

# Small Plant NEWS

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## Small Plant NEWS

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# 10 Years Later Reflecting on HACCP, Part II

*Despite initial concerns, and some painful experiences along the way, the Hazard Analysis Critical Control Point (HACCP) system has proven to be a regulatory model that works. Operators now have assumed control of and responsibility for their own processes, and FSIS' shift in how it does inspection has given it a legitimate claim to the title of USDA's public health agency. In last month's issue of Small Plant News, the first part of this special two-part series on HACCP featured reflections from four key stakeholders: William "Bill" Smith, FSIS' Assistant Administrator for Program Evaluation, Enforcement and Review; Rosemary Mucklow, Director emeritus, National Meat Association (NMA); Dr. Kerri Harris, President and CEO, International HACCP Alliance; and Carol L. Tucker-Foreman, Distinguished Fellow, Consumer Federation of America's Food Policy Institute. The following is the second part of this special report.*

**By Ralph Stafko**

**T**he U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) began the first phase of implementation with the hope that the large plants would blaze the path for the smaller plants to follow, along with the agency helping in the information transfer. The large plants were, for the most part, justifiably confident in their ability to develop good HACCP plans with little help from FSIS. However, as it turns out, the agency sometimes disagreed with the content of their plans. One commonly contested issue was the identification of hazards "reasonably likely to occur" that must, therefore, be included in the plan. Who should have the final say?

According to Smith, agency objections to some plants' efforts to unduly minimize the scope of their HACCP plans led to court cases which generally upheld the agency's authority. In addition, a series of high-profile recalls by large plants added support to the

agency's ability to pass judgment on the content of HACCP plans.

Says Smith, "HACCP today provides the foundation for most of what we are doing to reduce pathogens. Our pathogen reduction strategies for *Listeria*, *E. coli* O157: H7, and *Salmonella* are all based on interventions for them being built into plants' HACCP systems."

As for FSIS' workforce being prepared for HACCP, in many cases, its personnel were not adequately trained or supported sufficiently to go one-on-one with the plant over the content of a HACCP plan. The agency early on recognized it needed to make a much greater effort to train its field force and to communicate better with the regulated industry. But it took some time before it recognized how key, and interrelated, those two areas are.

"One lesson I learned was the importance of training," said Smith. "'Just in time' training on HACCP-

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# Designing Your HACCP Plan, Looking at the First Three Principles

By Ellyn Blumberg

*In the June issue of Small Plant News, we featured the first of a four-part series on Designing Your Own HACCP Plan. This month, we focus on the first three principles of HACCP.*

**S**ay what you do, do what you say, and prove it. That's HACCP. HACCP regulations require meat and poultry plants to have a plan—a written plan—to identify and prevent hazards before they occur, and to be able to correct problems if they are detected. Plants design their plan around the seven basic HACCP Principles.

## HACCP Principle 1

The first principle is to conduct a hazard analysis by addressing these two questions. What are your food safety hazards? Are they reasonably likely to occur? In this stage of designing a HACCP plan, your HACCP team, or point of contact, should prepare a list of the steps in the production process that are reasonably likely to cause injury or illness and the preventative measures the plant uses to control them.

First, look over the product or process description and look for information that could affect public health. You could ask yourself the following questions. Does the product need to be refrigerated or frozen during transit? Will the amount of acidic ingredients affect the growth and survival of bacteria? Or, have additives been added



**At each critical control point, you must identify critical limits, which are most often parameters such as temperature, time, pH, physical dimensions or absence of target bacteria. (USDA photo)**

to kill bacteria? Also look at the product ingredients and packaging materials. Ask yourself questions such as: could these ingredients or packaging materials contain any harmful bacteria, dangerous chemicals, or injurious physical objects?

While conducting a hazard analysis, it's best to determine if any food safety hazards exist for each processing step listed in your process flow diagram. You could ask yourself—could contaminants reach the product during this processing step? Or could bacteria multiply during this process step?

At the same time you're identifying hazards, think of possible preventative measures. Sometimes it's the case that more than one preventative measure may be required to control a specific hazard, or that more than one hazard may be controlled by one preventative measure. As you go through the hazard analysis, you may recognize preventative measures already in place in your production process. The key to a successful hazard analysis is to link these measures to the food safety hazards you have just identified and document your decisionmaking.

## HACCP Principle 2

The second HACCP principle is to identify critical control points. Where can controls be applied in your process to prevent, eliminate, or reduce a food safety hazard? The step at which the critical control point is located does not necessarily have to be at the point where the hazard is introduced into the system. For instance, harmful bacteria introduced into the process on raw meat may be controlled by a cooking step later in the process.

Common critical control points include chilling or freezing to a specified temperature to prevent bacteria from growing, or cooking that must occur for a specific time and temperature in order to destroy bacteria. Another common critical control point is prevention of cross contamination between raw and cooked product.

Different plants, preparing the same food, can identify different food safety hazards and different critical control points. Usually no two plants have the same floor plan, equipment, or ingredients, so the critical control points you identify will reflect the uniqueness of your processing plant.

## HACCP Principle 3

The third principle is to establish critical limits. Critical limits are measurable or observable values that can be used to judge whether specific food safety standards have been met. In a nutshell, if a process can



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based inspection proved very difficult. In retrospect, I would've had the agency do much more, earlier, on training and staffing. It proved to be much more complicated than we originally thought."

Fortunately, the agency has made great strides since. Among other things, it now has a cadre of inspection personnel trained and dedicated to assessing HACCP systems, including 175 Enforcement Investigation and Analysis Officers and 400 Public Health Veterinarians.

The improvements in agency technical capabilities have fostered confidence among agency personnel that in turn supports improved communications with industry. "The agency now recognizes that it cannot apply a single template to all plants just because they have similarities, and views good communications as fundamental to HACCP implementation," said Mucklow.

"Both sides agree that reasonable people can—and do—differ on what is needed for a validated HACCP plan. Questions now are more likely to evoke discussions than ultimatums," added Mucklow. She praised the agency for its willingness to innovate in that area, noting the agency's recent use of a third-party mediator to resolve a technical dispute with one of NMA's members.

Smith recalled that another problem initially faced by the agency was a lack of enforcement mechanisms. The agency's Rules of Practice followed the HACCP Rule by many months, and it then took time to fine-tune their application. After a rocky start, according to Smith, enforcement procedures now are "well established and widely understood."

## FSIS recognized that it needed to make a much greater effort to train its workforce and the regulated industry on HACCP. (USDA photo)

Overall, Harris, Mucklow, Smith, and Tucker-Foreman stated that the agency has done a remarkable job implementing HACCP, certainly better than most observers thought likely when the rule was promulgated. However, all also agree that the transition has been difficult, and that, as stated by Harris, "it is still a work in progress."

## What Next?

According to Harris, "there are people in both industry and the agency who are still having difficulty with the transition. Some plant owners still want the agency to 'just tell them what to do,' and some inspectors still are inclined to oblige. The key to continued progress is continued emphasis on training and communications."

Mucklow concurs on the need for continued work in those areas. "There needs to be more uniformity among inspection personnel. I would like to see some kind of HACCP credential for inspectors." She added, "The biggest remaining challenge is to complete the change in mindsets among all concerned away from command and control."

Tucker-Foreman, while endorsing agency efforts at improving its employee training, outreach, and communications with plant operators, thinks that the agency goes *too* far in helping some plants. "In effect, the agency devotes a disproportionate amount of its limited inspection program resources to companies that have chronic problems complying with the law."

She suggests that, in keeping with its public health focus, the agency should consider some sort of triage system that culls the worst plants out from the inspection program. "At a minimum," she asserts, "the agency should pursue its idea of charging 'compliance fees' to recover some of the public resources devoted to allowing extremely weak operators to continue in business."

Another challenge noted by Tucker-Foreman is the need to better distinguish between processing plants, where there is a "kill step" that assures

destruction of pathogens, and slaughter facilities producing raw products, where pathogens are not destroyed. The latter poses the much greater public health risk and the much greater challenge in designing—and inspectors' verifying—a HACCP plan.

Tucker-Foreman argues more broadly that in order for the HACCP rule to achieve its early promise, the agency needs two things: better data and data systems, and better enforcement tools. She maintains that in order for the agency to achieve its public health goals, it must have a better way to measure the public health outcomes of agency policies.

"The agency has made progress on this, but still doesn't have a way to link specific illnesses to specific categories of foods. We need to be able to determine the public health impacts of the agency's regulatory efforts before we will be able to build a credible public health-based inspection program," said Tucker-Foreman. She contends that more powerful enforcement mechanisms also are needed. "Ideally, the agency would get the statutory authority it needs to impose pathogen performance standards that plants must meet in order to operate."

The next frontier for the agency in meat and poultry food safety may be outside inspected establishments. Smith feels FSIS has largely succeeded in getting inspected operators under HACCP systems. He sees the next big development as extending HACCP-like controls over hazards to which meat and poultry are exposed during transport, storage, and at retail. "The original concept was that HACCP would deal with food safety hazards farm-to-table," said Smith. "We have a ways to go on that."

The reflections of these four stakeholders support the observation that implementation of the HACCP Rule 10 years ago launched a revolution in meat and poultry inspection. However, they also make clear that inspection in the era of HACCP continues to evolve. It is still "a work in progress."

**Briefs** By Sheila Johnson

## Podcasting

FSIS recently launched a series of educational podcasts to address food safety and education issues for consumers and other stakeholders.

As a part of the agency's outreach to small and very small establishments, FSIS is providing small and very small plant owners, operators, and employees with information via podcasts. Current podcasts cover a variety of topics relevant to small plants, ranging from food safety resources to preventing recalls.

To listen to individual podcasts or sign up for a free subscription, visit [www.fsis.usda.gov](http://www.fsis.usda.gov). For assistance or details concerning FSIS podcasts, send an e-mail to [podcast@fsis.usda.gov](mailto:podcast@fsis.usda.gov) or call (202) 690-6520.

## FSIS Releases FY 2008-2013 Strategic Plan

FSIS recently released *The FSIS FY 2008-2013 Strategic Plan*, which will guide the agency's activities over the next 5 years. The plan includes FSIS' public health mission, vision, goals, and the means and strategies for meeting those goals.

In the "Letter from the Administrator" section of the plan, FSIS Administrator Al Almanza states that the plan is the "foundation document for both the long range and day-to-day operations of the agency."

For more information visit [www.fsis.usda.gov](http://www.fsis.usda.gov) or call (202) 690-6520.

# Obtain Products from FSIS' Cooperative Agreements

By Jeff Tarrant

U.S. Public Health Service

**F** SIS occasionally funds cooperative agreements with State or local agencies, universities, or nonprofit organizations for projects to benefit the public as well as support FSIS' mission. In accordance with the Freedom of Information Act, FSIS makes the work products of such projects available to the public as they are completed. Products from the following cooperative agreements are now available:

- ▶ "Small and Very Small Federally Inspected Meat, Poultry, or Egg Product Establishments" work projects funded in 2004-2005.
- ▶ "Retail Stores, Food Service Establishments, and Other Inspection-Exempt Small Businesses Processing or Handling Meat, Poultry, and Egg Products" work projects funded in 2004-2005.

Since the work products produced in cooperation with FSIS are in the public domain, they are the property of the cooperators and do not necessarily reflect USDA policy. To access the work products, go to: [www.fsis.usda.gov/About\\_Fsis/Cooperative\\_Agreements/index.asp](http://www.fsis.usda.gov/About_Fsis/Cooperative_Agreements/index.asp). For personal assistance, contact Ralph Stafko at (202) 690-6592 or Kathleen Barrett at (202) 690-6644.

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meet specific food safety standards, then the resulting product will also meet an acceptable food safety level.

Each critical control point will have at least one (possibly more) preventative measures that need to be controlled to assure prevention, elimination, or reduction of food safety hazards. So, at each critical control point, you must identify corresponding critical limits.

Critical limits can come from a variety of sources. They may be based on FSIS regulations or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies or the recommendations of recognized experts in the industry, academia, trade associations or processing authorities. Most often, critical limits are parameters such as temperature, time, pH, physical dimensions, or the absence of target bacteria. To be effective, each critical limit must be actual values that can be measured and based on factual information.

When determining your critical limits, you should consider the type of equipment, the volume of product being produced, how the critical limit will be monitored, and frequency of the monitoring. In all cases, you must be able to provide a basis for how you selected and developed your critical limits, and the supporting documentation must be available for the inspector to review.

By designing and following an effective HACCP plan, you'll certainly do your part to protect public health. It makes good business sense as well. For additional information on the first three principles of a HACCP plan, visit FSIS' Web site at [www.fsis.usda.gov](http://www.fsis.usda.gov) or call (202) 690-6520. In the August issue of *Small Plant News*, we'll explore HACCP principles four through seven when designing your plan.