ENGINEERING, AUTOMATION and DESIGN, Inc.

Hygienic Separation Design Is the Key for Integrated Food Safety

Hygienic Segregation Design is the Key to Integrated Food Safety

Executive Summary

This white paper is addressed to the CEOs of Food Processing Companies, Food Processing Plant Engineers and Hygiene Specialists who are responsible for the design and construction of a new food processing plant, an addition to an existing one or the renovation of an existing one. To them, food safety is job number one. This paper discusses how to design a food processing plant to minimize Cross-Contamination. Hygienic Segregation is the key factor in this process. The design features of the ideal plant will be presented and the consequences of a less than ideal design will be described. Design features must comply with current Good Manufacturing Practice (GMP – 21CFR Part 110) for food processing plants and the Safe Quality Food 2000 Code (SQF 2000 Code). The SQF 2000 Code is the US food safety standard that has been benchmarked to the Global Food Safety Initiative (GFSI). The emphasis in this paper is on the Ready to Eat (RTE) food processing type of plant since the requirements for these plants envelop those for other food processing plants. Guidance is also provided on what to look for when hiring an engineer/constructor team to design the ideal food processing plant.

Introduction

Contamination –A Food Processing Plant's Worst Nightmare

What keeps food processing plant managers and engineers up at night? It's the possibility of shipping contaminated food and making people sick. While some plants believe that food safety can be inspected into the products, it is not the best way to ensure food safety and can result in a lot of wasted product. Remember, testing finished product is a validation that your food safety systems are working and nothing more.

In most cases when contamination has occurred it has been found to be the result of poor plant design, equipment design, maintenance or unsuitable construction methods during plant modifications or expansions. Therefore, the optimum solution is to design food safety into the facility through proper plant and equipment design followed by proper construction and maintenance practices. This way, the food safety goes into the box before the name goes on it and the plant manager has fewer nightmares.

Contamination comes in a variety of forms – raw materials, products, equipment, tools, personnel, shipping containers, animal/insect intruders, etc. The bottom line - it is stuff being in places it shouldn't be.

So, what does it take to design the ideal plant with Hygienic Segregation to minimize cross-contamination.

Hygienic Segregation Design Requirements for the Ideal Food Processing Plant

Design Of A Food Processing Plant Goes Beyond Conventional Industrial Plant Design

Completing a design project for a new food processing plant, a plant addition or a plant renovation is a complicated and detailed task. It involves activities above and beyond those normally associated with design projects at non-food industrial plants, namely, food safety hygienic processes. To ensure success, both the plant operator and the selected engineer/constructor must understand and implement Food Current Good Manufacturing Practices (21 CFR Part 110) (GMP) and the SQF 2000 Code (recognized by GFSI as meeting its benchmark requirements). SQF 2000 links the primary production certification to the certification of the food manufacturing process. The key factors that ensure the design of a successful food processing plant are described in this white paper. Since Hygienic Segregation is the key to a successful design, those areas and activities in which segregation is most beneficial will be discussed. These are:

Key Areas For Hygienic Segregation To Minimize Contamination

- Product Flow
- Personnel Flow
- Welfare Areas
- Environmental Control

Each of these areas involves a number of different processes, materials and equipment.

Product Flow

Product Flow Segregation

The single most effective means of minimizing contamination is the use or implementation of a straight through design. This means the downstream product never contacts any of the materials upstream in the process nor is it routed back through upstream processes. Under normal plant operations this design works well but what about under abnormal conditions? If a portion of a process line must be rerouted for repairs or modifications, how is Hygienic Separation maintained in the rerouted process flow? The project design and work scope must take this into account.

<u>Raw Ingredients and Packaging Materials</u>

Raw Ingredients

Raw materials can arrive at the plant in different ways and must be segregated as

follows:

- Bulk truck or rail car

  All bulk materials must be placed in temporary storage for microbial testing prior to transfer to bulk storage for process use. The following bulk materials must be stored separately and ideally handled with dedicated equipment:

  - Bulk allergen containing materials
  - Bulk organic materials
  - Liquid bulk material

- Palletized goods

  Upon receipt, palletized goods must be transferred from wood to plastic pallets

  Wood pallets cannot be sanitized and are prone to carrying hitchhikers of various types that can contaminate food ingredients or finished products. Wood pallets must be stored in a segregated storage area while awaiting return

- Hand add ingredients

  Hand add ingredients can be added at any point in the process and must not share process paths or equipment with other raw or in process materials and need separate storage.

- Packaging Materials

  Packaging materials should be handled with dedicated equipment and must be stored in a designated warehouse location.

<u>Ingredients Segregated from Storage to Point of Use.</u>

Ingredients Segregated from Storage to Point of Use

All raw ingredients must be verified throughout the use cycle of the ingredient to eliminate the possibility of contaminating a product with an ingredient that is not intended for use in the product. The ingredients must be segregated throughout their lifetime within the facility. The ingredient must also be verified between the following stages of their use cycle.

- Bulk receiving to warehousing
- Warehousing to staging

- Staging to point of use

Such verifications will eliminate cross contaminations associated with the actual ingredients themselves. An example of this would be an allergen accidentally making its way into an allergen free product. This can be as harmful to the consumer as a microbial contamination of the finished product.

Processing

Processing

Raw materials for each plant process should follow a separate route from storage to point of use. Each type of food ingredient must be segregated from other types such as Allergen from Non-Allergen, Organic from Non-Organic, etc. to avoid cross-contamination which, even though it may not be dangerous, does change the food type.

Equipment Layout and Design

Equipment Layout and Design

Equipment layout is critical in combatting contamination. A key principal of sanitary layout is that the equipment must be configured to make it accessible. Sufficient clearance around the equipment and between different pieces of equipment must be provided to allow access for cleaning. Also, equipment that requires disassembly for sanitation must be given additional space to allow for maneuverability of maintenance personnel and the parts being removed

- Equipment should be designed for pass through operation having one point for entry of raw materials with the exit of finished product at the opposite end. Some multi-pass dryers have incoming product and the product discharge on the same end with the raw product entering above the finished product. A pass through design is desirable to avoid routing raw ingredients adjacent to product or in-process product.

Equipment Design is critical to the sanitation effort and should include the following considerations:

- Equipment should be of stainless steel construction and provide adequate access points for cleaning
- Equipment must be designed to eliminate nooks and niches that can provide a home for microorganisms
- Equipment must be designed to avoid ledges and landings within the product path through the equipment
- Equipment must be easy to disassemble for sanitation. Equipment that is not easily disassembled is often times neglected when it is supposed to be cleaned.

- Last but not least, it must be possible to clean the Equipment at a microbial level

Product Line Segregation

Product Line Segregation

Cleaning and sanitation of the production lines is a must. This is typically done through the use of wash down or blow down procedures to bring the debris to the floor where it can be washed to a drain or swept up and discarded. However, how does this activity impact the adjacent areas? Are you spreading contaminants to another area of the facility when you are "cleaning."? Whether or not you realize or accept it, the answer is, yes. The best solution to this ongoing issue is the segregation of the production lines themselves. This is best accomplished by the inclusion in the design of walls or other contaminant impervious physical barriers between process lines. This may seem excessive. However, by doing this, one line could be taken out of production for maintenance, sanitation or even be completely removed and replaced without impacting adjacent areas in the facility. This would also enable Allergen and Non-Allergen product lines to operate next to each other.

Personnel Flow

Plant personnel are mobile and can become transporters of contamination between processes. The tools that the personnel use can also become transportation for contaminants. The foot traffic of personnel, such as in break rooms, can be a source of contamination passed from worker to worker. To prevent inadvertent contamination by personnel and the tools and equipment they use to perform their tasks, Hygienic Segregation is required.

Segregation of Personnel by Work Areas

Personnel Segregation by Work Areas

Since personnel mobility can be a major source of cross-contamination, the plant design and operating procedures should include segregation of plant personnel by their areas of responsibility as well as for the associated welfares areas. Training of personnel in segregation requirements is a must. The following can help with personnel awareness and compliance:

- Color coded work clothes
- Color coded badges
- Key pad access to plant areas

<u>Segregation of Maintenance Personnel</u>

Maintenance Personnel

One of the biggest challenges that facilities face is the segregation of the maintenance personnel. How do you restructure the maintenance staff to keep

out of certain areas? Based on the facility and equipment knowledge certain individuals have, it doesn't make much sense to keep them segregated to "their" part of the plant. As this is the case more often than not, captive clothing and footwear are the best solutions. Footwear and clothing worn in the areas shown below should stay in the area and when maintenance personnel change areas, their clothing and footwear are also changed.

If possible, separate maintenance personnel should be assigned to the following areas. However, if segregating your maintenance staff is impractical, the captive footwear and clothing program should be implemented for maintenance personnel traveling between the following areas:

- Raw Ingredients
- Processing
- Packaging
- Warehousing

Segregate Storage of Maintenance Materials and Equipment

Segregation of Maintenance Materials and Equipment

The plant design must include facilities for the sanitization of maintenance materials and equipment:

- Before entering the facility
- Before entering maintenance areas and again upon leaving maintenance areas for use within the plant
- Before introduction to any part of the plant

Tool Segregation

Segregation of Tools

Tools represent an attractive mode of transportation for contamination and bacteria from one part of the plant to others. Consequently, the design should include segregation of tool usage for the following areas:

- Maintenance shop areas
- Raw ingredient areas
- Process areas
- Packaging areas

Chemical Segregation

Chemical Segregation

Chemicals used in the facility should be segregated by area of use and access to these chemicals shall be controlled. Chemical storage areas are all too often overlooked. Chemical contamination of a product is unlikely if the chemicals are controlled

Welfare Areas

Welfare Areas

Welfare areas in the plant include: locker rooms, restrooms, break rooms and offices for personnel use. To avoid cross-contamination of plant areas each of the following areas should be provided with its own set of welfare areas:

- Raw ingredient receipt
- Processing
- Packaging
- Maintenance
- Warehousing

Welfare areas such as locker rooms, rest rooms, etc. should not open directly into process areas. Segregation of these areas from the operations portion of the facility is required.

Environmental Control

Environmental Control Key to Fighting Contaminants

Environmental control is possibly the most critical of all plant systems as far as contamination is concerned in that it affects airflow, temperature and moisture throughout the plant. Airflow can carry contaminants throughout the plant if the system is not properly designed. Temperature and moisture are essential to the growth and propagation of all types of contaminants and bacteria. If the air handling systems are not maintained, you may be creating a problem that will have long-term impacts on the facility.

Separate Systems for Each Area

- The plant should be designed so that each of the following areas has its own air handling system.
    - Raw ingredient receipt
    - Processing
    - Packaging
    - Maintenance
    - Warehousing

Air Management

- The venting of the systems should be designed such that the intakes are not close to process exhaust stacks. Contaminants can be recycled back

into the plant through roof top air handling equipment if it is located too close to adjacent product line exhausts.

- Processing and packaging areas within the facility that handle product after it has passed through the Critical Control Point in the production line should be designed with positive pressure to ensure that contaminant infiltration from adjacent areas is minimized.
- Welfare areas should be designed with negative pressure to ensure that any contaminants present in these areas remain there when a door is opened and the exhaust fans should be vented to the outside away from any air intake for process areas.
- The outside air entering the plant must be filtered with appropriate HEPA filters that are changed regularly.

Water and Waste Water

Water Management

Water is an essential ingredient for many of the processes in a food plant but if the water finds its way into places where it does not belong it can become a breeding ground for undesirable contaminants. This is particularly true if the water flows from the raw ingredient areas to the process and finished product areas. Pooling water is bad. Floors should be designed to take water away from process areas and direct it towards floor drains. A plant designed to stay dry is a safer plant.

Property and Surrounding Area

Exterior of Plant

Control of the environment outside the plant is also important. The design should avoid grass abutting the plant. Trees and bushes should be kept neat and located away from the plant. Site grading and maintenance is important to ensure that the exterior of the plant does not harbor contaminants, insects or vermin that could make their way into the plant. All openings in walls, floors and ceiling should be sealed to prevent ingress of contaminants and pests.

Outside lights can attract many types of insects. Locate them away from the plant buildings.

Plants should not be located close to landfills, sewage treatment plants, refineries, junkyards or any other facility that can produce airborne contaminants.

Sanitary and Process Waste

Waste Management

All food-processing plants produce waste products. The safe disposal of this waste must be factored into the plant design. Segregated routes must be provided to remove waste from the process areas. These routes should avoid passing

through raw ingredient, in process or finished goods areas to the greatest extent possible.

Negative Consequences of Non-Ideal Design

Negative Consequences of Non-ideal Design

There are a number of negative consequences, which can impact the food safety, and the cost of maintaining the same level of safety possible with an ideally designed plant.

A non-ideal plant design will consist of systems, structures, components and/or layouts that are not conducive to a food safety strategy. The use of a facility or a facility that was not built to suit the requirements of the food safety program(s) used will require increased efforts to prevent food safety risks. Often times these facilities were built with food safety in mind but due to customer demands, the plants are forced to expand their operating capacities. These "expansions" do not always include the addition of square footage but include the installation of more equipment that was not in the original plan for the facility. This can amplify food safety risks already present in the facility. It will take significantly more effort to prevent risk in terms of added personnel and added sanitation to manage a facility with a less than ideal design. An ideal plant will provide a higher level of protection (less risk) at a lower cost. This ongoing cost over the life cycle of the plant far exceeds the costs associated with the proper design, procurement and construction of a building suitable for the facility from the start.

What to Look for in an Engineer/Constructor for Food Processing Plant Design Projects

What to Look For When Selecting a Designer/Constructor for Food Plant

The key factor to consider when selecting an engineer/constructor is recent experience in food industry processing plant design - ideally in the type of plant under consideration.

The other factors which should be considered are:

- Principals or top management with food industry backgrounds
- Long-term clients in food industry
- Testimonials from satisfied clients
- Integrated team consisting of engineers and constructors under the same management to minimize handoffs and communication problems
- Team qualifications – food industry background preferred
- HACCP certification

- SQF 2000 Code practitioners on staff
- Engineer hiring criteria – food industry experience more important than training
- Project managers to monitor FDA, USDA and GFSI requirements to ensure compliance
- Training of design personnel in Food GMP, SQF 2000 Code and other GFIS requirements that may become effective during the design process period.

EAD Has What It Takes to Provide the Food Industry With the Ideal Design

About EAD

Founded in 2001, EAD Engineering was created around the food processing industry. As the relationships grew between EAD and their earliest clients it became apparent that there were several other avenues in which EAD could provide support to the food processing industry. This realization, along with the desire to support their clients, opened the doors for EAD Controls, EAD Constructors and EAD Management Services.

EAD Views Itself as An Extension of Client's Staff and Acts Accordingly

EAD regards itself as an extension of the client's staff rather than a separate entity. The company prides itself on providing a team approach thus eliminating the "us and them" mentality that is often associated with bringing in outside resources.

EAD manages their projects to the clients' requirements using all required reporting methods and procedures to eliminate data transfer or conversion from one report to another. EAD prides itself as being the go-to source for their clients. If a client is in need of project team or just one person to support a project, EAD's level of dedication is the same. EAD is client focused and strives to celebrate the success of the relationship as well as the project.

EAD's staff is familiar with the demands of an operating food processing facility and can offer a staff of Engineering, Automation and Construction professionals to support your needs. Currently 90% of the EAD staff is HACCP certified and both EAD Constructors and EAD Engineering have SQF practitioners on staff.

Contact Information

Many of our clients have been with our firm since its inception. Due to the confidentiality of our business, a client list can be provided only upon request.

To learn more about EAD's food industry experience, call Ryan C. Amys at 402-884-8650