Food Safety: Focused Facility & Equipment Hygienic Design Strategies

Presentation Overview:
Food Manufacturing facilities are required to review their production system to determine if they have any mitigation strategies to protect food against intentional adulteration or complete their own vulnerability assessment. Once that is completed, manufacturers would need to identify actionable process steps, which are points, steps, or procedures in a food process that will require focused efforts to reduce any such risks. Facilities are also required to complete a written food defense plan. Once in place, the Food Safety Modernization Act (FSMA) would establish measures that a food facility would be required to implement to protect against the intentional adulteration of food. A key deliverable in achieving this goal is designing facilities and equipment to proper hygienic design levels.

FDA Guidelines: Equipment, Tools, Buildings, and Sanitation: Subpart L

One item which is generally not discussed in food manufacturing is how to design facilities which provide the ability to perform proper cleaning and sanitization for low water activity products. As example, a typical approach for handling low water activity products is to dry clean and attempt to heat sanitize without introducing water or other fluids for cleaning and sanitization (which could increase the micro risk). This is a developing area with great importance for control of pathogens in oil processing preparation and extraction areas. Without a kill step in place, all oil processing operations and finished products developed from oil extraction have shown sensitivity to potentially harmful microbiological contamination.

In oil processing operations there are known micro contaminants (i.e., Salmonella) entering with raw materials used in the production of the finished product. To mitigate any possible risk, a microbial "kill" step is involved to eliminate the micro impact. This "kill" step requires raising the product ("the ration") up to 85 degrees C (185 degrees F). This step includes the addition of steam and water as a conditioning step within the extruder process and holding this ration temperature for a minimum of five (5) seconds at 19% minimum moisture content. This "kill" step allows a 5-log rate reduction to properly diminish any impact of Salmonella. Hygienic design equipment requirements need to comply; specifically, extruders, coolers, dryers, coating systems, packing bins and packaging equipment. In addition, dry material conveyance; e.g., "Post-Kill" dry material process handling and storage equipment need to also follow the hygienic design standards and the ANSI-BISCC (American Standard of Baking Equipment).

The purpose of this research is to define how to avoid intentional adulteration to our manufactured products. Having a "Kill" step to the manufacturing process of oil processing operations is not enough in the avoidance of microbiological contamination. Beyond having hygienic designed equipment with proper cleaning and sanitization processes for low water activity products, one must understand facility design, material flows and personnel transfers within the manufacturing environment. Before we jump to the conclusion of selecting the 'best' designs, we must provide the right technical solution(s), which is based on understanding current designs.

Current oil processing facility design problems:

1. Most oil processing sites are/were built as modifications to a feed mill operation (e.g., Prep and extraction areas).
   a) With most grain mill combinations, the problem is migration of contamination after the "Kill" step.
   b) Normally, raw materials stay on one end to the cooked side.
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c) With other oil manufacturing plants brought into contaminated materials (milled products; in-process materials with a high TVO count). Migration would then enter after the "Kill" step.
d) Personnel transverse raw material and the cooked ("Kill" step) areas. With these actions, plant personnel carried the contamination. If contamination was brought in, it was likely to migrate.

2. Incoming raw materials were never tested for pathogens such as salmonella.
3. The facility and equipment design made it impossible to properly disinfect and clean.
   a) Easy to dry clean; very difficult to disinfect without liquids.
   b) Options are heat or chemicals.
   c) Because of dry idea, tendency is not to use chemicals because this is a wet process.
   d) The scale of the equipment it was impossible to disinfect (e.g., hammer mills).

4. Existing cultures identified stigma that it is just "our products are not consumer finished products...this is the problem of the final manufacturer. Net, people will not get hurt from our processes."

**Desired oil processing facility design(s):**

1. Desired facility state and equipment design to facilitate cleaning and disinfections.
   a) Effective physical and operational segregation of raw materials (dirty side) and finished product (clean side) via the "Kill" step process.
   b) Proper HVAC pressurization between manufacturing processes and warehousing with special emphasis on "Post-Kill" pre-packaging areas.
   c) Clean design equipment standards applied that support proper cleaning and sanitization processes.
   d) Materials and flow of people facilitate the separation and segregations.

2. Raw materials tested and/or validated to meet microbial contamination limits.
3. Operating culture: Media and FSMA (Food Safety) actions have initiated appropriate actions.

Reference the below illustrations for existing vs. desired facility designs.
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Facility Design (Existing)

Facility Design (Desired)

Facility Designs (Do)
The Food Modernization Act (FSMA) proposed rule (21 CFR Section 110) identifies possible routes of microbial contamination of produce and sets requirements to prevent or reduce the introduction of pathogens. Equipment, tools, and buildings are one identified route of contamination because they may contaminate covered produce with pathogens, and adequate hygienic design standards along with executing properly timed cleaning and sanitation are important to minimize the risk of such contamination.

The potential for contamination is increased if equipment and tools come in contact with the produce, as well as the building in which growing, harvesting, packing, or storage activities take place are not sanitary. Making sure that equipment, tools, and buildings are clean and that they are also of adequate design and construction to be adequately cleaned and sanitized minimize contamination of the produce.

Up to today the FDA has controlled adulteration of food processing through the Hazard Analysis Critical Control Point (HACCP). HACCP has brought standardization to cleaning and standardization for food manufacturing facilities but has not provided preventive action. With the FSMA, the FDA will provide preventive steps to food facilities similar to what the pharmaceutical industry has been able to provide through Hazard Analysis and Risk Preventive Control (HARPC). Through the use of CAPA’s, the pharmaceutical industry provides vulnerability assessments with corrective and preventive action steps to document key control point design issues.

The subject of the FSMA act is to protect food from intentional adulteration when the intent is to cause large-scale public harm. For the purposes of this review, we will address the FSMA Part L (only) which addresses equipment and building design. Once in place, this proposed rule would establish measures that a food facility would be required to implement to protect against the intentional adulteration of food.

**There are four (4) steps required by the FSMA:**

1. Perform Vulnerability (Risk) Assessments

   - Completing the vulnerability (risk) assessments is the first step in understanding existing conditions. This risk assessment can also be used to identify potential design flaws within new projects. Actionable control steps, which can be points, steps, equipment touches or procedures in a food process, are developed to mitigate risk of intentional adulteration. Facilities are also required to complete a written food defense plan. The risk assessment can be used as a key component to document the site's food defense plan.

   - Risk Assessment is of sufficient robustness that answers the preventive design question. Format of the risk assessment is not as important as explaining to the FDA representative your thinking behind the identification of risks.

   - The risk assessment needs to be done by someone competent and experienced (Qualified Individual with background that identifies the individual is experienced performing risk assessments) Having done the risk assessments--the critical control points need to be identified and a plan developed to correct the design flaw or operation procedure. The FDA will ask of the food manufacturing facility what is being done to correct the design flaw or defect procedure. This leads to the sanitary design of equipment to prevent the risk or change to the procedure. Example: Hooking a transfer hose to a tank represents a control point. The preventive action is how to How to prevent contamination.
2. What are actions? (Linked to Risk assessment)

- The first question to ask is: Can I design the control point out?
- The second question to ask is: What are my operating procedures if I cannot design it out? (Tanker transfer hose example: A procedural change may be to steam clean the hose (CIP/SIP) prior to each use.
- The third question to ask is: Is there something in the process that minimizes the risk (e.g., "kill step" within the manufacturing process).

3. How do I know that my corrective actions worked?

- If designed out--no risk.
- If "kill step" is present within the manufacturing process--what data is present that verifies it is

If procedural mitigation--what new procedures are present that demonstrate they are working.

4. Feedback Loop to adjust Risk Assessment.

- A feedback loop that ensures the risks have been fixed or mitigated can include another risk assessment performed. This can be further supported by using qualified "outside" organizations such as the American Institute of Baking (AIB), National Foods Lab other forms that provide concurrence the action steps to fix the known control point issues have been remedied.

The FDA has identified four key food processing activities that are most vulnerable to such forms of adulteration. They include:

- **bulk liquid receiving and loading.**
- **liquid storage and handling.**
- **secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient); and**
- **mixing and similar activities.**

Recommendations are for food manufacturing facilities to follow the below phased approach:

- Site Risk Assessment (SRA)—”Vulnerability Assessment”
- Prioritize Equipment Standards from SRA exercises
- Develop Hygienic Equipment Standards (& Specifications) for the following:
  - bulk liquid receiving and loading.
  - liquid storage and handling.
  - secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient); and
  - mixing and similar activities.
  - Any areas defined as controlled environments ("Open" product, e.g., tanks, pumps, heat exchangers, primary packaging fillers, etc.
  - Equipment Surface Finishes
  - Construction/Piping Standards
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- Site Compressed Air
- Site Water Systems
- Facility Designs/Material/Personnel flows

Below are examples of a Site Risk Assessment (SRA) and Hygienic Equipment Standards to address each of the above noted four (4) FSMA action steps.

- SRA Example:

<table>
<thead>
<tr>
<th>System</th>
<th>Risk</th>
<th>Observation</th>
<th>Engineering Solution</th>
<th>Time &amp; Date</th>
<th>Operation solution</th>
<th>Trend &amp; Owner</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHA</td>
<td>H</td>
<td>The shut-off valve of the dust control is far from the tank, and the horizontal pipe will cause dust accumulate and steam/condensate accumulate when CBG potential risk for the dust come back to the tank.</td>
<td>Add a sanitary butterfly valve immediately after the tank vent. Make horizontal section (flexible) easily removable for cleaning/inspection by using hercule connections.</td>
<td>Nov 30, 2023</td>
<td>Clean it regularly in AQM. Control the opening and shut-off valve to avoid cross-contamination. Start the fan before open the valve-SOP</td>
<td>System owner</td>
<td>System owner validate the cleaning frequency by doing TVO testing.</td>
</tr>
</tbody>
</table>

- Equipment Standards/Specifications (Surface Finish Example):

For sanitary design, acceptable product contact surface finish is Ra 0.8 micron (μm) or 32 micro-inch (μinch). Sanitary tubing will normally be supplied to Ra 0.8 micron (μm) or 32 micro-inch (μinch). This finish ensures a surface that is smooth and free of pits and imperfections that can harbor residual material potentially laden with microbes. These surfaces also provide a smooth, cleanable surface, making it easier to remove materials from the internal surfaces during cleaning. Proper pipe slope and smooth finish will facilitate proper drainage, CIP, and SIP. Note: The Ra 0.8 micron (μm) or 32 micro-inch (μinch) finish does not apply to pipe or tubing welds. These welds must be orbital (machine) welded for best results, or hand welded and all splatter removed where possible.

**BPE (Bio Processing Equipment standard)** or equivalent BioPharma standards specify surface finish of Ra 0.41 micron (μm) or better 16 micro-inch (μinch) and Sanitary 3A or equivalent sanitary standards specify surface finish of Ra 0.8 micron (μm) or 32 micro-inch (μinch) or better.

<table>
<thead>
<tr>
<th>Ra(μm)</th>
<th>Ra(μinch)</th>
<th>RMS(μm)***</th>
<th>RMS(μinch)***</th>
</tr>
</thead>
<tbody>
<tr>
<td>71</td>
<td>1.8</td>
<td>30</td>
<td>2.02</td>
</tr>
<tr>
<td>52</td>
<td>1.32</td>
<td>58</td>
<td>1.48</td>
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<td>42</td>
<td>1.07</td>
<td>47</td>
<td>1.20</td>
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<tr>
<td>32</td>
<td>0.51**</td>
<td>36</td>
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<tr>
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<tr>
<td>16</td>
<td>0.41***</td>
<td>18</td>
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<tr>
<td>12</td>
<td>0.3</td>
<td>13</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Section 7.2 Table 1: **Sanitary/1A Standard surface finish requirement (Typical of hand polishing with 180 grit (U.S.)/320 U.K.)
**BioPharma/BPE surface finish requirement (Typical of mirror finish via electro polishing)
***RMS values calculated from Ra values using a factor of 1.12

Closing:

The results of this study indicate the importance of hygienic design for equipment and facilities within oil processing operations to avoid intentional adulteration. Implementing recommended design and process changes may just meet the target intended.