

Public Health Issues Facing FSIS

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Thank you for this opportunity to give an update on where we are in developing the food safety system of the future.

We have sharpened focus on public health. In the face of the crisis of the *E. coli* O157.H7 outbreak, the Secretary of Agriculture and the President made food safety their priority, calling upon FSIS to intensify enforcement efforts and accelerate our plans for reform.

To that end, FSIS is focused on a "micro" mindset and developing new science-based initiatives to protect the public health.

Now, I will describe the Agency's progress on planning an ideal regulatory system, the special reviews of beef slaughter plants, and mandating Hazard Analysis and Critical Control Point (HACCP) systems. Before concluding, I will report on the FSIS Pathogen Reduction Program.

Two-Track Approach for Reform

Since Dr. Cross became administrator of FSIS in February 1992, he has been striving to find the best ways to enhance the science base of inspection.

By January 1993 — shortly before the *E. coli* outbreak — Dr. Cross had introduced a two-track approach to reform. On Track I we are modifying the present system, building on its strengths and working within its limitations. At the same time, in Track II, we are examining all possibilities to devise the "ideal" regulatory program. In Track II, there are no limitations on our thinking — not even the inspection laws. But even under existing limits, we have been able to identify gaps and begin to make significant changes.

Plant Reviews

The reviews conducted in 90 beef slaughter plants are part of Track I which calls for intensifying enforcement in inspection. During the reviews, FSIS teams made unannounced visits to review 90 beef slaughter plants, selected because they were the kinds of plants which supply the meat most likely to be used in hamburger production. The Agency reviewers focused on potential sources of pathogens, including fecal contamination.

The reviews uncovered problems of concern to us as pro-

ductors of the public health and to the plants, as food providers. While 26 plants had no negative findings, in 30 plants deficiencies were found that required corrective action — sometimes these plants experienced down time in order to take actions needed to get back in compliance.

The most disturbing findings were at 12 plants, where conditions remained unacceptable at a follow-up review. We placed those 12 plants under Progressive Enforcement Action. If their non-compliance continues, we will take steps needed to withdraw inspection.

In addition, we halted operations at the Cornhusker Packing Co. in Omaha, Nebraska. This is the plant shown on CBS News on May 17. Our first actions closed the slaughter house down from May 19 to the 25th.

On May 25, we accepted the plant's program for strict adherence to our procedures, and FSIS imposed additional requirements. Only then could the plant re-open. But, we did not stop there. We had to determine what went wrong and why. The Secretary asked the Office of the Inspector General (OIG) to investigate. At the OIG's request, an FSIS reviewer accompanied them.

They found problems that were not being taken care of by inspection personnel. As a result, the plant was closed for more than three days. We hand-picked inspectors and supervisors for the plant, and they are devising an inspection plan. We also put the plant under "Establishments Requiring Additional Inspection Effort" (ERAIE). We said we mean business, and we do. Both the industry and the regulator have to protect the public health. Nothing less will do.

Outreach

The *E. coli* crisis accelerated our planning for inspection reform. Even so, planning is an open process. One of the first steps our Administrator took was to use the nationwide toll-free phone line for an all-employee call in. For several days — including a Saturday — members of the Pathogen Reduction management team talked to about 250 employees. They received 1,000 suggestions, many of which were excellent. These suggestions are being considered and used by the various pathogen reduction teams.

To gain broad public participation, USDA held hearings in six cities across the country, listening to ideas on inspection reform.

The first hearing was in Dallas (May 21), then Seattle (June 1), Des Moines (June 4), followed by Oakland (June 9), and Atlanta (June 11). The sixth hearing was June 18 in Philadelphia.

To conclude this round of public hearings, Secretary Espy will host a Food Safety Summit, perhaps as early as July. The

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forum will have panels of experts and consumers discussing food safety issues. We'll be providing more information shortly.

The suggestions we've received at the hearings have been excellent. The Seattle participants touched us most profoundly. We listened to families of the children affected in the outbreak. It is an understatement to say that the Seattle hearing reinforced our commitment to preventing foodborne illness.

HACCP

You know that the best way to handle problems is to prevent them. The best approach to prevention is HACCP — the Hazard Analysis and Critical Control Points system.

The Secretary's May 27 call for mandating HACCP in all meat and poultry plants came at an appropriate time — just as the FSIS is completing its HACCP study. By the end of August, pilot testing will be completed in nine plants — three plants each that make refrigerated foods and cooked sausage and three poultry slaughter plants. Now we are reviewing our HACCP experience to learn from it.

Both qualitative and quantitative data gathered during the pilot are being analyzed. We are focusing on safety factors that pose potentially high risks to consumers. We examined monitoring data at Critical Control Points, evaluation data at Critical Control Points, and verification data on finished product.

We gathered and analyzed microbiological, chemical and physical data. For instance, **microbiological** data included aerobic counts at 35 and at 20 degrees Centigrade, and *Staphylococcus Aureus* and *Listeria* on equipment and on finished product. **Chemical** data analyzed included chlorine in processing water, salt concentration and Ph values.

Physical data included temperature of product and the environment, plant records of lots shipped and expiration dates, and the plant's reactions when deviations occur. Also, we evaluated the plant's procedures for detecting foreign objects, and for conducting recalls.

Qualitative data gathered in the pilots help explain the quantitative findings. The degree of management commitment was evaluated by examining objective data on categories such as the facility's physical condition, and plant strategies to correct problems. In fact, we tabulated results of: (1) general housekeeping; (2) condition of facilities; (3) employee hygiene; (4) employee sanitary practices; (5) employee attitudes toward inspection requirements; (6) employee training; (7) management supervisory attitudes; (8) management responses to problems; (9) management strategies to prevent contamination hazards; (10) product quality; and (11) management programs and systems.

Mandating HACCP

When Secretary Espy announced that USDA will mandate HACCP in all meat and poultry plants, he also said that USDA will publish a proposed regulation in the Federal Register by the end of August. The Administration's commitment to food safety has accelerated our Agency's HACCP plans. The Secretary's charge gives HACCP the prominence it merits.

Despite the short timeline, we are creating opportunities for public participation. Last week — on June 8 and June 10

— we held meetings with consumer and industry representatives. While there was great support for HACCP in food production, both consumer advocates and industry representatives had concerns about implementing HACCP in USDA-inspected meat and poultry plants.

They were interested not only in the general approach of the regulation but also in **specifics**. For example, they discussed in detail approaches the Agency could take in implementing the regulation. Some suggested that it would be appropriate to phase in implementation, based on risk. Others had differing ideas on phasing in HACCP, or setting a fixed date for implementation.

Also, the issue of access to plant records was raised. Recognizing that records would have to be available to FSIS, there is a question about the access to proprietary information through the Freedom of Information Act (FOIA). In addition, there were discussions on the effects of HACCP on existing Agency safety requirements, and on how the Agency would set critical limits in the future. Still others made suggestions on establishing requirements for HACCP training and certification.

Some participants at the briefings sought assurances that mandating HACCP would strengthen regulations and be "additive" that HACCP would become a "substitute" for existing safety requirements. They said that once mandatory HACCP was implemented, there must be effective enforcement, with appropriate penalties for violations.

The first meetings were as successful as they were spirited. All attending wanted additional opportunities to meet. We assured the groups of future opportunities to provide input, and we are seeking their views on key issues such as the scope of HACCP, plan development, plan certification and plan verification.

Pathogen Reduction Program

As I suggested at the beginning of my presentation, the *E. coli* O157:H7 outbreak was a life and death call for action.

One of our responses was to accelerate our plan of attack against pathogens — from the farm to the dinner table. Let me update you on our progress in the Pathogen Reduction Program.

Rapid Methods

The development of rapid tests to detect bacteria in the plant is another top priority. At his May 27 press conference, Secretary Espy asked FSIS to publish a description of our needs in this area in the Federal Register — within 60 days. The notice will also outline the criteria FSIS will use to evaluate tests submitted to us. We hope to have more funds to award competitively for test development.

Risk Analysis

Quantitative Risk Assessment is another component of the Pathogen plan. We have set up a Risk Analysis Program in FSIS.

The Agency plans to institutionalize quantitative risk assessment, risk management and risk communications. We

must address the risks meat and poultry pose in a more systematic and scientific manner.

Already the Agency has requested that the Centers for Disease Control undertake infectious dose research, and they have agreed. Also, we have contracted for a risk assessment of chlorine use in water in meat and poultry plants. In addition, a subcommittee that Dr. Cross set up in the Microbiological Advisory Committee is looking at *Campylobacter* in poultry.

Post-Harvest Interventions

As you know, we need new technologies to control bacterial proliferation in the meat plant. For instance, we recently invited two researchers to describe to us their new methods for pasteurizing raw meat surfaces without cooking the product.

Micro Surveys

Our Agency's long-term microbiological survey of steers and heifers, which began in October, is on track. Recently, we have drafted a protocol for a similar survey of cows and bulls. The protocol is undergoing peer review. We will begin the new survey on cows and bulls this summer.

In addition, we are planning **one-time** microbiological surveys on downer animals and ground beef. The protocols will be out for peer review soon. The downer cows study is designed to show us whether these animals do, indeed, carry a heavier microbiological load than healthy animals.

We expect the ground beef study to give us a better idea on the prevalence of *E. coli* O157:H7 and other pathogens in ground beef as it leaves the plant.

HACCP Microbiological Testing of Beef

FSIS has decided to conduct pilot projects in beef plants this summer, using the HACCP approach to gather microbiological data.

Slaughter

We are now designing a pilot HACCP project to gather information on microbial pathogens in beef. We will take samples in five beef slaughter plants at critical control points, and analyze the samples for the following indicator organisms: total coliforms, *E. coli* biotype I, and aerobic plate counts at 35°F. We will randomly select one carcass and then test that same carcass at four CCPs:

- immediately after skinning,
- after evisceration,
- after the final rinse, and
- after chilling.

In addition, we will analyze swabs of a knife blade, taking samples at pre-op sanitation and during operations.

Processing

FSIS is also going to perform a HACCP microbiological project in beef processing plants. We will conduct pilot tests

this summer in five establishments that process raw beef patties. In the beef processing plants, we will test for the same indicator organisms we selected for the slaughter plants (that is, total coliforms, *E. coli* biotype I, and aerobic plate counts at 35°F.)

The CCPs at which we will collect samples are:

- incoming raw material, and
- raw patties after patty formulation.

We will also analyze swabbing of patty-forming equipment, taken:

- during pre-op sanitation, and
- after two hours of operation.

When we have sufficient data from these two microbiological monitoring projects, we can establish critical limits and prescribe correction actions where the plant is not doing the job. Our plan is to make the program operational in 1994.

Directives for Slaughter Plant Inspection

We expect to have directives out very soon on another point of critical importance to beef slaughter operations — contamination of carcasses by feces, ingesta and milk. These directives will provide further definition to “zero tolerance” and facilitate correlation among inspection personnel.

Pre-Op Sanitation Monitoring

In addition, FSIS has recently decided to incorporate microbiological monitoring into pre-op sanitation inspection for both slaughter and processing operations. We have set a target date of April 1994 for implementing pre-op microbiological monitoring in beef slaughter plants.

Retail: Safe Handling Labeling

The Pathogen team is also working on another area of intense public concern—labeling of meat and poultry products with handling instructions. In January 1993 — before the *E. coli* outbreak — Dr. Cross announced that mandatory labeling was needed to attack the problem of foodborne illness.

Later, the group called “Beyond Beef” filed suit to compel USDA to mandate warnings on meat and poultry labels. We firmly oppose warnings. Information and education are what is needed. On May 5, we reached a court-sanctioned agreement. FSIS agreed to publish — by August 15 — a proposal to mandate that labels carry handling and cooking instructions.

In meetings, our Agency and the FDA have agreed on the scientific content for temperature advice. Now, we are commissioning a focus group study on the best ways of providing this information to consumers.

Consumer Education

It's axiomatic that consumers must handle food properly to keep meat safe. And FSIS has long conducted a strong, targeted consumer education effort. In the Pathogen Reduction Program, the FSIS education program will be even more aggressive — and effective. We will take advantage of opportunities to be a facilitator and a convener of groups.

For example, soon, we will hold a video-conference for state and local health officials. (The probable month will be September.) The topic will be safe food handling requirements and methods of enforcement. The emphasis will be on restaurants and other kitchens serving the public.

We also plan to develop more intensive education programs and materials for food handlers, including those who work in day care centers, hospitals, restaurants and similar institutions.

Conclusion

The actions I've highlighted today send a clear message. Tough enforcement, our planning efforts, mandatory HACCP, and the Pathogen Reduction Program all demonstrate our commitment.