Chapter 6
Regulatory and Labelling

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Abstract Gluten in food is the major health concern for Gluten-intolerant people worldwide for many years. This can be minimized by the avoidance of gluten in the diet as it does not have a cure. The control and management of gluten in food have been recognized by many countries as an important food safety concern and risk management problem in recent years. Many nation governments and organizations have implemented laws, policies, regulations for the manufacturers, retailers, and marketers to indicate the label "gluten-free" on the package to communicate, control and manage the existence or non-existence of gluten in food. The regulations for gluten-free are designed to specify no adverse level of gluten (below 20 ppm) than fully gluten absence. Numerous countries such as South Africa, the united states, Canada, Europe, China, Japan, India, and Australia, etc., have issued "Gluten-free" regulations. The regulation for "Gluten-free foods" differs from the country. The public should know the regulations and labels of the organization to avoid the mis-consumption of "Gluten-free "foodstuffs". The word "Gluten-free" on labeling is provided by quantitatively detecting the gluten content by standardizing methods of Analysis like enzyme-linked immunoassay (ELISA). The regulations are the corporative linkage between the government, industry, and consumer.

Keywords Gluten-free · ELISA · Retailer

6.1 Introduction

The significance of diet and nutrition in food to prevent numerous health concerns was not established up to many centuries. The toxicity caused by food allergen-gluten and gluten intolerance in people leads to health issues such as celiac disease, dermatitis, gluten ataxia, herpetiformis, intestinal problems which leads to anemia, diabetes, cancer has been recognized internationally in recent years and became

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serious health concern worldwide (Ahmad et al., 2019; Cornicelli et al., 2018; Tovoli et al., 2015). Moreover, these health issues directly cause an economic burden and indirectly causes loss of cost due to less productivity and more diseases. The major health concern is gluten in food for many people which can be minimized by avoidance of gluten in the diet as it does not have a cure (Sharma et al., 2015). Even though gluten-free food is manufactured, the contamination i.e. food adulteration can be caused anywhere from farm to fork-like milling, processing, cross-contact machinery during manufacturing, retail outlets, common utensils used in households ultimately leads to a health concern (Dudeja et al., 2016; Tripathi et al., 2017; Rifna et al., 2019).

The control and management of gluten in food have become an important food safety concern in recent years. Hence, it's essential to enable the consumer to differentiate between gluten and gluten-free food and make health preferences. The clear indication of the presence of gluten and gluten-free in certain foods is required for gluten-intolerant people. This felt the need to start the regulatory process to achieve food safety by determining of an optimum standard of ingredient content in the food. The awareness of the need of regulation and food allergens came in period 1990s, but the implementation of regulation globally came in the 2000s (Astley, 2019; Lee et al., 2014). The regulations assist the manufacturer to communicate, control and manage the existence or non-existence of gluten in food. The numerous countries such as South Africa, united states, Canada, Europe, China, Japan, India, UK and Australia etc. has recognized the importance of the polices, regulations and standard for the safety of gluten-sensitive people (Haraszi et al., 2011).The regulation of food label differs with the country. The regulations are established to certify that the anyallegation on a food label is obvious and verified by scientific verification (Duttaroy, 2019). The regulation for labeling requirement has also been mandatory for the awareness of ingredients causing allergies as it provides the consumer the information to communicate and choose whether it is suitable for consumption or not (Popping & Diaz-Amigo, 2018). The regulation aims to provide the assurance of consumer protection about food information. The consumer has the opportunity of opting between the bundle of quality attributes labeled on the package (Martini et al., 2019; Rostami et al., 2017; Sainsbury et al., 2018).

Furthermore, different organizations have been developed for identifying the approaches for gluten-free standards and set label regulations. These organizations have focused on delivering information to avoid food that triggers gluten reaction in gluten-tolerant people (Gendel, 2012; Madhuresh et al., 2013). The regulations are the corporative linkage between the government, industry, and consumer (Desmarchelier & Szabo, 2008). The chapter showcases the regulations standards of different organizations and labeling requirements for gluten-free food.

6.2 Regulatory and Labelling for "Gluten-Free" Foods

Regulations for "gluten-free" are designed to indicate no adverse level of gluten other than fully gluten absence (Akobeng, 2008). The regulation enforcing regarding the term Gluten-free on labeling is provided by quantitatively detecting the gluten content by standardizing methods of Analysis. The reliable methods for quantification and detection of gluten are mandatory to certify the safety of gluten-free foods. There are many methods for quantification and detection of gluten like enzyme-linked immunoassay (ELISA) which is mostly accepted technique as per regulations followed by many countries and other detection methods include polymer chain reaction (PCR) for DNA quantification, MS for gluten protein detection, HPLC, potentiometric electron tongue, optical biosensor, etc., (Alimentarius, 2003; Laube et al., 2011; Rosell et al., 2014; Sharma et al., 2015; Thompson & Méndez, 2008).

The standards and regulations set by national and international bodies should be strictly followed while developing or manufacturing gluten-free food. The regulations have been adopted for many products such as snacks, baked products, Extruded products, food especially processed to reduce gluten content, restaurant food, etc., for gluten-free foods (Ahmad et al., 2019; Navarro et al., 2017; Jerome et al., 2019). The regulatory standards and policies set for the Gluten-free products need to be followed along with the existing well-recognized food safety management bodies like "Good manufacture practices (GMP)" and "Hazard analysis critical control point (HACCAP)" to identify, prevent and control the food issues for best products (Laube et al., 2011; Petruzzelli et al., 2014). The knowledge of ingredients gluten content and use of the gluten-free certified ingredients by manufacturers in the food chain should be aware for manufacturing gluten-free products (Muraro et al., 2014; Mishra et al., 2020). There are many organizations for gluten-free standards like Codex Alimentarius Commission, Food and Drug Administration, European Commission, etc., and there are many third-party organizations like US Gluten-free certification organization (GFCO), celiac support organization, etc., that work with government policies for gluten-free products (Casper & Atwell, 2016). There is significant variation among the emerged regulatory framework of organizations irrespective of international and scientific collaboration on gluten issues. Effective avoidance of gluten depends upon information acquired from food labels, people having complete and precise information on substance in food (Gendel, 2012). The organizations for Gluten-free regulations require a written plan for food safety guidelines that includes processing practices, tolerant level of gluten, food label, misleading policies, recall options, etc., for the product (Crawford, 2019; Desmarchelier & Szabo, 2008). Codex Alimentarius international food standards are the regulatory standards from which most of the countries adopt the policies and standards for gluten-free labeling and gluten quantitative detection (Lee et al., 2014).

6.3 Codex Alimentarius International Food Standards

The implementation of Codex Alimentarius commission standards (CXS 118-1979) of "world health organization (WHO)" and "Food and Agricultural Organization (FAO)" for gluten-free products was developed during 1976. The law is modified in 1983 and 2015 and revised in 2008, defined the products as "Gluten-free Foods" (Arentz-Hansen et al., 2004; Bustamante et al., 2017; Jnawali et al., 2016). This standard has identified "Gluten" as the protein from oats, barley, rye, wheat, or else crossbreed type and "prolamins" as a fraction from gluten i.e. gliadin from wheat; secalin from rye; hordein from barely and also avenin from oats (Commission, 2008).

The scope of this standard is to apply for the dietary function of gluten-sensitive people, food that has been developed, manufactured, or processed. The products well-defined by the standard are: "Gluten-free foods" as gluten content should not exceed above 20 mg/kg or 10 mg/Kg gliadin in food produced from (1) Ingredients other than oats, barley, rye, wheat, or else crossbreed grain varieties. (2) ingredients i.e. oats, wheat, barley, rye, or crossbred grain varieties that are processed particularly to remove gluten; "Foods particularly processed to lower gluten content to level >20 to 100 mg/kg" as food distributed or traded to consumer-produced from ingredients rye, barley, oats, wheat or grain crossbred varieties and treated to decrease the gluten content of food to content >20 to 100 mg/kg i.e. gluten content of food should not be above 100 mg/Kg (Hager et al., 2014; Haraszi et al., 2011; Lee et al., 2014; Mattioni et al., 2016; Vassiliou, 2009). The food manufactured to avoid the contamination of gluten should follow the guidelines of good manufacturing practice (GMP). The nutritional content of original food such as vitamins, minerals should provide approximately equal dietary content even though the gluten content of food is substituted or processed (Commission, 2008).

The guidelines for gluten-content analyzing techniques in food are also stated in codex standards. The quantitative detection of gluten content in food should follow the immunologic or other technique that has the same specificity or sensitivity. These methods should be calibrated and validated with reference material and have has a detection limit of 10 mg/kg or less according to the technical standard. The relevant methods that can be used for detection are R5 Mendez Enzyme-linked immunoassay (ELISA) or DNA technique (Commission, 2008).

6.4 Labelling Regulations

The following codex"Gluten-free food" labeling is applied in addition to the guidelines of the "General labeling of prepacked food" and "General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses"(Commission, 2008).

1. For the products having gluten content less than 20 mg/kg, the word "Gluten-free" can be designated on the product close to the product title (Bustamante et al., 2017).
2. For the products having a gluten content of about 20–100 mg/Kg which are specially processed they are not gluten-free products. Hence, for such products, the nature of the product should be designated close to the product name.
3. The food or product which is naturally gluten-free can be indicated with the term "this food is by its nature gluten-free" on the package but the terms "special dietetic" or special dietary" or any more equivalent labels should not be indicated so that the consumer is not misled by the labeling provided.

6.5 Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) of the united states has claimed the food label "Gluten-free" regulation in August 2014 (Jnawali et al., 2016) in which this is the first regulation in the united states for "Gluten-free foods". The "Department of Health and Human Services (HHS)" was addressed by"Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)" to approve and define the term "gluten-free" for practice in FDA-regulated foods labeling. The regulation was started such that "Gluten-free" labeled food provides a clear trustful standard for gluten-sensitive people to manage their health. The final rule was issued in 2013 for "Gluten-free foods" labeling and recently final was issued on August 12, 2020, for "Gluten-free" labeling of Fermented or hydrolyzed foods. The August 29, 2020, revised rule has established compliance regulations for hydrolyzed, distilled, and fermented foods in which the fermentation or distillation should do for gluten-free" ingredients only as there is no analytical method for detecting gluten content in the fermented or hydrolyzed sample. Hence, the FDA inspects the records given by the manufacture of "Gluten-free" ingredients used for claiming the label "Gluten-free". In the united states, it was estimated that three million people are affected due to the consumption of gluten. The FDA stated that according to the regulation, the manufacture is responsible for not misleading and fulfilling all guidelines furnished by regulation (FDA, 2014).

According to FDA, the foods can be labeled "Gluten-free" for the products which comply with the following specifications (FDA, 2014):

1. The gluten content in the foods should be less than 20 ppm (Ahmad et al., 2019).
2. The food produced should not include the ingredients related to wheat, barley, rye, or grains of crossbreed.
3. The food should not include ingredient is not processed to exclude gluten content from the ingredients obtained from grains.
4. The food should not include ingredients obtained from grains that are processed to exclude gluten but have a gluten content of food above 20 ppm.

The specifications met by the food can be labeled by the terms “Gluten-Free”; “no gluten”; “without gluten”; “free of gluten” that are regulated by the FDA which is manufactured gluten-free food or naturally gluten-free food.

The FDA regulation is applied for restaurant food including other processed food cereals, bread, grain-based foods, pasta, beverages. The FDA is associated with national and local government for the gluten-free food in restaurants. Beer can bear the label “gluten-free” if it is manufactured from Gluten-free grains or ingredients treated to exclude gluten before fermentation for 21 CFR 101.91 enforcement. The food imported to the united states should meet the regulation requirement for the “Gluten-free” label (FDA, 2014).

6.6 European Union Standard

The European Union follows the regulations of the Codex Alimentarius Commission standards. The European Union has issued “Commission Regulation (Ec) No 41/2009” for labeling for people who are gluten-intolerant in the year 2009. The regulation guidelines are revised later in the next following years as “Regulation (EU) No 1169/2011”; “Regulation (Eu) No 1155/2013”; “Regulation (Eu) No 828/2014” and has been implemented July 20, 2016. Regulation (EU) No 1169/2011 is for the information of the presence or absence of gluten in food for gluten-sensitive people (Popping & Diaz-Amigo, 2018). The regulation is given by the EU in agreement with the acceptance of the “committee on the food chain and animal health”. The scope of the standard is the same as the codex standard i.e. for gluten intolerant people, the standard is to apply for the dietary function of gluten-sensitive people, food that has been developed, manufactured, or processed. The regulatory information about “Gluten-free foods” given by food operators should not be misled or appropriately provided to the consumer (European commission).

According to the EU document, the grains or grain-derived ingredients containing gluten are reported to be Rye, barely, Wheat (Triticum species); the oats grain may exclude as it may not cause-effect to all intolerant people. The statement such as “Commission Directive 2006/125/EC” has set a regulation that the “Gluten-free” should be indicated on infant food and cereal-based food for the infant and young children below age six. The term “no-gluten” or “Gluten-free” could be labeled for the food that has a gluten content below 20 mg/Kg (Casper & Atwell, 2016), (European Commission). The regulation guidelines are given by Commission Regulation (Ec) No 41/2009 are:

1. The foods produced from ingredients from oats, rye, barley, wheat, or crossbred grain varieties and processed particularly to decrease gluten content of food should not have a level over 100 mg/kg and those foods could be indicated as “Very Low Gluten”.
2. The word “Gluten-free” can be indicated on foods having content below 20 mg/kg.

3. Gluten content should not exceed 20 mg/kg for the foods having oats for gluten intolerant people, to avoid cross-contamination with other gluten-containing grains the food should be processed.
4. The label "Gluten-free" is applicable for the ingredients having gluten content below 20 mg/kg which is used as a substitute for the oats, wheat, barley, rye, or their grains of crossbreed.

The "Association of European celiac society (AOECS)" for the food having gluten content <20 mg/Kg has licensed the usage of label symbol "Cross-grain" as a quality mark (Bustamante et al., 2017).

6.7 Canada Regulations

The Canadian population affected by celiac disease due to gluten is estimated to be 3,40,000 people or 1% of the population. The "Health Canada" of Government of Canada has issued their first labeling regulation for "Gluten-free foods" in 1995. The "Health Canada" and "Canadian Food Inspection Agency (CFIA)" work with the industrial food manufacturers, distributors, importers, consumer associations for the effective labeling of Gluten-free, food allergens added in prepacked food for Gluten-intolerant people. The CFIA has implemented regulatory guidelines for allergen control like cross-contamination in the industry. Division 24, Food and Drug regulation (FDR) of Canada has issued a regulation for the usage of the label for "Foods of special dietary use" in which section B.24.018 issued on August 4, 2012, is regulation for the "Gluten-free food". According to the regulation, it states that "The food is banned to package, sell, package or promote if food holds any gluten protein or improved gluten protein, including a fraction of gluten protein fraction" (Health Canada, 2012).

The scientific regulation by Health Canada for designating the label "Gluten-free", the food should contain gluten content below 20 mg/Kg which is manufactured under good manufacturing practices without any cross-contamination. Health Canada 2015 has declared that people with gluten-sensitive disorders should not consume regular oats that have not been processed (Allred et al., 2017). The "list of ingredients" or "contains" label should be declared on the food if the food contained gluten is intentionally added to food even though if it is added at a small quantity (Casper & Atwell, 2016). In some cases, the term "Gluten-free" can be included if the food undergoes recognized effective processing step to remove the gluten content in cereal-derived food. The detection of the gluten content of food and processed food can be done by analytical method Enzyme-linked immunoassay (ELISA) R5 Mendez technique that is assessed as an effective method by Health Canada (2012).

The Canadian celiac association is a federally registered organization also associated with a certification program for "Gluten-free foods". This organization helps in promoting the healthiness of people suffering from diseases like celiac or other

gluten- intolerance by providing information and regulatory guidelines. The gluten content threshold level is the same as issued by Health Canada i.e. less than 20 ppm (Health Canada, 2012).

6.8 Indian Regulation

Celiac disease and gluten- intolerant disorder has posed a public health concern and has estimated to affect 6–8 million people (Deora et al., 2014; Makharia et al., 2011). The food safety and standard, Act 2006 has started to reduce food adulteration and bring food safety in the country. The regulations by food safety and standards, Government of India has issued gazette regulation by "Food product standards and food additive" and "Food packaging and labeling" for "Gluten-free food". Regulatory labeling for gluten-free packaged food came into existence for product identification and to avoid contamination by "Food Safety and Standard Regulation (FSSR)" in 2011. The "Ministry of Health and Family Welfare (MoHFW)" in 2016 implemented new regulatory guidelines for 'Gluten-free food".

According to regulations, the term "Gluten-free foods" should be indicated for the foods having gluten content <20 mg/Kg whereas "Low-Gluten" for the foods having gluten content 20–100 ppm. The foods which are naturally gluten-free can claim the "This food by its nature gluten-free" label. The foods rice, millets, ragi, legumes, and pulses and product should not be contaminated with wheat or their respective ingredients can have the label "Gluten-free" containing gluten content below 20 mg/Kg. The "Low-gluten" for the food contains ingredients from rice, ragi, millets, oats, barley, rye, maize, wheat, legumes, and pulses which have gluten content between 20 and 100 ppm. The "Food packaging and labeling", 2016 of food safety and standard should provide a warning as "the food indicated as low gluten may poses hazard for people with celiac disease" (Dudeja et al., 2016).

6.9 Other Regulatory Labelling for "Gluten-Free Food"

The wheat-containing "Gluten" is one of the fourteen food allergens. In 1993, a codex committee was formed for the development of regulatory guidelines for food labeling of allergens and in 1999, a codex general standard for the labeling of prepacked was issued. Numerous regulations, laws, labeling has been implemented by countries for the allergens control are mostly based on European commission or codex standards (Gendel, 2012; Watson, 2013). In Japan by Japanese law, allergen labeling is compulsory and cereals such as wheat, buckwheat are among them. The japan government in 2006 for labeling has recommended analytical method "Polymerase chain analysis" for the detection of Allergen in wheat, buckwheat and has regulated that allergen protein should be below 10 mg/Kg to indicate the labeling (Akiyama et al., 2011). Brazil health authority in 2002 has issued a law that all

food products including beverages should indicate the gluten absence or presence from the rye, wheat, oats, barley, and their grain derivatives. The government has launched recently 2015, guidelines to help people with gluten intolerance and celiac disease (Mattioni et al., 2016). According to the Brazil regulation, the food possible to cross-contamination should be declared when the gluten ingredients are not intentionally added and the unintentional trace amounts to be avoided by the GMP and allergen management control are not adequate to avoid. It is mandatory for the warning "contain Gluten" if there is knowledge of cross-contamination by the cereal-grains or their grain derivatives (de Almeida, 2016; Pinto et al., 2020). The "Celiac disease foundation-AssociazioneItalianaCeliachia (AIC)" of Italy is a non-profit organization for celiac disease people as they gluten-intolerant people as 2,00,000 people are suffering from Gluten-intolerance by reports of Italian Health Ministry. The "National health system" of Italy provides 140 Euros/month for the "Gluten-free" products developed for Gluten-sensitivity people (Cornicelli et al., 2018) (AssociazioneItalianaCeliachia). The Argentina country regulation has lowered the threshold level to 10 ppm for the indication of "Gluten-free" label. According to regulation of chapter 17 Article 1383 of "Argentina Food code", food that is naturally free of gluten are "Gluten-free foods" and should follow GMP to avoid cross-contamination to products (Navarro et al., 2017). The Australia and New Zealand regulation are regulated in the Food standard codes of their country for "Gluten-free foods" labeling. According to their regulations, the label "Low Gluten" can be designated to foods that have gluten content less than 200 ppm while the "Gluten-free" can be given to foods prepared with no-gluten ingredients derived from even oats (<3 ppm) even that been hydrolyzed or malted (Canberra, 2017).

6.10 Misleading of Regulation

The countries are doing a huge effort for developing and following guidelines as per the regulations. Even though, there is a chance of misleading of the regulation intentionally or unintentionally. The gluten content more than threshold level even in less gluten quantity has a huge impact on the health of gluten-sensitive people. A study by (Verma et al., 2017) has estimated the level of contamination in certified "Gluten-free" food and naturally gluten-free products by a random collection of a sample from the Italian market which resulted that 9% of the samples have gluten content more than 20 ppm. (Halmos et al., 2018) has also experimented percentage of adulteration in Gluten-free products as part of the survey program of *Food Act 1984* by a collection of samples from food outlets in Melbourne, Australia, and has analyzed that 6% of Gluten-free samples have more than 20ppm gluten. Hence, the regulations must take active and immediate action on the food products that are violated from the rules to avoid such contamination for people. In some cases, the "Gluten-free" logo cross-grain on the package is misused by some manufacturers as they don't have the official license and place logo on the package without proper analysis of the product leading to a huge risk for the health of gluten-intolerant people as

they face the problem for identification of "Gluten-free" product (Bartczak et al., 2017; Grabowicz & Czaja-Bulsa, 2019; Silvester et al., 2016).

Some organization of different countries has issued some immediate actions if the "Gluten-free" product is misleading the regulations. According to the regulatory action of FDA, the individual can report a problem to FDA regarding the mismanagement of food or label if it is against the regulation. It has issued that individuals intolerant to gluten who have suffered from illness or injury due to the consumption of the certified food should seek medical care and report the problem to FDA (2014). In some cases, withdrawal of the product is requested to be done with proper procedure of investigation of adulteration if the gluten content of product are above 20 ppm or below 100 ppm and for the gluten content above 100 mg/Kg, the product is recalled (Dudeja et al., 2016). The Canada government, Health Canada recalls the product from market and warning to the public is given. In another case of violation of the Section B.24.018 FDR if the gluten content is above 20 ppm, the Health Canada enforcement with CFIA can recall the product (Health Canada, 2012). "Food Safety and Standard Regulation (FSSR)" of India has also the provision to recall the product if it there is food adulteration.

6.11 Conclusion

The different Nations government and organizations have taken different approaches for the regulatory labelling of "Gluten-free" foods for the Gluten-intolerant people as it is significant problem worldwide. The respective country or organization is responsible for the development of strict guidelines for the manufacturers, retailers, and marketers to indicate the label "Gluten-free" on the package without any violation of regulations. Many countries follow the regulations of "Codex Alimentarius commission standards", Food and Drug Administration (FDA) and European union (EU) commission. These regulations have issued the label "Gluten-free" for the food containing gluten-content below 20 ppm and also indicate the absence or presence of gluten as most Gluten-intolerant people are sensitive to even a small quantity of gluten. The organizations must assist the people to avoid the food that provokes the health issue as consumption of Gluten food can cause mild to severe health problems to Gluten-sensitive people. The public should know the regulations and labels of the organization to avoid the mis-consumption of Gluten-free products. There is an increase in consumption of "Gluten-free foods" due to the health consciousness and raise in the population of people suffering from Gluten-intolerance in the world. The cost of the "Gluten-free food" is higher than normal food as the "Gluten-free food" sometimes requires special processing for the removal of gluten. The organizations should effectively take preventive measures to reduce the contamination and misleading of the sample. Even though many methods for quantitative detection of gluten content has been invented only a few methods like ELISA, DNA is recommended for analysis by many "Gluten-free" organizations. Hence, more effective, rapid, and cost-effective methods for

detection of samples such that detection of gluten can be done in the in-line process of industry or by the consumers while purchasing. A few countries like India, the US, Ireland, Canada, Brazil, etc., have only issued regulations for gluten-intolerant people but the health issue of gluten-intolerance and celiac disease has also been in many other countries. Hence, the remaining countries should take risk management procedures for the people suffering from Gluten-intolerance.

References

Ahmad, I., Swaroop, A., & Bagchi, D. (2019). *An overview of gluten-free foods and related disorders Nutraceutical and Functional Food Regulations in the United States and around the World* (pp. 75–85). Elsevier.

Akiyama, H., Imai, T., & Ebisawa, M. (2011). *Japan food allergen labeling regulation – History and evaluation* (Advances in food and nutrition research) (Vol. 62, pp. 139–171). Elsevier.

Akobeng, A. (2008). The evidence base for interventions used to maintain remission in Crohn's disease. *Alimentary Pharmacology & Therapeutics, 27*(1), 11–18.

Alimentarius, C. (2003). *Draft revised standards for glutenfree foods*. Report of 25th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. November.

Allred, L. K., Kupper, C., Iverson, G., Perry, T. B., Smith, S., & Stephen, R. (2017). Definition of the "Purity Protocol" for producing gluten-free oats. *Cereal Chemistry, 94*(3), 377–379.

Arentz-Hansen, H., Fleckenstein, B., Molberg, Ø., Scott, H., Koning, F., Jung, G., … Sollid, L. M. (2004). The molecular basis for oat intolerance in patients with celiac disease. *PLoS Medicine, 1*(1), e1.

Association of European celiac society (AOECS). https://www.aoecs.org/aoecs-gluten-free-standard

Astley, S. (2019). *Health claims and food labelling* (Vol. 22). Royal Society of Chemistry.

Bartczak, A., Zhang, J., Oyedele Adeyi, A. A., Grant, D., Gorczynski, R., Selzner, N., … Levy, G. A. (2017). Overexpression of fibrinogen-like protein 2 protects against T cell-induced colitis. *World Journal of Gastroenterology, 23*(15), 2673.

Bustamante, M. Á., Fernández-Gil, M. P., Churruca, I., Miranda, J., Lasa, A., Navarro, V., & Simón, E. (2017). Evolution of gluten content in cereal-based gluten-free products: An overview from 1998 to 2016. *Nutrients, 9*(1), 21.

Canberra, A. (2017). Australia New Zealand Food Standards Code: Schedule 5—Nutrient profiling scoring method.[Google Scholar].

Casper, J. L., & Atwell, W. A. (2016). *Gluten-free baked products*. Elsevier.

Celiac disease foundation-AssociazioneItalianaCeliachia (AIC). https://celiac.org/eat-gluten-free/gf-services/italian-celiac-association/#:~:text=The%20mission%20of%20AIC%20(Associazione,in%20a%20calm%20and%20aware

Commission, C. A. (2008). *Codex standard for foods for special dietary use for persons intolerant to gluten*. http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf

Cornicelli, M., Saba, M., Machello, N., Silano, M., & Neuhold, S. (2018). Nutritional composition of gluten-free food versus regular food sold in the Italian market. *Digestive and Liver Disease, 50*(12), 1305–1308.

Crawford, W. M. (2019). *The Food Safety Modernization Act (FSMA)'s role in the safety of functional foods and their ingredients Nutraceutical and Functional Food Regulations in the United States and around the World* (pp. 61–74). Elsevier.

de Almeida, M. F. L. (2016). *Monitoramento e avaliação da regulamentação sobre rotulagem de alimentos alergênicos no Brasil: proposição de indicadores e métricas*. PUC-Rio.

Deora, N., Deswal, A., Dwivedi, M., & Mishra, H. (2014). Prevalence of coeliac disease in India: A mini review. *International Journal of Latest Research Science Technology, 3*(10), 58–60.

Desmarchelier, P. M., & Szabo, E. A. (2008). Innovation, food safety and regulation. *Innovations, 10*(1), 121–131.

Dudeja, P., Dudeja, A., Singh, G., & Mukherji, S. (2016). Regulatory framework for "gluten-free" foods in India: Magic bullet for celiac disease patients. *Medical Journal of Dr. DY Patil University*, *9*(6), 680.

Duttaroy, A. K. (2019). *Regulation of functional foods in European Union: Assessment of health claim by the European Food Safety Authority Nutraceutical and Functional Food Regulations in the United States and around the World* (pp. 267–276). Elsevier.

European Commision. http://data.europa.eu/eli/reg/2009/41/oj

Gendel, S. M. (2012). Comparison of international food allergen labeling regulations. *Regulatory Toxicology and Pharmacology, 63*(2), 279–285.

Grabowicz, A., & Czaja-Bulsa, G. (2019). Misleading labelling of gluten-free products in the light of EU regulations: Time for a change? *Journal of Consumer Protection and Food Safety, 14*(1), 93–95.

Hager, A.-S., Taylor, J. P., Waters, D. M., & Arendt, E. K. (2014). Gluten free beer – A review. *Trends in Food Science & Technology, 36*(1), 44–54.

Halmos, E. P., Di Bella, C. A., Webster, R., Deng, M., & Tye-Din, J. A. (2018). Gluten in "gluten-free" food from food outlets in Melbourne: A cross-sectional study. *The Medical Journal of Australia, 209*, 42–43.

Haraszi, R., Chassaigne, H., Maquet, A., & Ulberth, F. (2011). Analytical methods for detection of gluten in food – Method developments in support of food labeling legislation. *Journal of AOAC International, 94*(4), 1006–1025.

Health Canada's Position on Gluten-free food. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/securit/allerg/cel-coe/gluten-position-eng.pdf

Jerome, R. E., Singh, S. K., & Dwivedi, M. (2019). Process analytical technology for bakery industry: A review. *Journal of Food Process Engineering, 42*(5), e13143.

Jnawali, P., Kumar, V., & Tanwar, B. (2016). Celiac disease: Overview and considerations for development of gluten-free foods. *Food Science and Human Wellness, 5*(4), 169–176.

Laube, T., Kergaravat, S., Fabiano, S., Hernández, S., Alegret, S., & Pividori, M. (2011). Magneto immunosensor for gliadin detection in gluten-free foodstuff: Towards food safety for celiac patients. *Biosensors and Bioelectronics, 27*(1), 46–52.

Lee, H. J., Anderson, Z., & Ryu, D. (2014). Gluten contamination in foods labeled as "gluten free" in the United States. *Journal of Food Protection, 77*(10), 1830–1833.

Madhuresh, D., Mishra, H. N., Deora, N. S., Baik, O. D., & Meda, V. (2013). A Response Surface Methodology (RSM) for optimizing the gluten free bread formulation containing hydrocolloid, modified starch and rice flour. *The Canadian Society for Bioengineering (CSBE)*, 13–112.

Makharia, G. K., Verma, A. K., Amarchand, R., Bhatnagar, S., Das, P., Goswami, A., … Anand, K. (2011). Prevalence of celiac disease in the northern part of India: A community based study. *Journal of Gastroenterology and Hepatology, 26*(5), 894–900.

Martini, D., Del Bo, C., & Cavaliere, A. (2019). *Current legislation in the European context: A focus on food labeling, novel foods, nutrition, and health claims Nutraceutical and Functional Food Regulations in the United States and around the World* (pp. 253–265). Elsevier.

Mattioni, B., Scheuer, P. M., Antunes, A. L., Paulino, N., & de Francisco, A. (2016). Compliance with gluten-free labelling regulation in the Brazilian food industry. *Cereal Chemistry, 93*(5), 518–522.

Mishra, N., Tripathi, R., & Dwivedi, M. (2020). Development and characterization of antioxidant rich wheatgrass cupcake. *Carpathian Journal of Food Science & Technology, 12*(3).

Muraro, A., Hoffmann-Sommergruber, K., Holzhauser, T., Poulsen, L. K., Gowland, M., Akdis, C., … Schnadt, S. (2014). EAACI Food Allergy and Anaphylaxis Guidelines. Protecting consumers with food allergies: Understanding food consumption, meeting regulations and identifying unmet needs. *Allergy, 69*(11), 1464–1472.

Navarro, V., del Pilar Fernández-Gil, M., Simón, E., & Bustamante, M. Á. (2017). *Gluten: General aspects and international regulations for products for celiac people nutritional and analytical approaches of gluten-free diet in celiac disease* (pp. 15–27). Springer.

Petruzzelli, A., Foglini, M., Paolini, F., Framboas, M., Serena Altissimi, M., Naceur Haouet, M., … Cenci, T. (2014). Evaluation of the quality of foods for special diets produced in a school catering facility within a HACCP-based approach: A case study. *International Journal of Environmental Health Research, 24*(1), 73–81.

Pinto, C. A., de Souza, B. R., Peixoto, J. d. S. G., & Ishizawa, T. A. (2020). Rotulagem para alergênicos: uma avaliação dos rótulos comercializados com presença ou ausência de glúten e seus riscos inerentes a saúde dos celíacos no Brasil. *Research, Society and Development*, *9*(6), 4.

Popping, B., & Diaz-Amigo, C. (2018). European regulations for labeling requirements for food allergens and substances causing intolerances: History and future. *Journal of AOAC International, 101*(1), 2–7.

Rifna, E. J., Singh, S. K., Chakraborty, S., & Dwivedi, M. (2019). Effect of thermal and non-thermal techniques for microbial safety in food powder: Recent advances. *Food Research International, 126*, 108654.

Rosell, C. M., Barro, F., Sousa, C., & Mena, M. C. (2014). Cereals for developing gluten-free products and analytical tools for gluten detection. *Journal of Cereal Science, 59*(3), 354–364.

Rostami, K., Bold, J., Parr, A., & Johnson, M. W. (2017). *Gluten-free diet indications, safety, quality, labels, and challenges*. Multidisciplinary Digital Publishing Institute.

Sainsbury, K., Halmos, E. P., Knowles, S., Mullan, B., & Tye-Din, J. A. (2018). Maintenance of a gluten free diet in coeliac disease: The roles of self-regulation, habit, psychological resources, motivation, support, and goal priority. *Appetite, 125*, 356–366.

Sharma, G. M., Pereira, M., & Williams, K. M. (2015). Gluten detection in foods available in the United States – A market survey. *Food Chemistry, 169*, 120–126.

Silvester, J. A., Weiten, D., Graff, L. A., Walker, J. R., & Duerksen, D. R. (2016). Is it gluten-free? Relationship between self-reported gluten-free diet adherence and knowledge of gluten content of foods. *Nutrition, 32*(7–8), 777–783.

Thompson, T., & Méndez, E. (2008). Commercial assays to assess gluten content of gluten-free foods: Why they are not created equal. *Journal of the American Dietetic Association, 108*(10), 1682–1687.

Tovoli, F., Masi, C., Guidetti, E., Negrini, G., Paterini, P., & Bolondi, L. (2015). Clinical and diagnostic aspects of gluten related disorders. *World Journal of Clinical Cases: WJCC, 3*(3), 275.

Tripathi, R., Sharma, D., Dwivedi, M., Rizvi, S. I., & Mishra, N. (2017). Wheatgrass incorporation as a viable strategy to enhance nutritional quality of an edible formulation. *Annals of Phytomedicine, 6*(1), 68–75.

U.S Food and Drug Administration (FDA) for Gluten and Food Labelling. https://www.fda.gov/food/nutrition-education-resources-materials/gluten-and-food-labeling#:~:text=The%20rule%20specifies%2C%20among%20other,using%20scientifically%20validated%20analytical%20methods

Vassiliou, A. (2009). Commission regulation (EC) No. 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. *Official Journal of the European Union*, *21*, L16.

Verma, A. K., Gatti, S., Galeazzi, T., Monachesi, C., Padella, L., Baldo, G. D., … Catassi, C. (2017). Gluten contamination in naturally or labeled gluten-free products marketed in Italy. *Nutrients, 9*(2), 115.

Watson, R. (2013). Managing allergens from a food retailer perspective including an update on allergen labelling regulation. *Nutrition Bulletin, 38*(4), 405–409.