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Guidance and Strategies for an Effective Gluten Free Management Program

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GLUTEN-FREE™ FOOD PROGRAM

Your Premier Partner In Gluten-Free Certification

Agenda

- Gluten-Free Food Market
- Understanding Gluten
- Understanding Celiac Disease
- Compliance and Enforcement of Gluten-Free Claims in Canada
- Foundation for an Effective Gluten-Free Management System
- Gluten-Free Management – Key Factors for Manufacturing
- Gluten-free Management – Key Factors for Restaurants and Food Services
- Gluten Testing

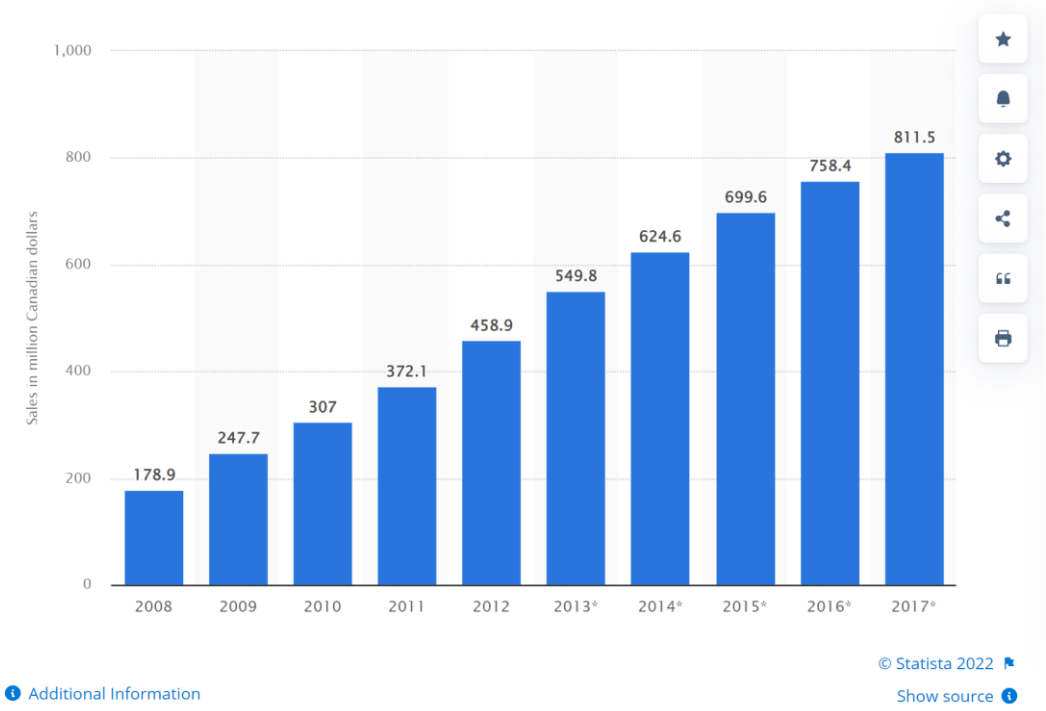
Gluten-Free Food Market

Retail Sales Projections

- Retail sales of gluten-free food in Canada were forecast to reach around 812 million Canadian dollars in 2017. This is an increase of over 450 percent since 2008, when retail sales amounted to approximately 179 million Canadian dollars.
  (Statista Research Department)

- The Canadian gluten-free foods & beverage market is projected to witness a compound annual growth rate (CAGR) of 9.1% during the forecast period 2022-2027.
  (Research and Markets).

Retail sales of gluten-free food in Canada from 2008 to 2017



Gluten-Free Food Market

Gluten-Free Consumers

- Over one third of Canadians who purchase gluten-free products generally considered gluten-free as healthier rather than purchasing gluten-free for specific medical conditions such as Celiac disease.

Source: Packaged Facts

Gluten-Free Food Market

Demand of Clean Label and Free From Ingredients

- Rising awareness of free-from ingredients has created an upsurge in the trend of gluten-free claims. (Mordor Intelligence)

Source: Mordor Intelligence

Gluten-Free Food Market

Bakery Segment a Large Portion of the Gluten-Free Market

- Demand for gluten-free food has increased recently because of the substantial increase in the demand for gluten-free bread and bakery products. (Mordor Intelligence)

Source: Mordor Intelligence

Gluten-Free Food Market

Restaurants and Food Service

- Today, restaurants and food service operators are more likely to serve dishes identified as gluten-free.

- Gluten-free options appear on 26% of US restaurant menus. (Deals on Health)

- Gluten-free restaurants are becoming more popular in the US with 182% more than the last four years and 10% more than the last year alone. This trend is expected to increase dramatically in the next four years. (Deals on Health)

- Restaurant and food service operators generally purchase gluten-free items from outside vendors:
  - manufactured products are more convenient.
  - cuts down on prep times.
  - limits the number of ingredients needed to prepare a dish.

Understanding Gluten

What is Gluten?

- Gluten is a protein found in the wheat, rye, barley and triticale (a cross between wheat and rye).

- Sometimes found in oats. Oats themselves don’t contain gluten, but because oats are often process in facilities that also process gluten-containing grains they can become cross-contamination with gluten.

- Gluten works as a binding agent in the manufacturing of processed foods and give the food shape.

- As an ingredient gluten has two sub-proteins – glutenin and gliadin, which are natural and can be extracted, concentrated and added to food and other products to add protein, texture and flavor.

- Common Uses of Gluten:
  - primarily used in the milling & flour industry and in bakery products.
  - holds bread together, helps dough rise, gives bread its unique texture, shelf-life.
  - used in meat, certain cold cuts, fish and pasta preparations.
  - plant-based foods to provide high nutritional values supplementing or partially replacing animal proteins in human nutrition.

Understanding Gluten

Common Sources of Gluten

- wheat
- rye
- barley
- triticale

Varieties and Derivatives of Wheat:

- wheatberries
- durum
- emmer
- semolina
- spelt
- farina
- khorasan wheat (kamut)
- einkorn wheat
- wheat starch

Malt in Various Forms:

- malted barley flour
- malted milk (milkshakes)
- malt extract
- malt syrup
- malt flavoring
- malt vinegar

Challenging Ingredients:

- flavors and flavor enhancers
- seasoning mixes
- blended coatings
- processing aids
- brewer’s yeast

Understanding Gluten

Surprising Sources of Gluten

- beauty products
- bleu cheese
- bouillon cubes
- bullion and broths
- candy
- carmel color
- cereals
- cold cuts
- condiments (ketchup, mayonnaise)
- french fries
- gravy / marinades
- hot chocolate
- ice cream
- imitation meat and seafood
- items labeled “wheat free”
- medications
- **oats (unless certified gluten-free)**
- pickles
- processed meats (hot dogs)
- processed cheese
- salad dressings
- sauces
- soups
- soy sauce / beverages
- veggie burgers
- vitamin supplements

Understanding Gluten

Oats and Gluten-Free – Health Canada's Marketing Authorization (MA)

- Regular (commercial) oats that have not been specially produced or processed to be gluten free should not be eaten by people with celiac disease or other gluten-related disorders.

- Regular oats can often contain some wheat, rye or barley as a result of the way they are grown, harvested and transported along-side these other grains.

- MA permits the use of gluten-free claims for gluten-free oats (that do not contain more than 20 ppm of gluten from wheat, rye, barley, or their hybridized strains) and for foods containing these oats as ingredients, under certain conditions.
  - the food contains no oats other than specially produced "gluten-free oats";
  - the finished product does not contain greater than 20 ppm of gluten from wheat, rye, barley or their hybridized strains;
  - the food contains no intentionally added gluten from wheat, rye, barley, or their hybridized strains; and
  - the "gluten-free oats" are clearly identified as such in all cases where 'oats' are referenced, including in the list of ingredients.

  Source: Government of Canada – https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/celiac-disease/gluten-free-labelling-claims-products-containing-specially-produced-gluten-free-oats.html

Understanding Gluten

Specially Produced or Processed Oats (‘Purity Protocol’) are Typically Produced in Two Ways

- Harvested, transported, stored, processed, and manufactured under good manufacturing practices (GMPs):
  - no gluten-containing grains previously grown on the land (at least 2-4 years).
  - pure uncontaminated oat seed.
  - dedicated or cleaned equipment.

- Mechanically sorted to picking out the contaminants:
  - unwanted grains are removed based on size, shape, and density by a mechanical grain sorter.
  - combination of mechanical and optical sorting (based on color, shape, and texture).
  - despite advances, these technologies are not fool-proof.

Understanding Celiac Disease

What is Celiac Disease?

- Celiac disease is an autoimmune response to gluten – affects approximately 1% of the population.
- Triggered by eating foods that contain gluten.
- Damages the small intestine's lining and prevents it from absorbing some nutrients.
- Symptoms include abdominal pain, diarrhea, fatigue, weight loss, bloating, anemia, mouth ulcers, and can lead to other serious complications including osteoporosis, neurological effects and cancer.
- People with a first-degree relative with celiac disease (parent, child, sibling) have a 10% chance of developing celiac disease.
- There's no cure for celiac disease — follow a strict gluten-free diet (often for life) to manage symptoms and promote intestinal healing.

Understanding Celiac Disease

What is Non-Celiac Gluten Sensitivity?

- Not an autoimmune disease – affects approximately 7% of the population.
- Medical evidence now recognizes it as a real condition apart from celiac disease.
- Eating gluten is the trigger and causes an inflammatory response.
- No intestinal damage occurs therefore nutrient absorption isn't affected.
- Common symptoms include gas, bloating, abdominal cramps, diarrhea, fatigue, balance problems.
- Treatment requires following a strict gluten-free diet (often for life).

Compliance and Enforcement of Gluten-Free Claims in Canada

Regulated by Health Canada and Enforced by the Canadian Food Inspection Agency (CFIA)

- Division 24 of the Food and Drug Regulations (FDR) sets out specific regulations that apply to "Foods for Special Dietary Use".

- Section B.24.018 of the Food and Drug Regulations:
  - it is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains any gluten protein or modified gluten protein, including any gluten protein fraction, referred to in the definition "gluten“:

- Gluten:
  - any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals: wheat (kamut or spelt), rye, barley, triticale or oats.
  - any modified gluten protein, including any gluten protein fraction, that is derived from the grain of wheat (kamut or spelt), rye, barley, triticale or oats.

- Gluten-Free:
  - levels of gluten in final products not exceeding 20 ppm of gluten as a result of cross-contamination.
  - no intentional addition of gluten sources, e.g., wheat, rye, barley, triticale or oats.
  - any modified gluten protein, including any gluten protein fraction, that is derived from wheat, rye, barley, triticale or oats.

Source: Government of Canada – https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/celiac-disease/health-canada-position-gluten-free-claims.html#a2

Foundation of an Effective Gluten-Free Management System

Objectives

- Establishment of a group of practices and procedures that will actively prevent cross-contact with gluten:
  - throughout the manufacturing of a gluten-free food product.
  - front and back of house preparation and serving of a gluten-free menu item/dish.

- Focuses on controlling underlying risk factors for contamination with gluten.

- The type of manufacturing facility or restaurant and food service operation will dictate the risk level:
  - dedicated gluten-free.
  - non-dedicated gluten-free.

- Manage gluten separately within an existing allergen program:
  - treat gluten as a chemical hazard.

- Understanding of HACCP principles is essential for active and effective gluten managerial control in the operation:
  - conduct a hazard analysis.
  - determine critical control points (CCPs).
  - establish critical limits.
  - establish monitoring procedures.
  - establish corrective actions.
  - establish verification procedures for the effectiveness of the HACCP system.
  - establish procedures for record keeping and documentation.

Foundation of an Effective Gluten-Free Management System

Manufacturing Facility Responsibilities

- Management Commitment
- Handling of Raw Materials
- Cleaning and Personal Hygiene
- Allergen and Gluten Management
- Transportation and Storage
- Product Information and Specifications
- Staff Training and Communication
- Audits and Internal Reviews
- Documentation and Record Keeping
- Monitoring and Reporting

Restaurant and Food Service Responsibilities

- Management Commitment
- Staff Training and Communication
- Gluten-Free Menu Planning
- Receiving and Storage
- Cleaning and Personal Hygiene
- Food Preparation and Equipment
- Greeting, Ordering and Serving
- Off-Site Deliveries
- Monitoring and Reporting

Gluten-Free Management - Manufacturing

Key Factors for a Manufacturing Facility

- Written specifications for all gluten-free ingredients, products, and packaging materials:
  - specification sheets, approved suppliers, possible hazards, storage, handling and preparation practices.
  - recipes/formulations, approval procedures for recipe changes.
  - gluten-free packaging, e.g., non-gluten containing glues and adhesives.

- Effective receiving, storage and transportation procedures:
  - inspect trucks upon arrival for potential traces of gluten.
  - gluten-free raw materials and products immediately inspected then stored separately or above gluten containing materials.

- Establish equipment maintenance and calibration and cleaning and sanitation schedules:
  - especially important for a non-dedicated gluten-free facility.
  - gluten-free production first part of the week or first shift of the day.

- All employees should receive training and/or follow documented requirements for personal hygiene and sanitation practices:
  - crucial when entering the manufacturing facility to keep gluten out
  - includes proper use of changerooms, lunchrooms and office areas.

Gluten-Free Management - Manufacturing

Key Factors for a Manufacturing Facility

- All raw materials and products should be lot-coded and a documented recall system in place:
  - ensure quick and complete traces and recalls can be done when a product retrieval is necessary.

- Conduct internal evaluations:
  - at least annually by trained internal staff or external expert.
  - assess preventative measures at key stages of the gluten-free operations.
  - continuously verifies and validates that all gluten-free activities and preventive controls are in place continually working as planned.
  - address any customer complaints.
  - process improvement recommendations.

- Consider gluten-free certification:
  - provides standards to effectively address the prevention and control of gluten in a manufacturing setting.
  - supports a manufacturer’s existing food safety management with gluten-free best practices, policies and procedures.
  - added consumer confidence of the manufacturer’s gluten-free processes and ultimate safety of the finished product.
  - increases product visibility at the point of sales with a ‘recognized’ gluten-free trademark/logo.

Gluten-Free Management – Restaurant and Food Service

Key Factors for a Restaurant and Food Service Operation

- Written specifications for all gluten-free ingredients, products, and packaging materials:
  - specification sheets, approved suppliers, possible hazards, storage, handling and preparation practices.

- Evaluate the establishment and identify potential places and crucial points in food planning, preparation and serving where gluten could be introduced:
  - at the time of receiving of ingredients and materials.
  - from customers entering the establishment.
  - gluten-free versus a non-dedicated gluten-free establishment.
  - formalize steps in the process to control, eliminate or prevent contact with gluten.

- Establish a critical limit value to which gluten should be controlled:
  - regulatory and scientific standards > 20 ppm for gluten.

- Gluten-free menu planning performed by a knowledgeable person:
  - trained gluten-free chef, registered dietitian.
  - well versed in celiac disease and the gluten-free diet.
  - access to an up-to-date copy of a pocket dictionary or reference guide listing acceptable gluten-free foods/ingredients.

Gluten-Free Management – Restaurant and Food Service

Key Factors for a Restaurant and Food Service Operation

- Have at least one knowledgeable and trained decision-maker onsite at all times responsible for overseeing the gluten-free food handling polices and procedures:
  - receiving and storage.
  - cleaning and personal hygiene.
  - label reading, food preparation and equipment.
  - necessary changes to recipes or ingredients.
  - greeting, ordering, and serving.
  - off-site deliveries.

- Train all staff with essential gluten-free requirements:
  - understanding the medical rationale of a gluten-free diet for people with celiac disease and gluten sensitivity.
  - fundamental knowledge of running a gluten-free kitchen including meal planning label reading and addressing customer questions about the gluten-free menu and ingredients being used.
  - strategies and procedures for avoiding contact with gluten.
  - trained staff are more confident and engaged and key to a reliable customer experience.
  - deliver high-level better customer service and receive fewer complaints.
  - improves job efficiency and job satisfaction for staff.
  - increase profits.

Gluten-Free Management – Restaurant and Food Service

Key Factors for a Restaurant and Food Service Operation

- Conduct management reviews to monitor, verify and report on how the gluten-free system is functioning:
  - verify and validate the gluten-free management systems are working.
  - confirm gluten-free menus, supplier records, ingredient receiving logs are as planned and in place.
  - document requirements for any corrective actions to be later implemented.

- Consider gluten-free certification:
  - provides standards and best practices to address the prevention and control of gluten in a restaurant or food service setting.
  - promotes high safety and confidence for the celiac community and those who require gluten-free food for other health reasons.
  - should include gluten-free training for staff.
  - receive a recognized gluten-free trademark/logo for use on establishment's windows and doors, menus and menu boards, on display cases, and in marketing communications, websites and social media networks
  - clearly promote the establishment as 'certified gluten-free'.
  - gain long-term customer loyalty and repeat business.

Gluten Testing

- Health Canada recognizes the Codex Alimentarius Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Stan 118-1979) which states that the gluten content of foods labelled gluten free shall not exceed 20 ppm (parts-per-million).

- Manufacturers, restaurants and food service operators alike should evaluate their risk for contamination with gluten and select the best testing methods and appropriate plans specific to their needs:
  - establish the appropriate and acceptable threshold for gluten.
  - using an ISO 17025 accredited third laboratory employing peer-reviewed gluten testing methods.
  - using industry approved commercial in-house gluten testing kits.
  - perform swab testing methods for assessing cleanliness of equipment surfaces.
  - sufficient frequency of testing to confirm the ongoing effectiveness of the gluten management protocols.

- Recommended testing methods and test kits certified by the AOAC (Association of Official Agricultural Chemists) that can reliably detect gluten from rye, barley and wheat and their sub-cultivars:

- Common method for detecting gluten in food are antibody-based systems such as R5 enzyme-linked immunosorbent assays (ELISA):
  - Sandwich R5 ELISA for measuring intact proteins.
  - Competitive R5 ELISA for smaller-sized protein fragments found in partially degraded gluten.

Gluten Testing

- Some ELISA gluten testing methodologies:
  - Ridascreen Gliadin (wheat, buckwheat, rice, corn, oats, syrup, sausage). rice- and corn-based products, soy, starches, pseudo cereals, legumes, spices, juice, nut nougat crème, cream cheese, pesto, meat, vegetarian meat alternative, cookies, dessert, cake, fish, bread, candies, and potatoes).
  - EZ Gluten (rice, flour, cooked dough, beer).
  - Veratox for Gliadin R5 (cooked hamburger, bread, rice, cereal, rice flour).
  - Aller-Tek Gluten-ELISA Technologies (rice flour, cooked dough).

- Other analytical techniques used for detection of gluten in foods:
  - Immunosensors/Dipsticks/Lateral Flow Devices (LFDS) – rapid and useful for on-site analysis.
  - Western Blots – separates and detects gluten proteins according to their size.
  - Mass Spectrometry – highly sensitive and can directly detect proteins/peptides that are not detected by immunological techniques.
  - DNA-based Methods – DNA is more efficiently extracted compared to proteins and can be used as a highly sensitive screening method for the presence of gluten containing cereals.
  - Aptamer-based Assays – highly sensitive new generation methods.

- Caution, no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented or hydrolyzed, fermented or enzymatic processed food products in terms of equivalent amounts of intact gluten proteins:
  - cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine.
  - hydrolyzed plant proteins used to improve flavor or texture in processed foods such as soups, sauces, and seasonings.

Thank You!

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