FDA's Gluten-Free Food Labeling Rulemaking

Global Issues and Impact of Gluten Allergy and Celiac Disease

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Rhonda R. Kane, M.S., R.D.
Consumer Safety Officer
Food Labeling and Standards Staff
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (FDA)

Focus of Presentation

- **Related Findings and Directives of *the Food Allergen Labeling and Consumer Protection Act of 2004* (FALCPA)**
- **FDA Activities Preceding Issuance of Proposed Rule on Gluten-Free (GF) Food Labeling**
- **Proposed GF Food Labeling Requirements**
- **Rulemaking's Current Status / Next Steps**

FDA CFSAN

FALCPA

Findings:

- Celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs.
- Prevalence of celiac disease in the United States is estimated to be 0.5 - 1% of the general population.
- Current recommended treatment is avoidance of glutens in foods that are associated with celiac disease.

FALCPA

Directed the Secretary of Health and Human Services to:

- consult with appropriate experts and stakeholders to define and permit use of the term GF in the labeling of foods
- issue a proposed rule by 2006 and a final rule by 2008 on GF food labeling

Consultation With Experts

- **June 2005: Issued Draft Thresholds Report** ***(Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food)*** **and Solicited Comments (70 FR 35258, 6/17/05)***
- **July 2005: Held a Food Advisory Committee Meeting and Solicited Public Comments (70 FR 29528, 5/23/05)***

* *Federal Register* Notice Citation

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Consultation With Experts

- **August 2005: Held a Public Meeting and Solicited Public Comments on a List of GF Food Labeling Questions (70 FR 41356, 7/19/05)***

- **March 2006: Issued the Revised Thresholds Report (http://www.fda.gov/downloads/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/UCM192048.pdf)**

* *Federal Register* Notice Citation

Possible Approaches to Establish a Threshold Level for Gluten

- **Analytical Methods-Based**
- **Safety Assessment-Based**
- **Risk Assessment-Based**
- **Statutorily-Derived**

Thresholds Report Findings

- **Analytical Methods-Based and Safety Assessment-Based Approaches:** only two feasible approaches to establish a threshold level for gluten
- **Risk Assessment-Based:** insufficient data from human clinical trials to develop a dose-response model for gluten and celiac disease
- **Statutorily-Derived:** FALCPA does not include requirements or exemptions related to gluten

Public Benefits of GF Rulemaking

- Would provide consumers with celiac disease more assurance that foods labeled GF are appropriate for them to eat
- Would promote fair competition among manufacturers of foods labeled GF

Purpose of GF Rulemaking

- Comply with a FALCPA directive
- Assist persons with celiac disease identify foods for use to follow a GF diet
- Ensure truthful, accurate and not misleading GF food labeling
- Establish uniform conditions for industry's use of the food labeling term GF

GF Proposed Rule

- **Published Proposal (72 FR 2795, 1/23/07)* Providing a 90-day Comment Period**
- **Posted Related Questions and Answers at FDA's Website Under the GF Subheading (http://www.cfsan.fda.gov/~dms/lab-cat.html#gluten)**
- **FDA received ~750 public comments**

**Federal Register* Proposed Rule Citation

GF Proposed Rule

- Addressed requirements for all FDA-regulated foods marketed in the U.S. that bear a GF or similar labeling claim (e.g., “free of gluten,” “without gluten” or “no gluten”)
- Used the “analytical methods-based” approach to establish a 20 parts per million (ppm) threshold level for gluten

GF Proposed Rule

- Tentatively determined that enzyme-linked immunosorbent assay (ELISA)-based methods can be used to reliably and consistently detect gluten at 20 ppm
- Tentatively considering using for enforcement an ELISA-based method that was validated in Europe at 20 ppm gluten
- Stated FDA's intention to conduct a "safety assessment" for gluten and consider its findings in developing a final rule

Other Considerations for GF Proposed Rule

- **FDA's establishment of a threshold level for gluten may require consideration of other factors too, e.g.:**
  - ease of compliance and enforcement
  - stakeholder concerns
  - economics
  - trade issues
  - legal authorities

Proposed Definitions

"Prohibited grain" means any of the following grains or their crossbred hybrids (e.g., triticale):

- **Wheat (i.e., any *Triticum* species)**
- **Rye (i.e., any *Secale* species)**
- **Barley (i.e., any *Hordeum* species)**

Proposed Definitions

“Gluten” means the protein that naturally occurs in a prohibited grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

Proposed Definitions

"Gluten-free" food cannot contain:

(a) ingredients that are a prohibited grain (e.g., spelt wheat) **OR**

(b) ingredients derived from a prohibited grain that have not been processed to remove gluten (e.g., wheat flour) **OR**

(c) ingredients derived from a prohibited grain that have been processed to remove gluten (e.g., wheat starch) if the use of that ingredient results in the presence of 20 ppm or more gluten in the food **OR**

(d) 20 ppm or more gluten

Proposed Misbranding Provisions

A food that bears a GF or similar labeling claim will be deemed misbranded if:

- **the food does not comply with the definition of GF OR**
- **with the exception of a food made from oats, the GF labeling claim for a food (e.g., milk) that inherently does not contain gluten from a prohibited grain does not refer to all foods of that same type (e.g., "milk, a gluten-free food" or "all milk is gluten-free") OR**
- **the food contains 20 ppm or more gluten**

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Proposed Misbranding Provisions

A food made from oats that bears a GF or similar labeling claim will be deemed misbranded if:

- **the claim refers to all foods of the same type (e.g., "all oats are gluten-free") OR**
- **the food contains 20 ppm or more gluten**

Proposed Compliance Provision

When compliance is based upon an analysis of the food, FDA will use a method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices (e.g., raw, cooked or baked).

Completed Rulemaking Activities Following the GF Proposal

- Reviewed and analyzed public comments on the GF proposed rule (2007)
- Planned and conducted a safety assessment on gluten exposure in individuals with celiac disease; drafted report that underwent expert peer review; revised report (2007-2010)
- Planned and conducted consumer studies on GF food labeling (2008-2010)

Upcoming Rulemaking Activities

- **Will announce in the *Federal Register* the availability of the FDA gluten safety assessment report and will solicit public comments**
- **Will issue a final rule on GF food labeling**
- **Will issue guidance on the final rule**