

Standard Operating Procedure (SOP)

Food Allergen Identification and Risk Assessment Procedures

This SOP details **food allergen identification and risk assessment procedures**, including the identification of major food allergens, risk assessment of allergen contamination, cross-contact prevention measures, labeling and communication protocols, employee training requirements, and regular monitoring and verification practices. The goal is to ensure the safety of consumers with food allergies by minimizing allergen risks and maintaining compliance with food safety regulations.

1. Objective

To identify and assess food allergen risks, implement preventive measures, and ensure accurate allergen communication to protect consumers and comply with regulatory standards.

2. Scope

This procedure applies to all personnel involved in the procurement, storage, production, packaging, and distribution of food products.

3. Responsibilities

- **Quality Assurance (QA):** Oversee allergen management, documentation, and verification activities.
- **Production Staff:** Implement allergen controls and report any cross-contact incidents.
- **Training Coordinator:** Organize and track employee allergen training.
- **Labeling Coordinator:** Ensure accurate allergen statements on labels.

4. Identification of Major Food Allergens

1. Review applicable regulations (e.g., FDA, FSA, EFSA) to identify major allergens (e.g., peanuts, tree nuts, milk, soy, wheat, eggs, fish, crustacean shellfish, sesame).
2. List all allergens present in raw materials, ingredients, and final products.
3. Update allergen list regularly and communicate changes to relevant staff.

Allergen	Source Example
Peanuts	Peanut butter, peanut oil
Tree nuts	Almond, cashew, walnut, pecan
Milk	Whole milk, whey, casein
Eggs	Egg powder, mayonnaise
Wheat	Bread, flour, gluten
Soy	Soybean oil, tofu, soy lecithin
Fish	Tuna, salmon
Crustacean shellfish	Shrimp, crab, lobster
Sesame	Sesame seeds, tahini

5. Risk Assessment of Allergen Contamination

1. Conduct a documented risk assessment for each product and process step:
 - Review supplier allergen declarations.
 - Map process flow identifying allergen introduction and potential cross-contact points.
 - Assess likelihood and severity of cross-contact or mislabeling.
2. Maintain risk assessment records and update annually or when there are process/ingredient changes.

6. Cross-contact Prevention Measures

- Designate dedicated equipment and utensils for allergen-containing products wherever possible.
- Implement appropriate scheduling to separate allergen-containing and allergen-free production runs.
- Require thorough cleaning and sanitation of all equipment and facilities between runs.
- Store allergenic ingredients separately, clearly labeled, and sealed.
- Establish and enforce good manufacturing practices (GMPs) to prevent cross-contact via staff, tools, or surfaces.

7. Labeling and Communication Protocols

1. Review and approve all product labels to ensure correct allergen information.
2. Verify ingredient lists and bold allergens as per regulatory standards.
3. Include precautionary allergen statements only as justified by risk assessment.
4. Communicate allergen risks and controls to supply chain partners, customers, and end users.

8. Employee Training Requirements

- Provide initial and refresher training on allergen identification, handling, and cross-contact control to all relevant staff.
- Document attendance and training content.
- Evaluate employee understanding through regular assessments or observation.

9. Monitoring and Verification

1. Perform routine inspections to verify implementation of allergen controls.
2. Conduct swab tests or product testing for allergen residues as needed.
3. Review allergen-related complaints or incidents and implement corrective actions.
4. Document all monitoring, verification, and corrective action activities.

10. Record Keeping

- Maintain allergen lists, risk assessments, training records, cleaning logs, labeling reviews, and monitoring documentation for the required retention period.

11. References

- Food Allergen Labeling and Consumer Protection Act (FALCPA)
- Codex Alimentarius: General Standard for the Labeling of Prepackaged Foods
- Local government/regulatory guidance on food allergens