards for various industry processes to improve food safety. The Agency is in the process of converting outdated command-and-control standards to performance-based standards, which provides industry with greater flexibility to meet the standards in a manner that best meets their needs.

As an example of our risk-based changes, let me talk about our residue program. Under HACCP, a food safety hazard is any biological, chemical or physical property that may cause a food to be unsafe for human consumption. Therefore, violative residues clearly present food safety hazards that should be addressed by HACCP plans. However, when FSIS implemented the Pathogen Reduction and HACCP rule, the subject of residues was placed on a back burner due to the enormous challenge of implementing the rule for microbial hazards. So FSIS has not yet altered its approach to residue control from the old “command and control” approach.

FSIS is now considering changes to more closely align the residue program with HACCP. The changes will reinforce the notion that inspected establishments are responsible for analyzing the hazards from chemical residues and for taking measures to control those hazards. If the industry takes on its proper responsibility for preventing residue violations, then FSIS will be able to assume a verification role.

One strategy we are exploring is shifting testing to detect residue violations to focus on certain classes that we know historically have problems. We do this now to a certain extent, but we are taking it a step further by analyzing the data available on residue violations to better inform our testing. This is an example of a risk-based approach that is not based on a formal risk assessment, but rather, on data analysis. It is an example of what I described earlier as turning data into information.

Another developing area is the Agency’s use of epidemiological data to contain foodborne illness outbreaks and to help evaluate in-plant operations. Over the past year or so, there have been a number of cases where FSIS has used data gathered from field and in-plant epidemiological investigations to make regulatory decisions about product recalls and the adequacy of plant food safety control systems.

Molecular fingerprinting technology has enabled us to make this advance. We are now able to detect foodborne outbreaks through PulseNet—a growing database of molecular fingerprints of foodborne pathogens that enables us to link outbreaks and sporadic cases of foodborne illness to specific products. For a regulatory agency such as FSIS, this new technology is important because it enables us to respond more quickly to prevent the continued spread of an outbreak by recalling implicated products.

This new development could not have occurred without the close cooperation among the federal and state agencies with public health responsibilities. For example, the Centers for Disease Control and Prevention maintain the PulseNet database as well as the FoodNet active surveillance system for foodborne diseases. FDA and FSIS contribute the “DNA fingerprints” from contaminated products to the PulseNet database, so epidemiologists around the country can match illnesses to specific products. And the system would not work without the state public health agencies that are on the front lines identifying cases of foodborne illness.

The changes I have so far described, such as HACCP and performance standards, address the in-plant environment, where FSIS has the large majority of its authority. But FSIS’ strategy encompasses the entire farm-to-table chain, from producers to consumers. This does not mean we are taking regulatory action at each stage of the farm-to-table chain. Rather, we are working with federal, state and local governmental agencies and with the appropriate industries to see what steps can be taken to address food safety broadly.

For example, our Animal and Egg Production Food Safety staff coordinates efforts to identify and encourage the adoption of practices at the producer level that reduce or prevent food safety hazards. This year, FSIS is working with 15 states to promote HACCP-compatible production practices such as residue avoidance, pathogen reduction, and animal identification. FSIS also works to improve food safety at the retail level through the Food Code, a model food safety code prepared by FDA and voluntarily adopted at the state and local level. And FSIS reaches consumers through the USDA Meat and Poultry Hotline (1-800-535-4555), which provides advice on how to safely handle and prepare meat, poultry and egg products. These are all risk management strategies that do not involve regulatory action at the federal level.

As government, industry, academia, and consumers work together to improve food safety domestically, it is apparent that we must work towards a unified food safety approach internationally as well. Consumers want their food to be safe regardless of what country it comes from. That is why the harmonization of food safety standards is so important. It helps to avoid food safety crises, maintains consumer confidence worldwide, helps developing countries to upgrade their national food safety programs, and helps to ensure fair trade.

Our involvement in Codex Alimentarius is important in achieving this unified approach because of Codex’s role in establishing international food safety standards. FSIS Administrator Thomas Bily was recently elected for a second term as chairman of Codex.

I’d like to end my remarks with a plug for more food safety research, because food safety regulatory agencies such as FSIS rely on it heavily, from basic research on pathogens to analytical methodologies to detect contaminants. Research has been extremely important in enabling us to get this far, and it will continue to play a major role in the future. FSIS does not conduct its own research, but it indeed relies on research agencies, academia, and industry to generate data for its public health regulatory program decisions. Because FSIS relies so
heavily on research but does not conduct its own, we try to communicate our research needs to others. We also are looking toward the Joint Institute for Food Safety Research, created several years ago, to coordinate food safety research within the Federal government, to set a food safety research agenda that meets our needs and those of other food safety regulatory agencies.

In closing, I hope I have provided you with insight on how a regulatory agency views and uses new science, and on the progress FSIS has made so far. Author Louis L’Amour once said, “There will come a time when you think everything is finished. That will be the beginning.” That pretty much sums it up for the Food Safety and Inspection Service.

References


