

# **NATURALLY GLUTEN-FREE GRAINS AND LEGUMES**

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**Minimizing Risk of Cross Contact with Wheat,  
Barley, and Rye (with a special emphasis on  
oats)**

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# Background Definitions/Standards/Rules

glutenfreewatchdog.org

*Should consumers with celiac disease avoid foods with these statements?*

"Made in a facility that also produces wheat"	"Manufactured on equipment that also produces wheat"	"Manufactured on shared equipment, may contain wheat"	"May contain traces of wheat"

In the September 2016 *EJCN* article on allergen advisory statements, authors retrospectively reviewed labeling information of 101 products tested for gluten content through Gluten Free Watchdog, LLC. Products reviewed for this analysis were not labeled gluten-free but appeared to be free of gluten containing ingredients based on a review of the ingredients list (no wheat, barley, rye, malt, brewer's yeast).

101 products tested	Contained quantifiable gluten
<i>DID NOT</i> include an allergen advisory statement for wheat or gluten on packaging (n = 87)	13
<i>DID</i> include an allergen advisory statement for wheat or gluten on packaging (n = 14)	1

*Allergen Advisory Statements for wheat:  
Not a useful predictor of gluten content in this database review.*

**FDA**  
Ideally, allergen advisory statements should be used by manufacturers to help consumers make choices about which foods they can eat given their particular health constraints.  
The FDA should strongly consider regulating allergen advisory statements, especially in light of the Food Safety Modernization Act.

**U.S. Food & Drug Administration**  
Your Health

**Clearing up any confusion...What's the difference?!**

Food Allergen Labeling and Consumer Protection Act	Allergen Advisory Statements
<i>"Contains"</i> Top 8 allergens, including wheat, are <i>required</i> to be identified if among ingredients <i>FDA regulated</i>	<i>"May contain"</i> <i>Voluntarily</i> added to labels <i>Not defined by any federal regulation</i>

For more information about this study, please contact:  
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For more details, free, full text article available: <http://rdcu.be/k1j1>

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# Cross Contact: Definition

- Unintentional contact of one product with another product
- Can occur anytime a gluten-free food comes into contact with a gluten-containing food:
  - In the field while being grown/harvested
  - In railcars or trucks during transport
  - At the grain processing plant
  - At the manufacturing plant
  - In the home or restaurant

# GIPSA Standards: Grains & Legumes

- US standards allow grains with standards to contain a certain percentage of foreign material/objectionable seeds
  - Foreign material/objectionable seeds includes wheat, barley, rye, and triticale
  - **Foreign grain is not included in the ingredients list**
  - Grains with standards include: barley, canola, corn, flaxseed, mixed grain, oats, rye, sorghum, soybeans, sunflower seeds, triticale, wheat, rice, whole dry peas, split peas, lentils, beans

USDA. US Standards for Grains. Available at <https://www.gipsa.usda.gov/fgis/usstandards.aspx>

# Allergen Advisory Statements

- "May contain" statements are used by some (**but not all**) manufacturers to alert consumers to food processing practices (e.g., "Processed in a facility that also processes wheat," "May contain wheat")
- These statements are:
  - Voluntary
  - Not currently defined by any federal regulation
  - Supposed to be truthful and not misleading and should not be used as a substitute for good manufacturing practices (according to the FDA)

# Allergen Advisory Statement for Wheat on Product Labeled Gluten-Free

- **Important:** Labels that include both a gluten-free claim & a may contain wheat statement must comply with the FDA rule for labeled gluten-free foods
  - Food labeled gluten-free should contain less than 20 ppm of gluten regardless of whether gluten comes from ingredients or cross-contact

# Allergen Advisory Statement for Wheat on Product NOT Labeled Gluten-Free

- NIH guidelines suggest that individuals allergic to identified allergens in "may contain statements" avoid these products
- Recent research finds that allergen advisory statements for wheat are **not** a useful predictor of gluten content
  - 87/101 products tested for gluten did NOT include AAS for wheat BUT 13 of these products contained quantifiable gluten
  - 14/101 products tested for gluten DID include AAS for wheat BUT only 1 contained quantifiable gluten

Thompson T, Lyons TB, Jones A. Allergen advisory statements for wheat: Do they help US consumers with celiac disease make safe food choices? *European Journal of Clinical Nutrition*. 2016;70:1341-1347

# Oats



# Oats: Cross Contact

- Remember under GIPSA standards oats can contain a certain percentage of foreign grain, including from wheat, barley, and rye
  - Foreign grain is not declared in the ingredients list
- In one study, gluten levels in "standard" oats sold in the US ranged from a low of less than 3 ppm to a high of 1,861 ppm
  - McCann's < 3 ppm to 745 ppm
  - Country Choice < 3 ppm to 220
  - Quaker 326 ppm to 1,861

Thompson T. N Engl J Med 2004; 351:2021-2022

# Oats: Labeled Gluten-Free

- Includes oats grown under a purity protocol and standard oats cleaned via mechanical and optical sorting
- Purity protocols vary but generally speaking suppliers:
  - Use pure seed
  - Plant in fields that have not grown wheat, barley, or rye in crop rotation for certain number of years
  - Use dedicated or thoroughly cleaned equipment for seeding, harvesting, and transporting
  - Use dedicated processing plant
- Mechanical/Optical sorting protocols vary but generally speaking suppliers use:
  - Traditionally grown oats that are sorted at the mill to remove foreign grain based on grain properties
    - Size; Color; etc

# Oats: Gluten-Levels in Labeled GF

- PepsiCo/Quaker studies:
  - **1 in every 57 servings** of commercial oats labeled GF and purchased in 2014 contained gluten at/above 20 ppm (0.25 g tested from each 45 to 50 g ground serving)
  - Researchers believe this is an underestimation of both the number of contaminated servings and the level of contamination:
    - *“In other words, much of the gluten from the contaminant kernel remains concentrated in a few pockets within the serving after grinding, not being well dispersed. So consequently, a small test amount, randomly selected from the serving, is more likely than not to undercount overall gluten.”*
  - Unclear whether oats tested were purity protocol, sorted, or both

Fritz R, Chen Y, Contreras V. Food Chemistry 2017; 216:170-175

Fritz R, Chen Y. International Journal Food Science and Technology 2016; 52: 359–365

# Gluten Levels in Labeled GF Oats, cont.

- Gluten Free Watchdog data:
  - 35 different products labeled gluten-free--oats listed as first or second ingredient
    - 28/35 (80%) tested below 5 ppm gluten
    - 2/35 (6%) tested at or above 5 ppm but below 20 ppm gluten
    - **5/35 or (14%) tested at or above 20 ppm gluten**
      - *Based on conversations with the manufacturers of products testing at or above 20 ppm of gluten, **oats from suppliers of purity protocol oats were not being used in these five products at the time of original testing***

# Gluten Levels in Labeled GF Oats, cont.

- Approximately **5%** of all gluten-free foods tested to date through Gluten Free Watchdog have tested at or above 20 ppm of gluten
- The **percentage of oat products** testing at or above 20 ppm of gluten (i.e., **14%**) is higher than gluten-free foods in general
- Testing done by Gluten Free Watchdog has always found gluten levels in purity protocol oats to be less than 20 ppm
- **BUT** we have been provided with detailed testing data on oats purchased from a supplier of certified gluten-free purity protocol oats
  - On a couple of rare occasions test results were at or above 20 ppm of gluten

# Oats: Sampling/Testing Protocols

- Regardless of whether gluten-free oats are sorted or purity protocol, sampling and testing for gluten contamination must be robust
- Industry standards for sampling and testing oats currently do not exist
- To protect consumers standards must be established for both purity protocol oats and sorted oats
- Under the FDA gluten-free labeling rule testing of raw ingredients and finished products is NOT required

# Oats: Testing Protocol for GF Cheerios

- General Mills is producing gluten-free Cheerios using what they term “validated gluten-free flour” from traditionally grown sorted oats
- General Mills determines gluten-free status of a “lot” of oats via lot mean
- General Mills defines a “lot” as a 24-hour production cycle

# Testing Protocol for GF Cheerios, cont

- To arrive at a lot mean, the following protocol is followed:
- Twelve to eighteen boxes of cereal are pulled
- The contents of each individual box are ground
- A sub-sample of ground product is taken from each box
- The sub-samples are composited—meaning they are combined
- The combined sub-samples are subject to additional grinding
- A minimum of twelve extractions are taken from this combined, ground sample
- Extractions are tested using either the Ridascreen Fast Gliadin (R7002) or the Ridascreen Gliadin (R7001), and R5 Mendez cocktail extraction solution
- **Results from these 12 extractions are averaged to arrive at lot mean**
- Lot **means** of Yellow box Cheerios are testing below 15 ppm gluten

# Oats: Testing Protocol for GF Quaker Oatmeal

- Quaker is producing gluten-free oatmeal from traditionally grown sorted oats
- 16 pouches or tubes are pulled during a production run (approximately 1 pouch or tube every ½ hour)
  - A 40-gram sample is taken from each pouch or tube
  - Each sample is homogenized
  - Two extractions are taken from each homogenized sample and tested using the Ridascreen Gliadin R5 ELISA (R7001) Mendez Method
- If any single extraction from any of the 16 pouches or tubes is above 12 ppm gluten the entire lot is discarded

# Oats: Lab Protocol for Testing

- R-Biopharm (manufacturer of the R5 ELISA) updated the protocol for labs to follow when testing oats because of:
  - Uneven distribution of gluten contamination
  - Difficulty homogenizing sample
- New protocol:
  - Homogenize 200 gram sample of oats
  - Test 1 gram extraction (sub-sample)
  - Test sample in duplicate (two separate extractions)

# Oats: Consumer Recommendations

- Choose only those oat products labeled gluten-free
- For the consumer concerned about oats:
- Choose oat products based on comfort level and level of information provided by manufacturer
- Consider whether the manufacturer:
  - Discloses their source of oats--purity protocol, sorted, or both
    - Certified gluten-free oats may be sorted
  - Discloses their testing protocols
  - Discloses the assay they use to test oats for gluten contamination
- If a manufacturer refuses to disclose their source(s) of oats, testing protocols, including the assay used for testing or responds by saying the information is proprietary, may want to move onto another company

# Other Naturally Gluten-Free Grains



# Naturally GF Grains: Cross Contact

- Remember under GIPSA standards grains with standards are allowed to contain a certain percentage of foreign grain
  - Corn, flaxseed, sorghum, soybeans, rice
- Grains without standards also may be contaminated
  - Buckwheat, amaranth, quinoa, teff, millet
- Cross contact depends on:
  - Growing conditions (e.g., grown in rotation with or next to wheat, barley, or rye)
  - Shared equipment for harvesting, storing, transporting, processing

# Naturally GF Grains: Gluten Levels

- Thompson, Lee, and Grace study (J Am Diet Assoc 2010;110:937-940)
- 22 naturally GF grains, seeds, & flours NOT labeled gluten-free
- 13/22 (59%) contained < 5 ppm gluten
  - Basmati rice; long grain brown rice; enriched corn meal; instant polenta; 1 sample of rice flour; hulled buckwheat; buckwheat groats; amaranth flour; flax seed; amaranth seed
- 9/22 (41%) contained quantifiable gluten: 8.5 to 2,925 ppm
  - Product/Mean ppm
    - Millet flour/305
    - Millet flour/327
    - Millet grain/14
    - Millet grain/25
    - White rice flour/8.5
    - Buckwheat flour/65
    - Sorghum flour/234
    - Soy flour/2,925
    - Soy flour/92

# Gluten Levels in Labeled GF Grains

- Gluten Free Watchdog data
  - With the exception of oats, most labeled gluten-free grains and flours are testing at levels < 20 ppm
  - Some products are testing at levels between 5 ppm and < 20 ppm
    - Buckwheat flour (7 to 9 ppm gluten)
    - Millet flour (14 to 17 ppm gluten)
    - Quinoa flour (10 to 15 ppm gluten)
  - One notable exception tested at/above 20 ppm gluten
    - Teff flour (25 to 48 ppm gluten)

# Contaminated Teff Flour



# Teff Flour from One Particular Grower

- Teff grain grown on farm that also grows wheat; processed in a mill that processes some non gluten-free grains
- Not known where contamination occurred
- According to the manufacturer teff **grain** tested gluten-free
  - Difficult to test grain for gluten due to heterogeneous contamination
- Manufacturer assumed teff **flour** would be gluten-free
  - Gluten contamination in flour should be better distributed than grain due to grinding BUT still may not be evenly distributed
- Flour tested **AFTER** gluten-free claim added to packaging
- Found flour to contain at/above 20 ppm gluten
- Gluten-free label remains on product packaging
- Disclaimer added to website; no recall issued
- FDA notified but product remains available on manufacturer website & Amazon

# GF Grains: Sampling & Testing Protocols

- There are no industry standards for sampling and testing grains
- Testing is not required by the FDA under gluten-free labeling rule
- Most naturally gluten-free grains with the notable exception of oats are NOT produced under a purity protocol
- Sampling and testing standards are needed to protect the health of gluten-free consumers
  - Grain specific
  - Based on growing, harvesting, transporting, storing, and processing practices

# GF Grains: Consumer Recommendations

- Choose products labeled gluten-free whenever possible
- For the consumer concerned about grains...
- Contact manufacturers and ask:
  - Do you have an allergen control program in place?
  - Do you test for gluten contamination
    - Do you test both the grain and the milled flour/flakes?
  - Do you periodically send grain & flour to a third party lab for testing?
  - Do you work with a third party lab to determine best practices in terms of sampling and testing?
- Manufacturers should be testing both grain and flour and working with a third party lab to establish best practices for sampling and testing
  - Some manufactures may not understand cross contact risk

# Legumes



# Legumes: Cross Contact

- Remember under GIPSA standards legumes with standards allowed to contain certain percentage of foreign material including grains
  - Beans, peas, lentils
- Cross contact depends upon:
  - Growing conditions (e.g., grown in rotation with or next to wheat, barley, or rye)
  - Shared equipment for harvesting, storing, transporting, processing

# Legumes: Gluten Levels

- Gluten Free Watchdog data
  - 10 bags/cans of legumes tested (only 2 labeled gluten-free)
    - All but one tested below 5 ppm gluten
    - One had very low levels of quantifiable gluten (product not labeled gluten-free)
- BUT...
  - We have been sent consumer photos of foreign grain found in lentils
    - 1 bag was not labeled gluten-free
    - 1 bag was labeled "naturally gluten-free"
    - 1 bag was certified gluten-free by GFCO
  - Photos were sent to oat farmers well versed in identifying wheat, barley, and rye grain
    - In one case grains were identified as barley
      - Grain tested "low gluten" using NIMA (defined as 5 to 15,000 ppm gluten)
    - In another case grains were identified as barley, wheat, oat & wild oat
      - Grains tested at > 84 ppm using R5 ELISA

# Contaminated Lentils



# Legumes: Testing Protocols

- There are no industry standards for sampling and testing legumes
- Testing is not required by the FDA under gluten-free labeling rule
- Not aware of any legumes grown under purity protocol
- Sampling and testing standards are needed to protect the health of gluten-free consumers
  - Based on growing, harvesting, transporting, storing, and processing practices

# Legumes: Consumer Recommendations

- **Regardless of labeling ("naturally gluten-free," "gluten-free," "certified gluten-free" or no gluten-free claim):**
  - Rinse canned legumes under rapidly running water
  - Pour dry legumes onto large flat surface such as a cookie sheet and pick through them one by one
  - Rinse dry legumes under rapidly running water
- **For the consumer concerned about legumes...**
  - Contact manufacturers and ask if they have an allergen control program in place
  - Ask about procedures used to sort out grains
  - If product labeled gluten-free ask if they test for gluten

# Final Thoughts

- Difficult to completely eliminate the risk of cross-contact between grains and legumes and wheat, barley, and rye
  - Even if plants are grown under a purity protocol, there are a lot of things that can be controlled but birds and wind are not two of them
  - A flock of geese flying over a field and doing their business may drop a few wheat, barley, or rye seeds; wind may carry seed from one field to another
  - Hopefully these rogue seeds and eventual plants are detected but keep in mind that fields can be vast
- To help minimize risk:
  - Purity protocols and sorting methods must be robust
  - Sampling and testing protocols must be robust
- Manufacturers should **never** label a grain, flour, or legume gluten-free before thorough testing

# Questions?

Please don't hesitate to email  
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