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Risk Assessment for Open or Partially Open Produce Packinghouses[1]

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This publication provides the food industry with information on conducting risk assessments for open or partially open produce packinghouses and packing facilities.

Introduction

In recent years, third-party food safety audits have placed greater scrutiny on open-air or partially open produce packinghouses and packing facilities. These facilities are often used for commodities that require only seasonal packing, and they may be multi-purpose (e.g., for off-season equipment storage). While food safety risks can sometimes be more difficult to control in these settings, a proper risk assessment and the implementation of food safety practices such as Good Manufacturing Practices (GMPs), Current Good Manufacturing Practices (CGMPs), Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), and environmental monitoring can be effective in identifying and reducing risks (FDA 2024a).

A hazard analysis and a risk assessment are foundational components of a comprehensive food safety plan, and they should be conducted in accordance with the packinghouse's specific design and operations. Open or partially open facilities pose unique challenges, particularly regarding exposure to the external environment and the ability to control potential sources of contamination (FDA 2023a). These facilities may require increased monitoring and more frequent food safety practices, such as surface cleaning and sanitation. A hazard analysis and risk assessment together help identify potential biological, chemical, and physical hazards; determine their likelihood and severity; and prioritize appropriate mitigation strategies, such as GMPs, CGMPs, SOPs, and SSOPs.

Conducting a Hazard Analysis

Conducting an effective hazard analysis in your facility requires an understanding of the many factors that can affect food safety, including facility use, off-season use, adjacent land use, pests, cleaning and sanitation, and other characteristics. To thoroughly identify hazards, consider mapping the flow or process of the produce as it moves throughout your operation (Figure 1).

After mapping the flow of product through your facility, assess each process step to determine whether biological, chemical, or physical hazards are present or could be introduced.

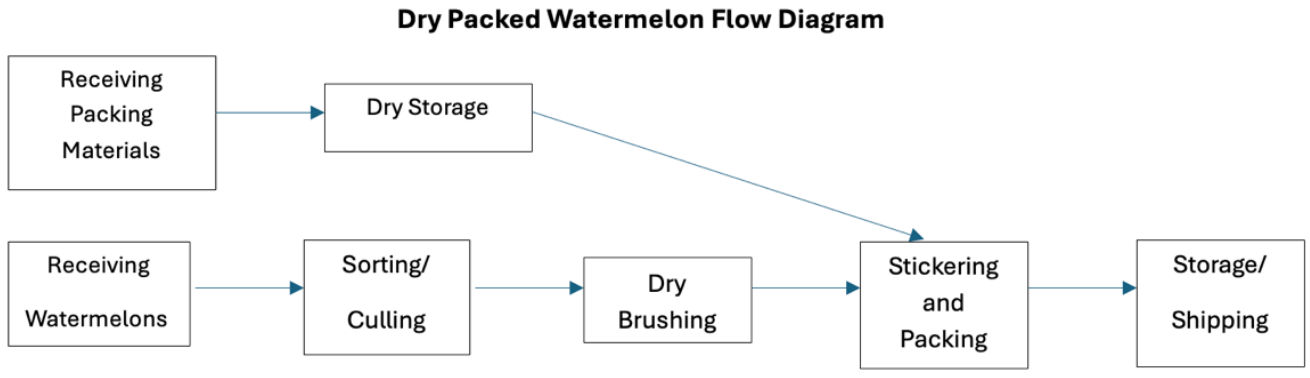

Figure 1. Unit operations of a traditional watermelon dry-packed line.
Credit: UF/IFAS.

Biological Hazards

Biological hazards are the most common cause of foodborne illness (FDA 2023b). They include bacteria (e.g., *Salmonella*, *Listeria monocytogenes*, *Escherichia coli* O157:H7), viruses (e.g., norovirus, hepatitis A), and parasites (e.g., *Cyclospora cayetanensis*, *Entamoeba histolytica*, *Giardia lamblia*). In open or partially open packing environments, these hazards can be introduced or spread through:

- Wildlife intrusion (e.g., birds, rodents, and insects)
- Domesticated animals on adjacent properties
- Poor worker hygiene or illness
- Agricultural water that is used for cleaning, cooling, or sanitation
- Improperly cleaned equipment or food contact surfaces
- Soil or dust transfer during high winds or equipment movement

It is crucial to identify areas where produce may be exposed to environmental contaminants or cross-contaminated from other sources. Seasonal and off-season use of facilities (e.g., for tool or fertilizer storage) should be evaluated, as it may contribute to residual contamination risks if not properly managed.

Chemical Hazards

Chemical hazards include residues or unintended contamination from the following (Wilson et al. 2026):

- Pesticides and postharvest chemicals (e.g., waxes, fungicides)
- Cleaning agents and sanitizers
- Lubricants or fuels used for machinery
- Unlabeled or improperly stored chemicals

In open-air environments, rain, wind, or runoff can lead to unintended exposure or movement of chemicals. Drift risk from adjacent land use (e.g., aerial pesticide applications) should also be assessed, especially if facility boundaries are not clearly demarcated or protected.

To minimize risk, facilities should verify that all chemicals are properly labeled, stored, and used in accordance with label instructions. Documentation of use, staff training, and restricted access to chemical storage areas are key components of risk mitigation.

Physical Hazards

Physical hazards include the unintended presence of objects that can injure consumers, such as:

- Wood fragments, stones, or metal shards
- Broken glass from lights or windows
- Loose or broken parts from equipment

In partially open facilities, increased airflow, open ceilings, or aging infrastructure can raise the risk of these materials entering the product flow. Regular maintenance, equipment inspections, and environmental monitoring can help prevent these risks from escalating.

Assessing Risks by Evaluating Severity, Probability, and Likelihood of Hazards

Risks from identified hazards are typically assessed by considering two factors: **severity** and **likelihood** (FDA 2018). **Severity** describes the potential impact on public health if a hazard is not controlled (e.g., minor, moderate, or severe illness). **Likelihood** refers to the probability that the hazard will occur under current practices and facility conditions (e.g., low, medium, or high).

Severity is generally categorized as low, medium, or high and reflects whether the presence of a hazard is unlikely or likely to result in unsafe food. Likelihood also uses low, medium, or high ratings to indicate the possibility that the hazard will occur. In general, the severity of a hazard remains constant, while its likelihood may change with controls and conditions.

Implementing control or mitigation measures can reduce the likelihood through CGMPs, SOPs, SSOPs, and other prerequisite programs that rely on food safety practices (FDA 2024a). For example, pathogens introduced by workers can result in severe consequences (critical) for consumers and the farm. However, worker training programs, including handwashing SOPs and health and hygiene GMPs, can reduce the frequency or likelihood that a pathogen will be introduced (low); therefore, the risk is considered medium risk (Figure 2). This indicates a moderate health risk and the importance of following GMPs and SOPs. Figure 2 illustrates one method that combines severity and likelihood in a matrix to determine whether a hazard is considered a significant risk.

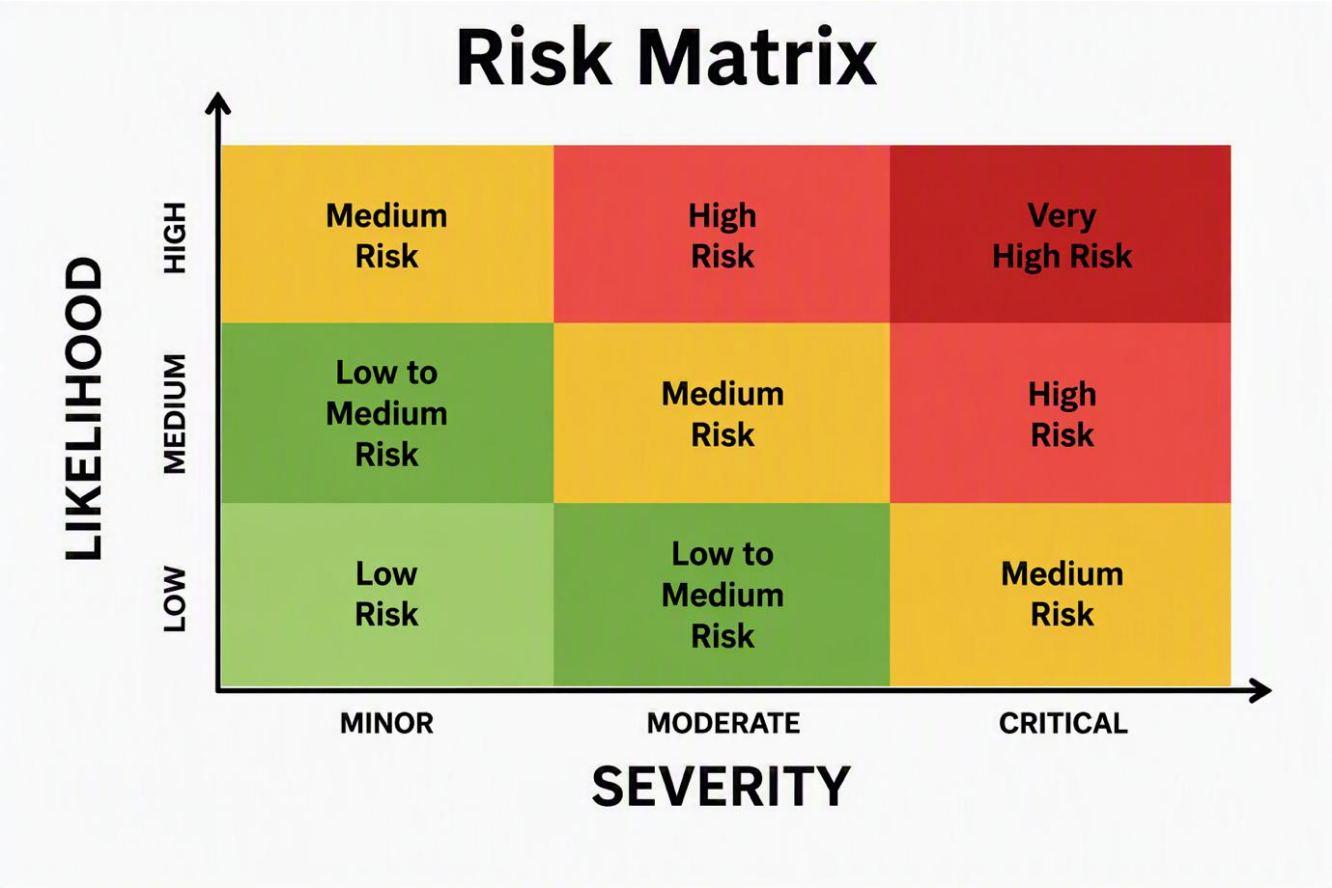

Figure 2. Risk Matrix for GMP Risk Assessment.
Credit: Image generated by Microsoft Copilot, October 5, 2026.

Control Measures or Mitigations

Control measures, or mitigations, can be applied at each step in the process to prevent food safety hazards and reduce the likelihood that these hazards will become risks. These measures are typically documented and applied through GMPs, CGMPs, SOPs, or SSOPs to prevent, reduce, or eliminate food safety hazards (FDA 2024b):

- **Pre-Operation Assessments**
  - Conduct visual inspections before operation to verify that all food contact and adjacent surfaces (walls, belts, tables, bins, etc.) are clean, dry, and in good repair.
  - Document pre-op findings and corrective actions.
- **Annual and Ongoing Worker Training**
  - Provide comprehensive food safety and hygiene training for all employees at least once annually.
  - Implement refresher training and targeted instruction throughout the season or as needed.
  - Maintain records of training content and attendance.
- **Worker Illness and Injury Policy**
  - Establish protocols to prevent ill or injured workers from handling produce or food contact surfaces.
  - Require prompt reporting of symptoms (e.g., vomiting, diarrhea, and open wounds).
  - Document procedures for exclusion, reassignment, and return-to-work.
- **Handwashing and General Hygiene GMPs**
  - Require proper and frequent handwashing, using designated handwashing stations.
  - Post visible signage reminding workers of proper handwashing and personal hygiene.
  - Provide proper handwashing facilities, including soap and single-use towels.
  - Reinforce personal cleanliness (e.g., clean uniforms, no jewelry, trimmed nails).
- **Designated Worker Break Areas**
  - Provide separate, clearly marked break and eating areas away from the packing and storage zones.
  - Prohibit eating, drinking, or tobacco use in any area where produce is handled or stored.

- **Pest Control Program**
  - Implement and maintain daily pest exclusion and monitoring protocols.
  - Conduct daily inspections for evidence of pest activity and document findings.
  - Use licensed pest control services and approved control measures.
- **Cleaning and Sanitation Program**
  - Develop SSOPs for the cleaning and sanitizing of all food contact surfaces, equipment, and utensils.
  - Include cleaning frequency, methods, verification (e.g., ATP testing), and documentation.
  - Ensure sanitizer concentration is routinely monitored and within label limits.
- **Environmental Monitoring Program**
  - Establish routine sampling in high-risk or hard-to-clean areas.
  - Adjust cleaning and sanitation protocols based on results.
  - Define corrective actions when pathogens or indicators are detected.
- **Standing Water Management**
  - Identify and eliminate sources of standing water on floors, drains, or equipment.
  - Grade floors properly and inspect drainage systems regularly.
  - Use squeegees or vacuums during cleaning procedures to remove pooling water.
- **Routine Equipment Maintenance Program**
  - Schedule and document regular inspection, cleaning, lubrication, and calibration of equipment.
  - Promptly repair damaged or malfunctioning parts that could contribute to contamination.
  - Keep records of service and repair activities.
- **Pre-Startup and Post-Operation Cleaning**
  - Conduct cleaning and sanitation before daily startup and after operations end.
  - Include checks for visible residues and sanitation effectiveness.
  - Document and sign off on pre-start and post-op checklists.

For more information about creating control measures or other prerequisite programs, see Ask IFAS publication FSHN10-11, "Food Safety on the Farm: Good Agricultural Practices and Good Handling Practices—Sanitary Facilities."

Summary

Many produce commodities are packed in temporary or seasonal packinghouses that may serve other functions throughout the year, such as storage for animal feeds and equipment, venues for recreational events, and other purposes. These activities can increase food safety risks due to their open design, introduction of food safety hazards, harborage areas for pests, and multi-use nature. By effectively identifying hazards, evaluating risks, and implementing appropriate control measures through GMPs, CGMPs, SOPs, and SSOPs, these facilities can effectively manage or reduce those risks and maintain the safety of fresh produce.

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