



## WEBINARS

# *Setting the Record Straight: Dispelling Gluten-Free Manufacturing and Production Myths*

*with Tricia Thompson, MS, RD  
The Gluten-Free Dietitian,  
Nutrition Consultant Celiac Disease, Founder Gluten Free Watchdog, LLC*

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*A total of 10 webinar participants will each win a special prize pack from Frito Lay!*

**Each gluten-free prize pack includes a chip and dip bowl set, a bag of Lay's® Classic potato chips and Tostitos!® Scoops!® tortilla chips and a copy of Nicole Hunn's cookbook, *Gluten-Free on a Shoestring*.**

**Valued at \$35.**



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# Welcome!

## Tricia Thompson, MS, RD



- *Internationally recognized gluten-free expert*
  - *Nutrition consultant celiac disease*
  - *Author of several books, including: The Gluten-Free Nutrition Guide and The Complete Idiot's Guide to Gluten-Free Eating*
  - *Contributing author to the Academy of Nutrition and Dietetics' Nutrition Care Manual*
  - *Founder: [www.GlutenFreeWatchdog.org](http://www.GlutenFreeWatchdog.org)*



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# Gluten-Free Food: Issues to be Aware of in Manufacturing & Production

## Learning Objectives:

- Describe what gluten-free means under proposed FDA rule
- Discuss why testing is so important to ensure labeled gluten-free food is truly gluten-free
- Clarify other terms often seen on food labels such as “Contains...” and “May contain...” statements



# What a *Gluten-Free Label Means*



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# What Gluten-Free Means Today

*“Currently, there is no FDA regulation that defines the term ‘gluten-free.’ However, FDA has not objected to the use of the term ‘gluten-free’ in the labeling of foods, provided that when such a claim is made, it is truthful and not misleading.”*

Source: <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm111487.htm>



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# Proposed Gluten-Free Rule

- ***The Food and Drug Administration (FDA) published a proposed rule for labeling of food as gluten-free in 2007***
- ***The FDA has stated publicly that they hope to have a final rule published by the end of their fiscal year (Sept 2012) and certainly by the end of 2012***





# Proposed Gluten-Free Rule, cont.

- **Food labeled gluten-free:**
  - Will **not** contain an ingredient that is a prohibited grain
  - Will **not** contain an ingredient derived from a prohibited grain that has **not** been processed to remove gluten
  - Can contain an ingredient derived from a prohibited grain that has been processed to remove gluten **ONLY** if the final food product contains less than 20 ppm gluten
  - Must contain less than 20 ppm gluten

Source: [www.fda.gov](http://www.fda.gov)



**ALL** *four stipulations must be met for a food to be labeled gluten-free!*



# Stipulation One

- Food labeled gluten-free will not contain an ingredient that is a prohibited grain
- What this means:
  - ***No wheat grain, barley grain, rye grain, or cross-bred varieties of these grains, such as triticale grain***



# Stipulation One, cont.

- **Areas of continuing confusion:**
  - *Spelt can NOT be included in a food labeled gluten-free*
    - *Spelt is a type of wheat*
  - *Wheat grass and barley grass may be included in a food labeled gluten-free*
    - *A “grass” is not the same as a “grain”*

Source: [www.glutenfreedietitian.com](http://www.glutenfreedietitian.com)



# Stipulation Two

- Food labeled gluten-free will not contain an ingredient derived from a prohibited grain that has not been processed to remove gluten
- What this means:
  - ***No hydrolyzed wheat protein, wheat germ, wheat bran, barley malt extract or flavoring, malt vinegar, or flours made from prohibited grains***



# Stipulation Two, cont.

- **Area of continuing confusion:**
  - *These ingredients can NOT be included in a food labeled gluten-free regardless of how much gluten the final food product contains even if it contains < 20 ppm gluten*



# Stipulation Three

- Food labeled gluten-free can contain an ingredient derived from a prohibited grain that has been processed to remove gluten ONLY if the final food product contains less than 20 ppm gluten
- What this means:
  - ***Food may contain wheat starch, modified food starch from wheat starch and dextrin from wheat starch***



# Stipulation Three, cont.

- **Area of continuing confusion:**
  - A food may be labeled gluten-free and include “wheat” in the ingredients list or “Contains” statement





# Stipulation Four

- Food labeled gluten-free must contain less than 20 ppm gluten
- What this means:
  - **Threshold level must be met regardless of whether gluten comes from an ingredient in the food or is in the food unintentionally due to cross-contact**



# Stipulation Four, cont.

- **Area of continuing confusion:**
  - *A food may be labeled gluten-free and contain an allergen advisory statement for wheat*



# How much is 20 ppm gluten?

- Parts per million or ppm gluten means **how many parts out of one million parts contain gluten**
- If you purchased a bag containing one million blue marbles and then discovered that it contained 999,980 blue marbles and 20 red marbles you could say that your bag of blue marbles was contaminated with 20 ppm red marbles



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# 20 ppm, cont.

- **20 ppm also means:**
  - 0.002% gluten
  - 20 mg gluten per 1 kg of food



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## 20 ppm, cont.

- *If you have a one-ounce slice of gluten-free bread containing 20 ppm gluten, the slice of bread contains 0.57 mg gluten*
- *If you take a one-ounce slice of “regular” white bread and break it into 7,030 pieces, each of these pieces contains 0.57 mg gluten*
  - Above calculation is based on the assumption that regular white bread contains 124,000 ppm gluten



*20 parts per million gluten is  
equal to a crumb of wheat bread!*



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# Ensuring Gluten-Free Means Gluten-Free



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# Testing Food for Gluten

- **State-of-the-art testing of finished gluten-free products is the only way manufacturers can know if their labeled gluten-free foods are safe for individuals with celiac disease and non-celiac gluten sensitivity**





# Sandwich R5 ELISA

- **The standard sandwich R5 ELISA (R7001 Ridascreen Gliadin by R-Biopharm) with cocktail extraction (Mendez method) is widely regarded as the best available validated ELISA for assessing final food product for gluten**
- **The competitive R5 ELISA (R7021 Ridascreen Gliadin Competitive) also should be used if the food product contains hydrolyzed or fermented ingredients**



## *Sandwich R5 ELISA, cont.*

- One of only two commercially available ELISAs formally validated at the levels used for regulatory purposes and official governmental methods (the other is the Morinaga Wheat Protein ELISA)
- The R5 ELISA (along with the Morinaga) is included in the FDA's proposed gluten-free labeling rule as a possible method for rule enforcement



# *Sandwich vs. Competitive ELISAs:*

## *Overview*

- Sandwich ELISAs can not accurately quantify gluten that has been highly hydrolyzed
- Sandwich ELISAs require two epitopes or antibody binding sites
- When a protein is hydrolyzed, the various fragments may not contain two epitopes
- As a result these fragments will not be measured



## *ELISA Overview, cont.*

- A Competitive ELISA may be used to help assess gluten content of hydrolyzed foods
- Competitive ELISAs require one epitope or antibody binding site



# ELISAs: A Bit More Detail

- Sandwich R5 ELISA is based on the R5 monoclonal antibody to the epitope QQPFP (*amino acid sequence glutamine-glutamine-proline-phenylalanine-proline*)
- **For the sandwich R5 ELISA to work, two QQPFP epitopes are required**

Source: Thompson, Mendez J Am Diet Assoc.  
2008;108:1682-1687



## *ELISA Details, cont.*

- When gluten protein has been hydrolyzed or broken into smaller protein fragments, the resulting peptides may no longer contain two epitopes or antibody binding sites
- If sandwich R5 ELISA is used to assess the gluten content of a product containing hydrolyzed or fermented gluten, gluten content may be underestimated



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# ELISA Details, cont.

- **For example:**

- “QQPFP” represents the epitope and “a” represents other amino acids:

- aaaaa**QQPFP**aaaaaaaaaaaaaaaa**QQPFP**aaa**QQPFP**aaaaa**QQPFP**

- If this protein undergoes hydrolysis, the following three fragments may result:

- 1.aaaaa**QQPFP**

- 2.aaaaaaaaaaaaaaaa**QQPFP**aaa**QQPFP**

- 3.aaaaa**QQPFP**

- Only the second protein fragment would be measured by the sandwich R5 ELISA



# Dedicated Facilities & Testing

- Using a dedicated facility is NOT a legitimate reason for not testing food products for gluten
- Grains, flours and other ingredients can arrive at a dedicated gluten-free manufacturing facility already contaminated with gluten
- Contamination can occur in the field, during transport and at the processing plant



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## *Dedicated Facilities, cont.*

- Finished products can only be as “clean” as the raw ingredients used to make them
- Ingredient vendors should provide a Certificate of Analysis that includes gluten
  - ***Manufacturers should also test at-risk ingredients; there is no such thing as too much testing!***



# Contamination: Gluten-Free Grains

- *U.S. Grain Standards Act allows contamination:*
  - *Grains with standards are allowed to contain a certain percentage of other grains for which standards have been established*
  - *Grains with standards include barley, corn, flaxseed, oats, rye, sorghum, soybeans, sunflower seeds, triticale, and wheat*
  - *Corn, flaxseed, oats, sorghum, soybeans, and sunflower seeds are allowed to contain wheat, barley, and rye*

Source: [www.gippsa.gov](http://www.gippsa.gov)



# Grain Contamination Study

- 22 single ingredient “naturally gluten-free” grains, flours and seeds not labeled gluten-free assessed for gluten contamination
- Samples homogenized and tested in duplicate (to evenly distribute the contaminant) using the sandwich R5 ELISA

Source: Thompson, Lee, Grace. JADA. 2010;110:937-940



## Study, cont.

- 13 of 22 products contained  $<$  limit of quantification for gluten (5 ppm)
  - *Basmati rice, brown rice, enriched cornmeal, polenta, hulled buckwheat, buckwheat groats, amaranth flour, flax seed, amaranth seed*
- 9 of 22 products contained  $\geq$  the LOQ for gluten (range 8.5 to 2,925 ppm)
- 7 of 22 products contained  $\geq$  20 ppm gluten



# Study, cont.

## Grain/Flour

## Mean Part Per Million Gluten

<i>Millet flour</i>	305.0
<i>Millet flour</i>	327.0
<i>Millet grain</i>	14.0
<i>Millet grain</i>	25.0
<i>White rice flour</i>	8.5
<i>Buckwheat flour</i>	65.0
<i>Sorghum flour</i>	234.0
<i>Soy flour</i>	2,925.0
<i>Soy flour</i>	92.0



# Gluten Content Labeled Gluten-Free Flours

- **Labeled Gluten-Free Flours (mean of 6 extractions)**
- Buckwheat flour brand A: < 5 ppm gluten
- Buckwheat flour brand B: 8 ppm gluten
- Corn meal: < 5 ppm gluten
- Millet flour: 15.5 ppm gluten
- Rice flour (brown): < 5 ppm gluten
- Sorghum flour: < 5 ppm gluten (1 extraction tested at 7 ppm gluten)
- Soy flour: < 5 ppm gluten (1 extraction tested at 6 ppm gluten)

Source: Gluten Free Watchdog, [www.glutenfreewatchdog.org](http://www.glutenfreewatchdog.org)



# Sourcing Gluten-Free Oats

- **Particularly important for manufacturers to source oats that are certified gluten-free**
- **Well established that “regular” commercial oat products may be contaminated with gluten-containing grains**
- **Producers of specially-manufactured gluten-free oats take extraordinary steps to ensure product is gluten-free**



# Gluten Content of Oats Not Labeled GF

<b>Brand</b>	<b>Mean ppm gluten</b>
McCann's Steel Cut Irish Oats (4 different lot numbers tested in duplicate)	< 3, 12, 23, 725
Country Choice Organic Oats (4 different lot numbers tested in duplicate)	< 3, 120, 131, 210
Quaker Old Fashioned Oats (4 different lot numbers tested in duplicate)	338, 364, 971, 1807

Source: Thompson. NEJM. 351;19:2021-22





# Testing Samples

- **How is a food tested when it arrives at a laboratory?**
- Kit instructions from R-biopharm for the R5 ELISA say to:
  - Homogenize a sufficient amount of sample by grinding it thoroughly to powder
  - Add 0.25 grams from the homogenized sample to the cocktail solution for testing

Source: [www.r-biopharm.com](http://www.r-biopharm.com)



# Testing Samples, cont.

- **To visualize 0.25 grams:**
  - Think of a 1-ounce packet of instant oatmeal which is approximately 28 grams
  - 0.25 grams is 1/112 of the packet



# Testing Samples, cont.

- **No uniform standards used by labs regarding:**
  - *What constitutes a “sufficient” amount of sample to homogenize*
  - *How to make sure the sample taken to homogenize is representative of the larger sample*
  - *What particle size is considered “powder”*



# Testing Samples, cont.

- *One way to help make sure the 0.25 grams tested is representative of the larger homogenized sample is to test each homogenized sample in duplicate – two extractions*
- *The results of the two extractions should be similar*
- *If they are not, the sample is not homogenized*
- *If the lab tests only one extraction, there is no way to know if the sample is sufficiently homogenized*



# Test Results GFW



<b>Labeled Gluten-Free Product</b>	<b>Extraction One</b>	<b>Extraction Two</b>	<b>Mean</b>
Flavor A	9 ppm gluten	9 ppm gluten	9 ppm gluten
Flavor B	15 ppm gluten	19 ppm gluten	17 ppm gluten
Flavor C	7 ppm gluten	7 ppm gluten	7 ppm gluten

Source: [www.glutenfreewatchdog.org](http://www.glutenfreewatchdog.org)



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# Test Results GFW



<b>Labeled Gluten-Free Product</b>	<b>Extraction One</b>	<b>Extraction Two</b>	<b>Mean</b>	<b>Notes</b>
First Round Testing	17 ppm gluten	68 ppm gluten	42.5 ppm gluten	Sample NOT homogenized Further grinding required
Second Round Testing	30 ppm gluten	28 ppm gluten	29 ppm gluten	Sample homogenized

Source: [www.glutenfreewatchdog.org](http://www.glutenfreewatchdog.org)



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# *Uniform Standards for Food Testing Laboratories are Desperately Needed!!!*



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# Other Terms on Food Labels



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# Contains Statements

- **Contains statements are regulated under the Food Allergen Labeling and Consumer Protection Act**
  - If an ingredient in an FDA-regulated packaged food product contains protein from one of the eight major allergens, the allergen must be declared in either the ingredients list or a Contains statement
    - Contains: wheat

Source: [www.fda.gov](http://www.fda.gov)



## Contains Statements, cont.

- **Refers to ingredients**
- **If a manufacturer chooses to include a Contains statement on product packaging, ALL of the eight major allergens found in ingredients in the food must be listed**



# Contains Statement & Gluten-Free Label

- **A food product may be labeled gluten-free and include a Contains statement for wheat**
  - If an ingredient in an FDA-regulated food contains any amount of wheat protein, the word “wheat” must be included in either the ingredients list or Contains statement
  - A food labeled gluten-free must contain less than 20 parts per million of gluten, including from wheat
  - Examples of ingredients that may contain wheat protein but still may be allowed in foods labeled gluten-free include wheat starch, modified food starch made from wheat starch, and dextrin made from wheat starch



# May Contain Statement

- **May contain or allergen advisory statements for wheat:**
  - *May contain wheat*
  - *Processed in a facility that also processed wheat*
- **Voluntary statement not defined by any Federal regulations**



# *May Contain Statement, cont.*

- *Refers to processing procedures*
- *Manufacturers may use “may contain” statements when there is a shared facility or shared production line*
- *Some manufacturers use them; others do not*



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# May Contain Statement, cont.

- **Grain Contamination Study:**

- *3 of 7 products containing  $\geq 20$  ppm gluten included an allergen advisory statement for wheat on product label*
- *3 of 13 products containing  $< 5$  ppm gluten included an allergen advisory statement for wheat on product label*

Source: Thompson, Lee, Grace. JADA. 2010;110:937-940



# *May Contain Statement, cont.*

- ***Voluntary allergen advisory statements for wheat can not be relied upon to determine whether product contaminated with gluten***



# May Contain Statement, cont.

- *The National Institutes of Health recommends that foods with allergen advisory statements be avoided by individuals with an allergy to the allergen named in the “may contain” statement*

Source: *J Allergy Clin Immunology*. 2010;126(6Suppl):S1-S58





# May Contain Statement and Gluten-Free Label

- A food may be labeled gluten-free and include a “may contain” statement for wheat
- Foods labeled gluten-free must contain less than 20 parts per million of gluten, including from ingredients and cross-contamination



# Summary

- *Currently, there is no FDA regulation that defines the term "gluten-free"*
- *FDA hopes to finalize proposed rule by end of fiscal year*
- *There is more to the rule than the stipulation that a food must contain < 20 ppm gluten*
- *All stipulations in the rule must be met for a food to be labeled gluten-free*



## Summary, cont.

- *State-of-the-art testing of finished gluten-free products is the only way manufacturers can know if their labeled gluten-free foods contain < 20 ppm gluten*
- *At-risk raw ingredients also should be tested*
- *The sandwich R5 ELISA (R7001 Ridascreen Gliadin by R-Biopharm) with cocktail extraction (Mendez method) is widely regarded as the best available formally validated ELISA for assessing final food product for gluten*



# Summary, cont.

- *Using a dedicated facility is NOT a legitimate reason for not testing food products for gluten*
- *Grains, flours and other ingredients can arrive at a dedicated gluten-free manufacturing facility already contaminated with gluten*



# Summary, cont.

- *Contains and “may contain” statements are not the same*
- *Contains statements are regulated under FALCPA; “may contain” statements are not defined by any Federal regulations*



# Frito-Lay Gluten-Free Commitment

- Many of our products naturally do not contain wheat, rye or barley. We are not reformulating to remove gluten.
- We are validating internally to comply with FDA proposed rule of < 20 ppm
- We are communicating with consumers on pack and on our website , Facebook, Twitter and blog
  - Fritolay.com, Facebook.com/FritoLay, @Fritolay, snacks.com

Check for the gluten-free icon or claim on Frito-Lay snacks, or visit [fritolay.com](http://fritolay.com) for a full list of our gluten-free options



GLUTEN FREE



Baked!



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The screenshot shows the Frito-Lay website's 'U.S. Gluten Free Products' page. At the top, there's a search bar and social media icons. The main navigation includes 'OUR SNACKS', 'RECIPES', 'YOUR HEALTH', 'OUR PLANET', and 'ABOUT US'. The breadcrumb trail reads: Home » Your Health » For Special Dietary Needs » U.S. Gluten Free Products and Products Not Containing Gluten Ingredients. The page title is 'U.S. Gluten Free Products'. Below the title, there are social media share buttons for Facebook (1k likes) and a 'SHARE THIS PAGE' button. The main content area lists 'Current Features' such as 'Naturally Delicious', 'How We Make Our Snacks', and 'Sensible Snacking'. A section titled 'For Special Dietary Needs' contains a paragraph about gluten intolerance and a list of products: BAKED! LAY'S® Original Potato Crisps, BAKED! RUFFLES® Original Potato Crisps, BAKED! TOSTITOS® SCOOPS!® Tortilla Chips, CHEETOS® Puffs SIMPLY NATURAL™ White Cheddar Cheese Flavored Snacks, DORITOS® Toasted Corn Tortilla Chips, FRITOS® Lightly Salted Corn Chips, FRITOS® Original Corn Chips, FRITOS® SCOOPS!® Corn Chips, and LAY'S® Classic Potato Chips. A note states that the information pertains only to products distributed in the U.S. The page was last updated on June 5, 2012.

## Dishes: Gluten Free



### Chipotle FRITOS® Meringues

This appetizer is light and crisp, but packs a kick of chipotle heat and earthy corn flavor. Serve on a platter on its own or as a topping for a...



Prep time: **10 minutes** Serves: **5**

great for: **Appetizers**



### TOSTITOS® Crust Party Quiches

This dish will be a hit among brunch guests. A warm and soft corn-flavored crust surrounds a veggie dense quiche topped with blue cheese and...



Prep time: **40 minutes** Serves: **3 quiches**

great for: **Main Courses**





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***Save The Date!***

***Thursday, August 16<sup>th</sup> at 2pm Eastern/11am Pacific***

***"Cross-Contamination in Restaurants: What You Need to Know"***

***Expert Panel:***

- ***Pam Cureton, RD, LDN, Clinical and Research Dietitian, Center for Celiac Research, University of Maryland***
- ***Amy Jones, MS, RD, LD, Chief Clinical Dietitian and Celiac Support Group Facilitator, Mary Rutan Hospital***
- ***Ken Schelper, Vice President of Davanni's; Board of Directors for Minnesota Restaurant Association***

**[CeliacCentral.org/webinars/schedule/](http://CeliacCentral.org/webinars/schedule/)**





Thank you!

Questions? Comments? Feedback?

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