

American Oat Workers Conference July 14, 2014

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With thanks to the Organizing committee for
the invitation.

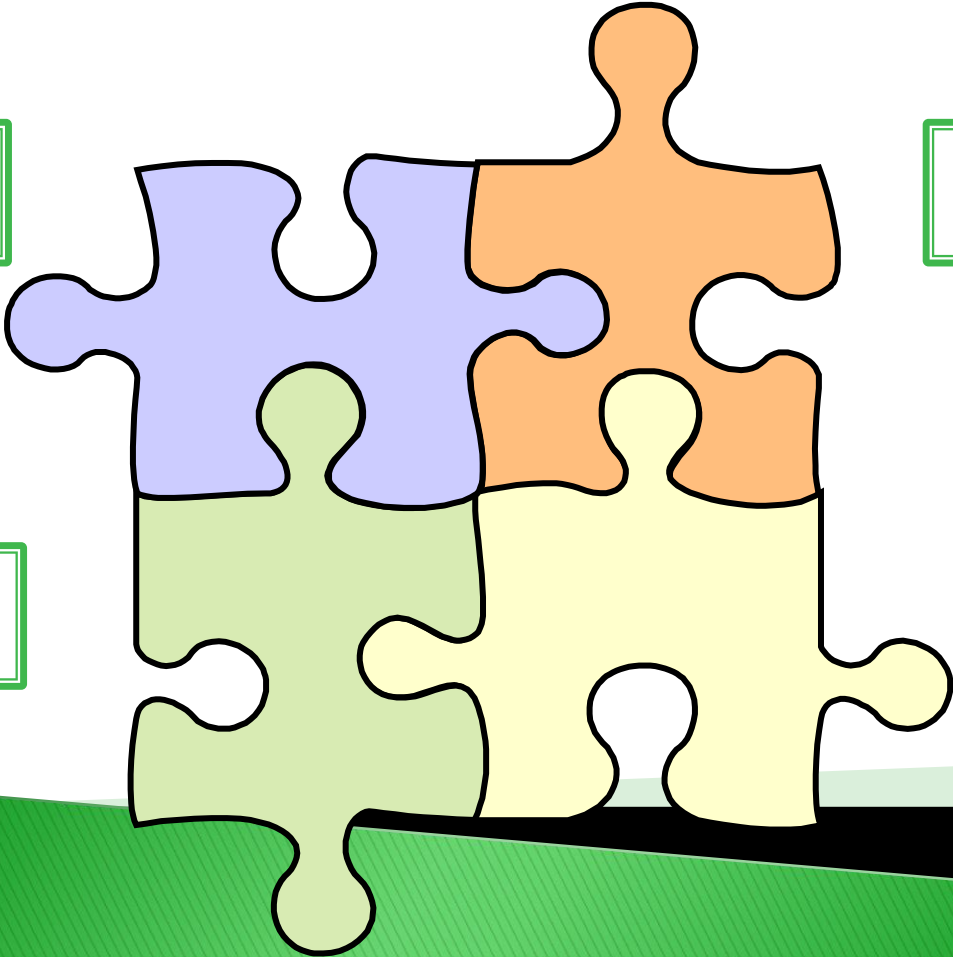
Pure Porridge Puzzle

People

Process

Purity

Price



Outline

- ▶ **People** involved in guaranteeing a quality gluten-free product, or in Canada, pure, uncontaminated oats
- ▶ **Processes** manufacturers use to guarantee purity
- ▶ **Purity** – how it is assessed for gluten-free products and by whom
- ▶ **Price** implications of guaranteeing purity
- ▶ **Popularity** of the “gluten-free” diet and gluten-free oats

Purity of Oats

- ▶ product closely monitored for purity because of history of cross-contamination: 88% Canadian commercial oat supply (Koerner 2011)
- ▶ maintaining purity is a challenge because of physical similarity to wheat, rye and barley and common crop rotation
- ▶ some people (5–7%) do not tolerate pure oats – questioning product purity



Lara enjoys pure porridge



Pure Porridge Puzzle

- Grower
- Ingredient Supplier
- Manufacturer
- Government
- Certification Programs
- Consumer

Grower's Responsibilities

- ▶ History of field crop rotation – no gluten containing grains for 2–3 years
- ▶ Purity of seed for planting
- ▶ Dedicated or thoroughly cleaned equipment for planting, harvesting, transporting

Ingredient Supplier's Responsibilities

- ▶ Dedicated or thoroughly cleaned equipment
- ▶ Certificate of Analysis – gluten
- ▶ Certificate of Analysis – microbiological
- ▶ Contract specifies frequency of testing, test used and that the results must be available

Gluten-Free Manufacturer



Manufacturer is ultimately responsible to ensure their product is safe from allergens, bacteria, and is good quality

- ensuring growers and ingredient suppliers are meeting contractual requirements for purity
- ensure they have done appropriate sampling and testing, even of ingredients
- processing & packaging facilities – dedicated or shared facilities, avoiding cross-contamination
- ensure their products have truthful labelling as required by the country's regulatory body e.g. Canadian Food Inspection Agency (CFIA)

International Regulations for Labelling Oats Gluten-free



- ▶ **Health Canada (HC)**
 - can not be called gluten-free: wheat-free, no contamination with wheat, rye or barley
- ▶ **Food and Drug Administration (FDA)**
 - can be called gluten-free as long as they test < 20ppm
- ▶ **European Union**
 - ▶ can be called gluten-free as long as they test < 20ppm
- ▶ **Australia**
 - can not be called gluten-free or even low gluten

Certification Programs



- ▶ Programs are available from associations supporting people with celiac disease e.g. Gluten Intolerance Group of North America, Canadian Celiac Association, Coeliac UK
- ▶ Application usually includes a questionnaire self-completed by the company, including:
 - identification of all activities carried out by the company
 - detailed processes
 - is an Allergen program in place
 - is the company HACCP certified (Hazard Analysis and Critical Control Points)
- ▶ Site visit by an auditor from the certifying body



The Celiac Scene™
Guides for the **Gluten Free**

Consumer's Role – Ask Questions

Guides for the Gluten-Free – **The Celiac Scene**™

When company not certified:

- how do they make sure that the ingredients they use are gluten-free?
- Is the product processed or manufactured in a facility that also handles gluten? Is it on the shared equipment?

Shared Facility



Facility also processing gluten-containing products:

- are there separate rooms for storage of ingredients?
- labelling of ingredients is critical
- are there separate production lines/rooms e.g. if the gluten-containing ingredient is flour – dust is everywhere unless separate HEPA filtered room is used for GF it is very difficult to prevent cross-contamination
- **thoroughly** clean equipment if used for gluten and GF
- education of staff is critical
- more and more there is a general recognition by manufacturers of the importance of dedicated facilities and equipment – but adds to costs



Consumer's Role – Ask Questions

Guides for the Gluten-Free – **The Celiac Scene**™

- Is the finished product tested for gluten on a regular basis? Which test do they use?
- If each Lot is tested, what is a Lot size?
- Are the tests done in-house or by an independent laboratory?
- Do they make the results public?



Consumer's Role – Ask Questions

Guides for the Gluten-Free – **The Celiac Scene**™

- Do they have a HACCP or Allergen Program in place?
- How do they train their staff to follow good practices to avoid cross-contamination?
- Have they ever had a recall for gluten contamination in your product?

HACCP – Hazard Analysis and Critical Control Points



Pure Porridge Puzzle

- Seed purity check, same for most grains
- Inspecting the fields – growers, CFIA
- Cleaning the equipment – seeding, harvesting
- Dedicated processing equipment – mill
- Sampling for gluten–testing

Seed Purity Check



- Samples taken before planting – to ensure pure seed planted
- Samples taken when harvested before processing

1 foreign seed in 1 kg oats = 6 ppm





Pure Porridge Puzzle

- Sampling
- Testing – quick, independent laboratory
- Consumer targeted tests
- Gluten-free statements on labels

Product Sampling



- Regular or periodic sampling?
- How is sampling done – no guidelines on this
- Is one retail package tested every production run – which might be 10,000 packages; is sampling done daily – which might be 100,000 packages...
- For pure oats we sample every 800–900kg tote bag which would be 900 x 1kg packages

Sampling for Gluten-Testing



Product Testing



- Which test is used?
- Is testing done in-house or external certified laboratory?
- “quick tests” have not been extensively validated: where a regular GF sample is compared to a pure sample of something spiked with a known amount of gluten

Product Testing



- Tests are able to determine the “gluten” in storage proteins: wheat – gliadin; rye – secalin; barley – hordein in a product.
- Results are reported as ppm – parts per million
- **R5-ELISA** – the gold standard for testing gluten; there is a regular test and a “quick” test (which has not yet been widely validated)
 - Regular test takes 3.5 hours to run @ \$75-\$175 / sample
- **Omega – Gliadin ELISA** – does not accurately detect “gluten” from barley so not good for pure oats

ELISA – Enzyme-Linked Immunosorbent Assay

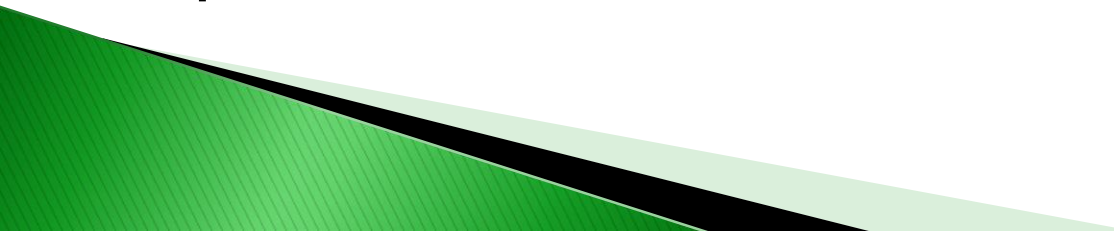
Consumer Test Kits



The Pure Oats Company™

- ▶ Glutentox Home (Spanish) new G12 antibody; can test for 5ppm
- ▶ EZ Gluten (ELISA Technologies – US) – can detect levels as low as 10ppm; 99% accurate; get results in 10 minutes; \$25/2 test strips; can be ordered online in Canada
- ▶ Imutest GFT (Gluten Flow Through)/ Haven (UK) – can detect levels between 10–20ppm; results in 20 minutes
- ▶ Neogen – Reveal 3–D Gluten tests– results in 10 minutes; hand held device; low and high levels of detection not specific number

An expert's thoughts... GF test kits

- ▶ Thom Grace – Bia Diagnostics in Vermont began testing for gluten in 1993.
 - ▶ in the past decade the demand for testing has increased exponentially
 - ▶ quick gluten tests have a place in food safety but should be used in very controlled settings
 - ▶ can get false negatives
 - ▶ food can have such extremes, what might work in some apple juice might not work in another because of a different pH in the product
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An expert's thoughts... GF test kits

- ▶ very difficult for these rapid methods without elaborate extractions methods to “see” or find the low ppm levels of gluten that might be hidden in the processed foods on the market today.
- ▶ Even with the best equipment and knowledge they sometimes find that the R5 ELISA does not work with a particular sample.
- ▶ Recently ran a sample for a person highly sensitivity to gluten:
 - the lab found ~40ppm gluten
 - the manufacturer's test found no gluten
 - the person who sent the sample used the G12 LFD (quick test) and it was negative.
 - Quick / rapid test only recognize a very specific sequence in the gluten protein



Pure Porridge Puzzle

- Premium price (at least double) for pure oat seed
- Premium price for processing seed, especially if plant is dedicated
- Purity check – \$40.00–\$50.00/1000g sample
- Testing – average \$120 / test for ELISA: sampling, sample preparation and testing
- Need for other tests – microbiological, nutrient \$\$\$



Pure Porridge Puzzle

- Certifications for gluten-free status are annual expense
- Monitoring / Traceability programs – in the event of recalls – all is essential but costly

Product GF Certification Programs

Canada

- Canadian Celiac Association has a new program – Gluten-Free Certification Program (GFCP); **oats not included**; have partnered with National Foundation for Celiac Awareness (U.S.)

United States

- GFCO – Gluten Intolerance Group < 10 ppm
- CSA – Celiac Sprue Association < 5 ppm (Recognition) (**oats not allowed**)

Product GF Certification Programs

- **International**
 - Coeliac UK
 - Coeliac Society of AUS (no oats allowed)
- **Cost (\$1,500 to \$3,000 per year per Org.)**
 - Impact on small companies
 - Impact on Consumers
- **Logo**
 - Is it important for consumers?



“Gluten-free” is critical terminology for manufacturers, consumers and certifying bodies

Benefits of a GF Certification Program



- ▶ “Gluten-Free”
 - Widely understood to mean “Safe Food”

- ▶ Credibility
 - Suggests manufacturer has implemented critical purity procedures; HACCP and / or Allergen Program in place

- ▶ Consumer trust and loyalty

Traceability



- ▶ Essential to have good documentation in the event of a recall
 - **Growers** – seed purity, crop history of fields, CFIA field reports
 - **Processor or ingredient supplier**– HACCP; Allergen Program; record of grower output /Lot #; Certificate of Analysis for gluten; written procedures for sampling and testing and audits of compliance
 - **Manufacturer** –Certificate of Analysis for gluten content for final product; samples of each Lot # for future analysis if needed; record of distribution of Lot #'s to customers (manufacturers, retail, individuals); written procedures for sampling and testing and audits of compliance



Pure Porridge Puzzle

- Staff training is important and costly
- Economies of Scale (ingredients, shipping, packaging are all higher with small volume sometimes seen in GF products)
- All result in expensive product for the consumer

Popularity – Gluten-Free Market

Gluten-free diets (GFD) are growing in popularity with the US market for gluten-free foods and beverages expected to exceed \$5 billion by 2015 (1).

- ▶ 1% of the population is estimated to have **celiac disease** (2)
- ▶ 6% are estimated to have **non-celiac gluten sensitivity** (2)
- ▶ 3% follow a gluten-free diet for **other medical conditions** (e.g. autism, attention deficit hyperactivity disorders, Down syndrome etc.) (3).
- ▶ It is estimated that **20%** of the U.S. population consume gluten-free foods because they think there are **health benefits**

Popularity – Gluten-Free Market

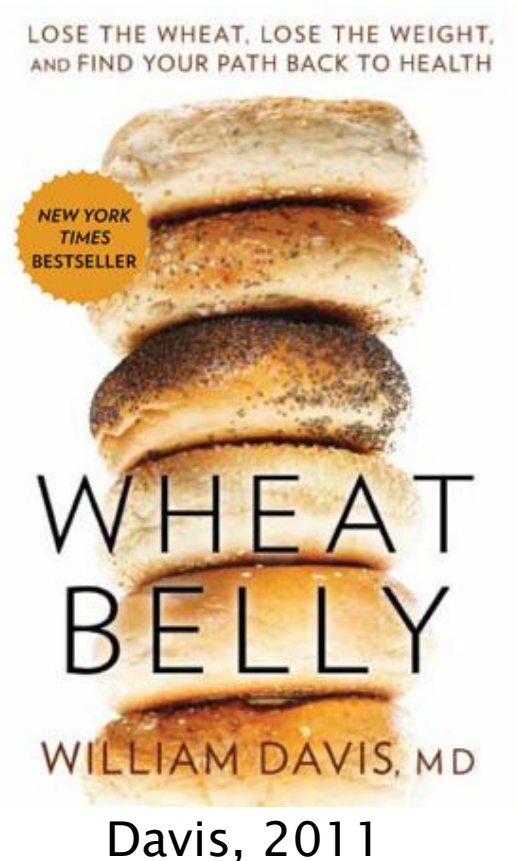
- ▶ Is the interest in the gluten-free diet a fad promoted by manufacturers to make money?
- ▶ Is it due to “star power” – Elisabeth Hasselbeck, Chelsea Clinton, Novak Djokovic, Gwyneth Paltrow, Kate Middleton.....
- ▶ A 2013 NPD Group market-research U.S. Survey:
 - nearly a third of adults say that they’re trying to either eliminate or cut back on gluten
 - resulting in a food industry valued at least \$4 billion and perhaps more than \$10 billion — and climbing.
 - the number of people with the disease is rising — doubling every 30 years similar to other autoimmune diseases such as Type 1 diabetes

NPD – Market Research Group. Is Gluten-free Eating a Trend Worth Noting. 2013. For more Information: <https://www.npd.com/perspectives/food-for-thought/gluten-free-2012.html>

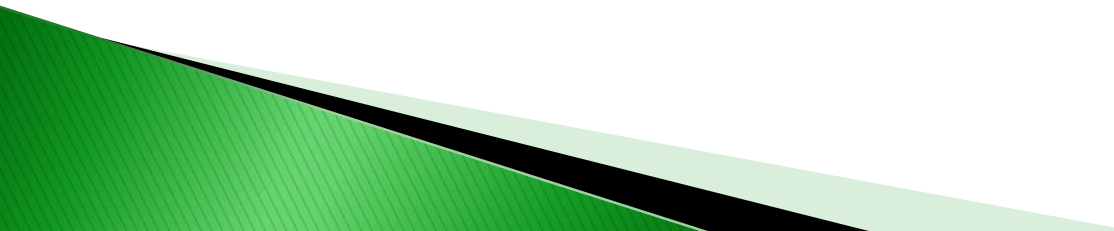
Popularity

Wheat Belly and Grain Brain

- ▶ Some of the claims discussed in the popular books Wheat Belly (4) and Grain Brain (5):
 - gluten-free diets lead to weight loss
 - the consumption of cereal grains cause inflammation which can lead to autoimmune diseases
 - concerns re: genetically altered wheat
 - ...and many more claims are made about the “harms” of consuming wheat



Concerns about Wheat Belly claims

- ▶ There is no research currently available to answer the question: is a gluten-free diet a successful weight loss method in healthy adults?
 - ▶ The studies that have examined weight change in individuals with celiac disease on a GFD can not be generalized to healthy individuals. Therefore research is needed in this area, especially considering the popularity of healthy individuals trying this diet for weight loss.
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Concerns about Wheat Belly claims

Does the intake of cereal grains lead to inflammation?

- ▶ Davis (the author of Wheat Belly) states that the consumption of wheat and other grains leads to increased intestinal permeability (4)
- ▶ A review article addressed how the intake of cereal grains can lead to chronic inflammation and autoimmune diseases by increasing intestinal permeability (6)
 - Gliadin must pass through the intestinal barrier to interact with the immune system
 - Some studies show that when gliadin binds to chemokine receptors, on the surface of cells, zonulin is released
 - Zonulin is a protein that weakens junctional complexes and therefore increases permeability of the intestines
 - Increased intestinal permeability has been associated with type 1 diabetes, rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease, asthma and depression
 - Zonulin activity is higher in those with celiac disease

Concerns about Wheat Belly claims

The risks of genetically modified foods

- ▶ Davis states that wheat is a product of genetic research and today we are eating genetically altered wheat (4).
- ▶ A review (7) discusses the concerns regarding health risks of genetically modified foods:
 - synthesis of new proteins that produce unpredictable allergenic effects. But, allergenic effects of the product can be assessed prior to public consumption
 - potential for toxic secondary effects due to changes in enzymatic activity and it can be difficult to assess these toxins in the products
 - benefits to genetically modified foods: potential to solve some of the world's hunger and malnutrition issues
 - Challenge: safety testing needs to be addressed to assure the public that genetically modified foods are acceptable for human consumption.

Is today's wheat different?

- ▶ Is wheat different because of hybridizing it to be drought-resistant, bug-resistant and faster growing?
- ▶ Estimated that 5% of the proteins in hybridized wheat are new proteins not found in older varieties of wheat plants.
- ▶ Are these "new proteins" what has lead to increased systemic inflammation, greater incidence of gluten-intolerance and celiac disease?
- ▶ Does deamination of wheat, allowing it to be water soluble and easier to mix into various types of packaged food, produce an immune response in people?

Popularity

Wheat Belly and Grain Brain

The importance of testing for celiac disease prior to commencing a GFD

- ▶ The prevalence of celiac disease is low but missing a diagnosis could be harmful
- ▶ Before treating any kind of symptoms with a GFD, it is important that individuals be tested for celiac disease
 - diagnosis requires the individual to be consuming gluten prior to diagnostic tests
 - Once an individual has started a gluten-free diet it is difficult to convince them to reintroduce gluten-containing foods for the purpose of a diagnostic test and it is unclear as to how long reintroduction to gluten needs to be before a blood test or biopsy would be reliable

References

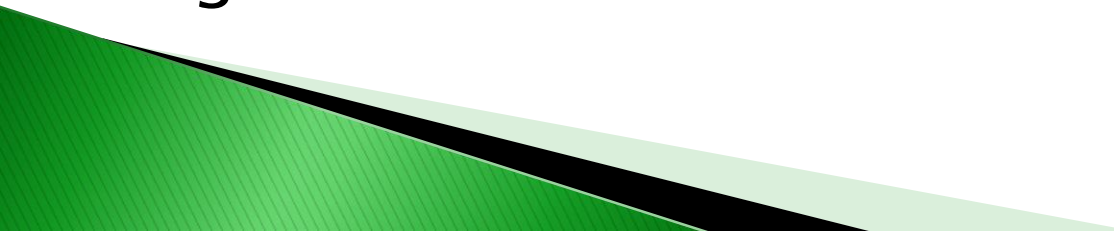
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Popularity

Growth in GF Oats Market

- ▶ North American – general acceptance of gluten-free oats as part of the gluten-free diet by the celiac and non-celiac gluten sensitivity populations
- ▶ U.S. FDA ruling on gluten-free labelling, oats are now included so more U.S. manufacturers are launching GF products with oats
- ▶ international markets are growing – general growth in popularity of GF foods, acceptance of GF oats, availability in local supply?
- ▶ Promotion of oats health benefits – beta-glucans

Future Product Ideas

- ▶ In U.S. Already lots of baked goods – mixes and ready-made products: granolas, cereals, cookies, breads, crackers....
 - ▶ oat beverage – substitute for milk for those with milk allergies, lactose intolerance, vegans
 - ▶ oat fiber powder (bran) for product fiber enrichment
 - ▶ cosmetics – oat oil
 - ▶ gluten-free beer
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Research for the Future

- ▶ more research needed on varieties of oats to see if some have less of the epitope sequence in the oat protein peptide that is similar to the sequence in wheat gluten peptide that causes problems for people with celiac disease – one proposed sequence is: (PYPEQEEPYPY versus PFPQPELPY)
- ▶ longer term follow-up studies of safety of gluten-free oats
- ▶ do the products on the market for consumer testing of gluten provide accurate or misleading results:
 - Gluten-test kits
 - 6 SensorLabs: a “breakthrough technology” allowing anyone to quickly and discreetly detect minute “traces of toxins” in their food –first one developed is for gluten; how accurate is it

Value-Added Crop for Oat Producers

Pros:

- ▶ diversification of crop, especially in oat growing climates
- ▶ if market for GF oats declines – can sell elsewhere
- ▶ access to international market
- ▶ \$\$\$ for the producer

Cons:

- ▶ If purity specs not met won't get the premium price, sell as regular commercial oats
- ▶ More expensive product for the consumer

Summary

- ▶ Many people, processes, monitoring and testing is needed to ensure purity of any gluten-free product and in particular pure, uncontaminated oats.
- ▶ There is a cost to purity.
- ▶ Gluten-free market is booming - 20% consume a GF diet for “health” reasons not medical reasons due to media and “star power”.
- ▶ Market for gluten-free oats is growing as will the commercial applications

Special thank you....

To Dr. Vern Burrows who worked with the CCA PAB to develop the CCA Position Paper on the safety of pure, uncontaminated oats for people with celiac disease. He was instrumental in setting us on the right path to purity – starting with the type of oat we use.



Dr. Vern Burrows
“Dr. Oat”

Pure Porridge Puzzle

People

Process

Purity

Price

