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CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Gluten-Free Food Labeling

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Celiac Disease Foundation Webinar
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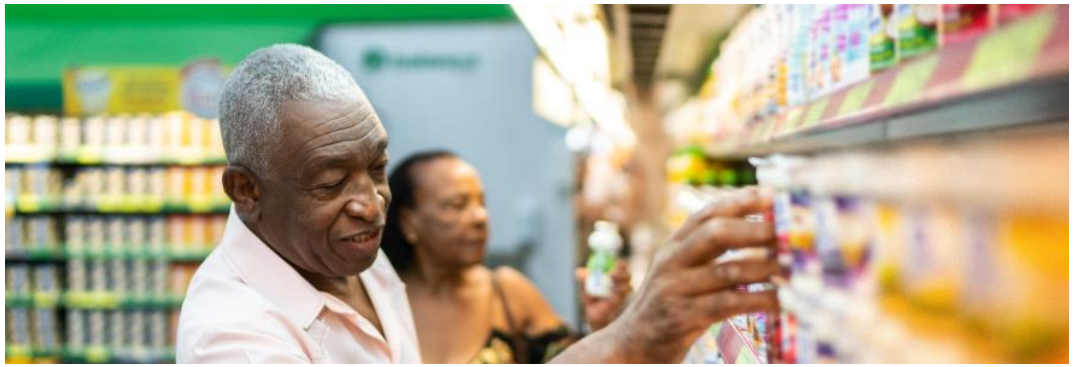
Overview

- Introduction
- Gluten-Free Food Labeling: Final Rules
- Gluten-Free Compliance
- Questions and Answers



FDA Food Responsibilities

- 20¢ of every consumer dollar in the U.S. spent on FDA-regulated products
- FDA regulates safety & labeling of ~80% of all food consumed in the United States
  - Ensure that consumers are provided with accurate and useful information in food labeling
  - Encourage food product reformulation to create healthier products
  - 93,000+ domestic registered food facilities
  - 124,000+ foreign registered food facilities
  - ~15% of overall food supply is imported
- Close collaboration with CDC, NIH, USDA* and other federal partners

* USDA has primary food safety oversight of domestic meat and meat products; domestic poultry and poultry products; frozen, dried, and liquid eggs; and catfish.

Statutory Authorities (Selected)

- The Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, as amended by for instance, the Food Additives Amendment in 1958 and the Nutrition Labeling and Education Act of 1990
- The Public Health Service Act (1944)
- The Fair Packaging and Labeling Act (1966)
- Nutrition Labeling and Education Act of 1990 (NLEA)
  - Explicit authority for nutrition labeling
  - Requires disclosure of certain nutrients
- Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history

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Gluten-Free Food Labeling Rules

Food Allergen Labeling and Consumer Protection Act (FALCPA)

- Enacted in 2004
- Peanut, Milk, Egg, Soybean, Tree nuts, Wheat, Fish and Crustacean shellfish
- FASTER Act 2021
- Sesame 9th major food allergen
- Two ways to declare
- Directed HHS to define “Gluten-free”

Effective January 1st 2023, Sesame will be added to the list of major food allergens.

Gluten-Free Requirements

- Two regulations (21 CFR 101.91)
  - Gluten-free Labeling of Foods – Final Rule (78 FR 47154)
  - Gluten-free Labeling on Fermented or Hydrolyzed Foods – Final Rule (85 FR 49240)
- Gluten-free is a voluntary claim
- **Gluten-free = Free of Gluten = No Gluten = Without Gluten**
- Wheat, Rye, Barley and crossbreeds. Not Oats
- Rationale:
  - Help consumers with celiac disease
  - Level the playing field for manufacturers

Gluten-Free Final Rule

- **"Gluten-free" food cannot contain:**
  - Ingredients that are a gluten-containing grain (e.g., spelt wheat) OR
  - Ingredients derived from a gluten-containing grain that have not been processed to remove gluten (e.g., wheat flour) OR
  - Ingredients derived from a gluten-containing grain that have not been processed to remove gluten (e.g., wheat starch) if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food
- Inherently does not contain gluten and
- Any unavoidable presence of gluten is below 20 ppm

Fermented or Hydrolyzed Foods

- Lack scientifically valid methods

- Alternative means to verify compliance
- Needs to meet the definition of Gluten-free and also meet the definition of Gluten-free prior to fermentation or hydrolysis
- Make and keep records
  - Food is Gluten-free before fermentation or hydrolysis
  - Gluten has not been introduced during manufacturing
- Distilled foods
  - Gluten unlikely to be present in properly distilled foods
  - Protein testing can be used to confirm that there is no protein present
  - Allowed to bear gluten-free claim is no detectable protein is present

Recordkeeping

- Before Fermentation and Hydrolysis
  - Conducted by manufacturer or ingredient supplier
  - Certificate of analysis

- Address Gluten cross-contact
  - Adequately evaluated process
  - Implemented preventive measures

Allergen and Gluten-free labeling Requirements

Major Food Allergen Labeling	Allergen Advisory Statements	Gluten-Free Labeling
FALCPA and FASTER Acts amended the Federal Food, Drug, and Cosmetic Act (sections 403(w) and 201(qq))	Truthful and not misleading Not used as a substitute for good manufacturing practices	21 CFR 101.91
9 major food allergens	Not specific	Wheat, rye, barley and cross breeds
Common name in "Contains" statement and/or ingredients list	Examples include "May contain X," Made in the same facility as X", "Made on the same line as X" etc.	Gluten-free, Free of gluten, No gluten, Without gluten (if requirements are met)
IgE mediated	Not specific	Autoimmune disease that is not IgE mediated
Mandatory	Voluntary	Voluntary

Codex Gluten-Free Labeling Standards

- Codex Stan 118-1979 – Standards for foods for special dietary use for persons intolerant to Gluten
- Codex does not directly address the issue of hydrolyzed and fermented gluten in their standards
- It does indicate that gluten-free foods can include ingredients from gluten-containing grains that have been processed to remove gluten but does not comment on what those processes may be
- Indicates that R5 ELISA method should be used for gluten determination (competitive vs. sandwich)
- Imported products are subject to U.S. regulations

Resources

- **Gluten-free Final Rule** (78 FR 47154)
  https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods

- **Final Rule for Gluten-free Labeling of Fermented and Hydrolyzed Foods** (85 FR 49240)
  https://www.govinfo.gov/content/pkg/FR-2020-08-13/pdf/2020-17088.pdf

- **Questions and Answers on the Gluten-free Food Labeling Final Rule**
  https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-gluten-free-food-labeling-final-rule

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Gluten-Free Compliance and Enforcement Activities

Goals

- Background
- Reporting issues to FDA
- FDA’s follow-up and enforcement activities
- Examples

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- Committed to protect the health of consumers with celiac disease
- Gluten-free labeling violation: misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act
- A variety of ways to monitor industry compliance, including:
  - Sampling and inspection (general and targeted; domestic and import; label review and record review; product testing; FDA and state regulatory partners)
  - Following up on complaints and adverse events

Reporting Issues to FDA

- Consumers, manufacturers, health professionals, or others can submit reports detailing product reactions or labeling concerns to FDA.

- How to report:

  – Online: use the MedWatch (FDA's Safety Information and Adverse Event Reporting Program) online reporting form: http://www.fda.gov/MedWatch.

  – By phone: contact FDA Consumer Complaint Coordinator for the state in which you reside (https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators); or call FDA at 1-888-SAFEFOOD.

Helpful Information to Include

- Detailed description of the product, such as:
  - When and where the product was purchased
  - Codes/identifying marks on the label or container, such as lot number, expiration date, and UPC code
  - Photos of the product (e.g., product label, ingredient list, claims, firm name, and firm contact information)
  - Other relevant information about the product as appropriate (e.g., changes in appearance/taste)
- Detailed description of adverse event, if experienced, such as:
  - Date of consumption and date of adverse reaction
  - Medical history of celiac disease
  - Symptoms experienced and how the symptoms related to prior reactions
  - Medications used to treat symptoms and any other medical care received
  - Other relevant medical conditions

What Happens After FDA Receives a Product Complaint or Adverse Event?

- Established follow up procedures
- Multiple organizational units within FDA
- Case-by-case evaluation and follow up
- Firm actions could include:
  - recalls
  - market withdrawals
  - label updates
  - reformulation
  - other corrective actions as appropriate

Gluten-free Related Recalls

- Recalls are posted on FDA website:
  - Searchable FDA Enforcement Report database (all recalls that have been closed by FDA): https://www.accessdata.fda.gov/scripts/ires/index.cfm#tabNav_advancedSearch
  - FDA posting of company announcement of recall, market withdrawal, or safety alert (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts) (not all recalls have press releases)
- Common recall root causes:
  - The product contained a gluten-containing ingredient.
  - The level of gluten due to cross-contact was 20 ppm or more.
- Both conventional food products and dietary supplements

Example 1

- Wheat was a sub-ingredient in a seasoning mix; the product was labeled as gluten-free.
- Root cause: lack of label review by the firm
- Firm actions:
  - Recall
  - Reformulation to remove wheat in the seasoning mix

Hypothetical examples based on real cases.

Example 2

- Product contained fermented soy sauce made from wheat; the product was labeled as gluten-free.
- Root cause: firm was unclear about FDA's gluten-free requirements for hydrolyzed and fermented ingredients
- Firm actions:
  - Recall
  - Updated label to remove the gluten-free claim

Hypothetical examples based on real cases.

In Closing

- FDA is committed to protect the health of consumers with celiac disease.
- We have ongoing work to monitor industry compliance, take appropriate regulatory actions, and further educate industry to encourage voluntary compliance.

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Questions and Answers