

From the Food Safety Committee

Allergen Control Plans

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Introduction

All food facilities that are required to comply with 21 CFR 117 subpart C must have hazard analysis and risk-based preventative control plans (FDA 2018). An allergen control plan fits neatly into this framework, since allergens can be deemed as a chemical hazard to a subset of consumers. While breweries are exempt from this requirement via 21 CFR 117.5(i), they may still voluntarily participate and should consider participation if they are making allergen or gluten claims on their labels (TTB 2020). The benefits of participating in hazard analysis and control are increased customer confidence, improved control of production and reduction of loss, increased ownership of food safety, improved product quality, and business liability protection.

The U.S. FDA considers the following as major allergens: milk, eggs, fish, crustaceans, peanut, tree nuts, wheat, soybean, and sesame (FDA 2023).

Fundamental Steps

There are several steps in development of an allergen control plan (FARRP UNL 2023).

1. Team Assembly

Cross-functional teams utilizing personnel from multiple departments are helpful for thinking outside the box when you perform risk assessments. Gather a team of four to six people who know the facility and production process well.

2. Risk Assessment

Identify which allergens may possibly enter your facility, at what levels and how they may enter, and the risk to consumers. Identify your critical control points where the risk of allergen presence must be monitored.

3. Process Flow Diagram

Create a plant diagram for how allergens move through the building and through your production process. Detail equipment and spaces that contain or are at risk of cross-contamination of allergens. Note any critical control points in the diagram.

4. Control Plan

More details are provided in the next section.

5. Review and Update

An effective plan will be implemented, audited, enforced, and updated. Review and updates should occur with any relevant production process

changes and/or at least yearly. It is helpful to incorporate a schedule of auditing and review into your plan.

The Plan

Your allergen control plan should touch on control strategies for each of the following categories (examples are provided).

Product Design

- Do not add allergens without purpose (function or flavor)
- Implement a new product review process to identify allergenic products
- Question suppliers on allergen usage and necessity in products

Ingredient Supplier Control

- Request allergen control plans from suppliers (and audit them!)
- Require guarantees of no undeclared allergens and notification of changes
- Ensure allergenic ingredients are correctly labeled and in sealed containers

Receipt and Storage

- Label review of incoming shipments
- Color code tags on incoming allergenic ingredients, warehouse areas/sections/pallets
- Avoid cross-contact through separated storage areas, no allergens stored above non-allergens, dedicated equipment, spill cleanup plan, and documentation

Production Scheduling

- Schedule allergen runs together to minimize changeover and at the end of run periods (before scheduled cleaning/CIPs)
- Add allergens as late in the production process as possible
- Lower traffic during production of allergenic products
- Add physical barriers to separate areas containing allergen

Product Labeling

- Comply with FD&C Act, FALCPA, and FASTER (as required or voluntary)
- “May Contain” is not used in place of GMPs
- Monitor, document, verify correct label usage, and destroy outdated labels
- Personnel training on label changeovers

Employee Training and Education

- Allergen awareness and documented training
- Explain reasoning and consequences of noncompliance for allergen control methods used

Ask the Food Safety Team

Ever have a food safety question you don't know the answer to or for which you would like a second opinion? The Food Safety team is there to help! Just post your question in the “Ask the Brewmasters” section of the community site, and the Master Brewers Food Safety Committee will weigh in or get another expert's answer for you!

Cleaning and Sanitation Procedures

- Plant design: easy to clean, no dead-legs, easy visual inspection
- Sanitation SOPs: clearly written, defined scope, application, equipment, product, responsibility
- Validation/verification: defined sampling and analytical procedure, detailed records, audit system

Additional Resources

FARRP UNL. 2023. [Allergen control in the food industry](#). University of Nebraska, Lincoln, NE.

- FDA. 2018. [Draft guidance for industry: Hazard analysis and risk-based preventive controls for human food](#). Silver Spring, MD.
- FDA. 2020. Final ruling for gluten-free for fermented food. Section V.B.5, [Labeling of beer](#). Federal Register.
- FDA. 2023. [Food allergies](#). Silver Spring, MD.
- MBAA. 2023. [HACCP—Food safety decision guide for the brewing industry](#). Master Brewers Association of the Americas, St. Paul, MN.
- TTB. 2018. FAQs: [Major food allergen labeling for wines, distilled spirits, and malt beverages](#). Alcohol and Tobacco Tax and Trade Bureau, Beltsville, MD.