SOP: Allergen Identification and Separation Protocols

This SOP details **allergen identification and separation protocols** designed to prevent cross-contamination and ensure consumer safety. It includes procedures for accurately identifying potential allergens in raw materials and finished products, labeling requirements, cleaning and sanitation standards, storage and handling guidelines to separate allergenic ingredients, employee training on allergen awareness, and documentation processes to maintain compliance with regulatory requirements. The goal is to minimize allergen exposure risks and protect sensitive individuals.

1. Purpose

To provide a standardized process for the identification, segregation, and handling of allergenic substances in the production facility, reducing the risk of cross-contamination and ensuring compliance with regulatory standards.

2. Scope

This SOP applies to all employees, contractors, and operations involved in the procurement, handling, processing, storage, labeling, and shipping of raw materials and finished products containing allergens.

3. Responsibilities

- Quality Assurance (QA): Ensure proper allergen protocols are implemented and maintained.
- Production Employees: Follow procedures for segregation and cleaning to avoid cross-contact.
- Supervisors: Monitor adherence to allergen controls and conduct regular training.

4. Allergen Identification

- Maintain an up-to-date list of all major food allergens, including but not limited to: peanuts, tree nuts, milk, eggs, soy, wheat, fish, shellfish, and sesame.
- Review ingredient specifications and supplier documents to identify allergens in all raw materials and finished goods.
- Update allergen lists promptly upon changes in suppliers, ingredients, or recipes.

5. Labeling Requirements

- All unpackaged and packaged products containing allergens must be clearly labeled according to regulatory requirements (e.g., U.S. FDA FALCPA, Canadian FDR).
- Storage bins, containers, and production lines for allergenic ingredients must be clearly marked with appropriate allergen information.

6. Storage and Handling

- Store allergenic ingredients on designated shelves or areas, physically separated from non-allergenic ingredients.
- · Use dedicated utensils, scoops, and containers for allergens; color-coded tools recommended.
- Handle allergens on separate production days or after non-allergen runs, where possible.

7. Cleaning and Sanitation

- Implement validated cleaning procedures after handling allergens, including equipment teardown if necessary.
- Conduct visual and, if appropriate, analytical verification (e.g., allergen swabbing/tests) after cleaning.
- Document all cleaning and verification activities.

8. Employee Training

- Provide annual allergen awareness training to all employees, including procedures for allergen handling, identification, and emergency response.
- Maintain training records for all personnel.

9. Documentation and Record Keeping

- Maintain records of ingredient allergen status, cleaning logs, training attendance, supplier documentation, and product labels.
- Review and update SOP and related documents annually or as significant changes occur.

10. References

- Food Allergen Labeling and Consumer Protection Act (FALCPA)
- FDA Food Code
- GFSI Global Food Safety Standard Documents

11. Revision History

Version	Date	Description	Approved By
1.0	2024-06-01	Initial release	QA Manager