An estimated 75 million cases of foodborne illness occur annually in the United States. A large majority of these result from poor hygiene practices. For example, it has been documented that between 30 percent and 50 percent of persons do not wash their hands after using the restroom. Proper training of employees is the primary means to reduce food contamination in a processing plant.

Introduction

A small meat processor must understand the basic principles behind Sanitation Standard Operating Procedures (SSOPs) and Good Manufacturing Practices (GMPs) and how to comply with them. For meat and poultry processors, SSOPs are the foundation of the plant’s many food safety programs. Creating and complying with SSOPs can be challenging for the small processor. And understanding the similarities and differences between SSOPs and GMPs is difficult. This fact sheet provides a basic understanding of these two food safety regulations and guidelines for complying.

1. What are GMPs?

Good Manufacturing Practices (GMPs) contain both requirements and guidelines for manufacturing of food and drug products in a sanitary environment. The Food and Drug Administration (www.fda.gov) has developed GMPs for all foods, and that agency enforces those GMPs for all foods except meat, poultry, and egg products. The U.S. Department of Agriculture’s Food Safety Inspection Service (www.fsis.usda.gov) has regulatory authority for those products. USDA-FSIS has developed a Sanitation regulation (Code of Federal Regulations Title 9 Part 416, www.access.gpo.gov/nara/cfr/waisidx_07/9cfr416_07.html) to address sanitary requirements for processing...
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of meat and poultry products. Within the Sanitation regulations are requirements to produce wholesome foods under sanitary conditions and specific Sanitation Standard Operating Procedures (SSOPs). When developing SSOPs to meet USDA-FSIS requirements, it is helpful to review GMPs for nonmeat products (21 CFR 110 www.access.gpo.gov/nara/cfr/waisidx_02/21cfr110_02.html), since FDA includes extensive details on defining sanitary conditions and allowable practices.

Good Manufacturing Practice (GMP) regulations were first introduced in 1969 by the FDA as Part 128 of the Code of Federal Regulations to further implement the Food, Drug and Cosmetic Act. In 1977 this was recoded as Part 110, and it was further revised and updated in 1986, to what is now regarded as cGMPs (current GMPs).

1.1 GMPs categories
1. General maintenance of physical facilities
2. Cleaning and sanitizing of equipment and utensils
3. Storage and handling of clean equipment and utensils
4. Pest control
5. Proper use and storage of cleaning compounds, sanitizers, and pesticides
6. Employee training
7. Plant design
8. Quality assurance assessment

These are the umbrella GMPs for all FDA-inspected food processing establishments regardless of size. Specific GMPs establish regulations for particular industries and products and are in addition to the umbrella GMPs. For example, there are specific GMPs for seafood processors and dairy processors.

Meat and poultry processors are required to adhere to Sanitation program requirements in 9 CFR 416. USDA enforces 9 CFR 416, while FDA enforces 21 CFR 110. Meat and poultry plants are responsible for preventing adulteration of their products through their written Sanitation program. Practically speaking, the meat and poultry processor should understand and know GMPs, because they can serve as a valuable guide and tool when formulating the plant's Sanitation program.

2. Let's look at some cGMPs
Let's look at the Code of Federal Regulations (CFR) under Title 21 and Part 110; so go to the Code of Federal Regulations (www.access.gpo.gov/nara/cfr/cfr-table-search.html - page1), scroll down to Title 21 that covers Food and Drugs and select the latest revision. Next, select the range that includes Part 110 that is Current Good Manufacturing Practice in manufacturing, packing, and holding human foods. Finally, browse through the GMPs to get a general overview of the regulations and how they are written.

2.1 cGMPs and personal hygiene
Cross-contamination of food by foodhandlers is the most frequent cause of contamination. Employee hygiene is essential, because the hygienic condition and habits of workers determine the amount of cross-contamination from worker to food products. It cannot be overemphasized that clean, sanitary workers are necessary to produce clean, sanitary food products.

Many cGMPs focus directly on reducing foodhandler contamination. Look at Code of Federal Regulations (CFR) Title 21, Part 110.10 (http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr110.10.htm). Examples of personal hygiene include washing hands, removing jewelry, and maintaining personal cleanliness. Also, the food processor should provide training for new employees in personal hygiene based on cGMPs, and that training should be part of a formal, written training program that consists of instruction in proper handwashing, personal cleanliness, and sanitary hygiene.

EXAMPLE:
GMPs Involved: Sanitary facilities and controls, 21 CFR 110.37e (http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr110.37.htm).
One small processor teaches correct handwashing to each employee by describing, in detail, the correct amount of soap to use, the correct water temperature, and the amount of lathering time, which is equal to the time needed to say the ABC’s. Each aspect of this employee training is written in the processor’s employee training program, with documentation that the materials were taught to employees. The GMPs about handwashing and facilities — such as sinks, toilets and towel racks — are presented in detail.

2.2 Employer’s responsibilities
1. Provide training in food handling and personal hygiene.
2. Conduct regular inspections of employees’ hygiene and hygienic work habits. Violations should be handled as disciplinary violations, and incentives for superior hygiene should also be provided.
3. Properly maintained sanitary facilities and supplies. This includes ample quantities of soap, disinfectant, working sinks, hairnets, etc.

3. Complying with cGMP regulations
As you may have noticed while browsing through the GMPs, some regulations are written so that compliance is easily evaluated. For instance, the regulation that “no pests shall be allowed in any area of the food plant” is clearly defined. If an inspector found a pest, such as a mouse, or evidence of a pest in the food plant, then there obviously is a violation of the regulation.

However, some GMPs contain phrases such as “clean as frequently as necessary to protect against the contamination of the food.” This vague regulatory language obviously is subjective. How often is it “necessary” to clean the processing line: daily, every two shifts, or when we think it needs it? Other GMPs might use the terms “adequately” or “sufficient,” which are both subjective terms. These issues highlight the potential problems of determining how often to clean and sanitize. USDA-FSIS has developed more prescriptive requirements for meat and poultry processing. The SSOPs require processors to document that the sanitation program and personal hygiene practices are adequate to ensure that foods are produced under sanitary conditions. As a processor changes technologies or practices, changes in the SSOPs are necessary and must be documented with appropriate validation.

4. What are SSOPs?
Sanitation Standard Operating Procedures — SSOPs — are the specific, written procedures necessary to ensure sanitary conditions in the food plant. They include written steps for cleaning and sanitizing to prevent product adulteration. SSOPs are required in all meat and poultry processing plants, CFR Title 9 Part 416. The cGMPs can help guide the plant when the plant’s SSOPs are being developed. The SSOP procedures are specific to a particular plant, but may be similar to plants in the same or a similar industry. All SSOP procedures must be appropriately documented and validated.

Both pre-operational (before daily processing begins) and operational (during processing) sanitation needs are included in SSOPs to prevent direct product contamination or adulteration. Therefore, the decision about how often to clean the processing line would be addressed in the plant’s SSOPs and supporting documentation.

4.1 Pre-operational SSOPs
These are established procedures that describe the daily, routine sanitary procedures that occur before processing begins. The procedures must include the cleaning of product contact surfaces of facilities, equipment, and utensils to prevent direct product contamination or adulteration. These might include: 1.) Descriptions of equipment disassembly, reassembly after cleaning, use of acceptable chemicals according to label direction, and cleaning techniques. 2.) Application instructions, including concentrations, for sanitizers applied to product contact surfaces after cleaning.
4.2 Operational SSOPs

These are established procedures that describe the daily, routine sanitary procedures that will be conducted during operations to prevent direct product contamination or adulteration. Established procedures for operational sanitation must result in a sanitary environment for preparing, storing, or handling any meat or poultry food product. Established procedures during operations might include, where applicable: 1) Equipment and utensil cleaning/sanitizing/disinfecting during production, as appropriate, at breaks, between shifts, and at mid-shift cleanup. 2) Procedures for employee hygiene, such as cleanliness of outer garments and gloves, hair restraints, handwashing, health, etc. 3) Product handling in raw and in cooked product areas.

SSOP records must be maintained on-site for 48 hours and maintained for a minimum of six months.

5. Meat and poultry SSOPs

The SSOPs for meat and poultry plants must meet the following regulatory requirements:

1. The plant has written SSOPs describing daily procedures that will be conducted before and during operations to prevent direct product contamination or adulteration. At a minimum, these procedures must address the cleaning of food contact surfaces, equipment, and utensils. The SSOPs state the frequency at which each procedure will be verified.

2. The SSOPs are signed and dated by plant management or plant owner. SSOPs should be reviewed periodically.

3. The plant must identify individual(s) who will be responsible for implementing and monitoring SSOPs and the daily sanitation activities.

4. Written records of SSOP activities along with corrective actions must be maintained for a minimum of six months (48 hours on site).

6. Action steps for the small processor

- Find, read, and retain a copy of the cGMPs for the specific type of food plant. These regulations are located in the Code of Federal Regulations (CFR), Title 21, Part 110.
- Find, read, and retain a copy of the SSOP requirements for meat and poultry processing. CFR, Title 9, Part 416.
- Develop written policies for personal hygiene that address SSOPs in the plant including handwashing, gloves, jewelry, hairnets, policies for sick employees, etc.
- Include written SSOPs in the employee training program, specifically those associated with personal hygiene and the plant’s policies on checking that employees are following the established procedures.
- Ensure that all sanitation procedures in the SSOPs include verification frequencies, identify responsible persons and supervisory personnel, and describe in detail all verification activities.

Meat and poultry plants are unique because they are required to develop, maintain, and adhere to written SSOPs. The plant must identify, by position, the officials who monitor daily sanitation activities, evaluate and document whether the SSOPs are effective, and take appropriate corrective action when needed. Finally, SSOPs must be routinely verified to ensure that they are working properly. Microbiological testing should be done periodically on food and noncontact surfaces to verify the effectiveness of the established procedures.
Other publications in this series
FS-20-W, Small Meat Processing Plants: Overview of HACCP (Hazard Analysis Critical Control Point)
  www.ces.purdue.edu/extmedia/FS/FS-20-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

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