Standard Operating Procedure (SOP)

Raw Material and Supplier Allergen Verification Protocols

This SOP details **raw material and supplier allergen verification protocols** to ensure the safety and compliance of incoming materials. It covers supplier qualification, allergen risk assessment, documentation review, testing procedures, and ongoing monitoring to prevent allergen cross-contamination. The protocol aims to maintain product integrity, protect consumer health, and adhere to regulatory requirements by verifying allergen information accurately before raw material acceptance.

1. Purpose

To establish robust procedures for verifying allergen status of raw materials and suppliers, thereby minimizing the risk of allergen cross-contact and ensuring compliance with regulatory and company requirements.

2. Scope

This procedure applies to all personnel involved in procurement, quality assurance, and receiving of raw materials at [Company Name].

3. Responsibilities

- **Procurement:** Source and approve suppliers, collect necessary allergen documentation.
- **Quality Assurance (QA):** Review allergen documentation, conduct risk assessments, coordinate testing.
- **Warehouse/Receiving Staff:** Check incoming materials for compliance and documentation before acceptance.

4. Procedure

1. **Supplier Qualification**
    - Obtain completed Supplier Allergen Control Questionnaire.
    - Review supplier's allergen control policies and certificates of analysis (COA).
    - Approve or reject suppliers based on allergen management capability.
2. **Raw Material Allergen Risk Assessment**
    - Collect and review ingredient/allergen declarations for each raw material.
    - Identify potential allergens present as ingredients or due to cross-contact at supplier's facility.
    - Document all allergen risks in the Raw Material Allergen Matrix.
3. **Documentation Review and Verification**
    - Confirm allergen declarations via supplier-provided specifications, COA, and other supporting documents.
    - Maintain complete records of allergen documentation for all approved materials and suppliers.
4. **Testing Procedures (As Needed)**
    - If risk is identified or documentation is insufficient, perform laboratory testing for relevant allergens in raw materials.
    - Document all test results and take necessary corrective actions.
5. **Ongoing Monitoring**
    - Annually review and update documents from suppliers, or upon any raw material or supplier changes.
    - Train relevant employees on allergen awareness and control protocols.
    - Conduct periodic internal audits to verify implementation of allergen controls.

5. Records and Documentation

- Supplier Allergen Control Questionnaires
- Raw Material Specifications and COAs
- Allergen Risk Assessment Matrix
- Testing reports (if applicable)
- Audit and training records

6. References

- Applicable regulatory requirements (e.g., FDA, EU, country-specific)
- [Company Name] Supplier Quality Manual
- Allergen Management Policy

7. Revision History

Version	Date	Description of Change	Approved By

1.0	[Date]	Initial SOP Release	[Name/Title]