



Gluten-Free Food Labeling

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Agenda

- **Provide overview of major legislative and other activities that led up to the Food and Drug Administration (FDA) “gluten-free” (GF) food labeling rulemaking.**
- **Explain FDA’s requirements for a food labeled GF marketed in the United States.**
- **Brief overview of FDA’s enforcement of GF labeling.**
- **Discuss the current status of FDA’s proposed rule for GF Labeling of Hydrolyzed and Fermented Foods.**



Events Preceding the Final Rule

- ***Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), August 2004 – rulemaking directive and recognition of celiac disease (CD)***
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm>
- ***Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food (Thresholds Report), draft June 2005 and revised March 2006***
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106108.htm>
- **Food Advisory Committee Meeting, July 2005**
- **Public Meeting on GF Food Labeling, August 2005**



Approaches to Establish a Gluten Threshold Level

FDA's report entitled *Approaches to Establish Thresholds for the Major Food Allergens and for Gluten in Foods*, Revised 2006 (Thresholds Report; <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106108.htm>) identified four possible approaches FDA could consider using to establish a gluten threshold level as a criterion to define the term gluten-free:

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



Nutrition Facts
Serving Size 1 Cup (28g)
Serving Per Container about 3

Description of Approaches to Establish a Gluten Threshold Level

- **Analytical Methods-Based:** Level is determined by the “sensitivity” of the gluten-detection analytical method used to verify compliance.
- **Safety Assessment-Based:** Level considered to be “safe” or well tolerated by persons with CD is “calculated” based upon data derived from controlled exposure studies that report “no” or “lowest” observed adverse effect levels (i.e., NOAELs or LOAELs) where one or more “uncertainty factors” are applied.
- **Risk Assessment-Based:** Quantifies both the degree of risk associated with specific gluten exposure levels and the degree of uncertainty inherent in the risk estimate based upon a systematic and scientific examination of the known/potential adverse health effects of gluten exposure on persons with CD.
- **Statutorily-derived:** Level is extrapolated from any pertinent information included in FALCPA or other laws FDA enforces.



Major Reasons for Using An Analytical Methods-Based Approach

- **Use of a < 20 ppm gluten threshold is consistent with:**
 - international standards that define GF adopted in Europe
 - statements by some researchers and epidemiologic evidence reported in the scientific literature indicating that variable trace amounts of gluten in foods can be safely tolerated by most persons with CD
- **Analytical methods validated to detect gluten in foods at lower than 20 ppm gluten are not available. -- Validated methods are essential to FDA's enforcement of a regulatory definition of GF.**



Major Reasons for Using An Analytical Methods-Based Approach

- **Uncertainty about the ability of manufacturers of multi-ingredient foods, especially grain-based products, to comply with a gluten threshold lower than < 20 ppm.**
- **Questionable whether a gluten threshold level lower than < 20 ppm would:**
 - make it more difficult or costly for persons with CD to adhere to a life-long GF diet
 - increase the prevalence of persons with CD not adhering to a GF diet; thereby, placing them at higher risk of developing serious health complications and other diseases associated with CD



Major Reasons for Using An Analytical Methods-Based Approach

- **Questionable whether a gluten threshold level lower than < 20 ppm would:**
 - influence some U.S. food manufacturers to discontinue labeling their products GF because they cannot consistently meet this lower gluten level
 - discourage other U.S. food companies from becoming manufacturers of products labeled GF
 - result in a significant increase in the cost of food labeled GF
 - negatively impact international trade of foods labeled GF which could affect the availability of certain foods to persons with CD



Purpose of This Rulemaking

- Responds to a *Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)* directive to define and permit the voluntary use of the food labeling term “gluten-free.”
- Intended to benefit consumers with celiac disease (CD) and food manufacturers by clarifying the specific requirements for gluten-free labeling claims:
 - Will ensure that consumers with CD are provided with truthful, accurate, and not misleading labeling information to better assist them in identifying foods they can use following a gluten-free diet.
 - Will promote fair competition among food manufacturers.



Rulemaking

- **Published Proposed Rule 1/23/07;** (90-day public comment period closed 4/23/07).
- **Reopened comment period;** 8/3/11; 60-day comment period closed 10/3/11) to solicit comments on the *Health Hazard Assessment for Gluten Exposure, in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten*, and on a number of issues related to defining the term GF.
- **Received about 750 comments**



Rulemaking

Published Final Rule – August 5, 2013

<http://www.gpo.gov/fdsys/pkg/FR-2013-08-05/pdf/2013-18813.pdf>

Effective compliance date - August 5, 2014. Products labeled by the manufacturer on or after August 5, 2014, bearing a “gluten-free” labeling claim that does not comply with the definition will be subject to regulatory action by FDA.



Gluten-Free Final Rule

- **“Gluten-containing grain”** means any of the following grains or their crossbred hybrid (e.g. triticale)
 - Wheat (i.e., any *Triticum* species)
 - Rye (i.e., any *Secale* species)
 - Barley (i.e., any *Hordeum* species)
- **“Gluten”** means proteins that naturally occur in a gluten-containing grain, may cause adverse health effects in persons with Celiac Disease



Gluten-Free Final Rule

- “Gluten-free” food cannot contain:
 1. Ingredients that are a gluten-containing grain (e.g., spelt wheat) OR
 2. Ingredients derived from a gluten-containing grain that have not been processed to remove gluten (e.g., wheat flour) OR
 3. Ingredients derived from a gluten-containing 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
- Inherently does not contain gluten
- Any unavoidable presence of gluten is below 20 ppm



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Gluten-Free Final Rule

- “gluten free,” “no gluten,” “free of gluten,” or “without gluten”
- We proposed that the definition would apply to the term “gluten-free” or “similar claims.”
- Other terms regarding the absence of gluten will be evaluated under our general false and misleading misbranding provisions.



Gluten-Free Final Rule

- **Universal Symbol or Logo**
 - Not discussed in our final rule
 - Comments supported and opposed the use
 - No data
 - FDA does not endorse symbols or logos
 - Symbols or logos may be used provided they are truthful and not misleading



Gluten-Free Final Rule

- **Proposed rule** – Oats cannot be used in foods labeled as Gluten-Free
- Comments supported and opposed
- **Final rule** – Oats can be used in foods labeled as Gluten-Free



Gluten-Free Final Rule

- **Proposed rule** – Cannot use Gluten-free claim on foods that were inherently free of gluten unless
 - “milk, a Gluten-free food” or “all milk is Gluten-free”
- Most comments opposed this
- **Final rule** – Must meet the requirements of Gluten-free rule with no additional qualifying language



Gluten-Free Final Rule

- A food labeled as “Gluten-free” that bears the term “wheat” in the ingredient statement or in a “Contains wheat” statement be deemed misbranded without the following statement”

**** The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods”***



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Beer that Bears a Gluten-free Claim

- FDA will exercise enforcement discretion for FDA regulated beers* that currently make a “gluten-free” claim and that are:
 - Made from a non-gluten-containing grain OR
 - Made from a gluten-containing grain, where the beer has been subject to processing that the manufacturer has determined will remove gluten.
- This enforcement discretion pertains only to beers subject to FDA’s jurisdiction that were making a “gluten-free” claim as of August 5, 2013.

*FDA regulates non-malt beers (beers made without malted barley or hops)



Hydrolyzed and Fermented Foods

- FDA intends to issue a proposed rule to establish how it will determine compliance for hydrolyzed and fermented foods because current test methods can not quantify gluten in these foods.
- In the interim, hydrolyzed and fermented foods that meet the definition may bear a gluten free claim (manufacturers can implement measures that are necessary to prevent the introduction of gluten into the food that will ensure that the finished product will comply with the definition).



Gluten-Free Labeling in Restaurants

- Gluten-free final rule applies to packaged foods
- We expect restaurants' use of "gluten-free" labeling will be consistent with the federal definition
- Work with, educate and monitor industry on the use of this claim



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Enforcement

- The final rule became effective August 5, 2014.
- Enforcement actions will be based on review of the label and, where indicated, testing of the product
- FDA laboratory scientists continue to work to develop methods that can analyze for gluten content in hydrolyzed and fermented foods.



Hydrolyzed, Fermented and Distilled Foods – Proposed Rule

- Fermentation and hydrolysis cause breakdown of proteins making it difficult to quantify intact gluten
- Examples: Yogurt, cheese, sauerkraut
- No accurate test methods
- Distillation when done correctly removes protein - distilled foods will also be covered in the proposal, e.g., Distilled vinegar
- FDA regulated beer



Hydrolyzed, Fermented and Distilled Foods – Proposed Rule

- Advise how FDA will determine compliance in the absence of available methods that can quantify gluten.
- Will solicit comments on whether new methods are available to quantify gluten in these foods.
- Will not propose to change the definitions for use of the term in the final rule.



Resources

- **Gluten-Free Labeling of Foods general web page**
<http://www.fda.gov/gluten-free-labeling>
- **Guidance for Industry: Gluten-Free Labeling of Foods; Small Entity Compliance Guide**
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm402549.htm>



Specific Questions

GlutenFreeFinalRuleQuestions@fda.hhs.gov



Questions?