

Open Sesame: New Allergen Regulations

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INSPECTIONS & APPEALS



IOWA
FOOD PROTECTION
TASK FORCE

“ Adverse allergic reactions may result from a single eating occasion of the food allergen and can vary in severity from self-limiting gastrointestinal symptoms or skin rashes to severe symptoms of anaphylaxis, which may include wheezing, laryngeal edema, and/or shock and can be fatal. ”

SEC. 555.250 MAJOR FOOD ALLERGEN LABELING AND CROSS-CONTACT DRAFT
COMPLIANCE POLICY GUIDE FOR FDA STAFF

Roughly 1.6 million Americans suffer from a sesame allergy (NPR 2023).

Sesame Added as 9th Major Allergen

AS PART OF THE FOOD ALLERGY
SAFETY, TREATMENT, EDUCATION, AND
RESEARCH (FASTER) ACT OF 2021;
THE ACT WAS IMPLEMENTED IN JANUARY
2023



Reactions from Industry

- ▶ Cleaning equipment that comes into contact with sesame is a more arduous process than cleaning other allergens off of equipment due to the small size and weight of seeds, as well as the oily nature of sesame
- ▶ To avoid the possibility of cross-contamination, many producers have simply added sesame to their products
 - ▶ Practiced instead of halting production and spending time and money to clean the equipment fully
 - ▶ Has made many products previously acceptable to those with a sesame allergy dangerous

Reactions from Industry

- ▶ In practice, the law has had the opposite effect than its intended effect; more food is inaccessible to those with sesame allergies than before the law
- ▶ The American Baker's Association has requested the FDA to use its regulatory authority to set allergen thresholds
 - ▶ A threshold would allow a trace amount of allergen that wouldn't cause an allergic reaction in most at risk consumers to be present in products



Background of IA DIAL's Regulatory Authority

- ▶ Iowa Code, Chapter 137F
 - ▶ Gives IA DIAL authority to license and regulated certain food establishments and food processing plants
- ▶ Iowa Administrative Rule, Chapter 31
 - ▶ Establishes inspection standards for retail facilities and food processing plants
 - ▶ Retail Establishments
 - ▶ Adoption of the 2017 FDA Model Food Code with Supplement Changes
 - ▶ Food Processing Plants
 - ▶ Adoption of various provisions from *Title 21, Code of Federal Regulations - Food and Drugs*
 - ▶ Adoption of provisions from 21 United States Code (U.S.C.), which includes provisions of the Food, Drug, and Cosmetic Act (FD&C Act).
- ▶ Iowa Administrative Rule, Chapter 34 - Home Food Processing Establishments

Major Food Allergens Recap

- **FALCPA**

- Defines “major food allergen”
- Source from which MFA is derived
- Ingredients or “Contains”

process

- **FASTER ACT**

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Foods commonly with sesame or sesame oil

Asian cuisine (sesame oil)

Baked goods (buns, bagels)

Cereals (granola and muesli)

Chips and crackers

Dipping sauces (tahini, hummus)

Protein and energy bars

Sushi and tempeh



IA DIAL's regulatory requirements related to major food allergens

RETAIL AND HFPE ESTABLISHMENTS



2017 FDA Model Food Code

- ▶ Includes definition for “major food allergens”
- ▶ Includes labeling requirements for foods packaged in the food establishment
- ▶ Does not prescriptively address practices associated with allergen cross-contact for prepared or packaged foods.
 - ▶ Section 3-307.11 - Miscellaneous Sources of Contamination
 - ▶ Section 2-102.11 & 2-103.11 - Person-In Charge demonstrates knowledge, and duties of PIC

Iowa Administrative Rule, Chapter 34 - Home Food Processing Establishment

- ▶ Includes definition for major food allergen which includes sesame
- ▶ Includes labeling requirements for foods packaged in the HFPE, which includes major allergen declaration

IA DIAL's regulatory requirements related to major food allergens

FOOD PROCESSING PLANTS

21 CFR Part 117 - CGMPs and PCHF

- ▶ Includes requirements to ensure food is not adulterated under section 402 of the FD&C Act & food is not misbranded under 403(w) of FD&C Act
 - ▶ Allergen cross-contact is unintentional incorporation of a food allergen into a food
 - ▶ Part 117, Subpart B: Includes CGMP requirements to protect against cross-contact or minimize their potential
 - ▶ Part 117, Subpart C: Hazard Analysis and risk-based preventive controls identified food allergens as chemical hazard which require preventive controls
 - ▶ Juice & Seafood HACCP

IA DIAL Inspector Feedback

PRIOR TO FASTER ACT

- ▶ Inform, educate, and discuss pending changes with operators
- ▶ Many operations already aware of sesame's addition as major food allergen
- ▶ Many were in process of incorporating sesame into their allergen control programs
- ▶ Some operations considered removal of sesame from all formulations and facilities
- ▶ One bakery operation considered adding sesame to all bun products produced on a shared processing line.

AFTER FASTER ACT IMPLEMENTATION

- ▶ Some new and smaller operators not aware of sesame being a major food allergen
- ▶ Many operations are aware of sesame being included as a major food allergen
- ▶ Operations have updated cGMP practices or HF preventive control food safety plans to include cross-contact and labeling practices for sesame
- ▶ Since January 1, 2023, starting to see published recalls due to undeclared sesame ingredients

Summary

- ▶ Allergen ingredients are common in most domestic and foreign foods
- ▶ Allergen ingredients can have a significant impact to consumer safety, health, and purchase choices
- ▶ Allergen ingredients have been, and will continue to be, relevant to food safety and food recalls
- ▶ FASTER Act adds sesame as the 9th major food allergen
- ▶ Food allergen cross-contact prevention practices are not well defined for retail establishments other than labeling, and duties of the Person-In-Charge to demonstrate knowledge and educate employees
- ▶ Food allergen cross-contact preventive practices for food processing plants addressed either through cGMPs, or requirements for Preventive Controls as part of the food safety plan.
- ▶ Food allergen labeling requirements exist for foods packaged in both retail and food processing plants
- ▶ Despite existing regulations - Adverse allergic reaction events, consumer complaints, and food recalls still occur