

# Allergen Management in 2023

## The What, Why & How of On-site Allergen Testing



A ~~webinar~~ fun,  
informational chat, with:

**Empo**rt & **MenuTrinfo**<sup>®</sup>  
LLC

# Certified Free From™ Testing Standards

- Monthly testing required from CFF clients
- Lateral Flow Devices
- Chemical validation of all other allergen-free protocols
- Best practice



# Who am I ... and why am I talking?



- 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

## *Today we'll talk about:*

- *What are allergen/gluten definitions/regulations?*
- *What does allergen testing entail?*
- *Why include allergen testing in your safety plan?*
- *How to include allergen testing in your safety plan?*



# Gluten and Allergen Overview

## allergen noun

al·ler·gen 'a-lər-jən

: a substance (such as pollen) that induces [allergy](#)

**allergenic** 'a-lər-'je-nik adjective

**allergenicity** 'a-lər-jə-'ni-sə-tē noun

## gluten noun

glu·ten 'glü-tən

: a tenacious elastic protein substance especially of wheat flour that gives cohesiveness to dough

**glutenous** 'glü-tə-nəs 'glüt- adjective



## allergen statement



The [allergy warning on the back](#) on anything that really tastes good, but can kill you in minutes.

**Allergen Statement:** *This product contains foods, that many contain other foods, that are processed in a facility that processes foods, that may contain milk, milk products, peanuts, nuts, tree products, plant products, or animals products, which many cause an [allergic](#) reaction, to this food, or any other food, that contains food when eaten properly or improperly; call 911 if eaten for food or if not conscious lie still, [don't panic](#) and wait until help arrives.*

by [Quido1](#) December 29, 2010

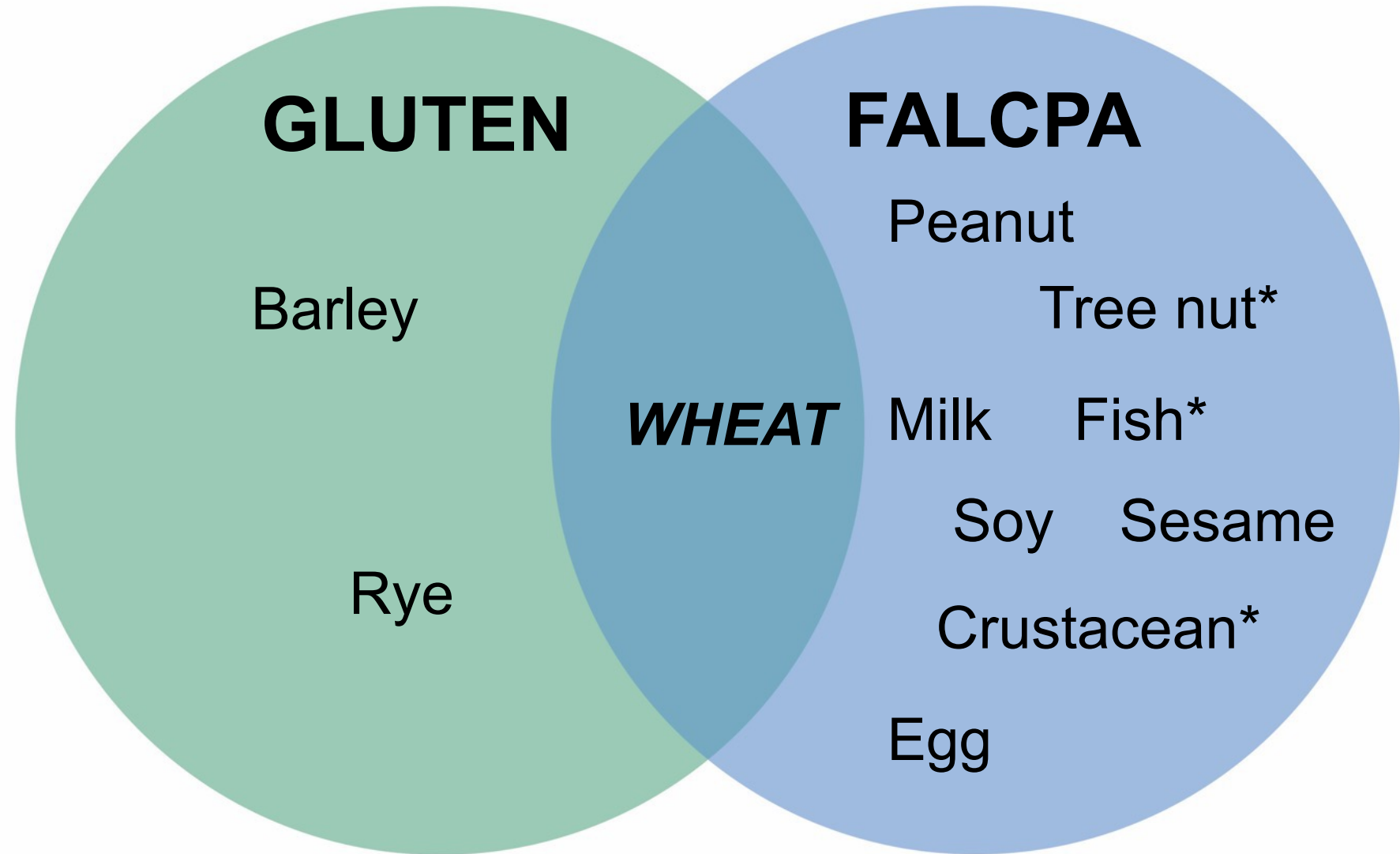
# What “allergen” means around the world

Food Allergens	Crustacean Shellfish	Egg	Fish	Milk	Peanut	Soy	Tree Nuts	Wheat	Cereals w/ Gluten	Sulfites	Buckwheat	Celery	Lupin	Molluscan Shellfish	Mustard	Sesame	Bee Pollen/ Propolis	Beef	Chicken	Latex (Natural Rubber)	Mango	Peach	Pork	Royal Jelly	Tomato
USA	x	x	x	x	x	x	x	x	x																
Canada	x	x	x	x	x	x	x	x	x					x	x	x									
EU <sup>1</sup>	x	x	x	x	x	x	x	x	x			x	x	x	x										
Australia/NZ	x	x	x	x	x	x	x	x	x														x		
Argentina	x	x	x	x	x	x	x	x	x																
Belarus	x	x	x	x	x	x	x	x	x			x	x	x	x										
Bolivia	x	x	x	x	x	x	x	x	x																
Brazil	x	x	x	x	x	x	x	x	x																
Caricom Std. <sup>4</sup>	x	x	x	x	x	x	x	x	x																
Central America <sup>5</sup>	x	x	x	x	x	x	x	x	x																
Chile	x	x	x	x	x	x	x	x	x																
China	x	x	x	x	x	x	x	x	x																
Colombia	x	x	x	x	x	x	x	x	x																
Cuba	x	x	x	x	x	x	x	x	x																
Egypt	x	x	x	x	x	x	x	x	x																
Fiji	x	x	x	x	x	x	x	x	x																
GSO <sup>3</sup>	x	x	x	x	x	x	x	x	x			x	x	x	x										
Hong Kong	x	x	x	x	x	x	x	x	x																
India	x	x	x	x	x	x	x	x	x																
Israel (Pending)																									
Japan <sup>2</sup>	x	x		x	x	x	x																		
Kazakhstan	x	x	x	x	x	x	x	x	x					x	x	x	x								
Malawi	x	x	x	x	x	x	x	x	x																
Malaysia	x	x	x	x	x	x	x	x	x																
Mexico	x	x	x	x	x	x	x	x	x																
Morocco	x	x	x	x	x	x	x	x	x																
Philippines	x	x	x	x	x	x	x	x	x																
Russia	x	x	x	x	x	x	x	x	x			x	x	x	x										
Singapore	x	x	x	x	x	x	x	x	x																
South Africa	x	x	x	x	x	x	x	x	x																
South Korea	x	x	x	x	x	x	x	x	x					x				x	x			x	x		x
Taiwan <sup>6</sup>	x	x	x	x	x	x	x	x	x																
Thailand	x	x	x	x	x	x	x	x	x																
Turkey	x	x	x	x	x	x	x	x	x					x	x	x	x								
Ukraine	x	x	x	x	x	x	x	x	x					x	x	x	x								
Venezuela	x	x	x	x	x	x	x	x	x																
Vietnam	x	x	x	x	x	x	x	x	x																

- Even the same word can mean different things in different places
  - Milk can be defined as from:
    - Cow;
    - Cow and goat;
    - Cow, goat and buffalo;
    - All farmed animals;
    - Milking animals;
    - All mammals
  - Egg and tree nut also vary
- Thanks to FARRP for this handy chart
- For a version you can actually see:
  - <https://farrp.unl.edu/IRChart>

# Is gluten an allergen?

- Gluten is not an allergen, but wheat is. Celiac disease is not an allergy.
- Food can be gluten-free, AND contain wheat.
- Food can be wheat-free, AND contain gluten.



# 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.

*Designed to regulate intentionally-included / known allergens*

# 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
- Fermentation/Hydrolyzation/Distillation guidance issued in 2020
  - Items must be **demonstrably** GF pre-fermentation/hydrolyzation
  - No exemptions for products/enzymes grown on gluten-containing media
  - cGMPs make distillation safe – protein tests can confirm
  - Records records records

*“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)*



# Food Safety Modernization Act (FSMA)

- Builds on FALCPA but focuses on undeclared/unintentional allergens
- Applies to FDA-regulated food packaged for human consumption
- HARPC plans introduce **Preventative Controls** to HACCP
  - “Hazards” includes allergens
  - Since you’ve identified the hazard, you must also identify the fix
- Greatly need for documentation: *If it isn’t documented, it isn’t done.*
- Umbrella plans: your suppliers’ plans are your problem too.

*Even though FSMA may not apply to your facility — the guidance is still best-practice for keeping food-allergic consumers safe.*

# What is allergen testing?



# What can allergen testing tell you?

- ✓ Are my ingredients safe?
- ✓ Is my process well-designed?
- ✓ Is my process being correctly implemented?
- ✓ Are my finished products safe?

# How and why to include testing in your plan?

## Validation (LFDs and/or lab tests)

- Are your ingredients safe?
- Is your cleaning program truly removing allergens?
- Does your Allergen Control Plan actually work?
- Pass 3x in a row, minimum

## Verification (LFDs and/or Protein Swabs)

- Did your team follow the plan today?

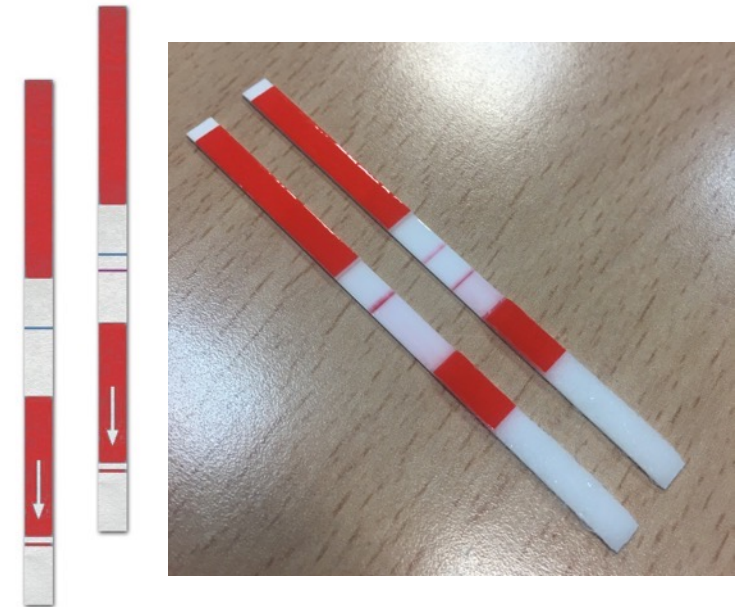
## Documentation

- Catch problems early
- Create a paper trail
- Satisfy third-party requirements



# What is 'testing for allergens'?

- Most allergen/gluten tests use antibodies to look for protein
  - ELISAs are the **quantitative** gold standard
    - Require time, gear and skill
    - Best to leave these to the labs
  - Lateral Flow Devices (LFDs) are more useful day-to-day
    - Quicker, cheaper and easier than ELISA testing
    - Clear yes/no answer (**qualitative**)
    - Often can test both foods and surfaces



**i** *Not all LFDs are suitable for all foods – there are many exemptions. Read the manual carefully and ask your vendor for guidance and/or validation data.*

# What even is 'testing for allergens'? Pt. 2

- General Protein Swabbing is a good supplement to specific-allergen tests
  - Can't differentiate between proteins (only measures cleanliness)
  - Cheaper and easier than LFDs
  - Less sensitive than LFDs
  - Surfaces only
- PCR testing checks for DNA, not protein
  - More suited to lab setting
  - Helpful when you're looking for a low-protein allergen like celery, but has limitations
    - Milk looks like a hamburger, egg looks like chicken



*ATP swabbing is a popular way to measure general cleanliness, but it's rarely appropriate for allergen monitoring.*

# On-site testing: Product Questions

- Ingredients: If I don't test for X, why am I confident the product is safe?
  - “We know it is because it just is” = **VENDOR RED FLAG!**
- 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?
- Do I have a testing responsibility for my third-party certification program?
- Has this product – or others like it – been recalled before?

*Swiss Cheese Defense! Risk-based Preventative Controls!*

# On-site testing: Environmental Best Practices

- Check rinsewater
- Check representative surfaces
  - Don't just pick 'easy' surfaces like a stainless steel countertop!
- Higher initial test volumes while validating plan
- Ongoing, lower test volumes for verification / monitoring
- Consider the risk level for your specific ingredient (peanut butter vs whole peanuts vs peanut flour)
- Know your next steps in the case of a positive result



# 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.

# Thanks for listening! Questions?

[emilyk@empportllc.com](mailto:emilyk@empportllc.com)

412-447-1888

[empportllc.com](http://empportllc.com)