

# **Gluten Free: An Industry Perspective**

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**Courtney Bidney**

**Lead, Global Regulatory Affairs and International Nutrition**

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**GENERAL MILLS**

# Worldwide People Turn to General Mills for Breakfast, Lunch, Dinner, and Snacks

Today people will eat....

**60 million**  
servings of  
ready-to-eat  
Cereal

**14 million**  
Nature Valley  
bars

**5 million**  
Pillsbury  
cookies

**9 million**  
of our KFC  
biscuits

**343,000**  
packets of  
Nature Valley  
Granola at  
McDonald's

**2 million**  
Wanchai  
Ferry  
dumplings

**2 million**  
pounds of  
Green Giant  
vegetables

**1 million**  
servings of  
Häagen-Dazs  
ice cream

**Sixth largest Food Company**

**operating in 130+ countries, with over 35,000 employees**



# Championship Brands







**Food must be trustworthy**

# Agenda for Today

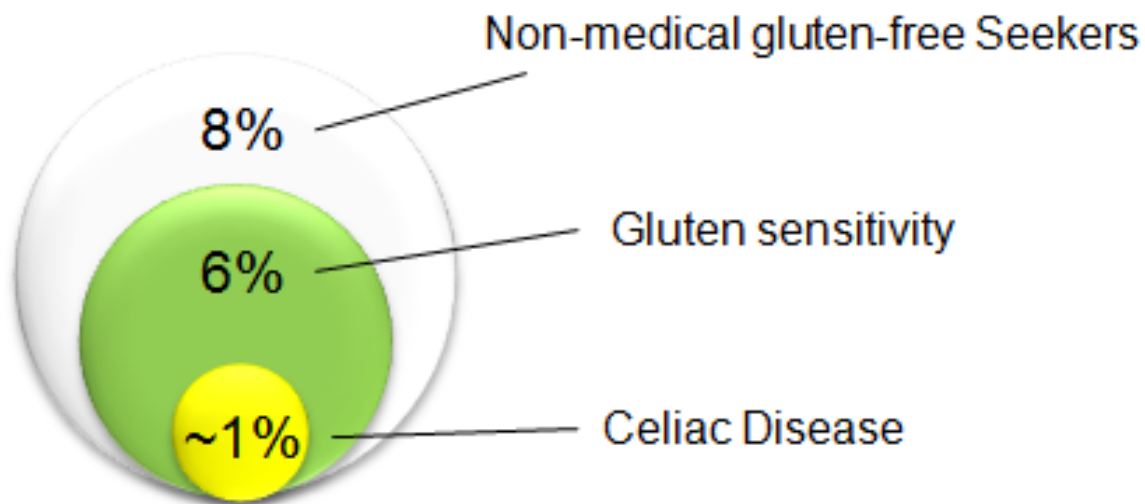
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- Introduction to Gluten Free
- Evaluation Process for Gluten Free
- Analytical Methods & Challenges



# 15% of Americans are Seeking Gluten Free

## 15% of Americans Seeking Gluten Free<sup>1</sup>



Thursday, March 10, 2011



UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE  
RESEARCHERS IDENTIFY KEY PATHOGENIC  
DIFFERENCES BETWEEN CELIAC DISEASE & GLUTEN  
SENSITIVITY



Dr. Alessio Fasano  
directs the Center for  
Celiac Research.



# A Leader in Gluten Free Products

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- A variety of products labeled as Gluten Free
- The first major brand with Gluten Free breakfast cereal
- Listening to the needs of consumers



# Evaluation Process for Gluten Free

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# Global Standards

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- **Codex**
  - 20 ppm
- **Individual Countries**
  - EU Countries – 20 ppm
  - Canada – 20 ppm
  - Australia – No presence
- **3<sup>rd</sup> Party Certification**
  - Gluten Free Certifying Organization (GFCO)
  - NSF



# U.S. Regulation

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- GF regulatory definition:
  - “[a]ny unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm”
- Expectations communicated in preambles to gluten-free rulemaking:
  - Use controls needed to prevent cross-contact.
  - Ensure gluten levels are as low as possible, and that food has < 20 ppm gluten.
- FDA issued guidance on appropriate test methods.
- As yet, no guidance on sampling and sample prep



# Safety Across the Product Life Cycle

From Concept to Consumer



Product  
Design

Supply Chain

Marketplace

Design Safety In

Manufacture as Designed

Consumer and Customer Feedback



# Safety Management System

## *Integrated Safety Management System*





# Systems Based Approach for Gluten Free

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- **Risk Based**
- **Validation**
  - Ingredients
  - Supply Chain
- **Verification**
  - Ingredients
  - Supply Chain



# Evaluation Process: Ingredient

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- Supplier qualification
  - Ingredient review
  - Review of supplier's controls
  - On-site qualification audits
  - Third party certification
  - Testing
    - By supplier
    - By General Mills
  - Certificates of analysis



# Evaluation Process: Finished Product

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- Operations Review
  - Evaluation of products made on the same line
  - Order of scheduling
  - Changeover practices
  - Cross-contact concerns
  - Testing



# Analytical Challenges

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# ELISA Testing

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- **Two ELISA Methods**
  - R-Biopharm
  - Morinaga Institute
- **AOAC Validation**
  - High Relative Standard Deviation
    - 20 – 50% RSD on R-Biopharm test kit
- **Very Small Sample Size**
  - 0.25 g test (R-Biopharm)
  - 1.0 g test (Morinaga Institute)



# Testing Challenges

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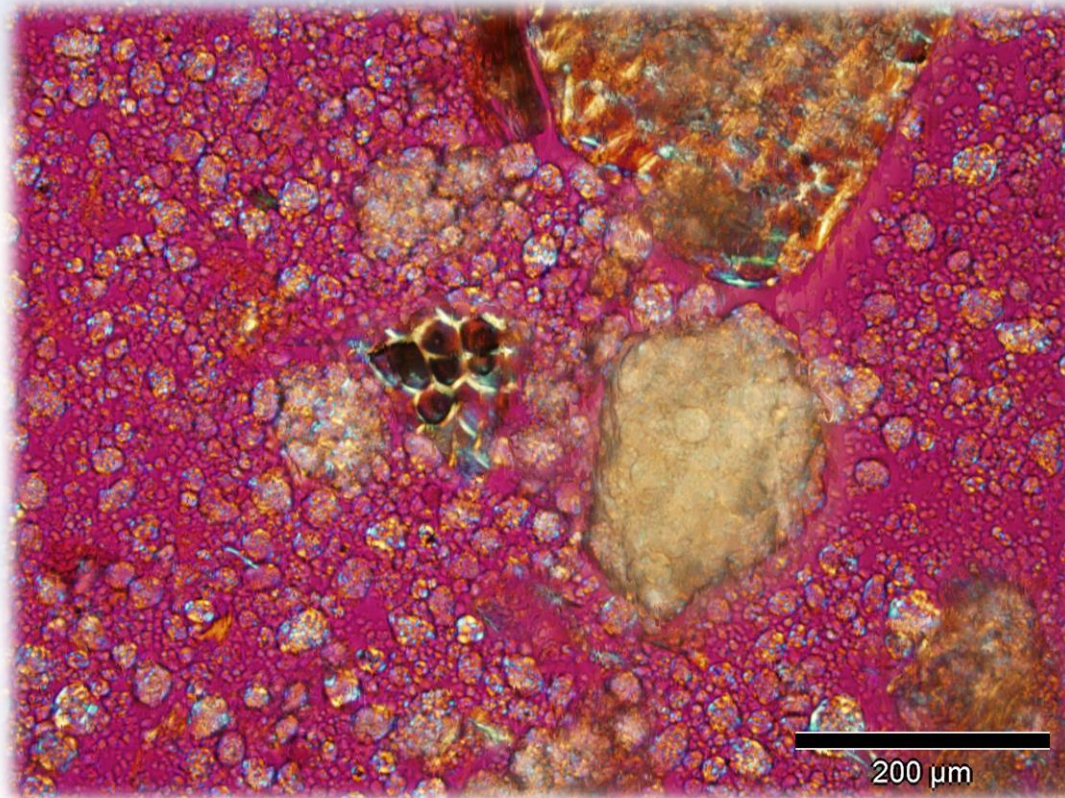
- The repeatability of the gluten test method is dependent on the particle size of the sample matrix.
- The overall variation of sampling and measurement will depend on several factors.
  - Mass of initial subsample
  - Grinding/homogenization equipment
  - Test Portion Size



# Testing Challenges

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- **Lack of homogeneity when grinding samples**



# Key Takeaways

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- Consumers are seeking gluten free products.
- For industry to develop gluten free products, a risk based approach and evaluation of the entire supply chain is needed.
- Verification involving analytical testing is complex due to lack of homogeneity and small sample size in some matrices.





# INCIDENT FREE



***We lead with safety***

***Every incident is preventable***

***We are all accountable***

# INCIDENT FREE