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Gluten and Gluten Free: Labelling Regulations Insight

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Abstract

During the last decade, the market of gluten-free products is noticeably emergent since enhanced diagnostic methods allow early identification of patients suffering celiac disease and also other gluten-related disorders such as dermatitis herpetiformis, gluten ataxia, wheat allergy and non-celiac gluten sensitivity. The only and safe treatment available nowadays for these types of disorders is to follow a strict and permanent lifelong gluten-free diet based on clear labeling rules and standards. To improve the quality of life availability of gluten-free products with proper labeling is of paramount importance. For this reason efforts must be focused on harmonizing the labeling and regulation across different countries. In this context, this review article aims to discuss the overall regulatory status across different countries.

Keywords: *Gluten Free; Celiac Disease; Allergy regulation; labeling standards; Non-celiac gluten sensitivity*

Abbreviations: CD: Celiac disease

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Introduction

Celiac disease (CD) is an enteropathy mediated by immunological mechanisms triggered by the interaction of gluten with the intestinal mucosa in affected individuals. The consequence of this activity is the atrophy of the mucosal villi, which are the intestinal extensions responsible for absorption of nutrients, leading to malabsorption and malnutrition [1,2]. CD can have different clinical manifestations: classical or typical (more common in children), characterized by symptoms of intestinal origin; and atypical (more common in adults), when the symptoms are primarily extraintestinal. The only treatment for celiac disease is the total avoidance of gluten from wheat and the related proteins from barley, rye, oats, or any Triticum species or their cross-bred varieties.

The total exclusion of gluten-containing foods and ingredients in foodstuffs is very important to avoid health hazards, however, this was extremely difficult to realize in the past because of inadequate labeling directives regarding (a) compound ingredients, (b) class names, and (c) the usage of wheat gluten for technological reasons. This has brought improvement of labeling directives worldwide across different countries. The enhanced regulation and proper labeling would further support the consumer about the choices of the food. The section below explains the International regulatory status for gluten free labeling.

International Regulatory Status: An Over View

In the reference to the intolerance towards gluten, mostly worldwide regulations on gluten-free labeling are based on the Codex Alimentarius Standard 118-1979. Codex Alimentarius normally sets recommendations and standards but not regulations. The year 2008, revised Standard not only provides the definitions for gluten-free foods, but also includes for the first time a definition for low-gluten foods. According to the codex standards, the following is the definition of gluten-free food:

Option 1 for gluten-free. -Consisting of or made only from one or more ingredients that do not contain wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, AND the gluten level does not exceed 20 mg/kg, in total, based on the food as sold or distributed to the consumer, and/or

Option 2 for gluten-free. -Consisting of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to remove gluten, AND the gluten level does not exceed 20 mg/kg, in total, based on the food as sold or distributed to the consumer. Therefore it could be inferred that to be eligible for gluten-free labeling, the gluten content in the final product must not be higher than 20 mg/kg, regardless of whether the product contains ingredients derived from wheat, barley, rye, and oats or not.

The definition of low-gluten foods is the same as mentioned in the option 1 however it permits gluten content to be between 20 and 100 mg/kg. It has been recognized by the codex that that oats are tolerated by some, but not all, individuals intolerant to gluten, and therefore suggests the inclusion of noncontaminated oats at a national level. Oats has been debated for a long time about its inclusion in the definition of gluten free. One of the reasons for considering oats in the gluten free definition could be due to the systematic contamination of oat with other cereals containing toxic gluten, such as wheat. This statement is infact supported by several studies in the past [3].

For Example, in year 2011, Health Canada has reported 88% of the samples of commercial oats tested where contaminated with gluten above 20 mg/kg, and only one of the pure oat samples was consistently negative [4]. It is possible to produce uncontaminated pure oats under the controlled conditions. In this context, the Canadian Celiac Association, in consultation with Health Canada, Agriculture & Agri- Food Canada, and the Canadian Food Inspection Agency, has established the requirements and parameters for growing, processing, and testing the purity of oat seeds for labeling purposes, which has allowed the certification and commercialization of pure oats [5].

At the beginning of December 2016, the "Codex Committee on Nutrition and Foods for Special Dietary Uses" (CCNFSDU), a board of the Codex Alimentarius Commission, met in Hamburg, Germany. An important decision in the official report: The analysis method to be used for the detection of gluten is an ELISA test based on the R5 antibody). Use of a G12 ELISA is not recommended due to the lack of comparability until further notice [6,7].

Gluten-Free Labeling in Europe

After codex in year 2008 revised the standards for gluten free, the European Commission also revised the gluten free definition to incorporate the limits established by Codex recommendation in Commission Regulation 41/2009 with the terminology "gluten-free" and "very low gluten." Commission Regulation 41/2009 was effective as of January 1, 2012. This regulations defines gluten as the protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0.5 M sodium chloride solution. The terms gluten-free and very low gluten in this regulation apply to products containing ingredients derived from wheat, rye, barley, and oats that have been specially processed to reduce the gluten content so that it does not exceed 20 mg/kg in gluten-free foods or 100 mg/kg in very low gluten products. Also, gluten-free can be used if the product contains ingredients that substitute the cereals containing toxic gluten, and the gluten content does not exceed 20 mg/kg. The regulation also addresses the special case of contamination in oats, indicating that oats must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats must not exceed 20 mg/kg.

The regulation also determines that the terms gluten-free and very low gluten must be positioned on the food package close to the name of the product.

EU regulations are mandatory for all manufacturers which sell their products in the EU. The following laws must be observed [8].

- Food Information Regulation/EU regulation No. 1169/2011: This resolution stipulates that information on potential allergens must always be provided to the consumer–even when the food is offered unpacked, for example in restaurants or bakeries. Previously, allergens had to be labelled only on packaged food.
- EC regulation No. 41/2009: An important point in this document is the specification of Europe-wide binding limit values for labelling products as "gluten-free" or "very low gluten". It adopts the limit values defined in the Codex standard.
- Implementing regulation No. 828/2014: This regulation became effective on July 20, 2016 and replaces regulation No. 41/2009. The paper now also contains rules concerning the use of the claims "suitable for celiac/people intolerant to gluten" and "specifically formulated for coeliacs/people intolerant to gluten".

Gluten-Free Labeling in United States

Commonly in the United States, the Food Allergen and Consumer Protection Act (FALCPA) mandates that the Secretary of Health and Human Services issue a proposed rule to define and permit use of the term gluten-free on food labels no later than 2 years after enactment of the Act in August 2004, and a final rule no more than 4 years later. In January 2007, the proposed rule was made public. After conducting a new safety assessment, the U.S. Food and Drug Administration (FDA) revised the proposed rule on gluten-free and opened a new period for public comments in August 2011.

In 2013, the FDA issued the gluten-free final rule, which addressed the uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods in terms of intact gluten. Due to this uncertainty, the FDA has issued this proposed rule to provide alternative means for the agency to verify compliance for fermented or hydrolyzed foods labeled "gluten-free" based on records that are made and kept by the manufacturer [9].

As of 2013, all foods labeled gluten-free must meet all requirements of the gluten-free labeling final rule published in August 2013. The requirements apply to packaged foods labeled on or after today. FDA recognizes that many foods currently labeled as gluten-free may already meet the new federal definition. However, consumers should be aware that there may be some products still on store shelves that were produced and labeled before the compliance date for FDA's rule. On June 25, 2014, the FDA issued a guide for small food businesses to help them comply with the final rule's requirements. FDA will continue to work with, educate and monitor industry on the use of the gluten-free claim.

The proposed rule introduces the concept of prohibited grains in the definition of gluten-free food; provides the criteria for use of gluten-free in food labeling and foods that inherently do not contain gluten, and mentions the use of the analytical method based approach to set a threshold of 20 ppm to define glutenfree as well as proposed methods to support the definition of gluten-free.

The FDA includes wheat, rye, barley, and their crossbred hybrids in the definition for prohibited grains and defines gluten as those proteins that naturally occur in a prohibited grain and that may cause adverse health effects in persons with CD (e.g., prolamins and glutelins). In the proposed rule, the FDA does not include oats in the definition of prohibited grains because oats can bring nutritional benefits to the majority of CD patients, who can tolerate this cereal. The definition of gluten-free in the proposed rule states that food bearing the claim in its labeling does not contain any of the following: An ingredient that is a prohibited grain; an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten; an ingredient that is derived from a prohibited grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food (i.e., 20 μg or more gluten per gram of food); or 20 ppm or more gluten. Although the FDA identified and proposes R5-ELISA and Morinaga methods that can detect gluten at the 20 ppm level in raw or processed food, it also indicates that compliance with the regulation does not need to be based solely on food analysis but also on such activities as label reviews and onsite inspections of food producers.

Gluten-Free Labeling in Canada

Canadian Food and Drug Regulations, in Division 24 (B24.018) regulates the definition of gluten free products. It indicates that no person shall label, package, sell, or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye, or triticale, or any part thereof.

Threshold level is not included while addressing gluten free in the past. However, 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 B.24.018 when a gluten-free claim is made. While additional evidence is being gathered to support the establishment of a regulatory 20 ppm threshold for Gluten free claims, including the development of an accepted standard reference material for Gluten, Health Canada is of the position that at levels not exceeding 20 ppm of gluten as a result of cross-contamination, when Good Manufacturing Practices are followed, a claim suggesting the food is gluten-free would not pose a health risk to individuals with celiac disease and would meet the intent of B.24.018 of the FDR. This would be in keeping with the availability of validated methods (and their associated limitations, as outlined above), and would be consistent with the approach being taken internationally.

Based on the enhanced labelling 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. In February 2011, Health Canada made public the amendments to the Food Allergen Labeling regulation under the title "Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites." Although most of the amendments address food allergy labeling, some aspects refer to gluten. It includes the definition of gluten as any gluten protein from the grain of any of the cereals listed in the definition or the grain of a hybridized strain created from at least one of these cereals.

The definition includes any modified gluten protein, including any gluten protein fraction, that is derived from the grain of these cereals or the grain of a hybridized strain mentioned above. Moreover, the amendments require food manufacturers to list the sources of gluten (wheat, rye, barley, oats, or triticale) when it is present. These am endments will come into force on August 4, 2012. The Canadian regulation mandates those food manufacturers and wholesale and retail facilities handling gluten-free foods must ensure that they take measures to prevent cross contamination of gluten-free ingredients and products.

Gluten-Free Labeling in Australia/New Zealand

The Australia and New Zealand Food Standard Code also defines in Clause 16 of Standard 1.2.8 the following terms: gluten means the main protein in wheat, rye, oats, barley, triticale, and spelt relevant to the medical conditions, CD and dermatitis herpetiformis; gluten-free means a food that contains no detectable gluten, and no oats or their products or cereals containing gluten that have been malted, or their products. Low gluten is a food that contains no more than 20 mg gluten/100g of the food. The Standard allows for claims indicating that a food contains or is high in gluten.

Gluten-Free Labeling in India

In 2015, Government of India had issued a draft gazette Notification with respect to gluten and gluten free products. A detailed proposal to FSSAI (Food safety and Standard authority of India) for gluten free labeling was given in this regard. In May 2016, FSSAI second amendment regulation, 2016, and food safety and standards (Packaging and labeling) First amendment regulation, 2016 relating to the standards for gluten free and low gluten food and there labeling requirement was issued [10,11].

In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, after regulation 2.13, the following regulations shall be inserted, namely:- 2.14 Gluten Free Food. –

1. Gluten free food consist of or is made of one or more ingredients containing rice, millets, ragi, pulses or legumes.
2. It shall bear the label declaration referred to in sub-regulation 2.4.5 (50) of Food Safety and Standards (Packaging and Labelling) Regulations, 2011.
3. A food which, by its nature, is suitable for use as part of a gluten free diet shall not be named as 'special dietary', "special dietetic" or any other equivalent term, however, such food may bear a statement on the label that 'this food is by its nature gluten-free'.
4. For the purpose of labelling of a product as gluten free, when such a product is analysed, the gluten levels shall be below 20 mg/kg as per the method declared by the Organization for Economic Co-operation and Development or the Association of Official Agricultural Chemists.

Provided that it complies with the essential composition provisions for Gluten Free food and such a statement does not mislead the consumer. 2.15 Food specially processed to reduce gluten content to a level 20-100mg/kg.-

1. This food consists of or are made of one or more ingredients which may contain rice, millets, ragi, oats, rye, barley, maize, wheat, pulses and legumes containing gluten content in range of 20-100 mg/kg.
2. It shall bear the label declaration referred to in sub-regulation 2.4.5 (51) and (52) of Food Safety and Standards (Packaging and Labelling) Regulation, 2011."

Conclusion

Improvements in the worldwide Codex Standard on Food Labelling and national food labeling legislations have resolved the health hazard posed by unknown gluten intake caused by insufficient declaration of gluten-containing ingredients and food additives in foodstuffs. Statements such as "may contain" should be avoided because they are not helpful for consumers in making their choice whether or not they can eat this food. The improvements of several Codex Standards and Guidelines have contributed to the safety and large variety of gluten-free foods and, as a consequence, guarantee a better quality of life for the gluten-intolerant population.

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