

IN COOPERATION WITH



# 2016 Gluten-Free Stakeholder Update & Planning Session

## FINAL REPORT



September 27-28, 2016 – Toronto, Canada

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## Acknowledgements

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## Executive Summary

On September 27 and 28, 2016, over 130 stakeholders from across the food value chain – consumers, food service and retailers, processors, laboratories, test kit manufacturers, auditors, grain and pulse producers, and government regulatory bodies – met for a two-day session to continue the advancement of safe and reliable gluten-free foods for the consumer marketplace. The Session was led and facilitated by the Canadian Celiac Association, the Allergen Control Group Inc., and Agriculture and Agri-Food Canada. Additional contributors and sponsors listed at the end of this document contributed to the success of the session.

Much has been accomplished since stakeholders first met in 2010 and 2013. At that time, the number of certified gluten-free foods on retailers' shelves was limited. In the intervening years, these stakeholders worked to establish and implement a Canadian gluten-free standard and gluten-free management program which was appropriate to their industries. An authentic and recognized certification program was established through the Canadian Celiac Association and administered by the Allergen Control Group, resulting in strict adherence to food management programs and building toward added consumer trust. Today, many hundreds of gluten-free products produced in a certified facility are available to the consumer, and more and more food service operators are offering gluten-free choices on their menus. As the value of the gluten-free food market is recognized and realized by all those in attendance, members met in Mississauga, Canada to share challenges, lessons learned, and successes.

During the first part of the session, stakeholders presented their observations and plans for the future within their industry sector group and were on a mission of discovery, learning that:

- The demand for gluten-free food continues to rapidly expand.
- Gluten-free is not a fad, and consumers are serious about receiving credible assurances that the food they choose to eat is safe.

- Consumers want access to clear and accurate information that will allow them to make informed choices about the gluten-free food products they select. For instance, they want to understand the regulatory framework; have accurate, complete labelling on products; and understand the technologies, practices, and processes that lead to each gluten-free end product.
- There are challenges in the scientific methods for testing gluten-free food inputs that require more research to resolve and more understanding in their use, to maximize the benefit of these tools.
- Gluten-free foods continue to be costly to develop and produce, in some segments. Consumers are willing to pay more for their gluten-free foods, but there remains strong pressure to lower the cost burden to consumers. This is especially challenging for producers and processors.
- Over time, work should proceed to harmonize gluten-free regulations across countries that participate in the value chain.

The second part of the session was devoted to exploring and discussing additional options which were designed to strengthen the entire gluten-free food value chain. Stakeholders brainstormed possibilities and selected three initiatives:

1. Establish a gluten-free information repository that disseminates educational information to all stakeholders across the value chain. The repository will facilitate coordination across sectors and enhance trust among suppliers, their customers and consumers.
2. Continue research to improve sampling methods and build an understanding about their limitations in order to remain within the established boundaries of the known and acceptable ranges of error.
3. Develop ways and means to increase gluten-free food safety among pulse and grain producers, with a particular focus on oats.

Stakeholders volunteered to participate in working groups that will lead each of these initiatives. As a next step, a proposal to fund these working groups will be developed and submitted to Agriculture and Agri-food Canada for consideration.

# 1 Presentations and Highlights

Copies of all the presentations which are summarized, below are available at:

[gfstakeholdersession.com/#/speakers](http://gfstakeholdersession.com/#/speakers)

## Opening Remarks and Welcome

**Anne Wraggett**, President of the Canadian Celiac Association (CCA), opened the Session. She noted that the Gluten-Free Certification Program (GFCP), which is now completely delivered by the Allergen Control Group, is a very valuable and fully accredited management system that is based on science.

Anne emphasized that, for sufferers, celiac disease is an emotional and social burden. People with celiac disease have challenging lives. For some, family and community, through chapters of the CCA, can provide support. However, for many others, the disease leads to social isolation.

Since the advent of the Gluten-Free Certification Program, consumers have said that gluten-free products have been easier to find and purchase. The CCA GFCP logo, which attests to a product's absence of gluten, has led to more consumer confidence. Food processors and manufacturers commitment to gluten-free foods has grown dramatically and there has been an explosion of food choices on grocers' shelves. As well, more people are being diagnosed with celiac disease, leading to a greater awareness. Consequently, the need for a reliable and affordable gluten-free food supply also has grown.

## Update From Last Session

**Frank Massong**, Vice President, Regulatory & Technical Services of the Allergen Control Group, described the chronology and historical success of the GFCP since the last Gluten-Free Stakeholders' meeting in March 2013 where consensus was achieved to focus on growing the supplier base, strengthening sampling and testing protocols, networking within the stakeholder community, and continuing to build the GFCP. That session lauded the common gluten-free threshold across the Canadian regulatory framework which was achieved in 2012, with the passage of new policies and regulations. More recently Health Canada issued a Market Authorization to allow the sale of gluten-free oats in Canada. As well, new science and testing protocols have been established and consumer demand has increased to the point where supply needs to catch up.

A successful application was made to Agriculture and Agri-Food Canada's (AAFC) Growing Forward 2 Program under the Assurance Systems Stream. The Canadian Celiac Association and the Allergen Control Group raised the requisite funds to participate in the Program, and the Prairie Growers Association and Pulse Canada endorsed the initiative. The Canadian Grain Commission is an active supporter. The projects supported by the initiative include:

- Growing the supply base of grain and pulse crops.
- Improving sampling protocols.
- Improving communications among stakeholder groups.

**Paul Valder**, President of the Allergen Control Group (ACG), noted that the ownership of the GFCP standard was transferred from the Canadian Celiac Association to the Allergen Control Group so that the resources and investment focus required of the GFCP could be brought to bear. A flourishing partnership ensued that has the CCA continuing to focus on consumer education, communications and marketing, while the ACG brings technical expertise and assurance to the GFCP. The GFCP Trademark that appears on the labels of gluten-free products coming from certified manufacturing facilities is evidence of the continued endorsement of the program by the CCA as well as a point of purchase signal to consumers that the product is safe.

The Allergen Control Group has forged forward, ensuring that the standards and manuals are kept up to date, and that they reflect changes to the regulations governing gluten-free products in the United States, Canada and the world. ACG has trained and individually approved more than 225 auditors worldwide, and now has the capacity to conduct audits around the world. It has recently launched an on-line training and exam program for gluten-free auditors in partnership with the Canada's Food Processing Human Resources Council.



## Keynote Address

The keynote address was delivered by **Dr. Benjamin Lebwohl**, the Herbert Irving Assistant Professor of Medicine and Epidemiology, The Celiac Disease Center at Columbia University. His topic was: Celiac Disease, Gluten Sensitivity and Non-Dietary Therapies. He began by dispelling several myths regarding celiac disease:

- Celiac Disease affects approximately 1% of the population.
- The disease occurs in children but adult onset is increasingly common.
- The disease primarily affects the small intestine, but can also affect the skin and other organs.
- A celiac sufferer does not “grow out” of the disease.

Dr. Lebwohl said that for many celiac sufferers, the disease is silent. Many do not know they have it, and these individuals remain mostly undiagnosed. As more reliable blood tests become available, however, more and more people are getting diagnosed. An endoscopy remains the gold standard for proper diagnosis of celiac disease. The incidence of celiac disease has grown dramatically over a generation, and the reasons for this are unknown. Something is going on but the science is not available yet to determine specifically what that is, he said.

The path to diagnosis is manifold. It tends to start with a clinical suspicion, followed by serology (a blood test), a biopsy, and then, upon confirmed diagnosis, a life-long gluten-free diet. Still, there is a lot of undiagnosed celiac disease (i.e. > 90%). The Tissue Transglutaminase - Immunoglobulin A (TTG-IGA) blood test is the best although not a perfect indicator. It catches 90% of patients; but it misses those with low IGA. Immunoglobulin G (IGG) blood tests can be used next; but they are less specific and there are many false positives. Genetic testing is also a possibility since all people with celiac disease carry the genes (HLA-DQ2 or HLA-DQ8). If clinical suspicion is high enough, the patient could go directly to an endoscopy on the recommendation of their doctor.

Four out of five sufferers still remain undiagnosed. Therefore, it is important to get the word out about the many faces of celiac disease. There are many clinical manifestations of celiac disease, and more than 50 possible signs. So, celiac disease is complicated and difficult to diagnose. The full path to diagnosis averages 8 years.

Dr. Lebwohl concluded:

- Gluten-free adherents have grown exponentially over the past five years, largely because they feel better. In fact, more people pursue a gluten-free diet than any other, including diets designed to reduce weight.
- Non-celiac gluten sensitivity remains a recognized, clinical condition without a biomarker.

- Several pharmacological remedies are being pursued. Most of these therapies are designed as an adjunct to the gluten-free diet and are not intended to replace it. The gluten-free diet is the only reliable treatment for celiac disease and non-celiac gluten sensitivity.

## Consumer Sector Perspective

**Sue Newell**, Operations Manager Canadian Celiac Association and **Jennifer North**, Vice President, Beyond Celiac (formerly the NFCA) in the USA, spoke on behalf of consumers. They said that they were growing their respective missions from increasing awareness to advocacy and want to help consumers take agency with their disease. They want the public to know that celiac disease is a serious autoimmune disease and as well, stimulate research and work with industry to grow the possibilities for safe gluten-free foods.

They said that because sufferers often begin with a self-diagnosis, they subject themselves to a great deal of misinformation. The stress associated with managing celiac disease has been likened to being on dialysis – the burden is high.

A recent survey of celiac sufferers, conducted by Beyond Celiac, highlighted how concerned they are about gluten as a food safety issue. Celiacs seek assurances that the foods they purchase and consume are indeed gluten-free. Therefore, assurances through independent, third party certifications are very important to consumers. The majority of consumers view independent third party certifications as somewhat important to very important.

Government regulation is not enough. New sampling, testing and manufacturing technologies that ensure grains and pulses are gluten-free are confusing to consumers. Consumers would like to have access to and confidence in the test results of the gluten-free foods they consume. This information needs to be understandable and concise. Gluten-free consumers want the information about the foods they eat to be consistent across all information providers, from government to industry, and across all media platforms, from the internet to the labels on the food products themselves. They noted that currently, consistency is not the norm, and this is confusing for consumers. For instance, precautionary statements (e.g. MAY CONTAIN: Wheat, Soya, Almond, Pecans) that appear on gluten-free products are contradictory and extremely confusing for consumers.

## Food Processor Sector Perspectives

Gordon Hayburn, Vice President of Food Safety & Quality at Trophy Foods Inc., Tom Doyle, Director at Cuisine Royale (Promise Brand) and Ron Judge, Director of Quality Assurance & Food Safety at Maple Lodge Farms, spoke on behalf of food processors.

**Gordon Hayburn** said that there are many challenges for industry in the audit process and these most often relate to time, money and knowledge. These incremental costs get passed on to consumers. He said that industry in Canada and the United States generally lacks the knowledge that comes with experience; but this is beginning to change. Industry needs to see spending related to gluten-free food safety practices as an investment. You get what you pay for, and industry should also count the substantial savings that accrue by avoiding a recall. Moreover, market conditions suggest that investing in a gluten-free safety program results in increased profits for food processors.

Gordon Hayburn said that food safety has to be embedded into the practices and culture of a manufacturing facility. Investments in people are key. A commitment to creating food safety career paths, along with investments in training programs, will attract and retain food safety professionals. As their experience grows, so will consumer confidence in your products, and so will your profits.

**Tom Doyle's** focus is on creating gluten-free breads of high quality and nutritional value. Consistently baking high quality breads is a challenge; but even more challenging is getting them on grocers' shelves, because the profit margins on most gluten-free manufactured products is low. Often, consumers find gluten-free breads unappealing. When many manufacturers responded by adding sugar and fat to the ingredients, media-based consumer advocates sharply criticized these products and advised gluten-free adherents who did not have celiac disease that they were making an unhealthy choice. Industry has responded again by balancing the nutritional value of its products using alternate ingredients and technologies. However, the consumer relations fiasco created by the media has continued to have a negative impact. Gluten-free food manufacturers need to focus on creating the quality and nutritional value that consumers want. Retailers need to be more open to supporting small, innovative processors by adjusting their profit expectations and by giving them shelf space. Without such adjustments, the innovation that often comes from small and medium sized manufacturers will be lost.

**Ron Judge** focused on the challenges inherent in the supply chain where food fraud – the false representation of ingredients as gluten-free – can occur. He said that it is important that ingredient suppliers have gluten-free management programs in place; and that they are auditable to prove that due diligence has been applied. He also remarked that maintaining strong relationships with trustworthy suppliers is a key to success at the manufacturing level.

## Retail and Foodservice Sector Perspectives

Samara Foisy, Sr. Manager, Dietitian-Product Development at Loblaw Companies Limited and Shanna Munro, President and Chief Executive Officer of Restaurants Canada spoke on behalf of food retailers.

**Samara Foisy** said that Loblaw's goal was to become a gluten-free destination for consumers. Their focus was on achieving the best tasting gluten-free food. Loblaw became the first private label gluten-free brand in Canada, and swiftly exploded their product line from eight to thirty, with more than 125 options by focusing on the product attributes consumers want. Taste was the number one priority for consumers, followed by nutritional value, price, freshness, pack size, variety, and finally, nut-free. Loblaw has achieved success in customer retention, taste, innovation and assortment. Samara noted that Loblaw has provided the possibility for gluten-free consumers to experience the same food trends as the rest of the population.

Loblaw has faced the following challenges along the way:

- Food vendors have been challenged to meet the food attributes specified by Loblaw; e.g. cakes are easy, while crackers are very difficult.
- Sourcing healthy ingredients. Gluten-free grains and pulse crops are becoming more readily available, and these inputs have high nutritional value; but they are also more costly, and may not work as well as gluten-available grains in certain products.

Loblaw's confidence in its gluten-free product lines extends to seeking to attract non-gluten-free consumers to them. More consumer education, more freely available basic research, more shared best practices, more vendor education and certification will continue the explosion of gluten-free foods in the market place. In the meantime, Loblaw intends to expand its product line of great tasting foods, support innovative vendors, encourage certification up the supply chain, and expand its marketing initiatives for gluten-free foods.

**Shanna Munro**, President and Chief Executive Officer of Restaurants Canada said that safeguarding gluten-free restaurant patrons through establishment-based food safety programs is priority one for Restaurants Canada. Her data indicates that 22% of Canadians choose a gluten-free diet. Chefs say that gluten-free food requests supersede all other requests in restaurant establishments. Canadians want gluten-free choices in restaurants, and they want restaurants that are dedicated to a gluten-free menu.

The costs to accomplish this are high, as are the potential liabilities, especially in the absence of a gluten-free standard in the restaurant setting. Operators need and want education, guidance and tools from credible sources in the food industry. The restaurant industry wants to work with partners to develop the right food handling practices and technologies, and concomitant educational tools that will tie gluten-free food safety across the front and back operations inside a restaurant. They want cost-effective gluten-free ingredients and pre-made foods to serve their customers.

## Gluten-Free Certification Body Panel Presentation and Discussion

Skip Greenaway, President & CEO of the Eagle Certification Group, Victor Muliyl, Food Technical Program Manager at SGS North America and Yuksel Eyyuboglu, Technical Manager, Agri-food at SAI Global represented gluten-free certification bodies in a panel discussion.

**Skip Greenaway** said that certifying bodies should employ approaches that focus on management systems, not on products. He said that the independent oversight provided by third party certification bodies is essential to building consumer confidence in gluten-free foods. Independent auditors are paid to be correct without any conflicts of interest and need to perform at a very high level of competence which is tracked by the certification body, he said. This will be confirmed in the future by an independent competent accreditation body to ISO 17021 requirements. Auditors must gain experience to address the nuances associated with each process and product. Managing an integrated food safety and GFCP audit is also a substantial challenge, but essential to retaining consumer confidence. A commitment to safe gluten-free food handling and manufacturing processes must be proven to be present across the value chain, Skip said: We will all be involved in a recall. There will be no pointing the finger and running. If everyone does their job, it can be managed. A strong management system can lead to improvements to prevent this from happening.

**Victor Muliyl** said that the possibility for making errors will always be with us. We need to ensure that we have the systems, tools, and attitudes that support continuous learning. Even so, we need to address the inconsistent understandings and practices present between countries regarding what constitutes a credible audit and a credible review of audits.

Victor said that there are varying understandings of and attitudes towards food safety among countries. But for all, a compelling business case based on increased sales to North American markets could align both views and practices over time. Multilingual management system manuals and guidelines, and a consistent focus on

managing risks associated with the management system are keys to moving forward to create a safe supplier base through the audit system.

**Yuksel Eyyuboglu** said that manufacturers need to seriously assess the risk of failing the <20 ppm for gluten threshold. They need to develop management systems that use pre-requisite programs and HACCP. The best tools need to be used to verify and validate management systems. Internal audits should consider the root causes of deviations, and manufacturers should invest in research and development to build appropriate corrections.

Common areas of failure are the inappropriate substitution of ingredients and cross-contamination. Proper risk analyses are not always implemented.

Top management needs to be totally committed to ensuring that their management systems are correct. The cost of failure goes both to profits and to the loss of consumer confidence. These costs need to be weighed against the cost of prevention. The GFCP acts as a preventative remedy by offering standards and a manual that guide third party audits.

## Grain Producer Perspectives

Mike Marshall, Director of Sales and Grain Procurement at Avena Foods Limited, Laura Anderson, National Manager at the Canadian Grain Commission, and Mehmet Tulbek, Director of Research and Development at AGT Food and Ingredients Inc. presented the Grain Producers Perspectives.

**Mike Marshall** spoke passionately about his personal journey to produce gluten-free grains by relying on the "Purity Protocol", which he said could be applied to the production of all foods. Start clean, stay clean is his motto. Gluten contamination is a food safety issue which needs to be addressed beginning on the farm.

Challenges to implementing the Purity Protocol are:

- Building a sustainable crop rotation plan.
- Seed contamination, which can be addressed by capturing or developing your own seed growers.
- On-farm contamination which is accelerated by neighbouring farms which are not gluten-free and migrating wildlife.
- Maintaining gluten-free farm equipment and storage facilities.
- Logistics – how farm produce is transported and stored once it leaves the farm gate.

Organic farming practices that involve reporting and third party audits are very compatible with the gluten-free production of oats. Mike said that regulations need to be couched in the realm of the possible, and then they need to have teeth. He ended by reminding us that food safety isn't free.

**Laura Anderson** described the CCA's pilot project to increase the supplier base of gluten-free grains (e.g. pulses and oats) in Canada, which is funded under the AAFC's Growing Forward 2 in partnership with the Allergen Control Group and the Canadian Grain Commission. This project will develop a voluntary risk-based control system for supplying gluten-free grains that are validated in pilot facilities. The Canadian Grain Commission is expert at designing and implementing food safety programs when it comes to the logistics of supporting the transport and storage of bulk grains. Handling specialty grains safely is another matter. A full blown management and verification system is still needed to address the safe handling of this sub-sector of grains. Bulk handling is a high volume, low margin, high tolerance business. How will the supply chain and consumers adjust to the low volume, high margin, low tolerance, high cost gluten-free grain business? The 20 ppm threshold for gluten in these grains involves considerable effort, though pulses may be easier to handle.

**Mehmet Tulbek** said that pulse crops are nutritionally good for consumers. They are naturally gluten-free and are likely also allergen free in addition to being environmentally ideal. New markets are emerging for pulse crops in North America and China, partly as a result of the growth of gluten-free diets. Importers are buying based on the assurances of gluten-free certification programs. Clearly, the management of crop rotation, harvest, transportation and then processing (e.g. receiving, peeling/ dehulling etc.) is essential.

### Gluten-Free Service Provider Perspectives – Sampling, Testing & Analytical Panel Presentations

Joseph Baumert, Ph.D. Co-Director at the Food Allergy Research & Resource Program (FARRP), University of Nebraska-Lincoln, Gabe Faubert, Midwestern US & Eastern Canada Regional Manager at R-Biopharm Inc., Scott Radcliffe, Technical Support Scientist at Romer Labs, and Luke Emerson-Mason, Laboratory Manager at Bia Diagnostics presented on behalf of gluten-free service providers. This was a dynamic panel presentation that demonstrated the complexity and uncertainties associated with gluten sampling, testing and analysis.

**Joseph Baumert** said that sampling and testing for gluten is an important tool for gluten-free management, particularly in manufacturing scenarios that include gluten-containing environments. Verification and validation of

controls are essential in these settings. Currently, there is no standardized sampling method for food allergens and gluten in raw ingredients/grains which need to contend with the possibility of non-homogeneity. The questions still requiring answers include: **1)** How many samples are needed? **2)** Is analysis of a composite sample acceptable due to dilution effect? **3)** Is there an optimal sample size? Analysis of more samples decreases sampling uncertainty but may not be economically feasible. Screening and/or optical sorting where the physical properties of the grain make separation more feasible can assist. Certainly, some grains and products are known to be higher risk to contamination and adjustments need to be made to accommodate.

Test methods:

- ELISA's which give more quantitative information, are robust and less prone to matrix interference but require more equipment and training which necessitates sending samples off-site and overall is more expensive than Lateral Flow Devices (LFDs). ELISAs are applied to end-product samples for validation or hold/ release purposes.
- LFDs are rapid and easy to run at the actual manufacturing site but provide qualitative information (not quantitative) and require validation in each ingredient matrix to prove accuracy.

**Gabe Faubert** presented three examples as case studies of consulting services that R-Biopharm has provided as an expert in the field of gluten testing.

#### Case #1:

- **Question:** Does the R5 antibody react with Oats? A variety of certified gluten-free oat samples were gathered and analyzed using multiple antibodies whereby positive results were confirmed with PCR (polymerase chain reaction).
- **Conclusion:** Pure gluten-free oats do not generate a false positive response with the R5 antibody.

#### Case #2:

- **Question:** Does horseradish cause false positives due to horseradish peroxidase (HRP)? Samples were taken of various test "positive" and "negative" horseradish powder with Antibody and PCR methods to determine contamination of false positive due to HRP.
- **Conclusion:** Horseradish peroxidase contained in horseradish does not cause false positives in either RIDASCREEN®Gliadin ELISA or RIDASCREEN®QUICK Gliadin Lateral Flow. Positives should be viewed as representative.



### Case #3:

- **Question:** Does a protease concentrate cause false negatives in sandwich ELISA and false positives in competitive ELISA? A series of spike & recovery analyses were done to determine the root cause of contamination using a denaturing step in the sample preparation due to the known interference of enzyme concentrates. All experiments were tested with a sandwich ELISA (RIDASCREEN®FAST Gliadin) and competitive ELISA (RIDASCREEN®Gliadin competitive).
- **Conclusion:** The untreated enzymes will cause false negatives in a sandwich ELISA and false positives in a competitive ELISA. It is theorized that the heating process accelerated the enzyme activity causing it to alter the spike before being denatured. The results from RIDASCREEN® Gliadin competitive indicated that there were still allergenic peptide fragments present in the sample, thus confirming contamination.

**Scott Radcliffe** said that using sampling and testing to provide proof for on-going verification and validation of gluten-free management systems is very technically and scientifically demanding. Many non-specific gluten tests other than ELISA and lateral flow devices can support verification namely protein swabs, ATP (which measures cleanliness), PCR (polymerase chain reaction) and liquid chromatography/ mass spectrography, as examples. However, they do not substitute ELISA and lateral flow devices for quantitative and qualitative detection respectively of gluten and allergens. Following the extraction methods and sample preparation, appropriate calibration to the matrix is important. Extremes in the matrix such as high protein concentration, high lipid concentration, high polysaccharide concentration and extremes of pH may push past pH-buffering capacity of kit reagents as would the presence of reactive biomolecules such as polyphenols, tannins and anthocyanins. In conclusion:

- Understand that every gluten detection method has strengths and weaknesses- no perfect method.
- Know the capabilities and limitations of any detection method prior to implementation.
- Validate that method will detect gluten in your matrices.
- When in doubt, contact the tech services department of the specific kit manufacturer.

**Luke Emerson-Mason** said that the sampling, extraction and method of analysis are critical to the detection and management of gluten. Sampling is normally done by the manufacturer and samples are shipped to an external laboratory for analysis. Finding particulate contamination is extremely challenging, the equivalent to finding the proverbial needle in the haystack. Homogenizing the sample is essential which is easier in liquid materials and

less so in dry products. Differing density in the product and the sample itself can lead to stratification which can lead to variable results.

The formulation of the product or ingredient matrix (e.g. gums, starches, polyphenols, tannins, flavonoids, etc.), as well as processing (e.g. heating, extruding, boiling, frying and baking), must be considered before selecting the test method (e.g. standard or competitive) and the other steps (e.g. addition of non-fat dry milk, fish gelatin etc.) necessary to ensure accurate and consistent analytical results.

In conclusion, there is no perfect test method. There is a need for more reference materials and clinically relevant standards. In addition, analysis is only as good as the sampling and extraction procedures and more guidance would be beneficial. Sampling should be representative of either ingredients or final product. In the case of final product, it should be done at the beginning, middle and end of the run.

## Government Sector Update

Michael Abbott, Section Head, Food Allergy and Intolerance Section at Health Canada and Roxane Baskett, National Operations Specialist, Food Labelling and Composition at the Canadian Food Inspection Agency (CFIA) provided updates from Canadian federal government regulators.

**Michael Abbott** offered that Health Canada has the mandate to develop and administer health and safety policies and standards for Canada whereas CFIA has the responsibility of enforcement. Celiac disease and the emerging issue of gluten sensitivity are a high public health priority where strict avoidance of gluten for life is the only treatment for celiac disease.

The Canadian *Food and Drug Regulations* were amended several years ago to enhance the requirements regarding the declaration of gluten sources in prepackaged foods as part of the new labelling regulations for priority food allergens, gluten sources and added sulphites which came into effect in August of 2012. The definition for gluten still includes wheat, oats, barley, rye and triticale or any modified protein thereof. Recently, Health Canada issued a Market Authorization (May 19, 2015) to allow gluten-free oats which meet the definition of Division 24 of the Food and Drug Regulations in gluten-free products but not regular oats. 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.

This is based on studies that have shown that there is variation in the amount of gluten that people with celiac disease can tolerate in the diet and the majority of people with celiac disease will not be negatively affected if they limit their gluten intake to less than 10 mg per day. The 20 ppm threshold for gluten supports the gluten-free diet.

The Market Authorization to allow gluten-free oats considered the fact that regular oats are generally contaminated by gluten-containing grains because of harvesting/ transportation practices, etc. Through managed production practices and/ or processing, gluten-free oats are possible. However, the Market Authorization stipulates:

- 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.

Overall, gluten-free consumption as reported by AAFC shows significant consumption by persons other than those medically requiring a gluten-free diet:

- 10 million Canadians (representing 29% or almost  $\frac{1}{3}$  of the population) purchase gluten-free foods
- Of those purchasing gluten-free, only 3.5 % had Celiac disease and 20.5% self-reported gluten sensitivity
- This means 76% of gluten-free foods are being consumed by people with no medical condition that requires gluten avoidance
- They may feel gluten-free is healthier or they may live with someone that has a medical reason to avoid gluten

However, while recognizing that a significant amount of gluten-free food is being consumed by the general public, the focus for gluten-free claims and the regulations governing these claims will continue to be protecting consumers who have to follow a gluten-free diet for medical reasons by ensuring that foods labelled gluten-free are safe for them to consume.

**Roxane Baskett** described the organization and the mandate of the CFIA as dedicated to safeguarding food, animal and plant resource bases, which enhances the health and well-being of Canada's people, environment, and economy. Health Canada (HC) establishes policies and standards respecting consumer health, food safety and nutritional quality of food. The CFIA is tasked with enforcing these policies and legislation through inspection and investigation.

Amendments to the Food and Drug Regulations (FDR) for enhanced labelling of food allergens, gluten sources and added sulphites came into force on August 4, 2012. This increased the number of named allergens, and considered gluten and sulphites as well, so that any level of allergens and gluten detected in a food but not declared on the label, is considered a food safety risk to consumers.

This did not change the requirements for "gluten-free". FDR B.01.010.1(1) defines gluten as any gluten protein, modified protein or protein fractions from the grain of any of the following cereals or from the grain of a hybridized strain created from at least one of the following cereals namely barley, oats, rye, triticale, wheat. Division 24 Foods for Special Dietary Use still applies so that these gluten-free products must be specially processed or formulated to meet the particular requirements of a person:

- (a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or*
- (b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods*

Health Canada's Position on Gluten Free Claims (2012) is that gluten levels not exceeding 20 ppm as a result of cross-contamination, when Good Manufacturing Practices (GMPs) are followed, would meet the safety intent of the FDR when a gluten-free claim is made.

CFIA inspection and investigation activities can be driven by National work plans for the current fiscal year, which may include projects focussed on allergens, allergen controls and labelling, regular inspections or sampling and targeted surveys. Other triggers could come into play such as consumer complaints, trade complaints, referrals from other government departments e.g. HC, Public Health Agency Canada (PHAC), provincial regulators or referrals from industry associations.

A targeted survey was conducted in 2012-2013 to gather information on the levels and prevalence of undeclared allergens and/ or gluten in domestic and imported prepackaged food products.

The main objectives of this targeted survey were to:

- obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in domestic and imported prepackaged products; and
- identify potential food safety concerns relating to undeclared allergens and gluten in domestic and imported prepackaged products.

An example of a recent survey (2012-2013) on undeclared allergens and gluten targeted domestic and imported prepackaged products such as desserts, snacks, Ready to Eat (RTE) meals, spices and flavour packets available in the Canadian marketplace. Samples were collected from major retail stores and smaller specialty retailers across Canada. No specific brands were targeted. This survey was conducted on 594 domestic and 586 imported prepackaged products. The majority were analysed for more than one undeclared allergen or gluten, including soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts, sesame and gluten. The results were as follows:

- Domestic products: 3705 analyses conducted, 23 products tested positive for one or more undeclared allergens → **3.9% unsatisfactory**; and
- Imported products: 3739 analyses conducted, 50 products tested positive for one or more undeclared allergens → **8.5% unsatisfactory**

Another survey (2013-2014) was conducted on undeclared soy and gluten in infant cereal. The objective was to obtain baseline information regarding the presence and levels of undeclared soy and gluten in prepackaged infant cereals, and to identify potential food safety concerns related to undeclared soy and gluten for the allergic and sensitive population. 196 samples of prepackaged infant cereal were collected at retail (including single, mixed grain, and flavoured infant cereals). The results were as follows and required no further action as all were found to be acceptable:

- 98 samples analyzed for undeclared soy (**no positives found**)
- 98 samples for undeclared gluten (**no positives found**)

Planned sampling for gluten in the 2016-17 fiscal year includes 2700 samples (no distinction between domestic & imported) as follows:

- Gluten in gluten-free oat products: **300 samples**
- Undeclared allergens & gluten in RTE meals: **500 samples**
- Undeclared allergens & gluten in refrigerated dips & spreads: **400 samples**
- Undeclared allergens & gluten in meal replacements & nutritional supplements: **300 samples**
- Undeclared gluten & sesame in salty snacks & crackers: **500 samples**

The CFIA will continue its surveillance activities, follow up on violative results and inform the Canadian public and other stakeholders of its findings.

## Summary of Presentations and Discussions

# 2

### Demand for Gluten-Free (GF) Foods is Growing

- Prevalence of celiac disease dramatically increasing
- Consumers avoiding gluten have recently doubled for medical and non-medical reasons
- Increasing awareness, spurred by growing information, marketing, and activist consumer groups
- 4/5 of the 1% of the population thought to have celiac disease go undiagnosed. There are expected to be more paths to diagnosis
  - When they are all finally diagnosed ...?
  - Lots of room to grow this market!
- GF diets are known to help non-celiac patients who have gluten sensitivity or other health issues (e.g. IBS)
- Increasingly, activist posture of consumer groups among target audience & industry is contributing to interdependence of both interests and knowledge

### Consumers Want Safe GF Food

- Our customers want to unload the burden of celiac disease to achieving a gluten-free diet which is their only treatment option
- Media sometimes works contrary to GF interests by calling it a fad
- 90% of consumers don't trust labels, and still they have high expectations for food safety and therefore seek out safe gluten-free foods produced in certified facilities

### Communicating in Complexity

- Higher interdependence of info and activity, and more knowledgeable, activist stakeholders = greater complexity
- Consumers want:
  - More, and more accessible, and clearer information (e.g. scrutinize test results and understand them)
  - Better confidence in the accuracy of labelling
  - More consistency in information provided across sectors and across platforms
  - Better understanding of new technologies and how they relate to their health issues

### We Love Science, but...

- Gaps in understanding across the value chain
  - Physicians need to be more open to benefits of GF diet to those suffering other maladies
- Reliability of test methods for gluten
  - Sampling, extraction, analytical methods are difficult
  - There is significant incidence of false positives and false negatives
  - Scientists continue to seek solutions
  - The audit process can be confusing and frustrating, and sometimes, not reliable
- Science is moving forward to develop medicines that will increase gluten tolerance
  - But the gluten-free diet is here to stay for the foreseeable future

### Food Safety and Corporate Culture

- Food safety has a cost; but benefits are greater reward
  - Industry is seeking efficiencies to reduce costs while preserving food safety outcomes
- Attract and grow food safety professionals
  - Train them up and recognize their expertise
  - Create career paths
- Gain experience that will make audits and working with auditors less of a burden
- Complex in restaurants- they want food safety programs geared across the back and front of house

### Grow the Supplier Base Activity

- Focus now is on grains (e.g. gluten-free oats and pulses)
- Purity protocol and other technologies to prove gluten-free status of oats
- Pilot projects will demonstrate best practices
- Pulse crops are the perfect food: nutritious, tasty, allergen-free and inherently gluten-free
- Considerable comfort that this will take us in the right directions



## Look Up the Value Chain for Help

- Processors and small producers as innovators need to provide products that meet retailer requirements
- Food fraud in the supplier chain needs to be addressed
- Confirm that ingredient suppliers are delivering on food safety is very important
- Industry needs to partner with suppliers so that the evidence for audits is available and testing protocols are correct for them

## Emerging Questions

- How to build consistency of information across platforms and sectors?
- How to respond to/educate the media?
- How to build a more knowledgeable food safety workforce?
- How to address the unique information, supply, and technological needs of the restaurant sector?
  - Give us the right tools from credible sources = build integrity
- How to become more audit-ready?
- How to manage an integrated audit?
- How to bulwark the audit review process?
- How can auditors, certification bodies and ACG strengthen their relationship?
- How to ensure audit process across countries so that the process is both culturally appropriate and to a reliable, uniform standard?
- How to build data and knowledge through audit case studies?
  - Show cost/benefit of doing the right thing
- How to increase # of certified vendors up the supply chain?
  - How to support supplier base through pilots, etc.?  
(Grains and other ingredients)?
- How to build a standard for sampling?
- Will gaps in what we can know in methods and protocols erode consumer confidence? Do consumers trust the science?
- The value of the GFCP
- How to roll out online training to target audiences?
- How to transition ANSI-ANAB to a new reality?
  - Standards and Policies
  - Manual
  - CB's and Auditors
  - Audit Reports
- SQFI (Safe Quality Food International) into their food safety standard as an addendum?

# 3

## What We Learned

### Regulations are Confusing to Consumers

- There is a disconnect between the regulations concerning gluten content and people's understanding of them. Consumers do not understand the regulations and regulators do not understand how consumers misunderstand the regulations. Therefore, more guidance is needed on how to interpret these regulations. Labels on food products do not seem to properly reflect "gluten-free" or "free from" regulatory requirements. When they get ill, this leads consumers to not trust labels. They wonder if there is too much latitude for manufacturers to interpret the regulations.

### Sampling Methods Can Leave Gaps

- Is sampling more art than science? The presentations raised more questions about sampling methods than we had previously.
- Using a purity protocol as the sole method to ensure oats are gluten-free won't meet the demand for oats among gluten-free consumers. We will need to use advanced sampling methods and technology to fill this gap. This is true for other gluten-free grains, as well; and it is the current practice for them.
- Establishing sampling methods for ingredients is very complicated. We need guidance on how to sample. The pharmaceutical industry, for instance, needs sampling standards. Health Canada needs to be part of developing sampling protocols in partnership with industry.
- It is important to emphasize that the testing kits provided by industry do an excellent and reliable job. The issue is in the sampling methods, not in the testing methods.

### CFIA Prosecutions

- The CFIA does not prosecute based on one negative sample. A negative sample would lead to an investigation to assess the real risk to consumers and corrective actions needed, but at least five negative samples would need to be found before the possibility of prosecution emerges. Even then, the decision to prosecute must pass through several internal hurdles before a court case is launched. A recall would likely happen first to protect the public.

### Increasing Supply Based on the Purity Protocol

- Why can't more grains be produced using the Purity Protocol?
- We can if consumers will pay for the much higher costs of production.
- Consumers will pay for the higher costs, but generally prefer not to.
- Keep in mind that the market for gluten-free grains will grow significantly. This could drive these costs down as the supply increases.

### Not all Gluten-free Trademarks are Created Equal

- Not all gluten-free trademarks are equal, and consumers are often not aware of that. Therefore, more consumer education is required about the integrity of gluten-free trademarks. Many marks are actually self-declarations giving the false appearance of 3rd party scrutiny when there is none.

### Harmonized Regulations are Needed Across Countries

- Gluten-free regulations across international jurisdictions are not harmonized. This creates problems across the value chain.

### Education

- Education is needed for those who are newly diagnosed with celiac disease. They are often at sea regarding diet, food choices, etc.
- Education is needed across the value chain regarding the regulations, and processes used to ensure that food is gluten-free. Processors and restaurants need to be targeted.
- The Hazards Analysis Critical Control Points (HACCP) approach to ensure food safety needs to be better understood, especially by consumers.

### HACCP

- The HACCP approach could be utilized across the gluten-free value chain to ensure gluten-free food safety but needs to be promoted.



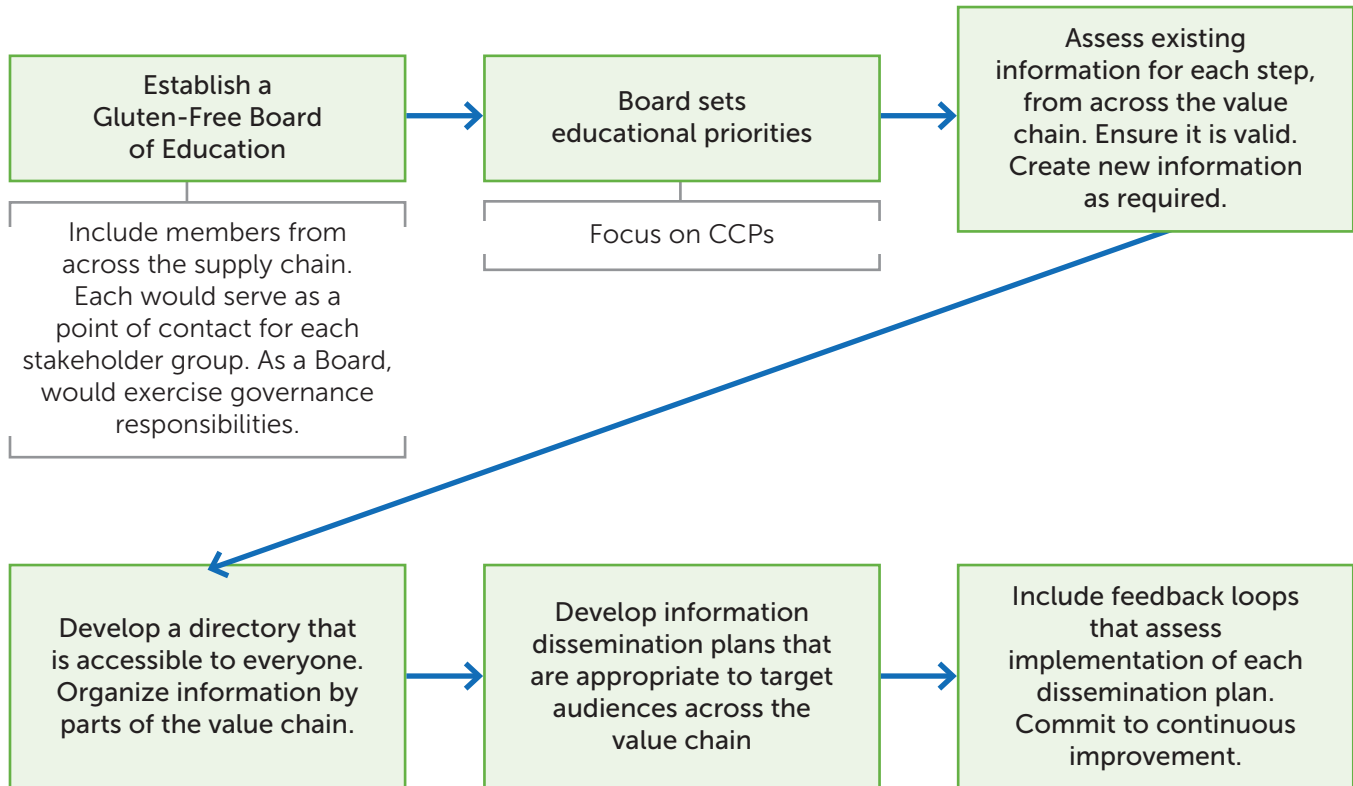
## What We Should Focus On

The consensus on the top four topics is:

- Gluten-free education across the value chain.
- Improved sampling methods.
- Increased gluten-free food safety across the value chain. This includes the purity protocol, increased testing, better sampling and using HACCP methods.
- Increased nutrition, quality and flavour of gluten-free foods.

## What We Could Do – Suggested Paths

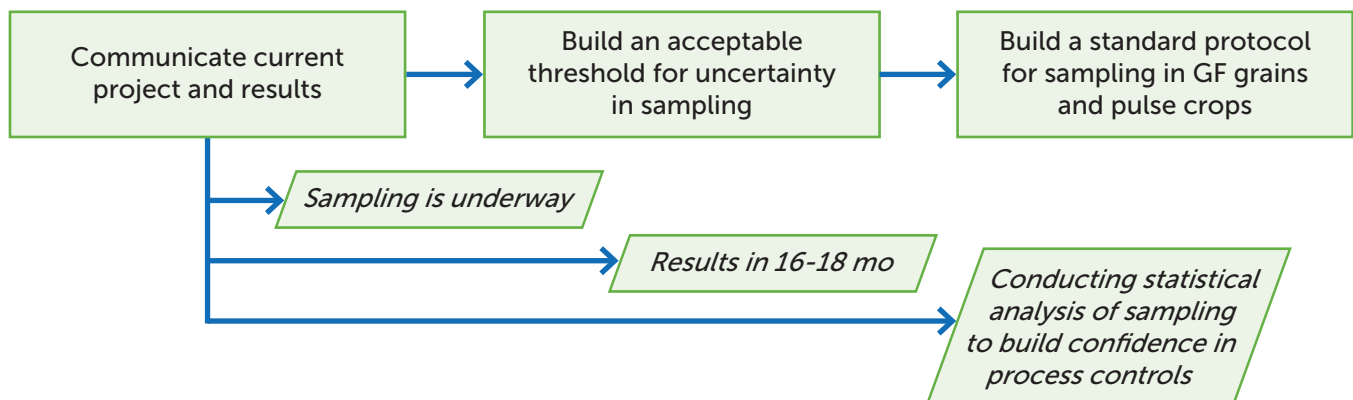
### Gluten-Free education across the value chain



#### Volunteers:

Marie Sguigna (coordinator), Jordon Cornwall, Angela Wiesel, Jennifer North, Frank Massong, Paul Valder, (connection to Canadian Partnership for Consumer Food Safety Education).

### Improved sampling (focus on grains and pulses):

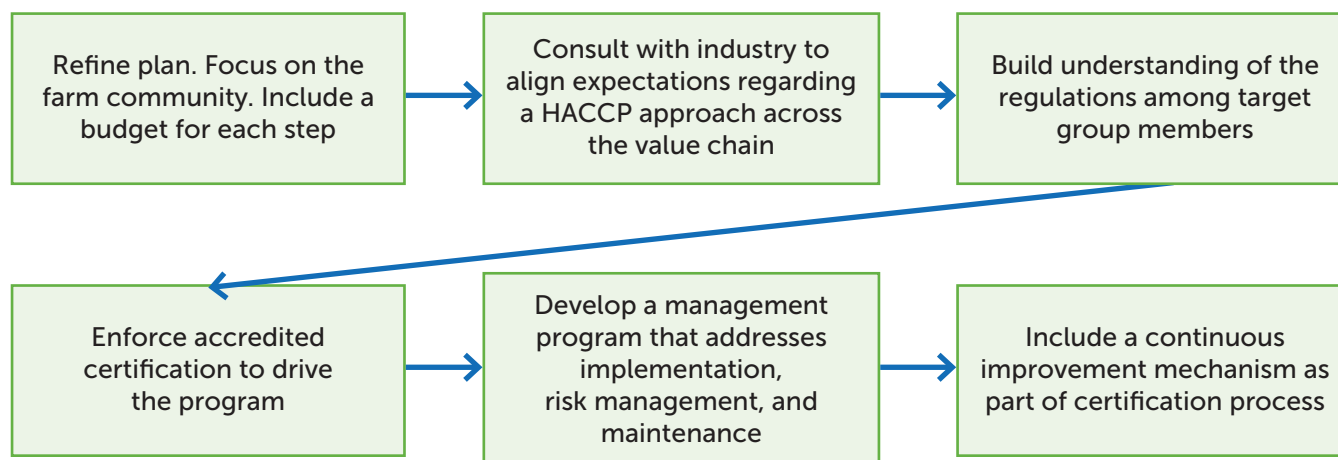


#### Volunteers:

Laura Anderson (coordinator), Nyla Dubiel, Frank Massong, Kurt Johnson, Melonie Stoughton, Chrystine Vanendriessane



## Increased gluten-free food safety (focus on farming)

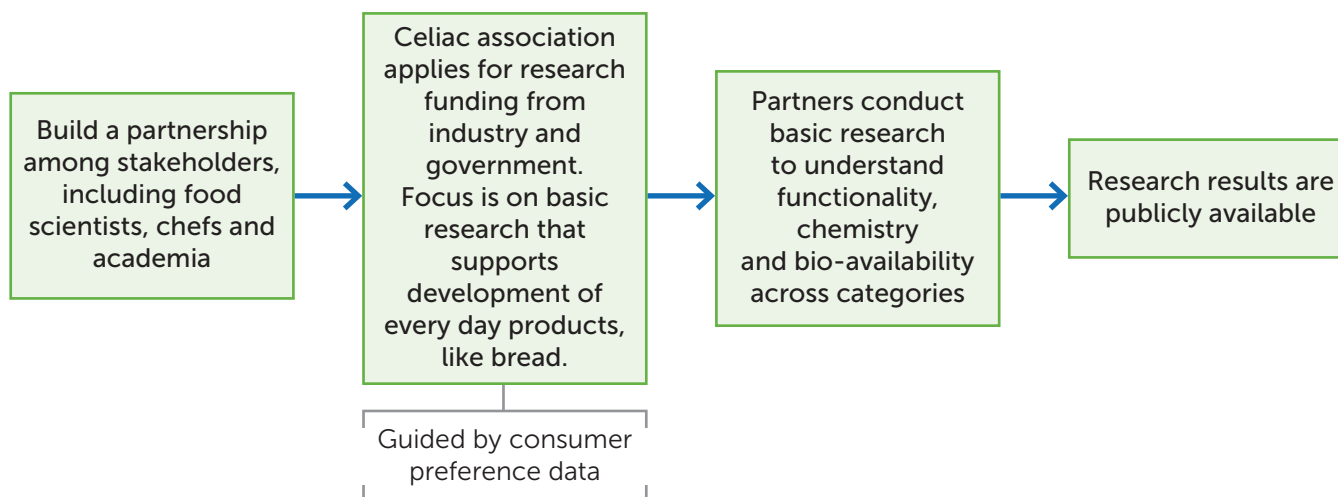


- A food safety program like this already exists in Canada, but take up has fallen short and does not include gluten management. Advocacy, engagement, and education are required to move the program forward, in Canada and elsewhere.
- The size of farms and an aging farm population are challenges to implementing this program.

### Volunteers:

Nancy Berger (coordinator), Nyla Dubiel, Nancy Post, Canada Grains Council, Frank Massong

## Increased nutrition and quality:



### Volunteers:

None. Not considered a priority.

## List of Attendee Companies

Company
AGT Foods
AIB
Allergen Control Group
ANSI-ASQ/ANAB
Avena Foods Ltd.
Beyond Celiac
Bia Diagnostics
Canadian Celiac Association
Canadian Food Inspection Agency (CFIA)
Canadian Grain Commission
Canadian Grocer
Canadian Seed Institute
Canadian Spice Association
Celiac Disease Center at Columbia University
Commercial Bakeries
Cream Hill Estates
Cuisine Royale
Diefenbaker Seed Processors
Eagle Certification Group
ED Smith/Bay Valley/Treehouse
El Peto Products
EnviroX Group
Fancy Pokket
FARMO
Food Allergy Research & Resource Program (FARRP)
Food Processing HR Council
Food Specialty
Food Technology Consulting
G Spot Creative
General Mills
Global Food Safety Resource (GFSR)
Gluten-Free Certification Organization
Glutenpro
Grain Millers Inc.
Health Canada
Intact US Inc.

Company
Integrated Explorations Inc.
Intertek
Jay Shirodker Consulting Inc.
Laboratory Services Division, University of Guelph
Leap! Corporation
Loblaw Companies Ltd.
M&M Food Market
Maple Lodge Farms
Mars Chocolate North America
McCormick Canada
Mérieux NutriSciences Certification LLC
Olymel
PCR Corp.
PepsiCo Canada
Pinnacle Foods
R-Biopharm
REM
Restaurants Canada
Richardson International Limited
Romer Labs
Safe Quality Food Institute
SAI Global
Seed Snacks Corp
SGS Canada Inc.
Sobeys Inc.
Sofina Foods Inc.
Ste. Anne's Spa
Superior Food Safety
The Original Cakerie
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