

Standard Operating Procedure (SOP): Allergen Control and Labeling Procedures

This SOP details **allergen control and labeling procedures** to prevent cross-contamination and ensure accurate product information. It includes guidelines for identifying allergens, proper cleaning and sanitation practices, segregation of allergenic ingredients, employee training on allergen awareness, and clear labeling requirements to inform consumers. The primary goal is to maintain product safety and comply with regulatory standards by effectively managing allergen risks throughout the production process.

1. Purpose

To define procedures for controlling allergens during production, handling, and labeling to minimize risk of cross-contamination, safeguard consumer health, and ensure regulatory compliance.

2. Scope

Applies to all production, storage, packaging, and distribution activities involving ingredients and products containing allergens at [Facility/Department Name].

3. Responsibilities

- **Quality Assurance:** Monitoring compliance, updating allergen lists, reviewing labels.
- **Production Staff:** Following allergen control procedures.
- **Procurement:** Verifying supplier allergen information.
- **All Employees:** Attending allergen training and adhering to protocols.

4. Allergen Identification

- Maintain an up-to-date list of allergens used or present in the facility (e.g., peanuts, tree nuts, milk, eggs, dairy, fish, shellfish, wheat, soy, sesame).
- Identify and document allergens in all incoming raw materials through ingredient specifications and supplier declarations.
- Label all allergen-containing materials clearly in storage and processing areas.

5. Segregation and Storage

- Store allergenic ingredients separately from non-allergenic ingredients (designated, clearly marked areas).
- Use dedicated utensils, containers, and equipment for handling allergens where feasible.
- Implement color-coding or labeling systems for allergen controls.

6. Production Controls

- Schedule production runs to process allergen-free products before allergen-containing products whenever possible.
- Use physical and procedural barriers to prevent cross-contact during manufacturing and packaging.
- Monitor and document changeover and cleaning procedures between products.

7. Cleaning and Sanitation

- Follow validated cleaning procedures for removing allergenic residues from equipment and surfaces.
- Conduct routine verification (e.g., swabbing, visual inspection) to confirm cleaning effectiveness.
- Document cleaning and verification results after each production changeover.

8. Labeling and Packaging

- All finished product labels must declare the presence of major allergens per regulatory requirements (e.g., bold font under "Contains").

- Verify labels for accuracy before printing and application.
- Include precautionary statements (e.g., "may contain" or "manufactured on equipment shared with") if applicable after risk assessment.

9. Training

- Provide initial and annual refresher training on allergen awareness and control procedures to all relevant employees.
- Maintain training records and assess employee understanding.

10. Documentation and Records

- Maintain records of allergen inventories, cleaning and sanitation, training, and label reviews.
- Document corrective actions for any identified allergen control failures or labeling errors.

11. Review and Revision

- This SOP will be reviewed **annually** or when process, ingredient, or regulatory changes occur.
- All revisions must be recorded and communicated to relevant staff.

SOP Number	[Assign SOP ID]
Revision Number	[Enter Revision]
Effective Date	[Date]
Approved By	[QA Manager/Responsible Person]