

SOP Template: Verification and Validation of Allergen Control Measures

This SOP details the **verification and validation of allergen control measures**, including procedures for monitoring allergen sources, assessing cleaning and sanitation effectiveness, conducting allergen testing and analysis, documenting compliance with allergen control protocols, training staff on allergen management, and implementing corrective actions when deviations are identified. The goal is to ensure that allergen risk is minimized throughout the production process, safeguarding consumer health and maintaining regulatory compliance.

1. Purpose

To provide a systematic approach for verifying and validating allergen control measures ensuring minimal risk of allergen cross-contact and compliance with safety regulations.

2. Scope

This SOP applies to all production, sanitation, and quality assurance staff involved in allergen control processes.

3. Responsibilities

- **Quality Assurance (QA):** Oversee verification and validation activities, record review, and corrective actions.
- **Production Staff:** Follow allergen control protocols and participate in training.
- **Sanitation Staff:** Ensure effective cleaning and sanitation of equipment and areas.
- **Trainers:** Deliver training sessions on allergen control.

4. Procedure

4.1 Monitoring Allergen Sources

- Review ingredient labels for allergen content.
- Verify proper storage and segregation of allergen-containing materials.

4.2 Assessing Cleaning and Sanitation Effectiveness

- Inspect equipment and areas post-cleaning for visible residues.
- Use allergen-specific rapid detection kits or swabs for high-risk areas.

4.3 Allergen Testing and Analysis

- Collect environmental and product samples during and after cleaning.
- Analyze samples for the presence of target allergens using approved analytical methods (e.g., ELISA).
- Document test methods, results, and corrective actions for any positive findings.

4.4 Documentation and Record-Keeping

- Complete and maintain allergen verification logs (see section 6).
- Review records regularly to verify adherence to protocols.

4.5 Staff Training

- Conduct initial and refresher training sessions on allergen awareness and control measures.

- Maintain attendance records and training materials for audit purposes.

4.6 Corrective and Preventive Actions

- Investigate causes of any allergen control deviations.
- Implement corrective actions (e.g., re-cleaning, retraining).
- Document actions taken and review for effectiveness.

5. Verification and Validation Frequency

- Routine verification (e.g., daily/weekly, as appropriate by risk assessment).
- Full validation undertaken annually or upon changes to processes, equipment, or allergens handled.

6. Example Allergen Verification Log

Date	Area/Equipment	Type of Allergen	Test Performed	Result	Corrective Action (if any)	Initials
2024-03-15	Line 1 Mixer	Wheat	Swab test	Negative	-	AB
2024-03-16	Packing Area	Peanut	Rapid Test	Positive	Re-cleaned area	CD

7. References

- Local and international food safety regulations (e.g., FDA, EU Allergen Labelling Directive)
- Company allergen management policy
- Allergen testing kit manufacturer instructions

8. Revision History

Date	Revision	Description/Changes	Approved By
2024-06-01	1.0	Initial version	QA Manager