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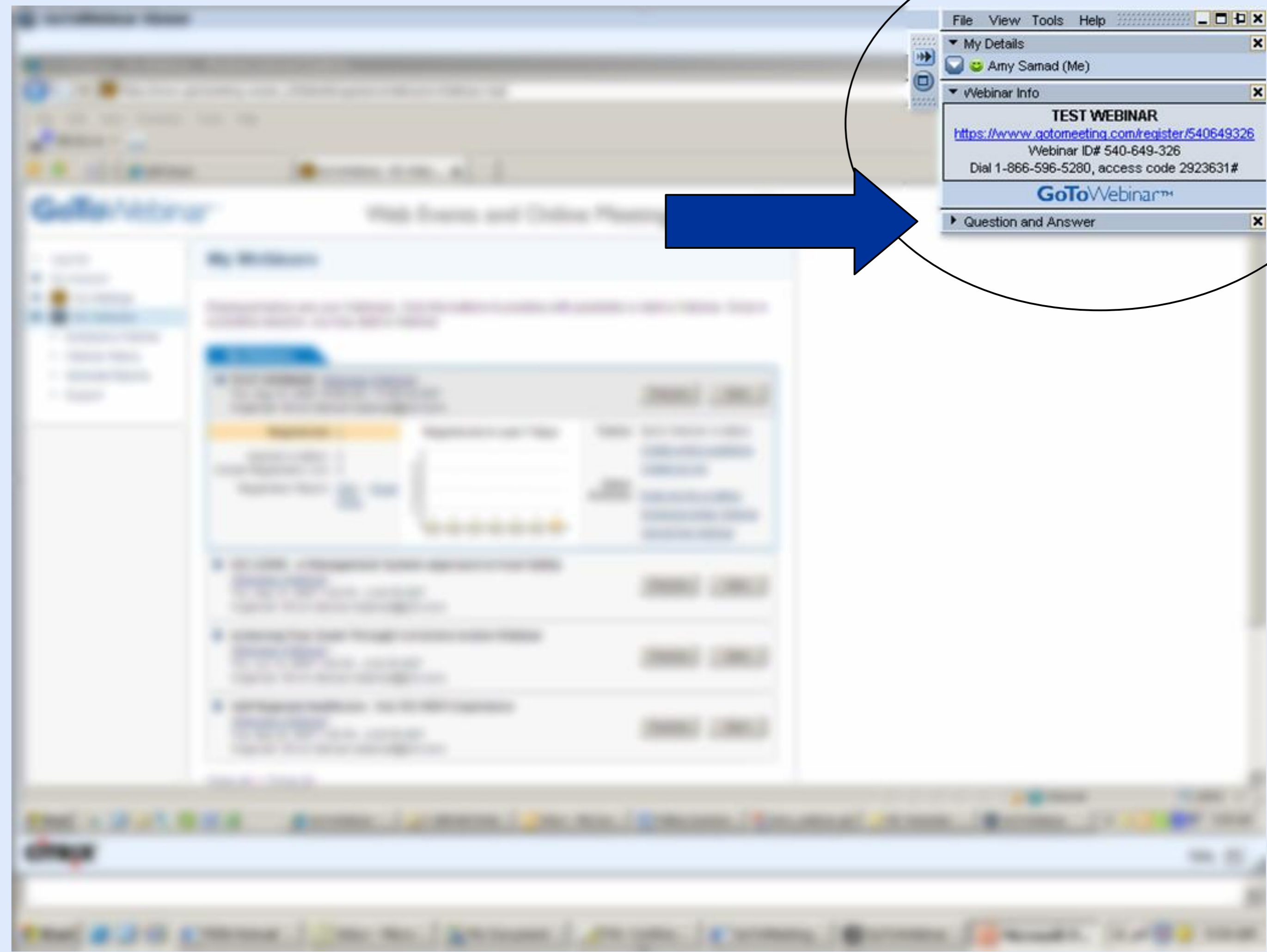


Emily Kaufman

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Allergen Management in 2021: Rules and Tools for Safe Foods



File View Tools Help

My Details

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Webinar Info

TEST WEBINAR

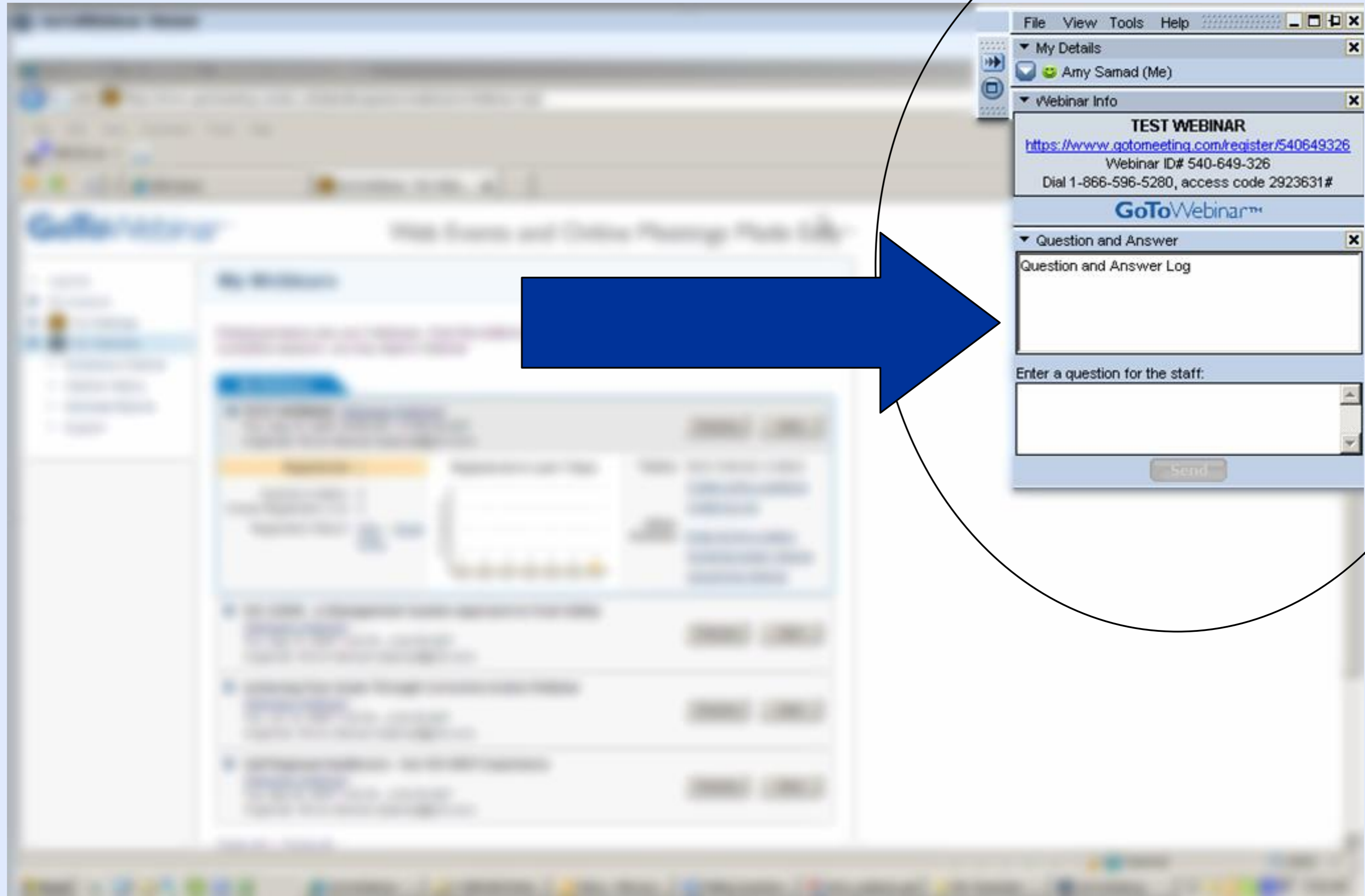
<https://www.gotomeeting.com/register/540649326>

Webinar ID# 540-649-326

Dial 1-866-596-5280, access code 2923631#

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Question and Answer





Paul Damaren

Senior Vice President of
Food Safety & Supply
Chain, PJRFSI



PJRFSI – Your Partner for Food Safety

Emily Kaufman, Founder,
President, Emport LLC.



Are You Prepared?



**Allergen Management
in 2021:
Rules and Tools
for Safe Foods**

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Emport LLC: More Safe Food, More
Happy People
emilyk@emporllc.com

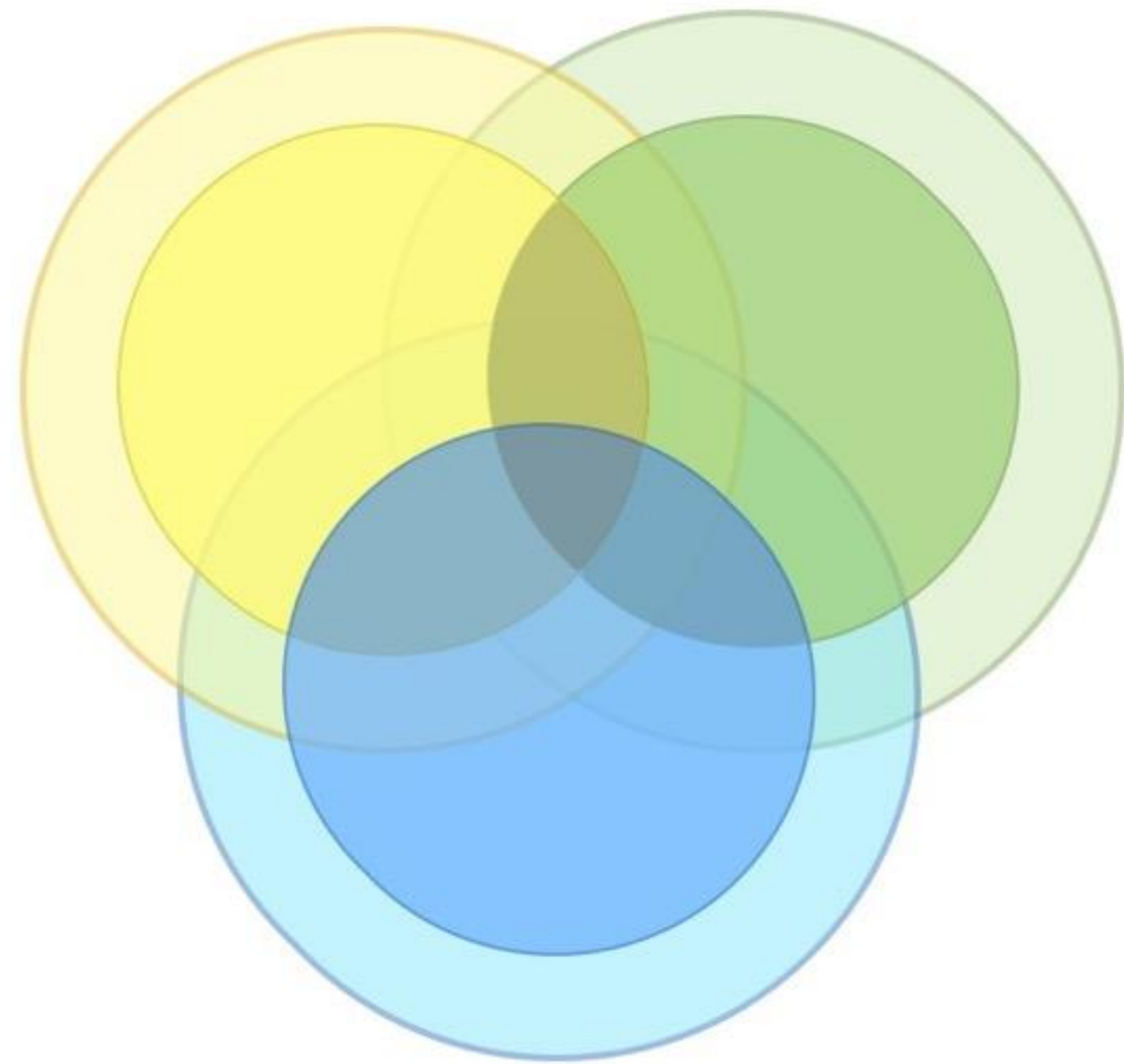
Today's Topics

- How do allergen rules differ between Canada and the USA?
- Alphabet Soup: What testing tools are available?
 - What are their strengths and ideal uses?
- Questions to consider when you're making a test plan
- What's all this about validation vs. verification?
- Proficiency Testing: Do I have to? How?

Allergen Labeling Laws

- **Required** labeling for all packaged foods
- No stated permissible ppm/ppb thresholds
- “May Contain” statements are not for CYA use
- “Free From X” statements are unregulated/voluntary
- “Allergen” refers to many foods: use your terms carefully
- Accidental cross-contact was not explicitly addressed, however: processors should implement cGMP controls that prevent allergen cross-contact.

Allergen Rules in Canada and the USA



- **Shared:** Sesame*, Egg, Fish, Milk, Peanut, Shellfish (Crustacean), Soy, Wheat
- **Only in Canada:** Mustard, Shellfish (Mollusc)
- Tree Nuts are **Complicated:**
 - In Canada, tree nuts covers 9 specific nuts (almond, Brazil nut, cashew, hazelnut, macadamia nut, pecan, pine nut, pistachio, and walnut)
 - In the US there are many more, most notably **coconut** and **chestnut**
- Gluten and Sulfites are **Complicated**

Allergens, Gluten, and Sulfites

- **Sulfites** must be labeled if ≥ 10 ppm.
 - A “priority allergen” in Canada
 - Not a “major allergen” in the US (but can still trigger a recall)
- **Gluten**
 - Mandatory in Canada (a priority allergen)
 - Voluntary in the US (not FALCPA)
 - Oats are treated differently
 - Gluten is not (always) from wheat, wheat does not (always) contain gluten



Food Safety Modernization Act (FSMA) / Safe Food for Canadians Regulations (SFCR)

- Logical evolution – covers unintentional allergen cross-contact
- Hazards require **Preventative Controls** (HARPC > HACCP)
 - Broader understanding of hazards now includes allergens
 - Since you've identified the hazard, you must also identify the fix
- Greatly expanded need for documentation
 - If it isn't documented, it isn't done
- Umbrella plans: your suppliers' plans are your problem too.

Now, 'reasonably likely' undeclared allergen hazards must be identified. Steps to proactively mitigate these hazards be documented.

US Gluten Labeling Laws (2014/2020)

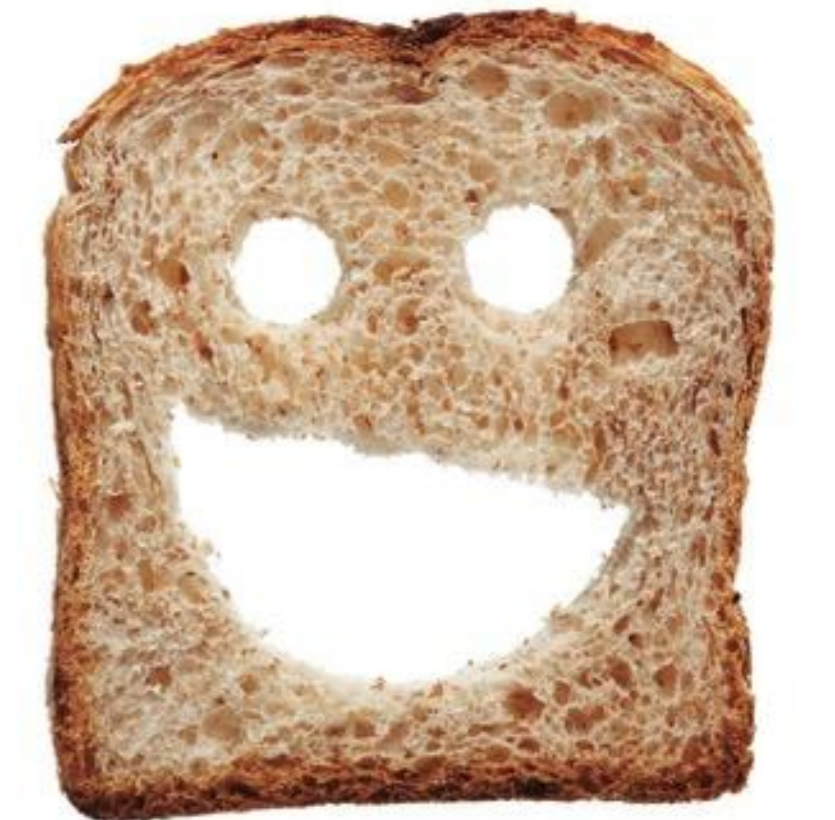
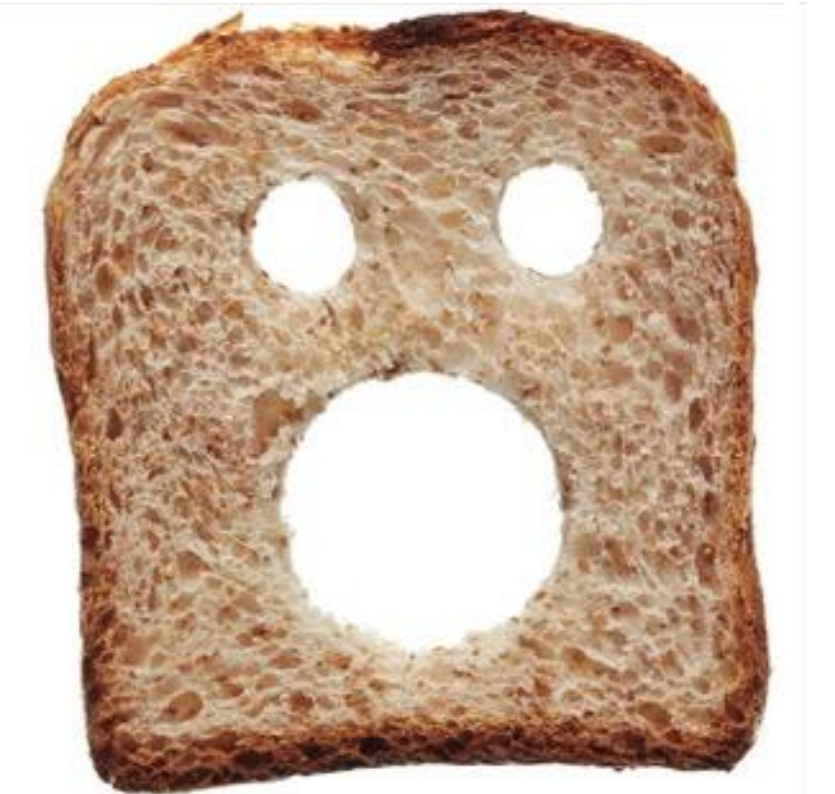
- Entirely voluntary – only applies if product labeled “gluten-free”
- Product must have < 20ppm gluten
- Any detectable gluten present must be from unavoidable cross-contact (despite following cGMP) – not from intentional inclusion
- Fermentation/Hydrolyzation/Distillation guidance
 - Items must be **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

So there's no rule about testing foods?

There is not.

- In theory you could produce compliant items without running a single allergen / gluten test.
- In reality:
 - If you look for hazards, you will find them
 - Many customers like to see CoA paperwork
 - **Budgeting time and money for testing can save you time and money in the long run**

“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)



The alphabet soup of allergen testing

Most allergen/gluten tests use antibodies to look for protein

- ELISAs are the quantitative gold standard
 - But require time, gear, volume, and skill
 - Best to leave these to the labs
- Lateral Flow Devices (LFDs) are ideal for day-to-day
 - Quicker, cheaper and easier than ELISA testing
 - Clear yes/no answer
 - Often can test both foods and surfaces



i *Not all kits are suitable for all foods – you need to validate. Your test kit vendor should be VERY happy to look at your unique situation and provide guidance.*

The alphabet soup of allergen testing con't.

- General Protein Swabbing is a good supplement
 - Cheaper, easier, less sensitive than LFDs
 - Not specific (lots of foods have protein)
 - Surfaces only
- PCR testing checks for DNA, not protein
 - More suited to lab setting
 - Can be really helpful, or useless
 - Milk looks like a hamburger, egg looks like chicken
 - Can help identify food at the species level (eg wheat vs barley)



i *ATP swabbing is a popular way to measure general cleanliness, but not all certification bodies accept it as a gluten/allergen management tool*

On-site testing: why?

Confirm your ingredients are free of X

- Test volume will vary based on your supplier's risk level
- “We know it is because it just is” = **RED FLAG!**



Confirm your environment is free of X

- Both surfaces and rinsewater are worth testing
- Positive result? Reclean, retest, reevaluate



Confirm your finished products are free of X

- First-off product = additional environmental validation
- May be required by your third-party certification program



Questions to ask before testing:

- If I don't test for it, why am I so confident that it's not there?
- Has the product been tested already?
 - 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 need to for my third-party certification program?
- Has this product – or others like it – been recalled before?

Proactive Mitigation!

How do I pick a good in-house test?

- Know your team – don't set them up to fail.
- Know your products. Some are easier for testing than others.
- AOAC and similar certification schemes are important, but....
- Whatever tests you decide to buy, get them from someone who can help you use them.
- *I'm a little biased, but:*

GlutenTox® AlerTox® Sticks

Validation vs. Verification

- Program Validation

- How do I know my program works?
- How do I know my tools work?
- Prove your kit can detect your allergens
- Prove your cleaning removes your allergens



- Verification (day to day)

- Now that you know you have the right tools and the right plan: did your team implement the plan correctly today?
- Records, records, records

Validation: Keep in mind

- Validation doesn't have to be expensive (but it can be)
- Ask your suppliers for ideas
- Whatever you decide to do: **document it!**
- Repeat your validation
 - Yearly, or more often if:
 - Ingredients* change, or
 - Processes change, or
 - Personnel change (maybe)

**Could be ingredients in your products, processing aids, or cleaning materials!*

And proficiency testing?

- You may be required to run PT for in-house tests
- Even if not – there may be a benefit
- Much like validation: PT helps confirm that your team is using equipment correctly
- There are a number of accredited PT studies for a variety of allergen matrices
- You can design a PT study on your own (but there are limits)



Upcoming Webinars



The Growth, Challenges, Certification and Sustainability of CBD in 2021 & Beyond

October 5, 2021 – 2:00 pm EST

Speakers: Allyn Shultis, Executive Director from the Global Retailer, Manufacturers Association (GRMA), CEO & President, Neshat Soofi of JIT Experts Hive, Brett McMillen, Cannabis & Hemp Division Manager, PJR, Jennifer Knaack, Sr. Director of Compliance and Science, KOI CBD



The Importance of ESG in the Food Industry

October 12, 2021 – 2:00 pm EST

Speaker: Fiona Humphries PIEMA, Technical Manager, Ethical Trade & Responsible Sourcing, BRCGS



2022 – A In-Depth Look at Emerging Challenges & Risk Factors in the Food Industry

October 21, 2021 – 2:00 pm EST

Speaker: Jennifer Crandall, CEO of Safe Food En Route, Jill Stuber, The Food Safety Coach and President, Evan Rosen of Excelsior Food Safety Solutions LLC





Audience Q&A

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