Are you confident that your sanitation program is working effectively to produce a safe product? How important are you going to make sanitation in your plant? It’s your call.

How important is sanitation? VERY! However, only you and your company can determine how seriously you are going to take it.

Most people have been part of a sanitation program from as early as primary school, but may not have recognized it. As children we were directed to clean our rooms, put our clothes away, wash our dishes, and do other dreaded chores. Whether a formal chore chart or an informal household rule, your family likely followed some sort of cleaning schedule: dishes were washed daily; laundry was washed, folded, and put away weekly; and cleaning your dungeon room may have ranged from weekly to yearly!

These tasks probably were not documented, frequencies assigned, or completion dates recorded, but you were learning your role in your home’s master cleaning schedule (MCS).

For each of those household chores there was likely a procedure to be followed. Dirty dishes probably need to be scraped and rinsed before placing in the dishwasher. Dirty laundry needs to be pre-treated, pulled right-side out, and sorted by color before loading in the washing machine. These procedures probably were not written, but your parents had specific
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Master cleaning schedules are used to track required and completed cleaning tasks that occur less often than daily. They should list the area or equipment to be cleaned, required frequency, and person(s) responsible for carrying out the task.

<table>
<thead>
<tr>
<th>Area</th>
<th>Frequency</th>
<th>Assigned To</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
<th>Week 9</th>
<th>Week 10</th>
<th>Week 11</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Box Erector</td>
<td>Weekly</td>
<td>Sanitation</td>
<td>1/3 TW</td>
<td>1/9 TW</td>
<td>1/15 TW</td>
<td>1/22 TW</td>
<td>1/29 TW</td>
<td></td>
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<tr>
<td>Fryer Boil Out</td>
<td>Bi-Weekly</td>
<td>Mark or Bill</td>
<td>1/2 TW</td>
<td>1/16 TW</td>
<td>1/30 TW</td>
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<tr>
<td>Warehouse Perimeter</td>
<td>Monthly</td>
<td>Warehouse</td>
<td>1/25 MW</td>
<td></td>
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</tbody>
</table>

Sanitation instructions they taught you to follow to ensure the cleaning activities were successful.

How many of your household chores were verified and validated? Probably all of them - even though you didn’t realize it.

Your parents most likely checked to make sure you completed the chores properly; that was verification. Validation happened when your parents opened the clean dishwasher, then informed you that food remained on the dishes because you forgot to pre-rinse them. The completed task did not achieve the desired results of clean dishes. That means that something in the MCS (e.g., cleaning procedures, cleaning equipment, cleaning chemicals, or operator training) needed to be modified to achieve the desired results.

Since we were trained to follow a “sanitation program” as children, why do so many adults still tend to struggle so much with sanitation programs in food facilities? Let’s take a look at some examples of how sanitation impacts the food industry and what is required of sanitation programs.

REGULATORY ACTION

The FDA and USDA-FSIS division provide information about inspections, recalls, warning letters, and other actions taken by regulatory agencies. These actions are often directly linked to sanitation issues within a company. One such example is USDA closure, for an indefinite period of time, of a California meat facility for failing to meet cleanliness standards. “FSIS withdrew our inspectors and suspended operations due to insanitary conditions at the establishment,” the agency said in an emailed statement to Food Safety News. “The plant’s suspension will be lifted once we receive adequate assurances of corrective action.”

Recent FDA Warning Letters. Additional examples found in FDA warning letters for which companies have 15 business days after receipt of a letter to respond to identified issues. These letters are typically addressed to the president, CEO, or owner of the affected company. In the following, dates and other identifying information have been changed to protect the food companies. Read through them twice: first as a sanitation supervisor, second as a president, CEO, or owner.

- Your firm failed to demonstrate the procedure used for cleaning and sanitizing of equipment is effective, as required by 21 CFR 110.35(d) (5). On [date] your firm was advised environmental sampling for Listeria would be performed in your production areas. Your firm performed a (b)(4) cleaning and sanitization of all equipment on [date]. On [date] investigators took environmental swabs from numerous production areas in your facility. A total of four swabs were positive for Listeria. These findings from areas in close proximity to food-contact surfaces are indicative of insanitary conditions in your facility and highlight the need for more effective cleaning and sanitation operations.

- Your firm failed to take reasonable precautions to ensure that production procedures do not contribute to contamination from any source, as required by 21 CFR 110.80. On [date] our investigators observed the cleaning of [equipment] using caustic foam cleaner, (b)(4) to clean food-contact surfaces of equipment in the [room]. During the inspection it was observed employees did not verify the proper strength of the cleaner as required per your firm’s standard operating procedure (SOP).

- Your firm failed to maintain gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

THE IMPORTANCE OF SANITATION GOES BEYOND REGULATORY ACTION. IT IS A SIGNIFICANT PROGRAM THAT IMPACTS ALLERGEN, MICROBIOLOGICAL, PEST ACTIVITY, AND/OR SAFETY ISSUES WITHIN THE PLANT.
condition, as required by 21 CFR 110.10(b)(5). For example, on [date] our investigators observed (b)(4) employees cleaning and handling spilled product in the [equipment] and touching inside of trash containers. The employees resumed packaging finished product without washing hands and replacing their gloves; your firm was manufacturing [product name].

• Your firm failed to maintain equipment, containers, and utensils used to convey and hold food in a manner that protects against contamination during manufacturing and/or storage [21 CFR 110.80(b)(7)]. Specifically, on [date], our investigator observed cobwebs and dust directly above a scale filled with [ingredient name]. This ingredient was being used to make [product name]. In addition, there were cobwebs directly above machinery being used to form [product name].

• Your firm failed to properly identify and store toxic cleaning compounds in a manner that protects against contamination of food [21 CFR 110.35(b)(2)]. Specifically, on [date] our investigator observed an unlabeled spray bottle filled with a red liquid lying on top of a rack just above [ingredient name] being held for the production of [product name].

• Your firm has not designated an individual or individuals to supervise overall sanitation in the plant as required by 21 CFR 110.80.

How do you feel as the supervisor? How do you feel as the president, CEO, or owner?

THE IMPACT OF SANITATION
It is clear that issues within the sanitation program can lead to regulatory action against a company. But, the importance of sanitation goes beyond regulatory action. It is a significant program that impacts allergen, microbiological, pest activity, and/or safety issues within the plant.

Allergens. Allergens are currently the #1 reason for a food recall in the United States. Sanitation is certainly not the main reason that an allergen control program fails, but it is an important component of an effective allergen control program.

When a company uses equipment or production lines that produce both allergen and non-allergen products, the allergen residue (protein) must be removed when the non-allergen containing products are ran. Sanitation is one of the most common and effective means to ensure the protein residue is removed from surfaces. Depending on the products being produced, this may be a dry cleaning method for some materials or it may require a wet/chemical wash. In all instances, the sanitation procedures established for
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this process must be validated to ensure they are effective. Once these procedures are validated and implemented, the actual task should be verified each time it is carried out. Each company must determine how the verification and validation of the allergen cleaning will be carried out and ensure these procedures are reviewed any time changes are made. Changes may include new equipment, different cleaning chemicals or tools, product modifications, etc.

**Microbiological.** Microbiological issues are a significant reason for food safety failures and may be introduced from the food plant environment, employees, ingredients/raw materials, or the equipment. Effective sanitation programs can reduce or eliminate the risk in many of these areas. Environmental monitoring has been and is becoming a greater focus of food companies and regulatory agencies.

Sanitation programs must address elements such as:

- Outside grounds
- Air handling equipment
- Ceilings, walls, and floor
- Transportation equipment (forklifts, pallet jacks, trailers, rail cars, etc.)
- Employee welfare areas (lunch rooms, break rooms, restrooms)
- Support areas (boiler rooms, chemical areas, maintenance shops, janitorial closets, etc.)

The focus of the sanitation program is to remove or destroy the microbiological organism and remove any organic material from those areas that may support the survival or growth of the organism.

**Pest Activity.** Most of the food products in our food plants are a food source for rodents, birds, and insects. The sanitation program should be designed to remove food residue from equipment, building, and structures frequently enough to prevent the pest attraction or support their growth and reproduction.

When pest activity is noted within a food plant, the common response is to point fingers at the pest management...
Sanitation

Sanitation and cleaning tasks must be completed in manner that will not harm employees carrying out the cleaning tasks. Some activities require employees to clean potentially dangerous equipment or areas of the plant. These must be carried out in a way that does not pose the risk of employee injury. Other cleaning activities may require the use of chemicals that can cause employee injury as well.

Sanitation also may be necessary to keep the workplace clean to prevent slips, trips, and falls and to prevent excessive dust from accumulating and developing into combustible dust situations. The frequency of the cleaning activity is key in these instances. Careful thought and consideration about how and how often these tasks are carried out is necessary.

Training and education must be provided to all employees carrying out sanitation tasks to avoid accidents and injuries.

Regulations. Sanitation has been part of the Good Manufacturing Practices (GMPs) in section 110.35 since their beginning. It is important to read and understand the GMPs to fully comprehend what is necessary for your sanitation program.

Some of the general requirements include that buildings, fixtures, and other physical facilities of a food plant are maintained in a sanitary condition to prevent food from becoming adulterated; that cleaning and sanitizing of utensils and equipment protects against contamination of food, food-contact surfaces, or food packaging materials; and that cleaning compounds and sanitizing agents are free from undesirable microorganisms and safe and adequate under the conditions of use.

A Hazard Analysis Critical Control Point (HACCP) program is required for some sectors of the food industry, and it is used by most food companies. But a HACCP program cannot be successful without effective prerequisite programs. Sanitation is one of those required prerequisites. A well developed and effective sanitation program is necessary to support the HACCP program and help control identified hazards identified.

The Food Safety Modernization Act (FSMA) is the most recent and significant change for the food industry. Within FSMA, sanitation will be a required preventive control that a food company must have in place to address hazards. FSMA will require the sanitation program to have specific monitoring, verification, validation, and corrective action measures in place. FDA inspectors will be inspecting records that prove those activities have occurred.

Food industry employees must understand how to implement, manage, and revise sanitation programs to ensure we produce safe food products and protect the employees carrying out sanitation tasks. Sanitation programs will continue to receive scrutiny and oversight by regulatory personnel. Are you confident that your program is working effectively to produce a safe product or are you fearful of receiving an FDA warning letter? Bottom line, how important is sanitation to you and your company? AIB

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