White Paper: Gluten-Free Labeling of Foods

Comply with new FDA regulations and deliver gluten-free products consumers can trust

By Jaclyn Bowen, NSF International

On August 2, 2013, the U.S. Food and Drug Administration (FDA) issued a final rule defining "gluten-free" for food labeling, which will help consumers, especially those living with celiac disease, be confident that items labeled gluten-free meet a defined standard for gluten content. The compliance date for this final rule was August 5, 2014.

The regulation provides a uniform standard for manufacturers who choose to label their products as gluten-free. It will also help the estimated one in every 133 people - about 3 million people in the United States – who have celiac disease, a condition that can only be managed by eating a gluten-free diet.[1]

This new federal definition standardizes the meaning of gluten-free claims across the food industry. It requires that, in order to use the term gluten-free on its label, a food must meet all of the requirements of the definition, including containing less than 20 parts per million (ppm) of gluten. The rule also requires foods with the claims "no gluten," "free of gluten" and "without gluten" to meet the definition for gluten-free.

This white paper provides an overview of this new gluten-free regulatory requirement which applies to all FDA-regulated packaged foods, including dietary supplements. However, companies can voluntarily choose to meet these gluten-free requirements for any other consumer product, such as cosmetics or personal care products, to demonstrate to concerned shoppers their commitment to gluten-free offerings.

[1] Source: National Foundation for Celiac Awareness

The FDA requirements in a nutshell

The Food Allergen Labeling and Consumer Protection Act of 2004 directed the Secretary of Health and Human Services to issue federal regulations that "define" and "permit use of" the term gluten-free food labels. The final FDA rule is a result of that directive and establishes requirements for the use of gluten-free claims.

Labeling foods as gluten-free is voluntary. However, *if* a manufacturer chooses to use the term gluten-free or another variation of the claim on its packaging, then the manufacturer *must* comply with the FDA's gluten-free food labeling final rule.

Products that *can* use "gluten-free"	Products that *can't* use "gluten-free"
• Foods that inherently do not contain gluten (e.g. raw carrots or grapefruit juice) • Foods with ingredients that are gluten-containing grains that have been refined to remove the gluten as long as the food contains less than 20 ppm gluten (e.g. wheat starch)	• Foods with any whole, gluten-containing grains (e.g. spelt wheat) as ingredients • Foods with ingredients that are gluten-containing grains that are refined but still contain gluten (e.g. wheat flour) • Foods that contain 20 ppm or more gluten as a result of cross-contact with gluten-containing grains

Additionally, if a product uses a wheat ingredient or any of its derivatives, it must also follow the appropriate labeling rules in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004.

Companies are responsible for ensuring that any gluten-free claim made on food labels is truthful, not misleading, and complies with the FDA regulations. The FDA may use the full range of its routine post-market monitoring activities to enforce the final rule on gluten-free food labeling, including periodic inspections of food manufacturing facilities, food label reviews, follow-up on consumer and industry complaints reported to the agency, and, when needed, gluten analyses of food samples.

What "misbranded" means

The FDA identified many other variations of the gluten-free claim and ensured that all label claims pertaining to gluten allergen content are subject to the regulation, including products that bear the claim "no gluten," "free of gluten" or "without gluten."

This is important to note because any products with gluten-free claims that are found out of compliance – whether through random off-the-shelf testing or as a result of a consumer compliant investigation - will be deemed misbranded.

According to the Federal Food, Drug, and Cosmetic Act (FD&C Act), a misbranded product has false or misleading information, lacks required information, has packaging that is difficult to interpret, is misleading, is improper or has label deficiencies regarding the Consumer Product Safety Commission's Poison Prevention Packaging Act (PPPA) requirements.

The FD&C Act prohibits, among other things, products that are considered misbranded or adulterated from being introduced or delivered into interstate commerce. It also prohibits receiving and selling misbranded products.

> *"The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise"[FD&C Act, sec. 301(c); 21 U.S.C. 331(c)].*

> *"The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded" [FD&C Act, sec. 301(k); 21 U.S.C. 331(k)].*

The term "misbranding" applies to products that:

- Advertise false or misleading information
- Lack required information
- Make it difficult to interpret the required information
- Have misleading packaging
- Exhibit improper packaging and labeling of color additives
- Are deficient where the PPPA requires special packaging

If an adulterated and/or misbranded product continues to be marketed, it may result in the FDA taking regulatory action, including, but not limited to, a civil money penalty, no-sale order, seizure and/or injunction. This means that all companies involved in interstate commerce, such as manufacturers, packers, distributors and retailers, are responsible for assuring that they are not dealing in products that are adulterated or misbranded, even if someone else caused the adulteration or misbranding in the first place.

Both those that introduce and those that receive the mislabel product into interstate commerce are responsible because the law applies to components and packaging as well as to finished products. In other words, it is essential to have strict purchasing practices or other processes in place to ensure compliance throughout the supply chain, from farm to fork.

Products covered by the FDA's gluten-free food labeling final rule

The final rule applies to all FDA-regulated foods, including dietary supplements. The rule excludes those foods whose labeling is regulated by the U.S. Department of Agriculture (USDA) or the Alcohol and Tobacco Tax and Trade Bureau. Generally, the USDA regulates the labeling of meats, poultry and certain egg products. The Tobacco Tax and Trade Bureau regulates the labeling of most alcoholic beverages, including all distilled spirits, wines that contain seven percent or more alcohol by volume and malted beverages that are made with both malted barley and hops.

With respect to restaurants, FDA guidance suggests that any use of an FDA-defined food labeling claim (such as "fat free" or "low cholesterol") on restaurant menus should be consistent with the respective regulatory definitions. This same approach would be followed with respect to gluten-free claims made in restaurants and other retail food service establishments. The FDA rule does not provide specific guidance on how restaurant, retailer and deli gluten-free claims will be enforced. However, the court of public opinion will swiftly judge gluten-free bad players.

The FDA's Q&A guidance on the gluten-free food labeling final rule is very clear that anyone who becomes ill or otherwise experiences adverse health effects they believe are associated with having eaten a particular food, including individuals with food allergies and those with celiac disease, should report such incidents to the Center for Food Safety and Applied Nutrition's Adverse Event Reporting System. In addition, consumers and manufacturers can report complaints about FDA-regulated foods (e.g., potential misuse of gluten-free claims on food labels) to an FDA Consumer Complaint Coordinator in the state where the food was purchased.

The rule does not currently apply to drugs or cosmetics. However, on December 21, 2011, the FDA's Center for Drug Evaluation and Research (CDER) issued a Federal Register notice to request information and public comments on a series of questions related to the presence of gluten in drug products (e.g. prescription, nonprescription, biologic and homeopathic drug products). The CDER is considering the public comments received in response to this notice as it evaluates options to help individuals with celiac disease limit gluten exposure from consumption of drug products.

What you need to understand about testing

The final rule does not specifically require manufacturers to test for the presence of gluten in their starting ingredients or finished foods in order to use the gluten-free label claim. However, manufacturers are responsible for ensuring that foods bearing a gluten-free claim meet this requirement. This means that any unavoidable gluten present in the product must be less than 20 ppm.

Manufacturers are encouraged to use effective quality control tools that ensure any foods labeled gluten-free do not exceed this 20 ppm of gluten limit. There are a number of methods and tools companies can use 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.

In the enforcement of its regulations, the FDA routinely uses scientifically valid methods that have undergone an independent multi-laboratory performance evaluation where the results have been published in the peer-reviewed scientific literature to ensure that the results obtained are accurate and reliable. For the gluten-free final rule, the FDA has currently identified two valid test methods that should be used. Both are sandwich enzyme-linked immunosorbent assays (ELISA)-based methods:

- R-Biopharm: Food & feed analysis
- Morinaga Institute of Biological Science, Inc.: Wheat/gluten (gliadin) ELISA kit

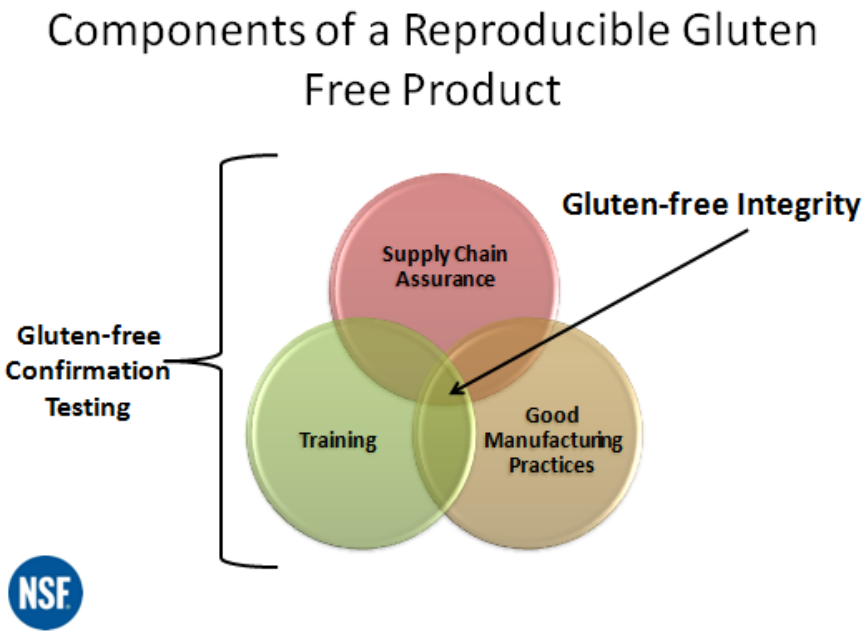
When necessary, the FDA will use these tests in tandem to determine compliance with the final rule. As discussed in the final rule, the FDA is aware that sandwich ELISA methods do not adequately detect gluten in fermented and hydrolyzed foods. Because scientifically valid methods are currently lacking, additional guidance from the FDA is forthcoming.

Labs at NSF International

Well developed quality assurance programs are essential

A well developed and well executed gluten management program goes hand in hand with other food safety management systems. The key to compliance is consistency once the system has been properly designed and implemented.

Testing alone is not sufficient to ensure the gluten-free compliance of products. An investment in a quality management system that evaluates supplier assurance, good manufacturing practices and ongoing training is your best option to ensure that products meet the requirements of the FDA gluten-free food labeling final rule. After necessary investments in training, supply chain assurance and good manufacturing practices, testing is just confirmation of an already effective quality management system.



Components of supply chain assurance

A common total quality management system philosophy is, "If your raw materials are well defined and controlled, and if your manufacturing process is well defined and controlled, you can't help but make consistently good product."

In order to credibly support a product's gluten-free claims, companies must control for gluten at every step in the manufacturing process, including from ingredient supplies. This includes ensuring that suppliers are capable of producing and delivering consistent, proven gluten-free ingredients. This can be achieved through a number of tools and strategies, including:

- **Conducting assessments of processes and sub-ingredients,** including applying the HACCP principles of developing a verified process flow and performing an in-depth risk assessment for ingredients such as processing aids, anti-caking agents and release agents
- **Requiring that suppliers obtain third-party certification of gluten-free claims**, which provides a high level of confidence in ingredients,

- **Implementing internal monitoring programs** (especially in mixed production facilities) including assessments to review shared processing equipment, production scheduling, personnel practices and sanitation
- **Enforcing pre-shipment verification testing (i.e. Certificates of Analysis)** as a due diligence practice to ensure gluten contamination doesn't enter the products

Keep them apart from the start

The best supplier program in the world can be quickly undermined if the gluten-free ingredients are cross contaminated. This is especially important in mixed-product facilities, which are at greater risk for cross-contamination. A good starting point is an allergen management program – gluten-free products, their ingredients and the processes they go through can be treated the same way as any allergen. This extends to warehousing and distribution, especially if exposed products of different types are nearby. Remember, the celiac community can be very sensitive to ***any*** exposure of gluten-free food to non-gluten-free products.

Keep It Separated:

- Segregated ingredient storage
- Separate preparation and processing
- Dedicated personnel
- Dedicated equipment and smallwares
- Segregated warehousing
- A well developed and executed allergen management program

Effective training approaches

All employees should go through training focusing on awareness and sensitivity, hygiene and separation. Personnel must understand that some celiacs are hyper sensitive and an oversight or mistake on their part can ultimately become a real health risk for some celiac customers. Personnel who handle, formulate, process and package gluten-free products must have specific training on awareness and proper procedures. This training should not be limited to just ingredients and processing, but also address compliance with internal label controls and verification procedures.

Supervisory staff must also go through the detailed training to take full responsibility for employee oversight and procedural compliance. If the supervising staff does not know or appreciate the processes behind meeting gluten-free recruitments, those tasks may not be given the priority they require.

Considerations for retailers

Although retailers are one link further down the supply chain, the same sourcing and control dynamics should be utilized by retailers and other specifiers as they seek confidence in their sources of gluten-free products. A structured and well managed supplier approval program is essential. Verification through supplier certification or internal verification testing is a good approach. Also, separation and hygiene rules must be applied in-store, especially for exposed products.

Implications for Global Food Safety Initiative (GFSI) benchmarked certification standards

Global food safety standards benchmarked under GFSI already have requirements for effective allergen control. Although they do not specifically call out gluten, auditors will likely look closely at a supplier's gluten management program as part of the audit if the supplier is making associated claims. It is an extension of the allergen management program as a sensitizing agent.

Global labeling guidelines for gluten-free products

Regulations for gluten labeling do not stop at U.S. shores. Manufacturers of products made for export should be aware of other regions' requirements – they may differ from the U.S. FDA requirements.

The U.S. FDA criteria that gluten-free food contains less than 20 ppm gluten is consistent with approaches taken by many other regions' food governing bodies. The United Nation's Codex Alimentarius Commission's revised Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten established a threshold of 20 mg gluten per kg of product (which is equivalent to 20 ppm gluten) for foods labeled gluten-free. Additionally, the European Commission's Regulation concerning "the composition and labeling of foodstuffs suitable for people intolerant to gluten" requires that foods labeled as gluten-free not contain more than 20 ppm gluten.

In June 2012, Health Canada described its new position on gluten-free claims:

> *"Based on the available scientific evidence, Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of when a gluten-free claim is made."*
>
> *"Based on the enhanced labeling regulations for allergens and gluten sources, any intentionally added gluten sources, even at low levels (e.g. wheat flour as a component in a seasoning mixture which makes up a small proportion of the final food), must be declared either in the list of ingredients or in a 'Contains' statement. In these cases, a gluten-free claim would be considered false and misleading. If, however, a manufacturer using a cereal-derived ingredient includes additional processing steps which are demonstrated to be effective in removing gluten, then the food may be represented as gluten-free."*

The Health Canada position that food labeled gluten-free not contain more than 20 ppm gluten is comparable to the U.S. FDA's final rule criterion. However, the Food Standards Australia New Zealand (FSANZ) standard requires that a food have "no detectable gluten" if it claims to be gluten-free.

Semantics also play a role in gluten-free labeling across regions. The Codex Standard and European Commission Regulation state that a gluten-free food is one whose "gluten level does not exceed" 20 mg/kg, and Health Canada's position is that a gluten-free food has a gluten content "not exceeding 20 ppm," whereas the U.S. FDA final rule defines gluten-free with respect to a gluten content of less than 20 ppm.

One difference in gluten-free definitions worldwide regards oats. The Codex Standard, European Commission Regulation, Health Canada and FSANZ standard include oats as gluten-containing grains, whereas the U.S. FDA final rule does not.

As another difference, some regions allow for "low gluten" claims. The European Commission Regulation allows foods not exceeding 100 mg/kg gluten to bear the term "very low gluten." The FSANZ standard states that a food can be "low gluten" if the detectable gluten content is no more than 20 mg per 100 g of food (no more than 200 ppm). The U.S. FDA final rule does not define the use of "low gluten" or "very low gluten" claims.

Is gluten-free certification the solution?

Gluten-free certification helps take the guess work out of supply chain assurance for manufacturers sourcing ingredients as well as retailers sourcing finished products. However, when choosing a third-party certification body, there are several attributes you should look for.

Certifiers should:

- Be credible
- Have ISO Guide 65 accreditation/compliance
- Have the capability to conduct chain of custody testing
- Have well trained and calibrated auditors for gluten-free facility inspections

Gluten-free products certified via NSF International's Gluten-Free Certification Program already meet the FDA's new gluten-free labeling regulation. In 2011, NSF International developed a voluntary gluten-free standard and certification program which verifies that certified products contain 20 ppm or less of gluten. In addition to product testing, NSF audits the manufacturing facilities to ensure the manufacturing process prevents gluten contamination of products and reviews formulations to ensure that the ingredients used are gluten-free.

Widespread cross-contamination of source ingredients means that even manufacturers who singularly produce gluten-free products must incorporate adequate testing and verification protocols into their operating procedures. The stringent nature of the NSF certification protocols helps to ensure prevention of contamination and co-mingling, which is critically important for those with celiac disease and gluten intolerance.

Take the quiz

This questionnaire will help you identify potential gaps in your food safety management systems and to take practical steps to develop and implement an effective control program. >>Take the quiz

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Jaclyn Bowen is the General Manager of NSF International's U.S. agriculture and label claim verification programs as well as its organic certification subsidiary Quality Assurance International (QAI), all part of NSF's Global Food Division. QAI is a leading advocate for organics and provider of organic certification for more than 20 years. Jaclyn oversees NSF Agriculture and QAI program, which include certification to the USDA's National Organic Program (NOP), as well as to international organic programs. In addition, NSF also offers gluten-free, Non-GMO Project, kosher, Eco-Social and personal care certification, as well as certification to Global Food Safety Initiative- benchmarked standards. Jaclyn earned a master's degree in management and policy from the University of Michigan, a master's degree in quality from Eastern Michigan University's College of Engineering Technology, and a bachelor's degree in environmental biology from Michigan State University.