Overview of HACCP
Hazard Analysis Critical Control Point

Kevin Keener, Ph.D., P.E.
Food process engineer, Extension specialist, and associate professor of food science

Outline
1. Brief background of HACCP
2. What is HACCP?
3. Prerequisite programs and HACCP
4. Developing a HACCP program
5. Meeting state and federal regulations
6. Action steps for the processor

Introduction
Federal regulations, phased in from 1998 until 2000, require all large, small, and very small meat and poultry processors to implement a HACCP plan. For a small or very small processor, sorting all of the vast information on HACCP can seem overwhelming, especially when time and resources are limited. This fact sheet explains the benefits of HACCP, presents an overview of HACCP principles, and looks at the big picture. It answers the questions: “Why is HACCP important?” and “Where does sanitation fit into HACCP?” This fact sheet also provides steps the small processor can take to implement a HACCP system.

1. Brief background of HACCP
Since the Federal Meat Inspection Act of 1906 and the Poultry Product Inspection Act of 1957, meat and poultry manufacturers have been directly charged with producing safe, wholesome, and unadulterated foods. As a whole, the U.S. food industry has done an excellent job of maintaining the safety of its products. Unfortunately, over the years, foodborne illnesses have resulted in thousands of sicknesses and many deaths. Investigators have always tried to trace foodborne illness outbreaks back to the food processor, determine what went wrong, and then require them to fix the problem. Over time, it became clear that taking action after the fact was inadequate to protect consumers from foodborne illness.
In response to consumer concerns, the U.S. Department of Agriculture (www.usda.gov) and the Food and Drug Administration (www.fda.gov) have required plants to implement a food safety program called Hazard Analysis Critical Control Point. This program was developed by the Pillsbury Co. for NASA in the late 1960s to ensure the complete safety of food for space missions. The program provides a proactive approach to food safety by requiring plants to identify all potential avenues of contamination (hazards) and determine how to control, reduce, and/or prevent them to ensure that safe food will be produced.

On July 25, 1996, the Food Safety and Inspection Service (www.fsis.usda.gov) of the USDA published a final rule on Pathogen Reduction: Hazard Analysis Critical Control Point Systems. The PR/HACCP rule requires all meat and poultry plants to take responsibility for identifying and controlling, reducing, or eliminating chemical, physical, and biological hazards (including pathogenic bacteria). The HACCP requirements that all plants must meet are described in Title 9, Part 417, of the Code of Federal Regulations (www.access.gpo.gov/nara/cfr/waisidx_02/9cfr417_02.html). (As part of complying with HACCP, processing plants must also develop a written sanitation program (9 CFR 416, www.access.gpo.gov/nara/cfr/waisidx_02/9cfr416_02.html).

The timeframe to implement a HACCP program was based on the size of the processing plant, starting with the very largest. However, all meat and poultry plants were required to phase in a working HACCP plan by January 2000. The very small plants were the last required to implement a HACCP program in January 2000. Many very small meat processors have had difficulty developing, writing, and implementing a HACCP plan because of limited expertise and resources. This fact sheet provides background information on HACCP requirements, steps a small processor can take to develop a HACCP plan, and a list of available resources.

2. What is HACCP?

HACCP stands for Hazard Analysis Critical Control Point. HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards. It is a proactive strategy where hazards are identified and assessed, and control measures are developed to prevent, reduce, or eliminate a hazard. For example, one identified hazard in ready-to-eat turkey (deli meat) is the presence of Salmonella bacteria. To eliminate Salmonella, one control measure is a cooking process where a minimum internal product temperature of 165°F for 15 seconds is achieved and documented.
There are seven fundamental HACCP principles:

- **Principle 1** — Conduct a hazard analysis.
- **Principle 2** — Determine the critical control points.
- **Principle 3** — Establish critical limits.
- **Principle 4** — Establish monitoring procedures.
- **Principle 5** — Establish corrective actions.
- **Principle 6** — Establish record-keeping and documentation procedures.
- **Principle 7** — Establish verification procedures.

### 3. Prerequisite programs and HACCP

Before developing the HACCP program, one prerequisite program is required: Sanitation (9 CFR 416). This prerequisite program requires that employees be trained in food safety practices and that wholesome meat and poultry products are produced under sanitary conditions. The minimum allowable sanitary conditions for the equipment and facilities are identified as Sanitation Standard Operating Procedures. SSOPs consist of written cleaning and sanitizing procedures, validation procedures, and records regarding sanitary conditions both pre-processing and during processing. The SSOP verifications by USDA-FSIS are frequently performed on a daily basis.

Because of management challenges, many plants have chosen to subdivide the Sanitation program requirements into separate programs. Also, some plants have determined additional prerequisite programs are needed to ensure food and worker safety. Examples of these are shown in Table 2, along with the relevant portion of the Sanitation regulations. It is important to note that when FSIS verifies the regulatory requirements, it will only examine those records required by 9 CFR 416.

**HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards.**

#### Examples of common prerequisite programs (Sanitation – 9 CFR 416 citations provided where appropriate)

<table>
<thead>
<tr>
<th>Maintenance</th>
<th>416.1–3. 416.6</th>
<th>Equipment is designed and constructed with sanitary practices in mind. Preventive maintenance and calibration schedules established and documented.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal Hygiene</td>
<td>416.1, 416.5</td>
<td>All employees and other persons who enter and work in the manufacturing plant must follow the proper hygienic practices.</td>
</tr>
<tr>
<td>Pre-operational Sanitation</td>
<td>SSOPs 416.1, 416.11–17</td>
<td>This program documents that food is produced using sanitary practices in a sanitary facility using sanitary equipment prior to the start of daily operations.</td>
</tr>
<tr>
<td>Operational Sanitation</td>
<td>SSOPs 416.1, 416.11–17</td>
<td>This program documents that sanitary practices are maintained during processing.</td>
</tr>
<tr>
<td>Pest Control</td>
<td>416.2</td>
<td>Effective pest control programs should be in place and monitored.</td>
</tr>
<tr>
<td>Storage and Shipping</td>
<td>416.1–416.4</td>
<td>All raw materials and products should be stored under sanitary conditions and proper environmental conditions to assure their safety.</td>
</tr>
<tr>
<td>Traceability and Recall†</td>
<td>Requirement of the Bioterrorism Act of 2002, Section 306</td>
<td>All raw material and finished products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.</td>
</tr>
<tr>
<td>Supplier Control</td>
<td></td>
<td>Facility should ensure that supplier has in place effective Good Management Practices and food safety programs.</td>
</tr>
<tr>
<td>Personal Safety (not part of HACCP)</td>
<td></td>
<td>This program discusses all nonfood safety issues including repetitive stress injuries, general health, MSDS (Material Safety Data Sheets), etc. Inspections performed by Occupational Safety and Health Administration.</td>
</tr>
</tbody>
</table>
Further details on Sanitation and other prerequisite programs, along with the HACCP principles, are covered in other fact sheets in this series. It is important to note that from USDA’s perspective, only those activities indicated in 9 CFR 416 are considered “Sanitation” and will be verified as appropriate. USDA will review other prerequisite programs only to the extent they support decisions made in the hazard analysis (HACCP Principle 1) when developing the HACCP plan.

The underlying Sanitation and prerequisite programs prevent the introduction of food safety hazards into the plant, and thus are a foundation for the HACCP plan. For example, not having an equipment maintenance program may lead to the physical hazard of broken machinery parts contaminating a ground product. One way of looking at the HACCP requirement is to think of the HACCP plan as a pyramid (Figure 1). The HACCP program is built upon the sanitation program and other prerequisite programs. These programs address the suitability and food safety of the process.

The HACCP plan is a proactive, continual assessment of ongoing food safety during the processing of the food. For the HACCP plan to be successful, all of the underlying programs must be working properly.

In the pyramid, the prerequisite programs and written Sanitation program uphold the HACCP plan as the critical food safety system.

4. Developing a HACCP program

Once a Sanitation program and necessary prerequisite programs are implemented, a HACCP plan can be developed. Several tasks are required prior to HACCP program development. Those preliminary tasks include:

- **Assemble the HACCP team** — The team consists of individuals who have specific knowledge and expertise appropriate to the product and process. Other team members include the person(s) responsible for plan maintenance. One person on the HACCP team must be HACCP-trained. A team can be as few as one or two people.
• Describe the food and its distribution —
  This provides information on the ingredients, processing methods, and distribution methods (frozen, refrigerated, or at ambient temperature). Classification of the product into a USDA process allows the processor to focus on likely hazards associated with this type of product.

• Describe the intended use and consumers of the food — These may be the general public or a segment of the population such as infants, elderly, military, hospital patients, etc.

• Develop a flow diagram describing the process — This provides a clear, simple outline of the steps involved in the making the product. A block flow diagram is usually sufficient.

• Verify the flow diagram — The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Perform a walk-through of the process to make sure all process steps are covered.

Once those preliminary tasks are completed, a meat processor can develop the actual HACCP plan by taking the following steps.

1. Conduct a hazard analysis — First, the HACCP team reviews the ingredients used, activities at each processing step, and method of storage and distribution of final product, including intended use by consumers. Then the team makes a list of food safety hazards that are reasonably likely to cause injury or illness if not controlled. Next, each hazard is evaluated and its likelihood of occurrence is determined. The hazards are categorized as chemical, physical, and biological. Supporting documentation is needed to justify all decisions about whether or not something is a hazard. For example, a physical hazard of metal shavings from grinding may not be a hazard likely to occur if your maintenance program (and its records) documents that periodic checks of the grinder are performed and worn parts are replaced.

2. Determine critical control points (CCPs) — This identifies a step in the process at which control must be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard. Examples of CCPs may include cooking times and temperatures, chilling times and temperatures, or pH control.

3. Establish critical limits — Provides a maximum or minimum value to which the biological, chemical, or physical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The critical limit distinguishes between safe and unsafe operating conditions at a CCP. Each control measure has one or more critical limits, and they must be scientifically based. For example, if a chilling step is selected as a CCP for controlling bacterial growth, a certain time and rate would be specified (e.g. product temperature must be reduced from 140°F to 40°F in six hours).

4. Establish monitoring procedures — These are a planned sequence of observations or measurements (e.g. collection of data) to assess whether a CCP is under control, and to produce an accurate record for future use in verification. Monitoring facilitates tracking of an operation, shows if there is a loss of control at a CCP, and provides written documentation for use in verification. For example, if the chilling step as indicated above was used as a CCP, then you may want to monitor and record temperatures every half hour.

5. Establish corrective actions — This part of the HACCP program specifies what is done when a deviation occurs: Who is responsible for implementing the corrective actions? What happens to the product? What caused the deviation? How can it be prevented from reoccurring? Producers must generate a record documenting these decisions.
6. **Establish record-keeping and documentation procedures** — These records should include the following:

- Sanitation program records — SSOPs and others required in 9 CFR 416.
- Prerequisite program records — USDA-FSIS will view prerequisite program records that are identified in HACCP plan.
- Hazard analysis and decision-making information — these records should include the rationale for identifying hazards and selecting critical control points.
- HACCP records — monitoring, pre-shipment review, corrective actions, verification, annual HACCP reassessment.

7. **Establish verification procedures** — Verification consists of those activities that determine the validity of the HACCP plan and show that the system is operating according to the plan. Part of verification is validation. Validation is the scientific information, in-plant data, or expert opinions documenting that the existing process(es) — and their respective critical control points, critical limits, and monitoring procedures — produce a safe food product. A validation example might be the documentation used to select a cook step to control salmonella in a ready-to-eat product, the minimum time and temperature needed to cook the product, and the frequency of temperature monitoring to ensure safety. The second part of verification is to “verify” that the validated plan is being followed correctly. Examples of “verifying” include: calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions, and review of records generated and maintained in accordance with 9 CFR 417.5(a)(3) ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr417.5.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr417.5.htm)). Verification procedures are the most difficult part of developing a HACCP plan for small and very small processors. A separate fact sheet in this series deals specifically with those issues.

5. **Meeting state and federal regulations**

Two laws directly pertain to meat and poultry processing food safety: the Federal Meat Inspection Act and the Poultry Products Inspection Act. In order to process meat or poultry, processors must comply with the regulations developed to assure that these laws are obeyed. These regulations are maintained in the Code of Federal Regulations in Title 9. Requirements for a sanitation program are contained in 9 CFR 416. Regulations mandating a written HACCP plan are contained in 9 CFR 417. At least one employee or their representative at a meat or poultry slaughter or processing plant must meet minimum HACCP training requirements (9 CFR 417.7). HACCP training is offered through many university Extension programs, private food consulting firms, the Food Products Association, and numerous trade organizations.
6. Action steps for the processor

✓ Look up, print, and read the sanitation regulation for meat and poultry processing in the Code of Federal Regulations Title 9, Part 416.
  ▶ www.access.gpo.gov/nara/cfr/waisidx_02/9cfr416_02.html

✓ Select the person(s) who will make up the HACCP team. Look up, print, and read the HACCP regulations for meat and poultry processing in the Code of Federal Regulations Title 9, Part 417.
  ▶ www.access.gpo.gov/nara/cfr/waisidx_02/9cfr417_02.html

✓ Enroll in an introductory HACCP course through the Purdue Department of Food Science (www.foodsci.purdue.edu) or another provider.

Other publications in this series
  ▶ www.ces.purdue.edu/extmedia/FS/FS-21-W.pdf

FS-22-W, Small Meat Processing Plants: A Pest Control Program
  ▶ www.ces.purdue.edu/extmedia/FS/FS-22-W.pdf

FS-23-W, Small Meat Processing Plants: A Recall and Traceability Program
  ▶ www.ces.purdue.edu/extmedia/FS/FS-23-W.pdf

FS-24-W, Small Meat Processing Plants: Verification Programs
  ▶ www.ces.purdue.edu/extmedia/FS/FS-24-W.pdf

FS-25-W, Small Meat Processing Plants: Selection and Maintenance of Temperature Measurement Devices
  ▶ www.ces.purdue.edu/extmedia/FS/FS-25-W.pdf

Additional resources
Purdue Department of Food Science,
  ▶ www.foodsci.purdue.edu/outreach

Food Safety and Inspection Service of the USDA,
  ▶ www.fsis.usda.gov

FSIS food safety resources for the small and very small plants,

Acknowledgement
The author would like to acknowledge the financial support of the United States Department of Agriculture/Food Safety Inspection Service/Strategic Initiatives, Partnerships, and Outreach Office in developing this fact sheet. This fact sheet was developed with a portion of the funds provided from cooperative agreement FSIS-C-30-2003.

For additional information
Kevin Keener
Associate professor, food process engineer, and Extension specialist
Director, Food Technology Development Laboratory
Purdue Department of Food Science
West Lafayette, IN 47907-2009
Phone: (765) 494-6648
kkeener@purdue.edu