

SOP: Allergen Control and Labeling Protocols

This SOP details **allergen control and labeling protocols**, encompassing identification of allergenic ingredients, cross-contamination prevention strategies, proper cleaning and sanitation procedures, accurate product labeling requirements, employee training on allergen awareness, and compliance with regulatory standards. The objective is to ensure consumer safety by effectively managing allergen risks and providing clear, accurate information on product labels to prevent allergic reactions.

1. Purpose

To establish consistent procedures for identifying, controlling, and communicating the presence of allergens in ingredients and products, thereby minimizing allergen risks and ensuring regulatory compliance.

2. Scope

This SOP applies to all personnel and processes involved in raw material receiving, production, packaging, labeling, and storage at [Company Name].

3. Responsibilities

- **Quality Assurance (QA):** Oversees allergen program, audits, and label verification.
- **Production Staff:** Follows allergen controls and cleaning protocols.
- **Procurement:** Ensures suppliers disclose allergen contents.
- **All Employees:** Participate in training and report concerns.

4. Allergen Identification

1. Maintain and regularly update a list of all recognized food allergens (e.g., peanut, tree nuts, milk, egg, soy, wheat, fish, crustacean shellfish, sesame).
2. Review all incoming raw materials and ingredients for potential allergen content, using supplier documentation and labels.
3. Flag and segregate materials containing allergens in the inventory management system.

5. Cross-Contamination Prevention

1. Store allergenic ingredients separately, clearly labeled, and sealed.
2. Implement dedicated utensils, tools, and processing lines for allergenic and non-allergenic products whenever feasible.
3. Schedule production runs to minimize allergen carryover (e.g. allergen-free products produced before allergenic ones).
4. Label all in-process products and storage containers to indicate allergen status.

6. Cleaning and Sanitation

1. Follow validated cleaning procedures between production of allergen-containing and allergen-free products.
2. Visually inspect and, where necessary, swab test equipment and surfaces for residues.
3. Maintain cleaning logs with detail of what was cleaned, when, and by whom.

7. Allergen Labeling Requirements

1. Review and verify ingredient lists for all finished products to accurately identify allergenic components.
2. Ensure all products are labeled in compliance with local and national regulatory requirements (e.g., FDA's FALCPA in the U.S., EU Regulation 1169/2011).
3. Highlight allergenic ingredients on product labels using bold text, separate statements, or other required notations (e.g., "Contains: milk, soy").
4. Apply "May contain" statements only if cross-contact cannot be fully excluded.
5. QA review and sign-off on all label proofs prior to printing and use.

8. Employee Training

1. All relevant staff must undergo allergen awareness and control training annually.
2. Training records are to be maintained by Human Resources or QA.

3. Employees must demonstrate understanding of allergen risks and controls.

9. Regulatory Compliance

1. Stay current with applicable regulations and update internal policies accordingly.
2. Maintain all required records for regulatory or internal audits.

10. Documentation & Records

- Allergen lists and inventory logs
- Cleaning schedules and verification checks
- Label proofs and approval records
- Employee training logs
- Audit and inspection reports

11. Review and Revision

This SOP shall be reviewed annually or upon significant change to processes, ingredients, or regulations. Revision history must be documented.

12. References

- FDA Food Allergen Labeling and Consumer Protection Act (FALCPA)
- EU Regulation (EU) No 1169/2011 on the provision of food information to consumers
- Local food safety regulations

Approved by: _____ Date: _____