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10 Years Later Reflecting on HACCP

The HACCP Rule launched a revolution in meat and poultry inspection. On the 10th anniversary of the implementation of this rule, Small Plant News, through the input of four key stakeholders, takes a reflective look at the past, present and future of HACCP in a special two-part series.

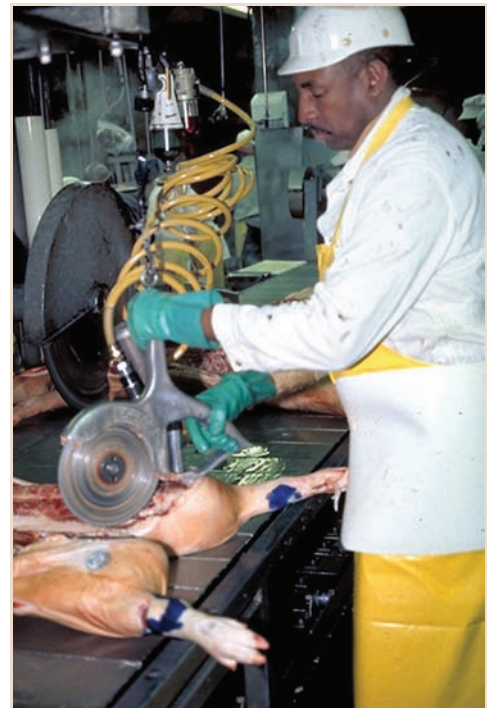
By Ralph Staffko

No one said it would be easy. After much effort, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), on July 25, 1996, published its groundbreaking Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) regulations, aka "the HACCP rule."

The HACCP rule first took effect in the largest federally inspected plants 10 years ago, on January 26, 1998. It recast meat and poultry inspection as a science-based, food safety program. It was actually a composite of several new regulations, including microbiological performance standards, routine microbiological testing, and mandatory Standard Operating Procedures for sanitation. At its core was "mandatory HACCP." Every plant was directed to develop and operate under a HACCP system designed to ensure the safety of every product it produced.

How are we doing 10 years after the launch of this revolutionary rule? Is HACCP a success, or something less? Where do we go from here?

To get some answers, *Small Plant News* contacted four individuals uniquely qualified to offer insights, albeit from



Under HACCP, establishment owners now have control of, and responsibility for, their own processes.
(USDA photo)

very different perspectives. William "Bill" Smith, currently FSIS' Assistant Administrator for Program Evaluation, Enforcement and Review and former Assistant Administrator for Field Operations, has been intimately involved in all the agency's HACCP implementation activities. Rosemary Mucklow is a long-time industry representative and advocate on HACCP matters, and the

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Food Safety Resources

By Mary Gioglio

An educational DVD designed for small and very small Federal and State beef plants and custom exempt facilities covers the topic of Specified Risk Material (SRM). The DVD, *Specified Risk Material, Identification, Removal and Disposal*, was developed by the New York State Department of Agriculture and Markets through a cooperative agreement with FSIS and demonstrates how SRMs are identified and removed in cattle as well as how to dispose of SRMs in a beef plant. Accompanying the DVD is an illustrated color-coded card that shows the location on the animal of all SRMs, as indicated in the FSIS regulations. You can also read more about SRMs in the October 2007 issue of *Small Plant News*.

To request this DVD or any other food safety resource, fax the order form found on FSIS' *Food Safety Resource Brochure* to (202) 690-6519, or complete an online version of the form and send it to FoodSafetyResources@fsis.usda.gov. The online form can be found at www.fsis.usda.gov/Science/HACCP_Resources_Order_Form/index.asp.

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Director Emeritus of the National Meat Association. Dr. Kerri Harris, Associate Professor of Animal Science at Texas A&M, is President and CEO of the International HACCP Alliance, an organization formed in 1994 to provide HACCP expertise to industry. Carol L. Tucker-Foreman is a respected consumer advocate known for her work on food safety issues. She was Assistant Secretary of Agriculture for Food and Consumer Services from 1977 to 1981 and currently serves as Distinguished Fellow at the Consumer Federation of America's Food Policy Institute.

A Sea Change

On the question of the most significant change caused by HACCP, they all agreed that the biggest change has been how the industry and agency view their respective responsibilities.

"This has been a sea change event," said Mucklow. "We've gone from an often counter-productive command and control inspection model to one where companies are responsible—and are appropriately held accountable—for producing safe foods in their own plants."

According to Smith, the HACCP rule shifted the focus of inspection. "Inspectors previously focused primarily on finding adulterated products. Now they focus on verifying that systems are

preventing adulterated products from being produced in the first place."

A major goal of the HACCP rule was to clarify responsibilities—to distinguish those of inspectors from those of the plants. Previously, FSIS regulations blurred responsibility for food safety. In exercising "command and control" oversight of operations, inspectors effectively assumed much of the responsibility for "their" plant's performance. This led to frustration by plant operators who felt their management prerogatives were being co-opted by inspectors. In some cases, it fostered an unhealthy dependency on inspectors to direct operations. An oft-cited illustration was the "bucket brigade" approach to pre-op sanitation procedures, where plant employees would follow the inspector with mops and buckets ready to swab where, and only where, the inspector pointed. The agency asserted similar control over facilities, equipment and processes, requiring prior approval of most changes. Inspectors too were frustrated. Try as they might, they could never control all the hazards in a plant.

The new HACCP requirement reflected the agency's recognition that safety cannot be inspected into a product—it must be built in by the processor. Its traditional model for inspection had to change if FSIS was to achieve its public health-driven pathogen reduction goals. Thus, the agency worked to recast its relationship with inspected establishments, making plants responsible for their own operations,

and using inspections to establish, through testing and verification procedures, whether a plant is adhering to an effective HACCP system.

Tucker-Foreman contends that the most important change has been the agency's adoption of a public health mission. "This was a fundamental change in the concept of inspection. Al-



In a HACCP system, food safety is built into the product by the plant. (USDA photo)

though much remains to be worked out, this paradigm shift alone was a monumental task.”

Tucker-Foreman goes on to argue that HACCP’s successes must be considered in concert with two other changes—one legal, and one technological—occurring about the same time. The first key change was the 1994 determination (and court decision upholding it) that *E. coli* O157:H7 in raw ground beef is an adulterant. Although still the only situation where a pathogen in raw product per se is an adulterant, according to Tucker-Foreman, “it is the legal precedent that gives the agency the leverage it needs to implement all its other pathogen reduction efforts.” The other change is the ability to “obtain DNA fingerprints of pathogens, and match them via the Web against the fingerprints of other samples around the country. Companies can no longer easily hide their responsibility for adulterated products. These developments have provided impetus for many companies to make large investments in risk reduction technologies.”

The Transition, Factoring in Small Plants

HACCP is a regulatory model that by design is very dynamic, and thus requires a lot of work to implement. According to Harris, “Every operation is unique. Furthermore, the nature of the differences among plants is constantly changing as new technologies and products are introduced. HACCP plans will be a reflection of that.”

For that reason, the HACCP rule gives plants wide latitude in designing HACCP plans appropriate for their particular products and circumstances.

On the industry side, the transition to HACCP was most challenging for small and very small plants, most of which do not have the technical and other resources that large plants have.



HACCP clarified the responsibilities of the inspectors from those of the plants. (USDA photo)

For that reason the agency phased in implementation of the regulation over 3 years, based on plant size. It became effective in small plants (under 500 employees) in 1999, and very small plants (under 10 employees and \$2.5 million in sales) in 2000.

About 90 percent of the roughly 6,200 federally inspected plants, and all of the 2,500 State-inspected plants, are small or very small plants.

The agency committed itself to providing guidance and outreach to help these operators develop their HACCP plans. Generally, the agency gets good marks for its outreach efforts. “The agency has done a good job on outreach,” said Mucklow. FSIS provided a variety of materials including HACCP self-study guides, hazard analysis guidance, and model HACCP plans. In addition, the agency collaborated on establishing the International HACCP Alliance, a cadre of HACCP experts to provide instruction and advice to industry, and developed a list of State HACCP coordinators and Extension

contacts to work directly with individual companies that needed it. It also has offered a series of training classes, workshops, and educational seminars around the country. In the past few years, the agency has relied more on Web-based distribution of information, but also has reached out to operators and employees who do not spend much time online with guidance materials available by mail, including this publication, which is sent to all establishments by mail.

On March 7, 2008, the agency announced the establishment of a new Office of Outreach, Employee Education, and Training reporting directly to the Administrator. This office provides increased support for agency improvements in employee training and in outreach to the regulated industry. This is especially important as the agency considers additional changes in inspection to target its resources on public health risks better.

Harris points out that everyone should also credit HACCP with at least one valuable side effect. “Plants have been forced to develop a much better understanding of their own processes, which has led to more efficient and cost-effective operations as well as safer ones.”

Along the same lines, HACCP has fostered a more holistic view of operations among plant operators. Hazards cannot always be controlled adequately by addressing conditions only inside the plant. One has to look at how incoming raw product and ingredients have been produced and handled, and at hazards to which finished product is exposed during distribution. There now is more recognition of the fact that external hazards affect the company’s product and the bottom line. This has led to an increasing use of interlocking contract specifications that in effect extend HACCP controls outside the plant to both suppliers and distributors.

(Part II of 10 Years Later—Reflecting on HACCP will continue in the July 2008 issue of Small Plant News.)

Take the Preliminary Steps to Design Your HACCP Plan

By Ellyn Blumberg

Small Plant News is featuring a four-part series on Designing Your Own HACCP Plan. This month we focus on the preliminary steps you need to take. In the following months, we'll cover the seven principles of HACCP, as well as lessons learned, tips and resources you can refer to for assistance.

HACCP is a science-based control system designed to identify and prevent problems before they occur, and correct deviations as soon as they are detected. So, how do you design a HACCP plan? Where do you start?

FSIS and most HACCP experts believe that you'll write a better HACCP plan if you take some preliminary steps before attempting to apply the seven HACCP principles.

First, you should assemble a HACCP team within your establishment, including one person who is HACCP-trained. The team members should be aware of your product, process, food safety programs, and hazards. It's perfectly acceptable for this team to be only one person in a very small plant. In others, the team may be composed of managers, microbiologists, and quality control officers.

Next, your HACCP team should describe the product(s) and your methods of production and distribution. If your team includes the people who know how things work in your operations, they should be able to do this quite easily. The important thing for them to keep in mind is that they need to include every step in the process.

Provide details or descriptions about your product(s) such as: "What is the common name?"; "How will the product be used?"; "What is the shelf life?" and "Is special distribution control needed?"

Capture the big picture of your business. You should answer these questions as completely as you can; however, the answers can be brief. For example when answering the question, "How will this product be used?" you could simply answer "ready-to-eat" if that's applicable.

After determining all of the processing methods and modes of distribution, your HACCP team should develop a list of all the ingredients and raw materials for each product and process. The list should include everything used for your product including packaging materials.

The final preliminary step before you can begin designing a HACCP plan is developing and verifying a



An important step before you design your HACCP plan is to look at your plant's floor plan and visualize a process flow diagram. (USDA photo)

process flow diagram for each product. This diagram is a simple schematic picture of the process you use in your plant to produce the product. It doesn't need to be complex. Look at your plant's floor plan to help you visualize the process from receiving to shipping.

The best way to make sure your flow diagram is accurate is to have your HACCP team verify it by walking through the plant and making sure all the steps in the process are included in the flow diagram. Your team should be sure to verify the flow diagram carefully. Auditors and inspectors commonly use that method to verify that a particular flow diagram is correct and complete.

Once you complete these preliminary steps, you'll have the information needed to apply the seven principles of HACCP to your own HACCP plan. Your preliminary steps produce two critical pieces of information. The first is a comprehensive list of ingredients and raw materials. The second is a step-by-step production process breakdown, represented in a simple flow diagram. This information forms the basis of your HACCP plan.

For additional information on designing a HACCP plan and the preliminary steps, visit FSIS' Web site at www.fsis.usda.gov or call (202) 690-6520. In the July issue of *Small Plant News*, we'll explore how to apply the first three principles of HACCP when designing your plan.