

Standard Operating Procedure (SOP): Handling Allergen-Related Incidents and Product Recalls

This SOP details the procedures for **handling allergen-related incidents and product recalls**, including identification and assessment of allergen contamination risks, immediate containment and notification protocols, communication strategies with regulatory bodies and customers, product traceability and recall execution, staff training on allergen management, and documentation and review processes. The goal is to ensure consumer safety and regulatory compliance by effectively managing allergen incidents and minimizing public health risks.

1. Purpose

To outline systematic procedures for the prompt and effective management of allergen-related incidents and product recalls to safeguard consumer safety and maintain regulatory compliance.

2. Scope

This SOP applies to all employees, products, and operations that handle, produce, or distribute food products containing allergenic ingredients.

3. Responsibilities

- **Quality Assurance (QA) Team:** Coordinates incident management and recall execution.
- **Production Supervisors:** Ensure immediate containment and communication.
- **All Staff:** Participate in training and report incidents promptly.
- **Recall Coordinator:** Maintains traceability records and communicates with external stakeholders.

4. Procedures

1. **Identification & Assessment of Allergen Contamination Risks**
 - Monitor production and storage areas for potential allergen contamination.
 - Conduct regular allergen risk assessments.
 - Document and investigate any reported or detected allergens in products.
2. **Immediate Containment and Initial Notification**
 - Isolate affected products and halt distribution immediately.
 - Notify QA and supervisory teams without delay.
 - Restrict access to contaminated batches.
3. **Communication Protocols**
 - Inform all relevant regulatory bodies within statutory timelines.
 - Inform customers and distributors affected by the recall through established channels (e.g., email, notices, website updates).
 - Develop public announcements if required.
4. **Product Traceability & Recall Execution**
 - Retrieve traceability information for all affected batches.
 - Initiate recall by following the company's recall plan.
 - Track and verify the return/destruction of recalled products.
5. **Staff Training & Awareness**
 - Conduct regular training sessions on allergen identification, handling protocols, and incident response.
 - Document attendance and training outcomes.
6. **Documentation & Post-Incident Review**
 - Maintain records of the incident, actions taken, communications, and corrective measures.
 - Review incidents to identify gaps and implement improvements.

5. References

- Allergen management guidelines as per external regulatory agencies (e.g., FDA, EFSA)
- Internal Recall Policy and Procedure Manual
- Staff training manuals on allergen awareness

6. Revision and Approval

- SOP effective date: [Insert Date]
- Next review date: [Insert Date]
- Approved by: [Name, Title]