



Understanding the FDA's Gluten-Free Labeling Rule: What You Need to Know



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Featuring Panelists:

Matthew Cox, Marketing Director, Bob's Red Mill Natural Foods

Tricia Thompson, MS, RD, Owner/Founder Gluten Free Watchdog, LLC

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Welcome!

Tricia Thompson, MS, RD



- Founder of glutenfreedietitian.com and glutenfreewatchdog.org
- Internationally recognized nutritional consultant, researcher, and writer on celiac disease and the gluten-free diet
- Has written for numerous publications including *Gluten-Free Living* magazine, *The Journal of the American Dietetic Association*, and *The New England Journal of Medicine*
- Author of a variety of books and book chapters including *The Gluten-Free Nutrition Guide* and *The Complete Idiot's Guide To Gluten-Free Eating*



Welcome!

Matthew Cox



- Marketing Director at Bob's Red Mill Natural Foods, Inc., a leader in natural, whole grain and gluten-free foods



Objectives

Educate, Empower, Advocate and Answer Your Questions

- Tricia Thompson:
 - Provide an overview of the FDA gluten-free labeling rule
 - Address issues about the FDA gluten-free labeling rule that are causing confusion in the gluten-free community
 - Discuss what isn't covered by the FDA's gluten-free rule
- Matthew Cox:
 - Discuss the role of gluten-free food manufacturers, including how the new ruling may impact the industry



Special Notes

- Please pay close attention!
- FDA's gluten-free ruling is complex
- As a result, this presentation is detailed
- Attendees have varying levels of knowledge:
 - Basic, Intermediate, Advanced
- Please save your questions until the end as there is the chance the presentation will address your inquiry



Rule Summary





Gluten-Free Labeling of Food

- The Food and Drug Administration's final rule for VOLUNTARY labeling of food as gluten-free was published in the Federal Register on August 5, 2013
- The rule became effective on September 4, 2013
- The compliance date for the rule is August 5, 2014
 - 12 month period is consistent with FDA's history of compliance for voluntary food labeling claims
 - Between now and then: Manufacturers may use stickers to modify their labels provided the stickered products are in compliance

Source: <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>





The Labeling Claim Gluten-Free

• Under the FDA rule if a food carries a gluten-free claim, it either:

– **Inherently does not contain gluten** (e.g., bag of raw carrots, bottled water)

OR

– **Meets the following criteria:**

- Does NOT contain an ingredient that is a whole, gluten-containing grain (*i.e., wheat, barley, rye, crossbred hybrids of these grains*)
- Does NOT contain an ingredient that is derived from a gluten-containing grain and has NOT been processed to remove gluten (*e.g., wheat flour*)
- May contain an ingredient that is derived from a gluten-containing grain and has been processed to remove gluten (*e.g., wheat starch*) as long as the food product contains less than 20 ppm gluten

AND

– **Any unavoidable gluten in the food due to cross-contact or migration of gluten from packaging materials is less than 20 ppm gluten**





Additional Provisions of the Rule: Terms Other Than “Gluten-Free”

- The FDA considers the following terms synonymous with “gluten-free” when used on a food label:
 - “No gluten”
 - “Free of gluten”
 - “Without gluten”
- Food labels making the above claims must comply with the gluten-free labeling rule
- Food labels making the claims “made with no gluten-containing ingredients” and “not made with gluten-containing ingredients” do NOT have to comply with the gluten-free labeling rule





Additional Provisions of the Rule: Foods Declaring Wheat on Labels Under FALCPA

- If a food is labeled gluten-free and also includes the word “wheat” in the ingredients list or Contains statement due to the use of ingredients such as wheat starch, the word “wheat” must be followed by an asterisk and the statement, “The wheat has been processed to allow this food to meet the Food and Drug Administration requirements for gluten-free foods.”
- This stipulation applies to the declaration of the allergen wheat as required in the Food Allergen Labeling and Consumer Protection Act (FALCPA)
- Remember that under FALCPA if an ingredient in an FDA-regulated food contains protein from wheat, the word “wheat” must be included on the food label either in the ingredients list or Contains statement
- The use of a “gluten-free” labeling claim does not replace or eliminate the need to comply with mandatory allergen labeling under FALCPA





Does this provision also apply to voluntary allergen advisory statements for wheat?

- This stipulation in the rule does NOT apply to voluntary allergen advisory statements related to manufacturer processing practices, e.g. “processed in a facility that also processes wheat”
- Therefore:
 - Voluntary allergen advisory statements may be included on foods labeled gluten-free without additional clarifying language





Does this provision also apply to voluntary allergen advisory statements for wheat?, cont

- However, foods with allergen advisory statements for wheat that also are labeled gluten-free must comply with the gluten-free labeling rule
 - In other words, if you come across a product labeled gluten-free that also includes the statement, “processed in a facility that also processes wheat” the food is NOT mislabeled
 - Because it is labeled gluten-free it must contain less than 20 ppm gluten





What products must comply with this rule?

- **This rule applies to:**

- Foods as packaged regulated by the FDA (including dietary supplements) and intended for human use that are sold in the U.S. (and either made in the U.S. or imported)

- **This rule does not apply to:**

- Foods regulated by the U.S. Department of Agriculture (USDA)
- Alcoholic beverages regulated by the TTB
- Cosmetics
- Prescription and non-prescription drugs
- Pet food





Now, let's address common questions and comments!





Why was the < 20 ppm threshold chosen?

- The FDA chose to use the analytical methods-based approach to establish a threshold for gluten in food
- Under this method, thresholds are based on the sensitivity of the analytical methods used to assess compliance
- This choice was based on an evaluation of the method and its:
 - Potential impact on availability of gluten-free food
 - Potential impact on the health of people with celiac disease
 - Availability of analytical methods to evaluate manufacturer compliance
 - Consistency of the rule with other international standards

Source: <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>





Why was the < 20 ppm threshold chosen?, cont

- **Impact on foods:**

- The FDA believes that “lowering the gluten level below 20 ppm will make it far more difficult for manufacturers to make food products that could be labeled gluten-free, thereby reducing food choices for individuals with celiac disease.”

- **Impact on health:**

- The FDA believes that, “the available data and information support a determination that retaining the < 20 ppm part of the criteria for defining ‘gluten-free’ is protective of public health.”

- The Agency also states, “Although clearly defined gluten thresholds cannot be determined at this time of this final rule, there is no evidence that consumption of food products containing less than 20 ppm gluten would pose a risk of adverse health effects for the large majority of individuals with celiac disease. Future research and improved data defining gluten thresholds may lead us to revisit our conclusion.”





Why was the < 20 ppm threshold chosen?, cont

- **Availability of analytical methods:**

- FDA believes that, “Twenty ppm remains the level of gluten that can reliably and consistently be detected in a variety of food matrices.”

- **Consistency with international standards:**

- The FDA states that, “the final rule’s definition is similar, but not identical to requirements or positions by the Codex Alimentarius Commission, the European Commission, and Canada.”





My Personal Take

- Just because up to but not including 20 ppm gluten is allowed in foods making a gluten-free claim does not mean they contain anywhere close to this amount
- Based on testing hundreds of samples of food products labeled gluten-free through Gluten Free Watchdog using the formally validated sandwich R5 ELISA Mendez Method, the vast majority of product samples are testing well below 20 ppm gluten
- Also important to note:
 - Products can NOT be tested to 0 parts per million gluten
 - The formally validated sandwich R5 ELISA has a lower limit of detection of 3 ppm gluten and a lower limit of quantification of 5 ppm gluten





Confusion Over 20 ppm

- What exactly is meant by 20 parts per million gluten?
 - It is a proportion: “How many parts out of one million parts are gluten?”
 - If you bought a bag containing one million blue marbles but the bag actually contained 999,980 blue marbles and 20 red marbles, you could say that your bag of marbles was contaminated with 20 ppm red marbles





Confusion Over 20 ppm, cont

- 20 ppm is also the same as both of the following examples:
 - 20 milligrams of gluten per 1 kilogram of food (*1 kg of food contains 1 million mg of food*)
 - 20 milligrams of gluten per 35.27 ounces of food
- To put this amount into context, a 1-ounce (28.35 grams) slice of gluten-free bread containing 20 parts per million gluten would contain 0.57 milligrams of gluten





What exactly does 0.57 milligrams gluten look like?

- If you could take a one-ounce slice of regular bread and break it into 7,030 tiny pieces, one of these tiny pieces would contain the same amount of gluten found in an entire one-ounce slice of gluten-free bread



Confusion Over 20 ppm, cont

- 20 ppm is NOT based on serving size
- What matters is the amount of food eaten
- Key information:
 - IF a loaf of bread is tested and found to have a gluten level of 20 ppm AND assuming any gluten contamination is evenly distributed within the loaf, a slice of bread contains 20 ppm gluten and the whole loaf contains 20 ppm gluten
 - Remember each one ounce serving of a food product containing 20 ppm gluten contains 0.57 milligrams of gluten
 - BUT you have to eat an ounce of the product to take in 0.57 milligrams of gluten





Are manufacturers required to test food for gluten?

- No
- Under the gluten-free labeling rule manufacturers are not required to conduct any testing on the ingredients used in their foods or on the final food product
- But manufacturers who choose to make a gluten-free claim must comply with the rule which includes the stipulation that foods bearing a gluten-free claim must contain less than 20 ppm gluten

Source: <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>





Gluten Testing, cont

- The FDA writes in the executive summary of the rule, “given the range of food products and methods of manufacturing, it would be impractical and inefficient use of our resources for us to require, through regulation, a precise manner in which manufacturers must or should certify or verify the gluten content of their products.”





Gluten Testing, cont

- In the online document, “*Questions and Answers: Gluten-Free Food Labeling Final Rule*” the FDA does offer some suggestions to industry on ensuring foods contain below 20 ppm gluten
- “Manufacturers may choose to use effective quality control tools to ensure that any foods they label gluten-free do not contain 20 ppm or more gluten, such as:
 - Conducting in-house gluten testing of starting ingredients or finished foods,
 - Employing a third-party laboratory to conduct in-house gluten testing,
 - Requesting certificates of gluten analysis from ingredient suppliers, or
 - Participating in a third-party gluten-free certification program.”

Source: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm>





Testing Methods Used by FDA

- The FDA decided not to put into the actual rule the testing methods they will use to test foods for gluten as part of rule enforcement
- Instead, in the online Q&A document, the FDA has named the specific scientifically valid methods they intend to use as a pair when determining compliance with the rule:
 - Sandwich ELISA R5-Mendez Method and Morinaga Wheat Protein ELISA Kit (Gliadin)





My Personal Take

- If a manufacturer wants to make a gluten-free claim on a product they should have a testing protocol in place developed in conjunction with a third party food testing laboratory or a certifying agency
- A manufacturer should make sure that the testing method used to test their ingredients and final food product is (or performs just as well as) the formally validated sandwich R5 ELISA Mendez method





Are oats allowed?

- Yes
- Under the gluten-free labeling rule, oats are NOT considered a gluten-containing grain
- The FDA does note in the executive summary that oats may come into contact with gluten-containing grains during production, processing, and storage but that this co-mingling is preventable

Source: <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>





Oats, cont

- All single ingredient oat products carrying a gluten-free claim — whole oats, rolled oats, steel-cut oats, oat flakes, etc. — must contain less than 20 ppm gluten
- All mixed food products made with oat ingredients carrying a gluten-free claim must contain less than 20 ppm gluten





My Personal Take

- Manufacturers using oat ingredients in multi-ingredient products labeled gluten-free should make sure the oat ingredients have been specially produced to minimize cross-contact with wheat, barley, and rye
- They should either test the oats themselves, send them to a third party lab, or require a certificate of gluten analysis from the ingredient supplier
- Commercial oat products available in the U.S. are highly likely to contain small amounts of wheat or barley
 - A certain percentage of “other” grain is allowed under U.S. grain standards

Sources: <http://www.gipsa.usda.gov/fgis/standproc/usstands.html>

Thompson T. *NEJM*. 351;19:2021-22. Available at <http://www.nejm.org/doi/full/10.1056/NEJM200411043511924>





Personal Take, cont

- In my experience at Gluten Free Watchdog, there are rare instances when gluten-free manufacturers are not aware of cross-contact issues with oats
- There have been two instances when mixed food products containing oat ingredients tested ≥ 20 ppm
 - In both cases specially produced certified gluten-free oat ingredients did not appear to be used





Gluten Content of Oats NOT Labeled Gluten-Free

Brand	Mean ppm gluten
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





Should I eat only foods labeled gluten-free?

- No
- The gluten-free labeling rule allows a gluten-free claim on foods that are inherently gluten-free (i.e., naturally do not contain gluten) such as grapefruit juice, raw carrots, and bottled water provided any unavoidable gluten in the product is less than 20 ppm gluten





Should I eat only foods labeled gluten-free?, cont

- The FDA writes in their Q&A guidance document:

“Producers of foods that are by nature free of gluten (e.g., bottled spring water, fresh fruits and vegetables, and fresh seafood) may not choose to label these foods gluten-free even though the foods could be consumed as part of a gluten-free diet.”

“For foods that are by nature free of gluten, but are at high risk of gluten cross-contact (e.g., products made from grains, legumes, and seeds), the appearance of a gluten-free claim on the labels would provide consumers with the expectation that any gluten present is less than 20 ppm.”





My Personal Take

- Just because inherently gluten-free foods may be voluntarily labeled gluten-free does not mean that all food items purchased at the grocery store must be labeled gluten-free
- Many food items have a low to no risk of cross-contact with wheat, barley, or rye
- Because of the risk of cross-contact with wheat, barley, and rye, naturally gluten-free grains, flours, and starches used by individuals with celiac disease should be labeled gluten-free
- Mixed food products made with naturally gluten-free grains, flours, and starches (e.g., corn tortillas, buckwheat noodles, rice noodles) also should be labeled gluten-free

Source: Academy of Nutrition and Dietetics. Evidence Analysis Library Celiac Disease Toolkit. 2011





Why purchase labeled gluten-free grains and flours?

Flour	Mean ppm Gluten Labeled Gluten Free (1 brand tested)	Mean ppm Gluten Not Labeled Gluten Free (1 or 2 brands tested)
Millet	15.5 ppm	305 ppm, 327 ppm
Buckwheat	< 5 ppm	65 ppm
Sorghum	< 5 ppm	234 ppm
Soy	< 5 ppm	92 ppm, 2925 ppm

Sources: Thompson, Lee, Grace. JADA. 2010;110;937-940; Gluten Free Watchdog, LLC www.glutenfreewatchdog.org





Is food served in restaurants covered?

- It's complicated!
- The FDA does not provide a simple yes or no response to this question in either the executive summary of the rule or in the Q&A guidance document
- In the executive summary the following statement is made:
 - “With respect to restaurants, FDA guidance suggests that any use of an FDA-defined food labeling claim (e.g., “fat free” or “low cholesterol”) on restaurant menus **should** be consistent with the respective regulatory definitions (Ref. 35).”





Restaurant Food, cont

- Ref 35 is a document entitled, “Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods”
- It contains nonbinding recommendations (*they are not legally obligated to follow these recommendations*)
- The document states, “While ‘A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods’ represents the best advice of FDA, it does not have the force and effect of law”
- The document also states, “The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.”

Source: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053455.htm>





My Personal Take

- I have written to the FDA for clarification regarding use of a gluten-free claim on menus
- Restaurants serving gluten-free food must do everything in their power to ensure that meals represented as gluten-free truly contain less than 20 ppm gluten
- Testing restaurant meals for gluten to check compliance is not an easy thing to do





Can you clear up the confusion about ingredients processed or not processed to remove gluten?

- Under the gluten-free labeling rule a food making a gluten-free claim may contain an ingredient derived from a gluten-containing grain that has been processed to remove gluten as long as use of that ingredient in the food does NOT cause the food to contain 20 ppm or more gluten
 - The only example of such an ingredient provided by the FDA is wheat starch





Ingredients, cont

- Under the gluten-free labeling rule a food making a gluten-free labeling claim may NOT contain an ingredient that has not been processed to remove gluten
 - The only example of an ingredient NOT processed to remove gluten provided by the FDA in the rule is wheat flour





Ingredients, cont

- The FDA does provide some indication of what they mean by an ingredient processed to remove gluten when they write in the executive summary (concerning beta glucan):
 - “Similar to wheat starch, we consider beta glucan derived from barley to be an ingredient that has been processed to remove gluten because the process of deriving this ingredient is designed to selectively yield the desired polysaccharide and exclude other naturally occurring components, including protein.”
- The operative word in the above passage appears to be “protein”

Source: <https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>





My Personal Take

- In the proposed rule the difference between ingredients processed to remove gluten and ingredients NOT processed to removed gluten is protein
 - Ingredients NOT intended to contain gluten protein, such as wheat starch and wheat starch hydrolysates (e.g., glucose syrup made from wheat starch) are allowed
 - Ingredients containing gluten protein, such as hydrolyzed wheat protein and barley malt extract or flavoring are not allowed





Personal Take, cont

- The final rule does not expressly state whether malt and hydrolyzed wheat protein are still considered ingredients NOT processed to remove gluten and therefore not allowed
- The FDA should provide additional guidance to consumers and manufacturers on ingredients processed/not processed to remove gluten
- Based on my experience with Gluten Free Watchdog, it is not unusual for a manufacturer to use a barley-based ingredient (e.g., barley malt) in a labeled gluten-free food:
 - While the rule was in the proposed stage I could point to the language in the proposed rule and the manufacturer without exception would remove the malt ingredient
 - This will be a far more difficult issue now that FDA guidance is so poor
- Individuals with celiac disease should continue to not consume products containing barley malt or hydrolyzed wheat protein





What is the FDA's position on fermented and hydrolyzed foods?

Let's first address background information:

- The assay known as a sandwich ELISA is used to assess the gluten content of foods when the gluten protein is intact or relatively intact
- With this type of assay, two epitopes or antibody binding sites are needed
- When an ingredient or food is hydrolyzed or fermented the gluten protein is broken into smaller protein fragments
- These protein fragments may no longer contain two epitopes and gluten content may be underestimated if the food is assessed using a sandwich ELISA





Background Info, cont

- Consider the following protein where “QQPFP” represents the potentially celiac toxic epitope and “a” represents other amino acids:

aaaaa**QQPFP**aaaaaaaaaaaaaaaaa**QQPFP**aaa**QQPFP**aaaaaa**QQPFP**

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

1. aaaaa**QQPFP**
2. aaaaaaaaaaaaaaaaa**QQPFP**aaa**QQPFP**
3. aaaaaa**QQPFP**

- The sandwich R5 ELISA (which utilizes the R5 monoclonal antibody to the potentially celiac toxic epitope QQPFP) would be unable to measure the first or the third protein fragments because these peptides contain only one QQPFP epitope
- Only the second protein fragment would be measured by the sandwich R5 ELISA

Source: Thompson T, Mendez E. *J Am Diet Assoc.* 2008;108:1682-1687. Abstract available at: <http://www.ncbi.nlm.nih.gov/pubmed/?term=thompson+gluten+assays>





The FDA's Position on Fermented/Hydrolyzed Foods

- When only one epitope or antibody binding site is available (which may be the case when ingredients/foods are fermented or hydrolyzed) a competitive ELISA (e.g., competitive R5 ELISA) should be used
- BUT the FDA does not consider these methods scientifically valid for the purposes of analyzing fermented or hydrolyzed foods to determine compliance with the gluten-free labeling rule
- The agency states in the executive summary: “Evidence in the scientific literature is currently lacking about a scientifically valid competitive ELISA method which confirms that any gluten peptides detected in a food sample can be accurately quantified in terms of ppm intact gluten protein.”





FDA Position, Cont

- The FDA is planning rule-making for fermented or hydrolyzed foods or foods that use fermented or hydrolyzed ingredients
- In the meantime, the FDA is allowing gluten-free claims on these products provided they meet all of the requirements for bearing a gluten-free claim even though the gluten content cannot be reliably measured
- This proposed rule will include discussion of distilled vinegar, malt, malt extract, and beer under the jurisdiction of the FDA (i.e., beer that is NOT made from BOTH barley and hops)
 - Currently there are several gluten-free beers available on the market that are made using a substitute for malted barley and are regulated by the FDA





My Personal Take

- By not providing guidance on ingredients not processed to remove gluten—hydrolyzed wheat protein and barley malt — this portion of the executive summary of the rule is very confusing
- The FDA should provide guidance for manufacturers and consumers as soon as possible
- My concern is that some manufacturers may start labeling foods containing malt (e.g., malt vinegar) and hydrolyzed wheat protein (e.g., soy sauce) gluten-free





Personal Take, cont

- **The AACCI (American Association of Cereal Chemists International) very recently published a technical report on the findings of a collaborative study on the competitive R5 ELISA**
 - This international collaborative study to validate the competitive R5 ELISA (Ridascreen Gliadin Competitive R7021, R-Biopharm) was jointly run by the Prolamin Working Group and AACCI
 - This multi-lab performance trial involved 16 labs and 7 foods/beverages
- By means of comparison, when the sandwich R5 ELISA (Ridascreen Gliadin R7001, R-Biopharm) was validated in a collaborative trial with the Prolamin Working Group, 20 labs and 12 food samples were involved
- To the best of my knowledge the FDA has not commented publicly on this collaborative trial and I do not know if the study was considered during rule making (the article was published in June 2013)

Source: Koehler P, et al. Cereal Foods World. 2013;58:154-158





What is NOT covered by the rule?



Rx





What about foods regulated by the USDA?

- Foods regulated by the USDA are NOT covered by the gluten-free labeling rule
- Foods regulated by the USDA include:
 - Meat products
 - Poultry products
 - Egg products (dried, frozen, or liquid eggs, with or without added ingredients)
 - Mixed food products that generally contain no more than 3% raw meat, or 2% or more cooked meat or poultry meat



USDA, cont

- The easiest way to tell whether a product is regulated by the USDA is to look for the USDA egg products shield or the USDA mark of inspection





USDA, cont

- A few years ago I was told the following about gluten-free labeling via email correspondence with the USDA and on August 29th I was advised by USDA that this remains their position:
 - “FSIS is not planning at this time to conduct rulemaking to define ‘gluten free.’ Rather, once FDA’s final rule becomes effective, if a meat, poultry, or egg product establishment chooses to make the claim ‘gluten free’ they will need to follow the requirements for the use of the claim in FDA’s regulations. This is similar to what FSIS has required when establishments choose to make health claims and label trans-fat on meat, poultry, and egg products (i.e., FSIS allows the use of FDA regulated health claims and the declaration of trans-fat on labels provided the establishments follows FDA’s regulations). This would ensure consistency for the use of the claim ‘gluten free’ across all food groups for consumers. FSIS will clarify this position through policy guidance published on its web-site.”

Source: www.glutenfreedietitian.com





What about beverages regulated by the TTB?

- Beverages regulated by the TTB are NOT covered by the FDA's gluten-free labeling rule
- The TTB regulates almost all alcoholic beverages:
 - All distilled spirits,
 - Wines that contain 7% or more alcohol by volume, and
 - Malted beverages (e.g., beer) that are made with BOTH malted barley and hops (e.g., Omission beer)





TTB, cont

- In May 2012, the TTB issued an interim policy on gluten-free labeling of alcoholic beverages under its jurisdiction
- Under the interim policy, the TTB:
 - Will not allow gluten-free claims to be included on product labels or in product advertising if the alcohol is made with wheat, barley, rye, or crossbred varieties of these grains OR any ingredients derived from these grains.
 - Will allow gluten-free claims on products labels and in advertisements if the alcohol is made without wheat, barley, rye, or crossbred varieties of these grains OR ingredients derived from these grains. BUT producers must ensure that their raw ingredients and finished products (among other things) are NOT cross-contaminated with gluten.

Source: <http://www.ttb.gov/rulings/2012-2.pdf>





TTB, cont

Under the interim policy, the TTB:

– Will allow the statement, “Processed or treated or crafted to remove gluten” for products made with wheat, barley, rye, or crossbred varieties of these grains OR any ingredients derived from these grains IF these grains or ingredients have been processed (or treated or crafted) to remove all or some of the gluten.”

IF

– One of the following statements is also included on the product label or in the advertisement:

- “Product fermented from grains containing gluten and [processed or treated or crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten.” OR
- “This product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten.”





TTB, cont

- The TTB issued the following statement on August 22, 2013 following the release of the FDA's gluten-free labeling rule:
 - “We are currently reviewing our policy on gluten content statements in the labeling and advertising of wines, distilled spirits, and malt beverages in light of the recent U.S. Food and Drug Administration (FDA) final rule on the use of the term "gluten-free" for products under FDA's labeling jurisdiction. While we are reviewing this, we would like to remind industry members that TTB Ruling 2012-2, Interim Policy on Gluten Content Statements in the Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages, is still in force for alcohol beverage products that are subject to TTB's labeling regulations under the Federal Alcohol Administration Act.”

Source: <http://www.ttb.gov/announcements/announcement-gluten-free-content-statements.pdf>





What about cosmetics?

- The gluten-free labeling rule does not cover cosmetics
- The FDA defines a *cosmetic* as “a product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance.”

Source: Thompson T, Grace T. J Acad Nutr Diet. 2012;112:1316-1319





Cosmetics, cont

- Based on personal correspondence with the FDA, the presence of gluten does not need to be definitively declared on cosmetic labels and there are no rules or guidance documents specifically addressing the use of the term gluten-free in the labeling of cosmetics regulated by the FDA
- The FDA does not, however, prohibit cosmetics companies from labeling products gluten-free
- If a cosmetics company does label a product gluten-free and this labeling distinction is found to be inaccurate or misleading, the product may be declared misbranded

Source: Thompson T, Grace T. J Acad Nutr Diet. 2012;112:1316-1319

<http://www.glutenfreedietitian.com/newsletter/personal-care-products-do-you-need-to-worry-about-gluten-update/>





What about pharmaceuticals?

- The gluten-free labeling rule does not cover prescription and non-prescription drugs
- In the Q&A document the FDA states:
 - “On December 21, 2011, FDA’s Center for Drug Research and Evaluation (CDER) issued a Federal Register notice (76 FR 79196) to request information and public comments on a series of questions related to the presence of gluten in drug products (i.e., prescription, nonprescription, biologic, and homeopathic drug products). CDER is considering the public comments it received in response to this notice as it evaluates options to help individuals with celiac disease limit gluten exposure from consumption of drug products.”





Pharmaceuticals, cont

- In November 2011, NFCA received a \$50,000 grant from the FDA for scientific research in the area of gluten in medication
- The project entitled, “Gluten in Medication: Qualifying the extent of exposure to people with celiac disease and identifying a hidden and preventable cause of an adverse drug event,” will characterize the problem of unlabeled gluten in medication
- Testing of the identified medications will conclude in September 2013 and the final report will be delivered to the FDA no later than mid-December 2013





Summary Statement

- We finally have a gluten-free labeling rule and this is a very good thing for our community.
- It took a lot of work by a lot of individuals and groups both outside and inside of FDA to get this rule finalized.
- It is by no means perfect and parts remain confusing but FDA can help out a lot in this regard by issuing further guidance.





Food Manufacturer's Perspective – Q#1

As a company who has been a loyal supporter of strict testing of gluten-free products for more than a decade - during a time when federal standards were not in place - **can you speak to the progression of gluten-free labeling?**





Food Manufacturer's Perspective – Q#2

Can you **highlight some important testing processes and methods** you use to uphold the strict standards that Bob's Red Mill is so well known for?

Bob's Red Mill products labeled Gluten Free are batch tested in our quality control laboratory. We use an ELISA Gluten Assay test to confirm that a product is gluten free.





Food Manufacturer's Perspective – Q#3

In your opinion, **what type of impact will manufacturers experience?**





Food Manufacturer's Perspective – Q#4

From your point of view, **will small gluten-free businesses still be able to compete with large companies?**





Questions & Answers!





FDA's Gluten-Free Labeling Rule: Resources from NFCA

- Dedicated web section: www.celiaccentral.org/fda
- Coming soon on Tuesday, October 8th:
 - *Gluten-Free Labeling Fact Sheet* will address topics and Q&A from tonight's webinar
 - Follow-up survey to webinar participants and registrants
- Sign up for NFCA's free e-newsletter: www.CeliacCentral.org/subscribe
- Related: Q&A with Dr. Koehler, co-author of recent technical report on the findings of a collaborative study on the competitive R5 ELISA on NFCA's Research News Feed
 - www.CeliacCentral.org, search "Study Validates the R5 Competitive ELISA"



Gluten-Free Certification Program (GFCP)

- In July 2013, NFCA endorsed the GFCP as our stance on advocating for gluten-free food safety
- GFCP: A North American solution, using a single process to certify products for distribution in the U.S. and Canada
- Watch for announcements about certified brands - Coming soon!
- Learn more: www.gf-cert.org





Gluten in Medications: Resources from NFCA

- Dedicated web section: www.celiaccentral.org/gluteninmeds
- Free continuing education for pharmacists:
www.celiaccentral.org/greatpharmacists



NFCA's 10th Anniversary!

A Decade of Restoring Health and Reclaiming Lives

- Since 2003, NFCA has led the way in providing you, your family and millions of others *free* helpful resources such as:
 - Evidence-based education
 - Webinars
 - Expert insights
 - Timely news articles
 - Monthly e-newsletter
- With your continued support, we will continue to lead the way!
 - CeliacCentral.org/donate --- every dollar counts!
- October 10th, Philadelphia:
 - CeliacCentral.org/10years/celebrate



Save the Dates!

- **Topic:** *“Kids Central Special: Packing the Gluten-Free School Lunchbox”*
Date: Thursday, October 3, 2013
Time: 8:30 p.m. Eastern/5:30 p.m. Pacific
Speaker: **Garrett Berdan, RD, Chef**

- **Topic:** *“Holiday Special Part 1: Gluten-Free Baking”*
Date: Wednesday, November 13, 2013
Time: 8:30 p.m. Eastern/5:30 p.m. Pacific
Speaker: **Chef Richard Coppedge, Professor at the Culinary Institute of America**

- *NFCA’s second webinar in it’s 2013 FDA-series – Stay Tuned!*



Thank You!

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