



# Allergen Management in Food Production: How to make the most of in- house and third-party testing

Empoort  
LLC

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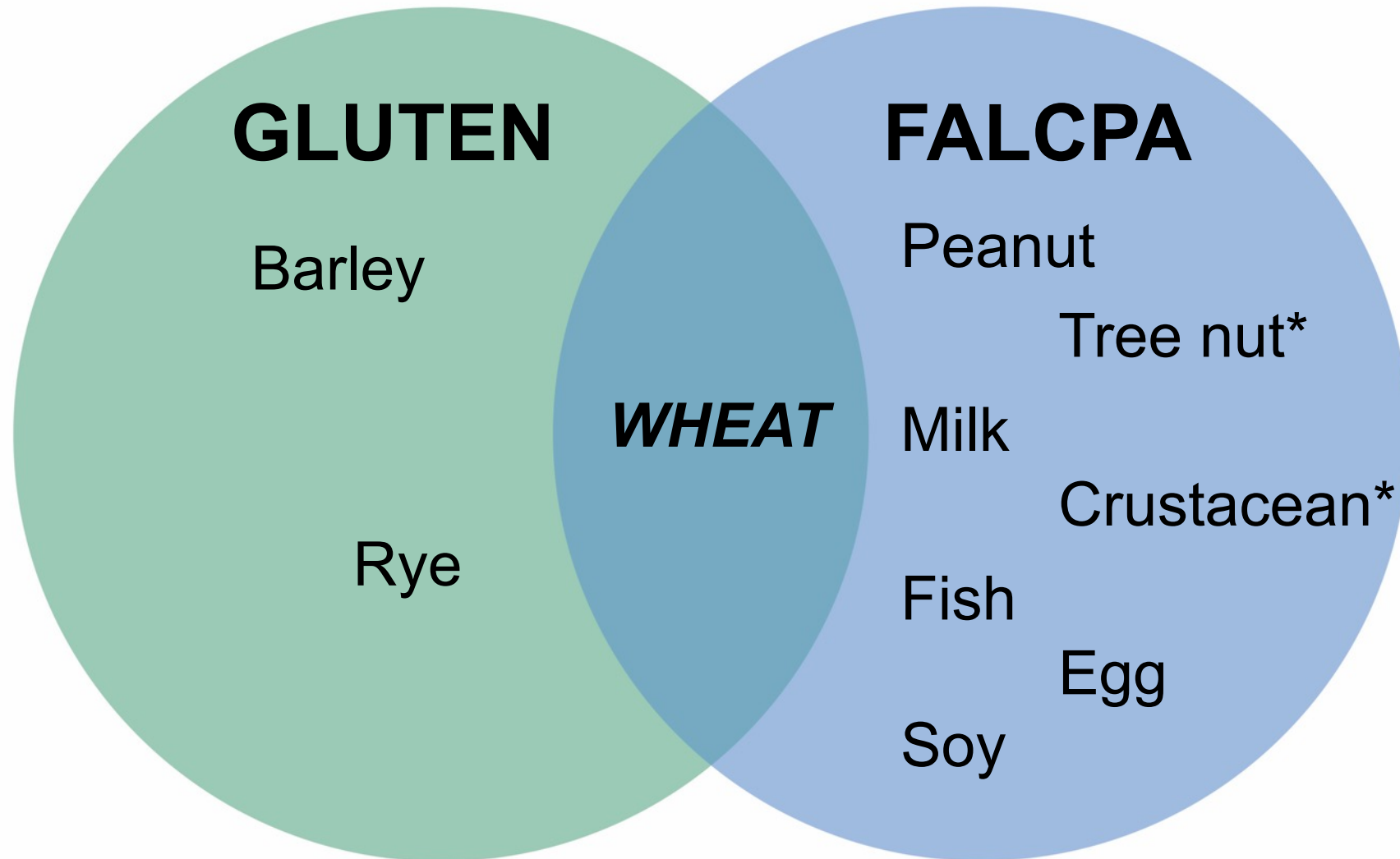
# Who are you, why are you giving this talk, and when should I go get a snack?



- Emily Kaufman, president of Emport LLC
- US launch of both GlutenTox Pro and AlerTox Sticks
- 10 years of working with gluten-free and allergen-free food manufacturers
- 20 years of eating gluten-free

*“Today we’ll touch on the gluten and allergen laws and the types of tests available, then dig into the decision-making process for choosing a test.”*

# What are the rules?



# Gluten Labeling Laws (2014\*)

- Entirely voluntary – only applies if product labeled “gluten-free”
- Product must have < 20ppm gluten
- Any detectable gluten present must be from unavoidable cross-contact (despite following cGMP) – not from intentional inclusion
- No gluten-containing ingredients may be used\*
- Fermentation guidance issued in 2020
- How you confirm that your product is gluten-free is entirely up to you
  - *“The final rule does not specifically require manufacturers to test for the presence of gluten .... However, manufacturers are responsible for ensuring that foods bearing a gluten-free claim meet the requirements of the final rule.”*  
(fda.gov)

# Allergen Labeling Laws (FALCPA, 2004)

- Required labeling for all packaged foods under FDA purview
- No stated permissible ppm/ppb thresholds
- “May Contain” statements are unregulated/voluntary
- “Free From” statements are unregulated/voluntary
- Accidental cross-contact is not regulated, however: processors must implement cGMP controls that prevent allergen cross-contact.
  - *Under FSMA, HARPC Rule requires that ‘reasonably likely’ undeclared allergen hazards be identified and steps to proactively mitigate these hazards be documented.*


# So there's no rule about testing foods?

There is not.

- In theory you could produce items fully in compliance with allergen/gluten laws without running a single test.
- In reality:
  - A careful look for potential hazards will often expose few places where testing is advantageous
  - Many customers (ingredients buyers, grocery stores, etc.) will want to see CoA paperwork before purchase.
  - **Budgeting time and money for testing can save you time and money in the long run.**

# What type of testing do I do on-site?

- With the right lab set-up, team, budget, and timeframe, the sky is the limit!
- If not, lateral flow tests are your best bet.
  - Quick (12-20 minutes for AlerTox Sticks / GlutenTox Pro)
  - No equipment or lab background required
  - Shelf stable
  - Clear yes/no answer

 Not all lateral flow tests are suitable for all testing needs. A reputable vendor will be happy to talk with you about your specific matrices.

# What type of testing does a lab do?

Depending on the sample, either an **ELISA** or **PCR** test

**ELISA** (enzyme-linked immunosorbent assay) tests use antibodies raised to detect specific portions of allergenic protein

- Quantitative results (specific PPM count)
- Different labs will use different kits
- LFD kits also use antibodies


**PCR** tests look for DNA/RNA

- Qualitative results (usually)
- Helpful when the sample has low amounts of detectable protein (e.g. celery)
- The presence/absence of DNA does not always correlate with the presence/absence of allergenic material (e.g. egg whites, milk)




# How should I think about on-site and lab tests?

On-site rapid tests are your stoplights / early warning system


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- Incoming ingredients
  - Cleaning validation (surface/rinsewater)
  - Finished product

Lab tests are your toll booths / crossed t's and dotted i's


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- The lab techs are truly impartial
  - Quantitative analysis
  - Documentation
  - Challenging matrices

# On-site testing: Product Testing

## Confirm your ingredients are X-free

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- Test volume will vary based on your supplier's risk level
  - Do they also supply allergen-containing ingredients?
  - What is their ACP? What do their suppliers' ACPs look like?
  - “We know it is because it just is” = **RED FLAG!**

## Confirm your finished products are X-free

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- First-off product can act as an additional environmental validation
  - May be required by your third-party certification program
  - Guard against hot spots by using a tighter net

# On-site testing: Environmental Testing

- Check rinsewater
- Check surfaces
  - Don't just pick 'easy' surfaces like a stainless steel countertop!
- Higher initial test volumes while validating HARPC/ACP
- Ongoing, lower test volumes for verification / monitoring
  - Consider the risk level for your specific ingredient (peanut butter vs whole peanuts vs peanut flour)
- Positive results = reclean and retest

# How to decide whether to test on site:


- If I don't test for X, how will I be confident that my product is not contaminated with X?
- Has the product been tested for X? When? Why then? Why only then?
- Am I responsible for moving this product from one area to another, and does that transition come with contamination risk?
- Do I have a testing responsibility for my third-party certification program?
- Has this product – or others like it – been recalled before?

*Proactive Mitigation!*

# Outside Lab: Product Testing

- Confirm that your in-house team is performing tests correctly.
- Confirm your LFD is suited to your matrix.
- Positive result from your LFD? Lab can quantify.
- Customers/stockists may demand it before taking your product.
  - *Your suppliers may demand it before accepting returns!*
- Challenging matrices often require more detailed extraction.

# Outside Lab: Surface Testing

-  Infrequently indicated when it comes to allergens and gluten (except for scenarios where the allergen is undetectable by LFD)

# How to decide whether to send samples out:

- How complex is my matrix? Will my LFD kit do the job or is a more involved process required?
- What do my customers and auditors require of me?
- To what extent am I relying on my vendors' assurances?
- Has this product tested positive for allergen X on previous runs? If so, am I confident the problem is fixed? How am I proving it?
- What are my next steps if I see a positive on-site test?

# How do I pick a good in-house test?

- Clearly, I'm a little bit biased, but:

**GlutenTox**<sup>®</sup>

**AlerTox**<sup>®</sup>•Sticks

- Know your team and their capabilities – don't set them up to fail.
- Know your products. Some are easier than others.
- AOAC and similar certification schemes are important, but they are not the be-all end-all.



# How do I pick a good third-party lab?

- Helpful if their ISO17025 scope includes allergens/gluten.
- What is the turnaround time?
- What other tests can they run?
- How hard is it to get someone on the phone?
- Will they charge me extra for quantification above a certain threshold?



While Emport LLC does not perform lab analysis directly, we are pleased to offer third party testing for gluten and allergens through a partnership with an ISO17025-accredited lab.

# Thanks for listening! Questions?

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