Manufacturing

HACCP for Organic Processing

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America's food is among the safest in the world. Nevertheless, in a paper published in 1999 by scientists at the U.S. Centers for Disease Control and Prevention (CDC), it was reported that approximately 76 million illnesses, 325,000 hospitalizations and 5,000 deaths are due to foodborne disease in this country each year. More than 200 known diseases are transmitted through foods, originating from viruses, bacteria, parasites, toxins, metals and prions. The symptoms of foodborne illness range from mild gastroenteritis to life-threatening neurological, hepatic and renal syndromes. Since no food company wants to make its customers sick, the industry has developed several strategies aimed at reducing potential contamination of products.

One principal food safety standard that has emerged as a powerful tool to help mitigate the incidence of foodborne illness is the Hazard Analysis and Critical Control Points (HACCP) model. This systematic approach to food safety focuses on the evaluation and control of foodborne hazards. It is a powerful and practical concept that can be applied at every link in the supply chain—from farm to fork. In the case of foodborne illness causing pathogens, such as *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes*, recent food regulatory agency reports have credited the implementation of HACCP in regulated industries as a key factor in reductions in the incidence of microbial contamination of food samples. *Listeria monocytogenes*, for example, is a widespread bacteria in the environment, can grow in cold temperature environments such as home refrigerators and food processing plants, and can cause a deadly disease (listeriosis) in at-risk populations that include pregnant women, immunocompromised individuals and the elderly. In October 2003, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA FSIS) released new data showing a one-year, 25% drop in the occurrence of positive *Listeria monocytogenes* in food samples, and a 70% decline compared with years prior to the implementation of HACCP in the meat and poultry industries.

The use of HACCP is a regulatory requirement for the seafood, meat, poultry and juice industries, and the approach has been voluntarily and widely adopted by many other segments of the food manufacturing industry. Developing a HACCP plan demands broad knowledge of the food, its intended use and hazardous constituents. HACCP development also requires an exquisite understanding of the processes used in the production, packaging, storage and distribution of the food. Moreover, HACCP development demands knowledge of the manufacturing process' capability with respect to preventing the production of foods that contain dangerous biological, chemical or physical defects. For these reasons, the organic food processor is uniquely positioned to effectively incorporate this process control strategy into its operations since the principles of HACCP dovetail with the Organic Processing and Handling Plans strategies of the USDA National Organic Program (NOP) Standards, Part 205.

What is HACCP?

HACCP was developed about 30 years ago, initially for the National Aeronautics and Space Administration (NASA) program. Traditionally, industry and regulatory agencies depended on spot checks of manufacturing facilities and random sampling of final products to ensure safe food. This approach,

however, tended to be reactive rather than preventive. With the advent of HACCP, the U.S. Food and Drug Administration (FDA) and USDA have developed a more efficient and proactive set of regulations, and have begun to apply these gradually to the food industry.

"Hazard analysis" refers to the identification of any ingredient, material or procedure that may pose an unacceptable health risk. The hazard analysis is an evaluation of potential microbiological, chemical and physical hazards associated with a particular product and process. It is used to determine which hazards are reasonably likely to occur and, if they do occur, how they can best be controlled. A critical control point (CCP) is a point, step or procedure in a food process at which a control measure can be applied and where such a measure is essential to prevent, eliminate or reduce an identified food hazard to an acceptable level. Government regulations require that the hazard analysis and the critical control points are documented.

> "A HACCP plan can be utilized to assure that organic materials are not commingled with non-organic materials."

HACCP techniques assess everything from raw ingredients to product packaging and distribution, define the points where potential hazards (biological, chemical, and physical) may occur, and establish a means of monitoring these points to control these hazards. A HACCP plan is developed in two stages: First, the food processor must complete five preliminary steps and second, he or she must implement the seven principles of HACCP.

These five preliminary steps should be taken during the initial planning of the HACCP program:

1. Assemble the HACCP team. Some HACCP guidelines recommend, and some companies' practices involve, a team to discuss each potential hazard and to develop the HACCP system for each food that is processed. Such teams have representatives from the quality control department and processing operations and often are supplemented by others, such as representatives from engineering, maintenance and legal departments. This provides for a variety of inputs by persons with a diverse knowledge of operations; aids those involved to understand the hazards associated with the food and operations and controls specified in the HACCP system; and stimulates cooperation in implementing the system.

2. Describe the product. Include raw materials and ingredients, formulations or recipes, physical and chemical characteristics, process steps, preservation systems, packaging, storage and distribution.

3. Identify the intended use of the product. Is it ready-to-eat (RTE), fully cooked? What type of consumer will consume the product? What are the serving requirements? Identifying these

4. Construct process flow diagrams. Provide a clear and simple description of the process.

5. Verify the process flow. Knowing how the product moves through the plant, from receipt of raw materials to the formulation area, through the lines to the shipping door, is critical to preventing cross-contamination incidents.

Careful attention at this stage of development will have an impact on how well the company is able to implement the seven principles of HACCP.

Principle 1. Conduct a hazard analysis. Collect and evaluate information on relevant hazards. Decide which are significant and should be addressed in the HACCP plan. List all hazards that may be reasonably expected to occur in ingredients and at each step, from primary production until the point of consumption. The hazard could be biological, such as a microbe; chemical, such as a toxin; or physical, such as glass or metal fragments.

Principle 2. Identify critical control points. For each process step at which a significant hazard has been identified, determine whether it is a CCP or not. These are points in a food's production, from its raw state through processing and shipping to the consumer, at which the potential hazard can be prevented, reduced or eliminated. Examples are cooking, cooling, packaging, and metal detection.

Principle 3. Establish critical limits for each CCP. Establish critical limits for each CCP. These may include measurements of temperature, time, moisture level, acidity (pH), water activity (a_w), and sensory parameters such as visual appearance and texture.

For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes. Care should be taken to account for process capability when determining set points versus critical limits.

Principle 4. Establish procedures to monitor the critical control points. The Codex Alimentarious definition of monitoring is "The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control." Monitoring procedures should specify what, where, when, how and by whom the monitoring is carried out.

Principle 5. Establish corrective actions in order to deal with deviations when they occur. These are written procedures to be followed when a deviation occurs. For example, this may include reprocessing or disposing of food if the minimum cooking temperature is not achieved.

Principle 6. Establish procedures to verify that the system is working properly and to validate the effectiveness of critical controls. These verification procedures may include auditing methods, as well as random sampling, procedures, and tests. For example, time-and-temperature recording devices would need to be used to verify that a cooking unit is working properly. Published microbiological studies on time and temperature factors for controlling foodborne pathogens is one example of validation.

Principle 7. Establish effective record keeping and documentation to document the HACCP system. This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Records must be dated and signed, reviewed for completeness and compliance and retained.

Application of HACCP to the Organic Processor

Many of the principles of HACCP have been in place in the FDA-regulated low-acid canned food industry for a number of years. The FDA established HACCP for the seafood industry in a final rule on Dec. 18, 1995, for the meat and poultry industries in July 1996, and for the juice industry in a final rule released Jan. 19, 2001. The FDA is now considering developing regulations that would establish HACCP as the food safety standard throughout other categories in the food processing industry for both domestic and imported food products. To help determine the degree to which such regulations would be feasible, the agency is conducting pilot HACCP programs with volunteer food companies. The programs have included dairy, frozen dough, breakfast cereals, salad dressing, bread, flour and other products. Several retail HACCP pilot programs also have been conducted.

Good food is safe food, and by the judicious application of a HACCP program, the organic food processor can implement a program whereby both safe production conditions and compliance with national organic standards are achieved. The principles of organic processing plans and HACCP plans are quite similar in terms of documentation and how one analyzes each step of the process. For example, a HACCP plan can be utilized to establish procedures to assure that organic materials are not commingled with non-organic materials and that they do not come in contact with non-approved substances.

A HACCP plan can, in fact, incorporate an Organic Production and Handling System Plan, as defined in the *Code of Federal Regulations* (7 *CFR* 205.201), to ensure organic integrity. Templates for Organic Processing and Handling Plans are available from certifying agents in each state. An Organic Production and Handling System Plan is meant to provide objective evidence that the ingredients, materials, processes and procedures employed by a certified producer or handler are consistent with NOP standards. Functioning much like a HACCP plan, Organic Production Plans assess critical concerns of the organic processor including pest management practices, sanitation, and ingredient control and labeling.

For a food item to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of: (a) synthetic substances and ingredients, except those approved in the NOP standards; (b) nonsynthetic substances that are prohibited in the standards; and (c) ionizing radiation. Allowed and prohibited substances, methods and ingredients in organic production and handling can be found in the National Organic Program Standards, Part 205.105. The NOP also requires an organic producer or handler to develop an organic production or handling system plan that includes the following six elements. In almost every case there is a parallel HACCP principle:

- *"A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed."* The first step in developing both a HACCP system for food safety and

a certified organic production process is to clearly identify each and every phase in production and processing. In HACCP, this is a critical step leading to effective hazard analysis (Principle 1) and subsequent identification of appropriate CCPs (Principle 2).

- *"A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable."* Ingredient assessments (as required by the NOP) and hazard analysis (as required by HACCP) are conducted for different reasons but the information collected can be gathered simultaneously for efficiency. Certified organic production is focused on the process used to produce the food, making a thorough knowledge of sources and composition of the raw materials and production inputs critical. Similarly, this knowledge is critical to one's ability to assess substances in terms of food safety. If an organic processor uses an ingredient that is sourced from a produce farm situated near a cattle ranch, the company may incorporate the knowledge that this may pose a higher risk of *E. coli* O157:H7 contamination of the raw material when establishing a CCP for receipt of the material.
- *"A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented."* To state the obvious: If you cannot measure it, you cannot control it. This concept is at the heart of HACCP Principle 4, Monitoring Procedures. Whether it is a food safety or organic program, careful consideration must be given to determining what is monitored, how and where it is monitored, who will monitor it and when it is monitored.
- *"A description of the recordkeeping system implemented to comply with the requirements established in 7 CFR 205.103."* A key element of this section is that records "be sufficient to demonstrate compliance with the Act and the regulations in this part." There is a direct parallel between this and HACCP Principle 7, Recordkeeping. Complete and verified process records are your proof of due diligence and effective control.
- *"A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances."* The standard operating procedures associated with a HACCP plan document the proper handling of ingredients, production scheduling, process control and sanitation required to ensure that the potential for cross-contamination between allergenic and nonallergenic products, or between raw and finished product that may result in a microbial contamination, is eliminated. As one would do in a HACCP program, physical separation, dedicated ingredient handling personnel and equipment, and label verification also may be incorporated into organic process controls. These techniques are consistent with NOP requirements and can be directly applied with good effect to organic production and processing.
- *"Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations."* [for example?]

The HACCP Advantage

While the methods and materials might differ between organic and nonorganic operations, the desired end results are the same: To develop and employ a systematic approach to effective process controls and to provide objective evidence that the system is under control on an ongoing basis. In the case of HACCP, the measure of effectiveness is food safety; for Organic Processing and Handling Plans, it is compliance with the standards set forth in the USDA National Organic Program Standards, Part 205. HACCP offers a number of advantages to the food industry, and especially to the organic processor because the system:

- Focuses on identifying and preventing hazards from contaminating food
- Is based on sound science
- Permits more efficient and effective government oversight, primarily because the recordkeeping allows investigators to see how well a firm is complying with food safety laws over a period rather than how well it is doing on any given day
- Places responsibility for ensuring food safety appropriately on the food manufacturer or distributor
- Helps food companies compete more effectively in the world market
- Reduces barriers to international trade

As a practical matter of operations the two types of plans go hand in hand. For example, while conventional application of chemical pesticides and insecticides may be replaced in an organic processing environment with natural and physical techniques, the goal in either case is to reduce

contamination and damage by pests and to maximize productivity. A combined HACCP / Organic Processing Plan would also consider the use of allowed or prohibited substances. Whether a process is organic or conventional, elimination of cleaner and sanitizer residues is a key concern in producing wholesome food. Again, a combined plan would take allowed or prohibited substances into account. Finally, standard techniques are universally applied for effective ingredient control and label accuracy regardless of the food category. By this we can see that HACCP and Organic Processing and Handling Plans are highly compatible concepts that, when applied together, provide a compelling bundle of benefits to the consumer both in terms of food safety and quality.

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