Crisis Management & Risk Assessment

Joe Baumert
Professor, Director
Food Allergy Research & Resource Program
University of Nebraska-Lincoln

Scott Hegenbart
Manager, Scientific Affairs
Conagra Brands
Omaha, NE

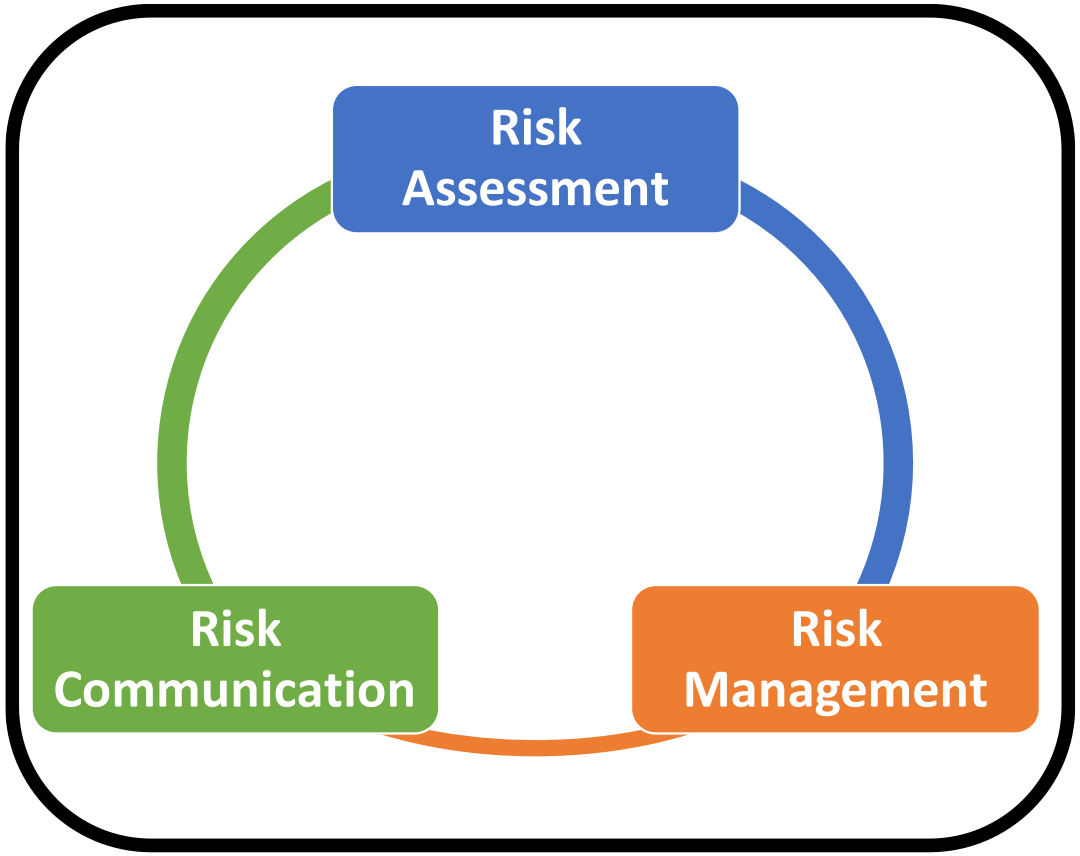
FARRP Effective Food Allergen Management Workshop
Chicago IL
October 16, 2025

You have a potential undeclared allergen situation: What do you do??

FOOD SCIENCE & TECHNOLOGY

Risk Analysis In Food

- Risk analysis is made up of three equally important parts:
  - Risk Assessment
  - Risk Management
  - Risk Communication
- No single piece stands alone and all three are part of an interactive process



Risk Assessment of Unintended Food Allergens

- Risk assessments should be evidence-based
  - Scientific data for the hazard characterization
  - Qualitative and quantitative data collected across the supply chain and manufacturing process

- The outcome of a risk assessment can be used for risk management and risk communication decisions
  - Risk mitigation strategies (e.g. minimizing cross-contact)
  - Risk-based decisions on use of advisory/precautionary allergen labelling (PAL)
  - Recall decisions (crisis management)

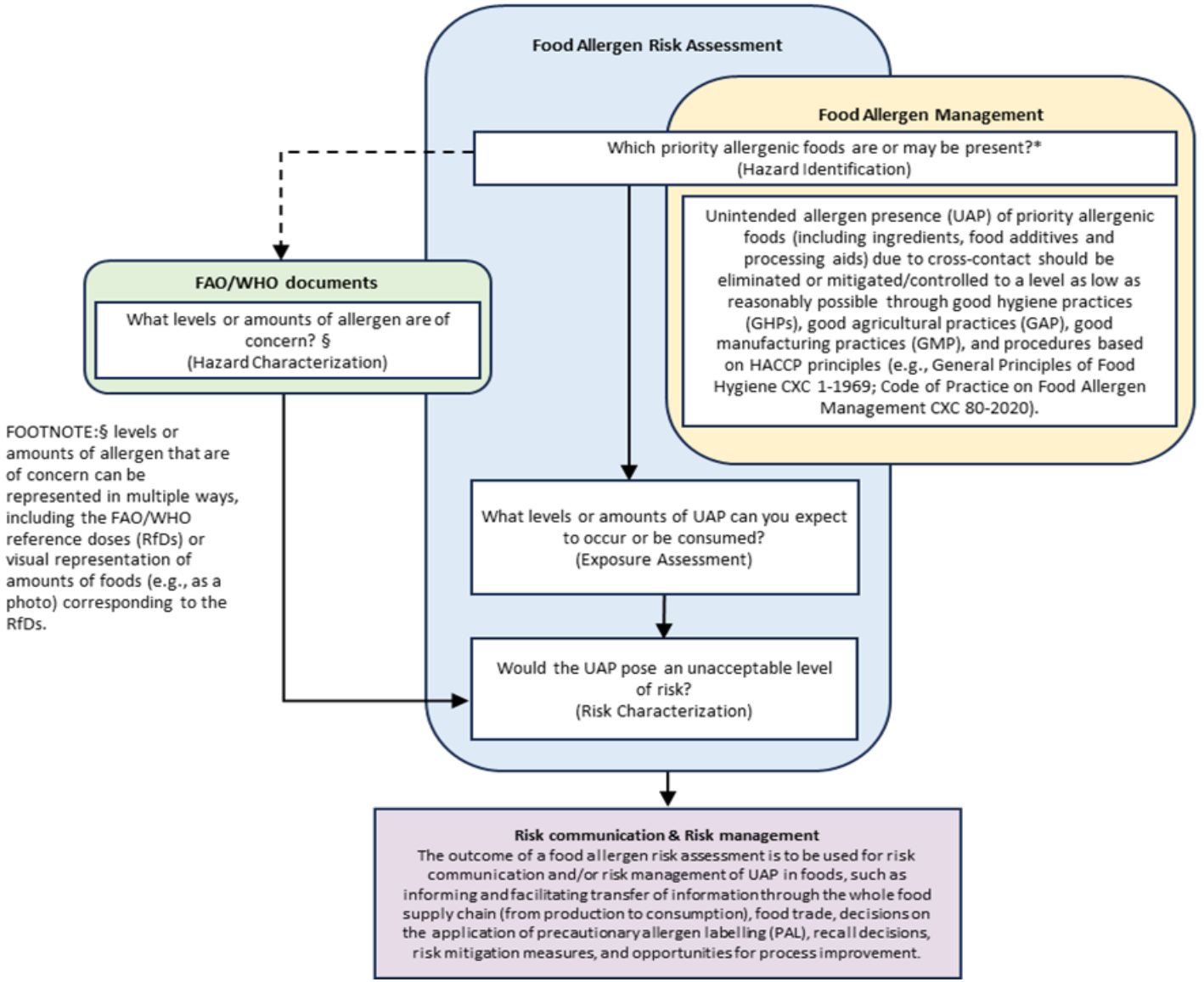
Where to Start With the Risk Assessment? Consider What Controls Are in Place

1. Identify Hazards
2. Identify established control points or preventive controls
3. Review procedures and standards that are in place
4. Were the control points or preventive controls monitored?
5. Were corrective actions or corrections made?
6. Were records in place?
7. Were the HACCP/Food Safety Plan and allergen control program steps verified?

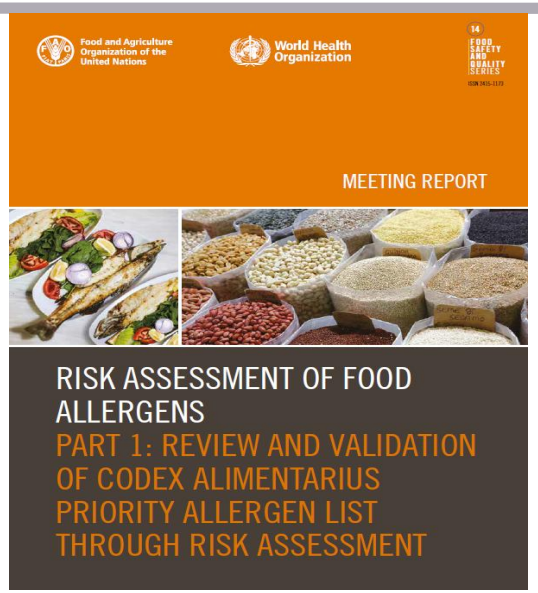
FAO/WHO Expert Consultation Guidance for Risk Assessment (June 2025)

[Summary Report]

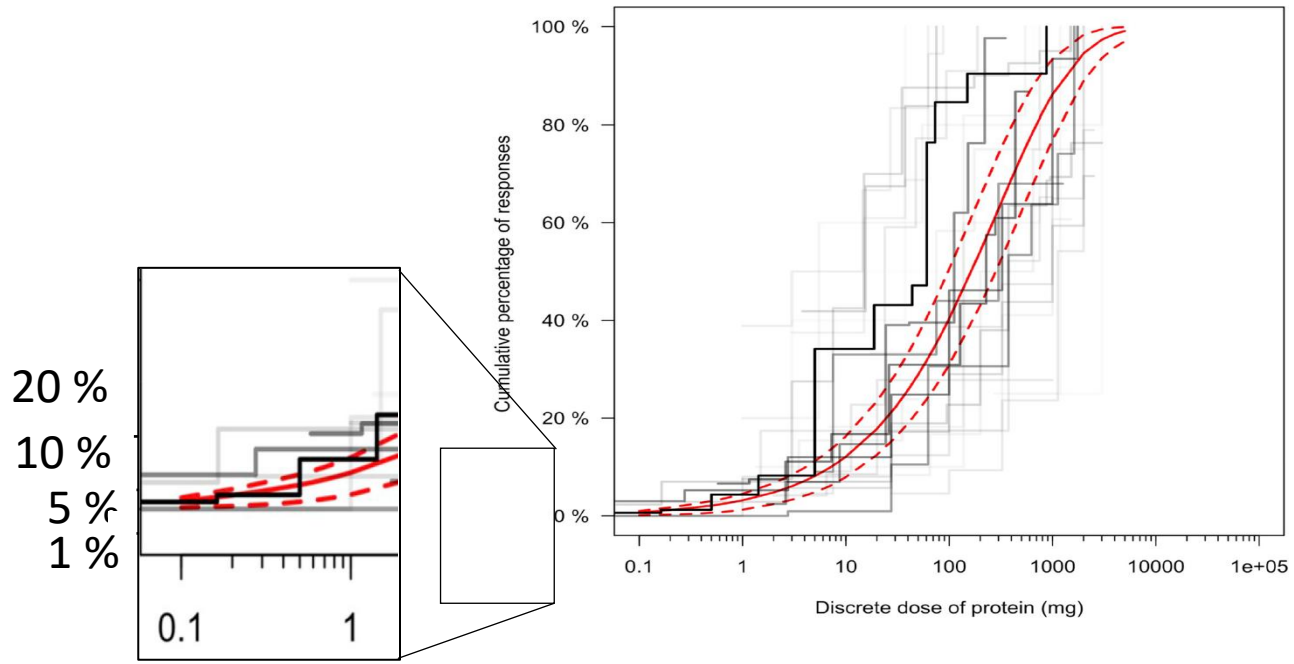
Figure 1. Summary representation of the food allergen risk assessment framework developed to enable risk communication and informed risk management decision-making.



Hazard Characterization



- Prevalence
- Potency
- Severity



FOOD SCIENCE & TECHNOLOGY

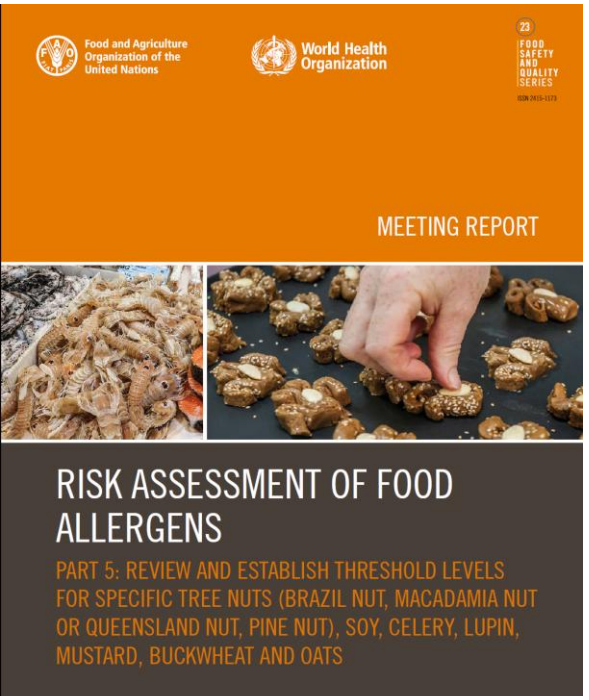
Primary Risk Assessment Input Parameters:

RfDs based upon clinical threshold data from low-dose food challenges

- Note: data from food-allergic individuals rather than extrapolation from animal models as in classical toxicological approaches

Exposure Dose Assessment Data

- Food Consumption (amount consumed per eating occasion; perhaps frequency of consumption)
- Concentration of total protein from the allergenic source of concern in the food in question (perhaps frequency of allergen residue is present); ppm or mg/kg



Global Priority Food Allergens	RFD Recommendation (mg total protein from the allergenic source)
Walnut, Pecan, Cashew, Pistachio, Almond	1.0
Egg, Milk, Peanut, Sesame	2.0
Hazelnut	3.0
Fish, Wheat	5.0
Crustacea	200
FAO/WHO Potential Regional or National Priority allergens	**RFD Recommendation (mg total protein from the allergenic source)**
Celery/Celeriac	1.0
Soy	10.0
Oats	Oat-specific RfD not appropriate
FAO/WHO Potential Regional or National Priority allergens	**Value of risk management (mg total protein from the allergenic source)**
Brazil nuts*, Macadamia or Queensland nuts*, Pine nuts*	1.0
Mustard*	1.0
Lupin*, Buckwheat*	10.0

RfDs are mg total protein NOT a concentration (ppm)

Food and Agriculture Organization of the United Nations
World Health Organization

FOOD SCIENCE & TECHNOLOGY

Translating Reference Doses into Action Levels (ppm)

$$\underset{\text{(in mg total protein from the allergenic food/kg food)}}{\text{AL}} = \frac{\underset{\text{(in mg total protein from the allergenic food)}}{\text{RfD}}}{\underset{\text{(in kg)}}{\text{Amount of food consumed}}}$$

Part 2 Report: https://www.fao.org/documents/card/en/c/cc2946en

Fundamental Allergen Risk Assessment for the Allergic Population

- A function of the exposure dose (mg of protein from the allergenic source) compared to the reference dose (mg of protein from the allergenic source)

Exposure Dose < Reference Dose* = no predicted risk of an allergic reaction in a defined proportion of the allergic population

Exposure Dose ≥ Reference Dose* = a predicted risk of an allergic reaction in a defined proportion of the allergic population

Which Consumption Quantity Should Be Used for an Exposure Assessment?

- Nutritional serving size?
- Average/Mean serving size?
- 90th, 95th, 97.5th percentile consumption estimates?
  - (p90, p95, p97.5)

Sliced Bread Example

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3]

Product category	Reference amount	Label statement [4]
Breads (excluding sweet quick type), rolls	50 g	__ piece(s) (__ g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/__ inch slice) for unsliced bread

eCFR :: 21 CFR 101.12 -- Reference amounts customarily consumed per eating occasion.

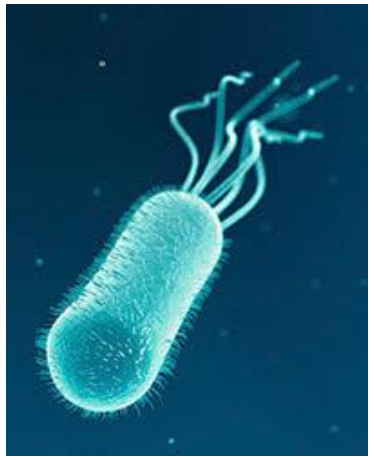
Bread Consumption Estimates Using the 2003-2010 NHANES Dietary Surveys.

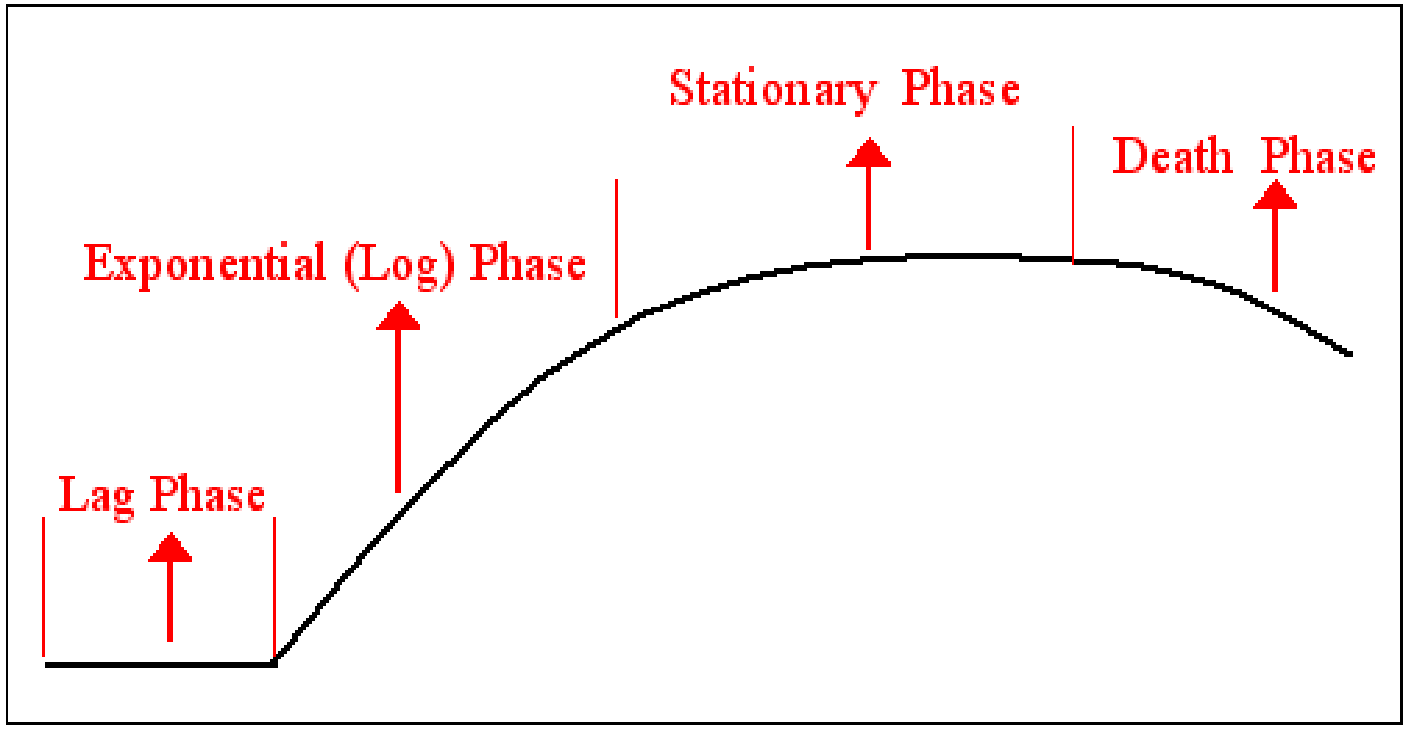
			Consumption Estimates (g per eating occasion)		
Prepared Food Product Category*	# of Individuals Who Reported Consuming the Product	Estimated % of U.S. Population that Consume the Product	Average	75th Percentile	90th Percentile
Bread	18,852	57%	44	52	60

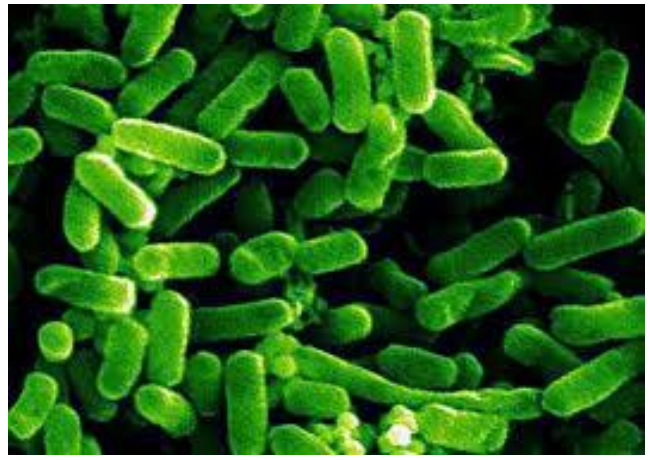
Risk Assessment Examples

Allergens ≠ Microbes

- Allergenic proteins do not “Grow”







Reference Doses in Day-to-Day Management

- Sound allergen management is the best way to help and protect food allergic consumers
- Risk assessment offers a tool to help create a common language for determining and communicating risk
- Threshold-based reference doses will not reduce allergen management efforts, but will adjust the focus
- Using risk assessment to optimize allergen management practices
  - Affirms effectiveness of changeover and sanitation
  - Supports appropriate labeling
  - Helps identify those certain situations where testing may be valuable
  - Helps assess risk when something new or unexpected happens

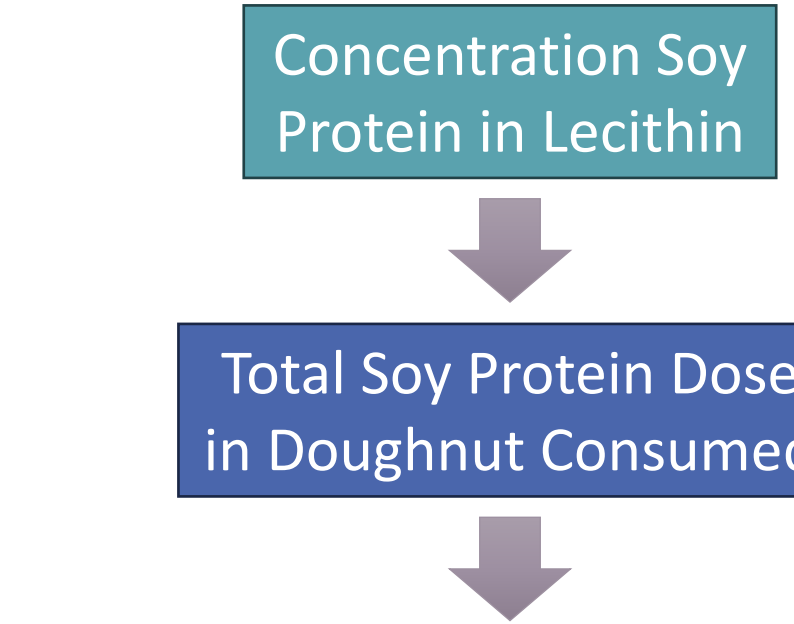
New Product! White Chocolate Sprinkle Doughnut

- Typical coatings supplier uses sunflower lecithin
- Preferred white chocolate glaze supplier uses soy lecithin:
  - 0.1% soy lecithin in white chocolate glaze
  - White chocolate glaze: 2% of final doughnut formulation (weight)
- Will this new ingredient result in cross-contact risks that require allergen controls?

Soy Concentrations → Reference Doses

- Doughnut Weight: 70 g
- Final Doughnut: 2% white chocolate glaze (weight)
- White chocolate glaze: 0.1% soy lecithin
- Lecithin: maximum 3,000 ppm total soy protein

Worst case based upon allowed level of hexane-insoluble solids



VITAL 3.0 Reference Dose, ED_{01} (mg total soy protein)	FAO/WHO Reference Dose, ED_{05} (mg total soy protein)
0.5	10

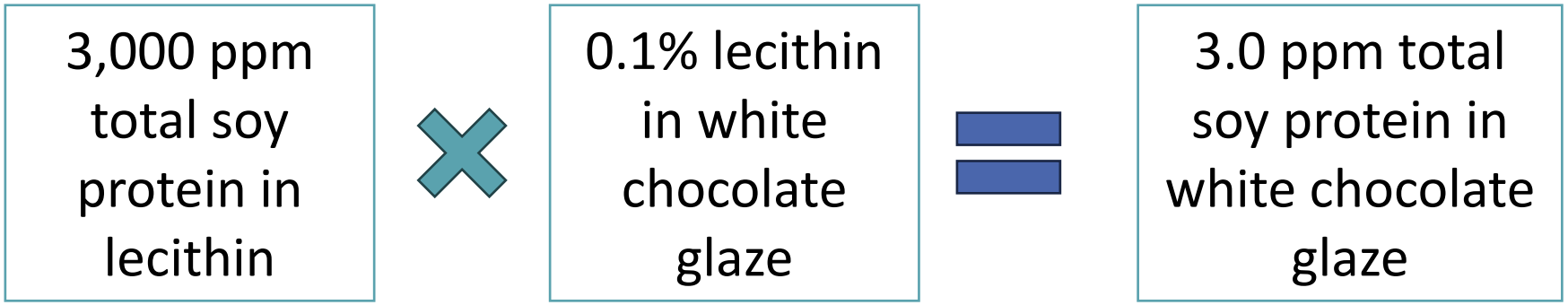
Soy Concentrations → Reference Doses

3,000 ppm total soy protein in lecithin

0.1% lecithin in white chocolate glaze

What concentration of total soy protein is present in the white chocolate glaze?

Soy Concentrations → Reference Doses

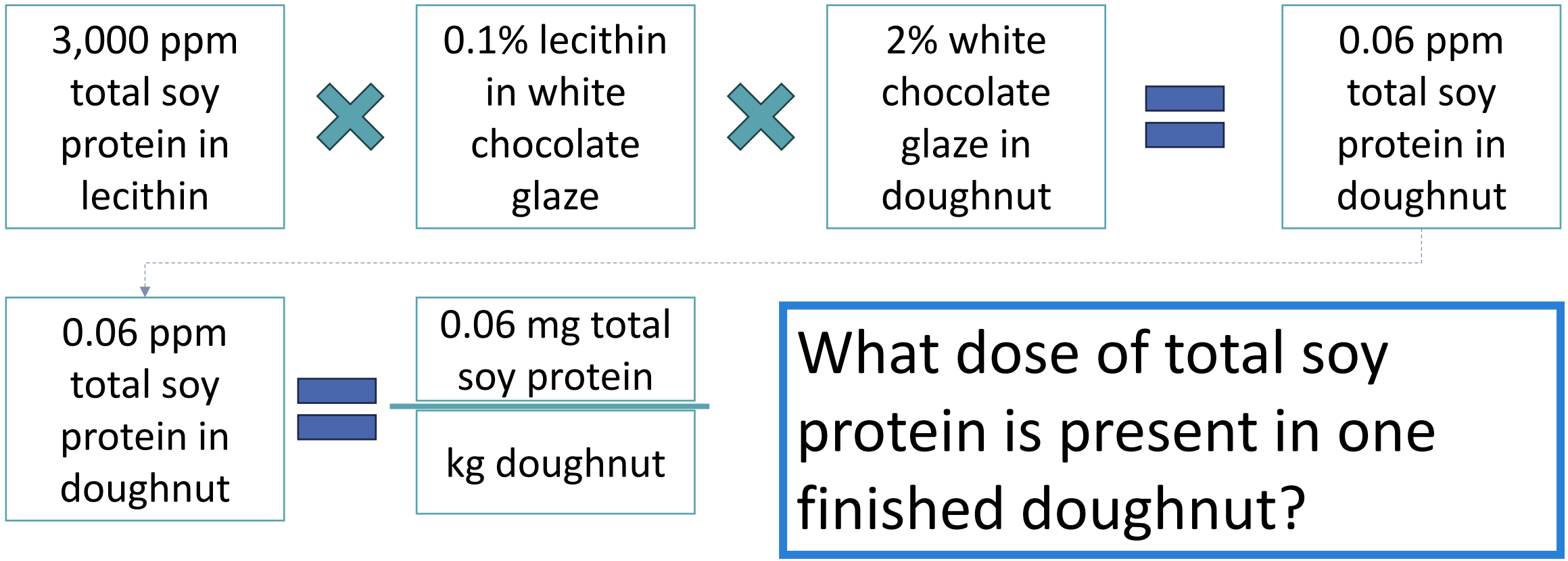


Soy Concentrations → Reference Doses

3,000 ppm total soy protein in lecithin	0.1% lecithin in white chocolate glaze	2% white chocolate glaze in doughnut

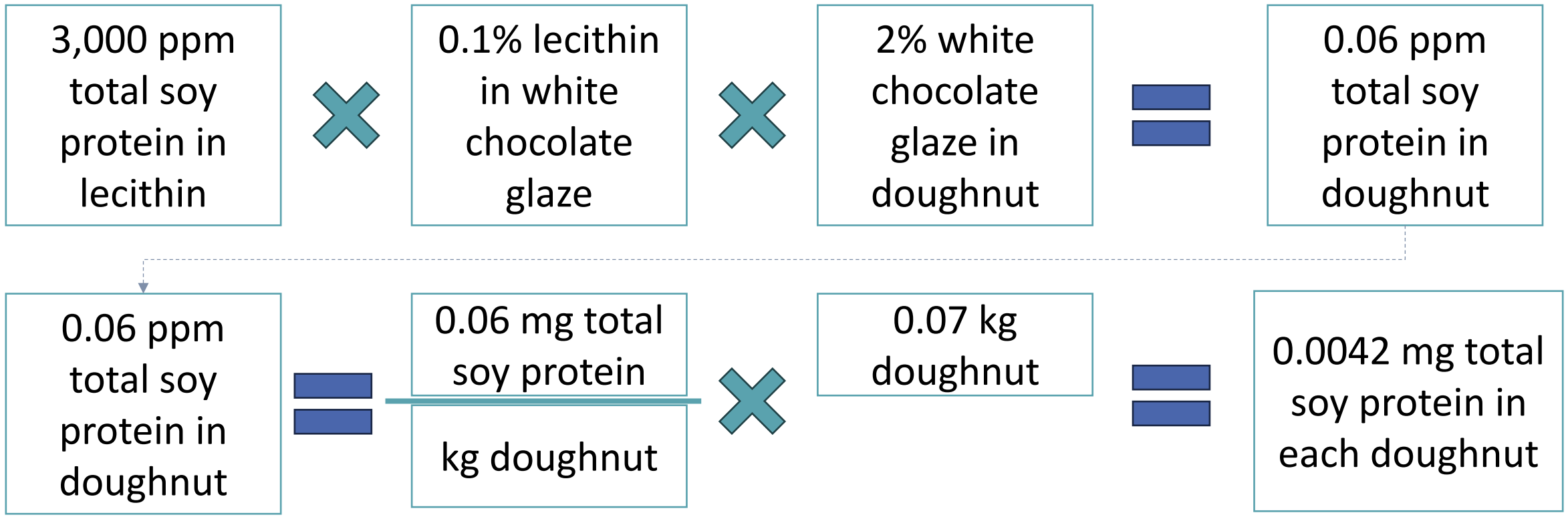
What concentration of total soy protein is present in the finished doughnut?

Soy Concentrations → Reference Doses



What dose of total soy protein is present in one finished doughnut?

Soy Concentrations → Reference Doses



Soy Concentrations → Reference Doses

Concentration Soy Protein in Lecithin	Total Soy Protein Dose in Doughnut Consumed
3,000 ppm total soy protein in lecithin	0.0042 mg total soy protein in each doughnut

VITAL 3.0 Reference Dose, ED_{01} (mg total soy protein)	FAO/WHO Reference Dose, ED_{05} (mg total soy protein)
0.5	10

Would the introduction of this new allergen source require extensive allergen cleaning for shared equipment?

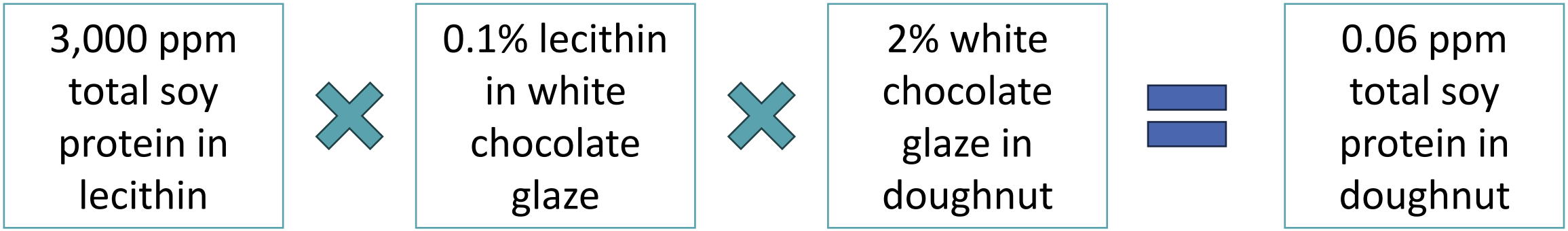
Soy Concentrations → Reference Doses

Concentration Soy Protein in Lecithin	Total Soy Protein Dose in Doughnut Consumed
3,000 ppm total soy protein in lecithin	0.0042 mg total soy protein in each doughnut

VITAL 3.0 Reference Dose, ED_{01} (mg total soy protein)	FAO/WHO Reference Dose, ED_{05} (mg total soy protein)
0.5	10

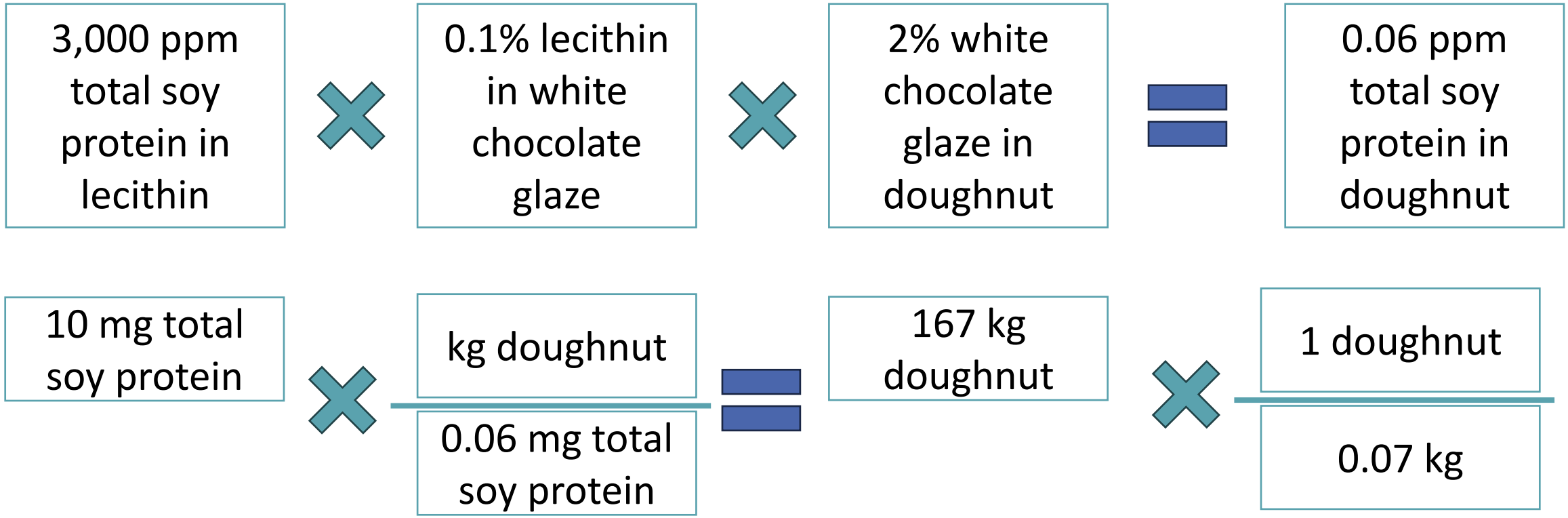
Does the label of this product need to indicate that it contains soy?

Soy Concentrations → Reference Doses



Bonus: How many doughnuts would need to be consumed to reach the ED05 (10 mg total soy protein)?

Soy Concentrations → Reference Doses



Changing the Question

- Historically, industry asks: “How clean is clean enough?”
  - The answer is often the unattainable “zero!”
- Change that question to: “How much soil is too dirty?”
  - In many situations, unacceptable residue is obvious
  - Reserve verification with testing for situations that may need it

A Tale of Two Sauces

A company makes two sauces. Sauce A contains milk in the form of sweet whey. Sauce B contains no milk. The company wants to assess cleaning effectiveness. They know:

- Sweet Whey contains 2.50% milk protein
- They use 5.80% sweet whey in sauce A

2.50% Milk Protein in Sweet Whey	×	5.80% Sweet Whey in Sauce A	=	? How much milk protein is in sauce A?

Determining Protein Content

A company makes two sauces. Sauce A contains milk in the form of sweet whey. Sauce B contains no milk. The company wants to assess cleaning effectiveness. They know:

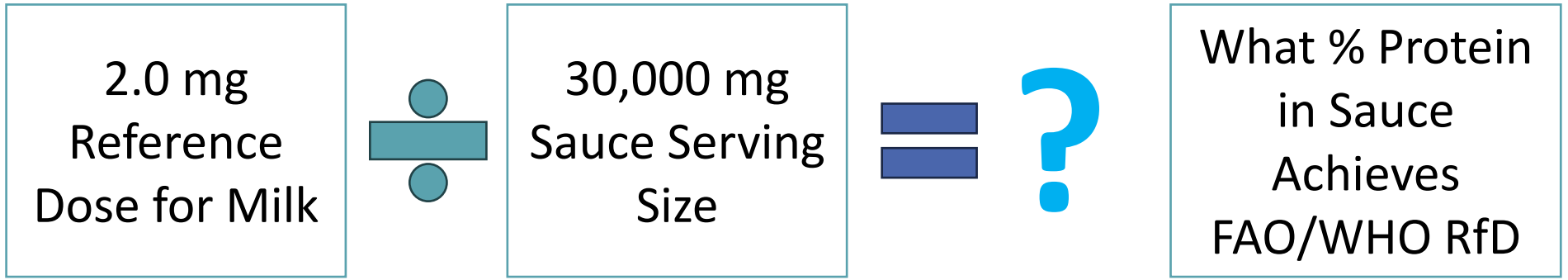
- Sweet Whey contains 2.50% milk protein
- They use 5.80% sweet whey in sauce A

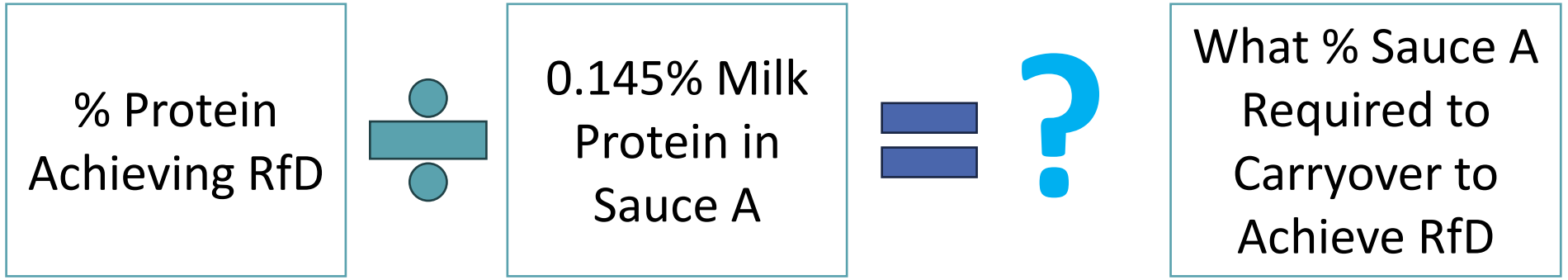
2.50% Milk Protein in Sweet Whey	×	5.80% Sweet Whey in Sauce A	=	0.145% Milk Protein in Sauce A

Determining Risky Carryover

Now that we know how much milk protein is in the sauce, we need some additional information to continue assessing the risk:

- The sauce serving size is 30 g (30,000 mg)
- The FAO/WHO Reference Dose for milk is 2.0 mg





Determining Risky Carryover

Now that we know how much milk protein is in the sauce, we need some additional information to continue assessing the risk:

- The sauce serving size is 30g
- The FAO/WHO Reference Dose for milk is 2.0mg

2.0 mg Reference Dose for Milk	÷	30,000 mg Sauce Serving Size	=	0.00667% Protein in Sauce Achieving FAO/WHO RfD
0.00667% Protein Achieving RfD	÷	0.145% Milk Protein in Sauce A	=	4.5977% Sauce A Required to Carryover to Achieve RfD

Assessing Batch Carryover

Now that we know how much sauce A represents a risk. We translate it into quantities to assess the risk:

- The sauce batch size is 5,500 lb

4.5977% Sauce A in Sauce B Achieves RfD

×

5,500 lb Sauce Batch Size

=

?

How Much Sauce A Carryover Achieves RfD in Sauce B?

Assessing Batch Carryover

Now that we know how much sauce A represents a risk. We translate it into quantities to assess the risk:

- The sauce batch size is 5,500 lb

- Visual inspection sufficient to verify sanitation
- Put ingredient controls in place for the sweet whey
- Have sound label verification

4.5977% Sauce A in Sauce B Achieves RfD	×	5,500 lb Sauce Batch Size	=	252.87 lb Sauce A Carryover Achieves RfD in Sauce B

But the News Isn’t Always Good

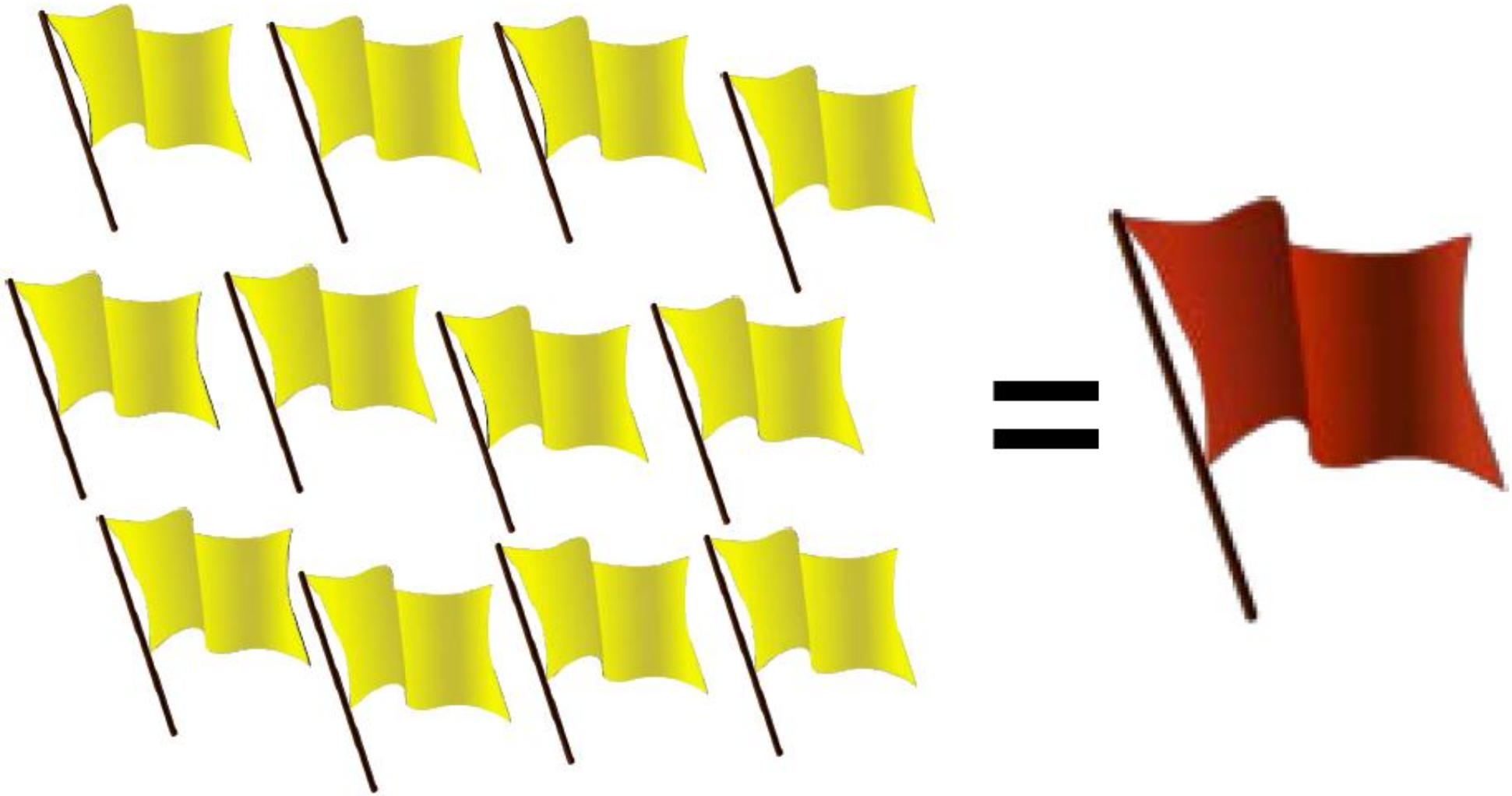
- Risk assessment is a very useful tool
- Some situations it only affirms the extent of the hazard

If Assessing an Undeclared Allergen in the Marketplace: Crisis Management

- Define the Scope
  - Is the product in your control? In the market? How many units?
- Which regulatory agency has oversight for the facility/product?
- What concentration of undeclared allergen is present in the product? (by calculation – verified analytically?)
- Does the level pose a reasonable probability of a health hazard to an allergic consumer?
  - The FDA would need to be notified of a potential food safety hazard through the Reportable Food Registry (RFR) in the case that **an article of food conveys a reasonable probability that use of, or exposure to, such article of food will cause serious adverse health consequences or death in humans or animals**

(Sections 201(f) and 417(a)(2) of the FD&C Act; See also FDA Guidance for Industry).

Many Yellow Flags = Red Flag



Additional Input Parameters

- Prevalence of the Food Allergy
- Market Share for Specific Product in Category
- Number of Packages of Food Manufactured
- Propensity to Buy Advisory Labeled Products

Assessing the Level of Risk

- Based on consumer complaints a company learned that its vegetarian Juicy Burger patties had been packed into its Savory Burger patty packages
- The Juicy Burger patties contain milk protein in the form of a cheese blend not contained in the Savory Burger
- Investigation showed non-milk packaging was left on machinery when milk-containing product began production

Putting the Numbers Together

The company immediately determined the situation most likely required public action but wanted to assess the degree of risk. They gathered the following information:

- The cheese blend in product has 15.5% protein
- The cheese blend is used at 2.5% of the product formula
- The product serving size is 112 g (112,000 mg)
- The FAO/WHO Reference Dose (RfD) for milk is 2.0 mg

15.50% Milk Protein in Cheese Blend × 2.50% Cheese Blend in Formula × 112,000 mg Burger Serving Size = ? What is the mg Milk Protein Per Serving?

2.0 mg Reference Dose for Milk ÷ 0.3875% Milk Protein in Formula = ? How Much Product Achieves FAO/WHO RfD

Determining the Risk

The company immediately determined the situation most likely required public action but wanted to assess the degree of risk. They gathered the following information:

- The cheese blend in product has 15.5% protein
- The cheese blend is used at 2.5% of the product formula
- The product serving size is 112 g (112,000 mg)
- The FAO/WHO Reference Dose (RfD) for milk is 2.0 mg

15.50% Milk Protein in Cheese Blend × 2.50% Cheese Blend in Formula × 112,000 mg Burger Serving Size = 434.0 mg Milk Protein Per Serving

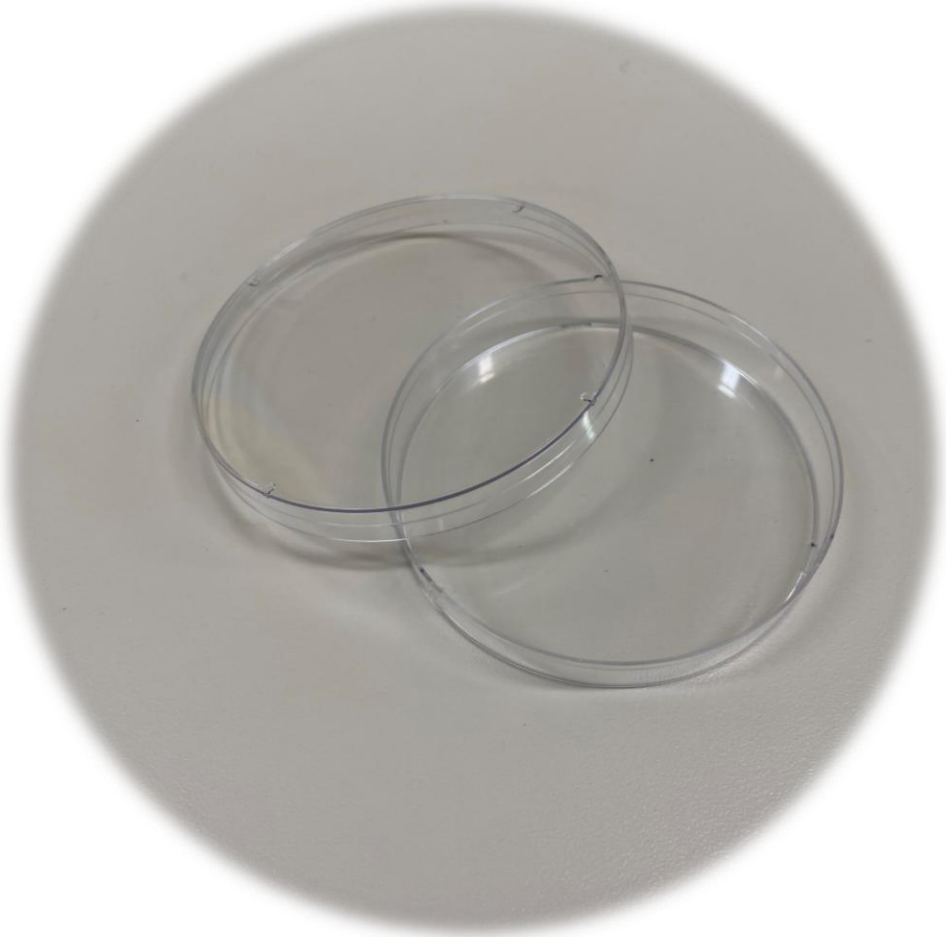
2.0 mg Reference Dose for Milk ÷ 0.3875% Milk Protein in Formula = 516.13 mg product achieving FAO/WHO RfD

Incident Debrief

- Was this incident the result of cross contact?
- Would more cleaning and equipment swabbing have helped?
- What manages this significant risk?

Label verification and management!

Thoughts on Dust



It is generally not an issue, but studies using settling plates can give insights:

- Dust collects in petri dishes placed where product is exposed
- Amount of allergen collected and quantified
- Allergen amount related to product size, weight and exposure time to determine concentration

Thank You for Your Attention

Joe Baumert

Professor, Co-Director

Food Allergy Research & Resource Program

University of Nebraska-Lincoln

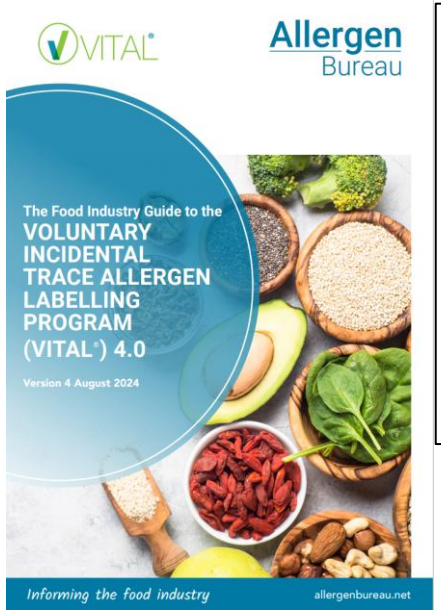
Scott Hegenbart

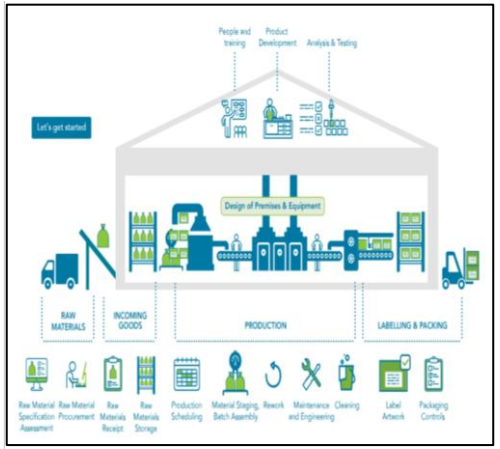
Manager, Regulatory Affairs

Conagra Brands

Omaha, NE

VITAL®





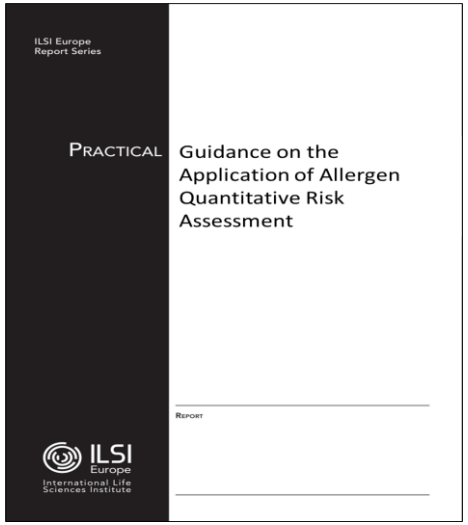
https://vital.allergenbureau.net/vital-program/

https://info.allergenbureau.net/infographic/

Food Allergy Canada

https://foodallergycanada.ca/professional-resources/foodservice/allergen-management-guidelines-for-food-manufacturers/

ILSI-Europe



https://ilsi.eu/publication/practical-guidance-on-the-application-of-food-allergen-quantitative-risk-assessment-qra/

Links to the Published FAO/WHO Risk Assessment of Food Allergens Reports:

Part 1: Review and Validation of Codex Alimentarius Priority Allergen List Through Risk Assessment:

- Part 1 Report
- Part 1 Summary Brochure
- In Brief: Priority Food Allergens

Part 2: Review and Establish Threshold Levels in Foods for the Priority Allergens:

- Part 2 Report
- Part 2 Summary Brochure
- In Brief: Food Allergen Reference Doses

Part 3: Review and Establish Precautionary Labelling in Foods of the Priority Allergens

- Part 3 Report
- Part 3 Summary Brochure
- In Brief: Precautionary Allergen Labelling (PAL)

Part 4: Establishing Exemptions from Mandatory Declaration for Priority Food Allergens:

- Part 4 Report
- Part 4 Summary Brochure
- In Brief: Exemptions from Mandatory Food Allergen Declaration

Part 5: Review and Establish Threshold Levels for Specific Tree Nuts (Brazil Nut, Macadamia or Queensland Nut, Pine Nut), Soy, Celery, Lupin, Mustard, Buckwheat and Oats:

- Part 5 Report

FAO/WHO Expert Consultation Guidance for Risk Assessment

- Summary Report

Allergen Labeling & Claims:
what consumers see & what they get

Steven Gendel
Principal
Gendel Food Safety LLC

Starting with the end in mind

Starting with the end in mind

The 4 Cs of food allergen labeling

Starting with the end in mind

The 4 Cs of food allergen labeling

Food Allergen labels that are always

- Clear
- Complete
- Current
- Accurate

Starting with the end in mind

The 4 Cs of food allergen labeling

Food Allergen labels that are always

- Clear — To the consumer
- Complete
- Current
- Accurate

What consumers are getting

What consumers are getting

FDA allergen recalls

Cause	% of Allergen Recalls
Label/packaging errors	50.1
Supply chain related	16.3
Process/cross-contact related	9.4

FDA Only
2013-2019

Source: Sharma et al., https://doi.org/10.1016/j.jfp.2023.100069

What consumers are seeing

What consumers are seeing

Label
Ingredient / Contains
Advisory (PAL)
Gluten-Free
Free-From

What consumers are seeing

Label	Status
Ingredient / Contains	Regulated
Advisory (PAL)	Voluntary
Gluten-Free	Voluntary/ Regulated
Free-From	Voluntary

What consumers are seeing

Label	Status	Message
Ingredient / Contains	Regulated	Stay Away
Advisory (PAL)	Voluntary	Stay Away
Gluten-Free	Voluntary/ Regulated	Enticement
Free-From	Voluntary	Enticement

Demands a higher degree of responsibility

What consumers are seeing

Label	Basis for Use
Ingredient / Contains	Presence/absence
Advisory (PAL)	Voluntary (TANM)
Gluten-Free	Absence/ Concentration
Free-From	Voluntary (TANM)

Truthful and not misleading?

What consumers might see in the future

What consumers might see in the future

Label	Basis for Use
Ingredient / Contains	Presence/absence
Advisory (PAL)	Numerical ?
Gluten-Free	Absence/ Concentration
Free-From	?

What consumers will ask in the future

What consumers will ask in the future

- How do I know that the labels and claims match reality?
- Who is checking to be sure?

What industry must ask in the future

What industry must ask in the future

- What is needed to ensure label accuracy?
- Will the medical community understand a (new) numerical system?
- Will any system work if it is not mandatory?
  - If it is, will FDA effectively enforce it?
- What about USDA-regulated food labels?

Reminder

Food allergen safety depends on having effective

- **GMPs**
- **Supply Chain Controls**

A note on data quality

A note on data quality

The #1 Dimension of Data Quality

Accuracy — how well data represents real-world entities or events and whether it can be validated against trusted sources

Preparing for the future

Exercise 1

What's wrong?

Exercise 1

What's wrong?

Recalled 03/17/26

Exercise 1

What's wrong?

Recalled 03/17/26

"packaging that did not reveal the presence of wheat and soy allergens."

Exercise 1

What's wrong?

Recalled 03/17/26

"packaging that did not reveal the presence of wheat and soy allergens."

Exercise 1

What's wrong?

Recalled 03/17/26

"packaging that did not reveal the presence of wheat and soy allergens."

Exercise 1

What's wrong?

Recalled 03/17/26

Exercise 2

What's wrong?

Exercise 2

What's wrong?

Exercise 2

What's wrong?

Recall descriptions

Incorrectly placed ingredient label for non-diet beverage on bottles of diet beverage.

Product is labeled as decaf, but might contain caffeine.

Preparing for the future

- Be sure that your allergen safety plan is working, and that you can show it
- Think about your numbers

Starting with the end in mind

The 4 Cs of food allergen labeling

Food Allergen labels* that are <u>always</u>

- Clear
- Complete
- Current
- Accurate

*Saying nothing is a way of saying something

One more vision of the future

One more vision of the future

- **For help in bridging the gap between the present and the future:**
  - **steve@gendelfoodsafety.com**
  - **https://www.linkedin.com/in/stevenmgendel/**
  - **@foodallergensafety.bsky.social**

Navigating Food Allergens: Insights and Strategies for Effective Management

Monica Khoury, Nestlé

Steven Gendel, Gendel Food Safety LLC

Joe Baumert, Food Allergy Research and Resource Program

Scott Hegenbart, Conagra

Let’s Start With You: Allergens in the Real World

- Are you or someone you know personally impacted by a food allergy?
- Who here manufactures products with free-from claims?
- What keeps you up at night more:
  - Label development was incorrect
  - Sanitation cross contact from shared equipment
  - Supplier mislabeling or cross contact
  - Mishandling of materials (wrong ingredient in wrong batch)

FAACT

Food Allergy & Anaphylaxis Connection Team

AWARENESS • ADVOCACY • EDUCATION

www.FoodAllergyAwareness.org

Navigating Food Allergies
Ingredient Transparency & Emerging Allergens

Adapted from an original by **Caroline Moassessi**
FAACT Vice President Community Relations

THE VOICE OF FOOD ALLERGY AWARENESS

Food Allergy

90%

of food allergic reactions in the U.S. are caused by nine foods:

- **Milk**
- **Egg**
- **Wheat**
- **Soy**
- **Peanut**
- **Tree-Nuts**
- **Fin Fish**
- **Crustacean Fish**
- **Sesame**

Any food can cause an allergic reaction

#KnowtheFAACTs

FoodAllergyAwareness.org

Food Allergy – The Term

- "Food Allergy"
- An immune system response to a food the body mistakenly believes is harmful
- Food related conditions & diseases often confused with a food allergy
- **Food allergy can be fatal**
- Allergy & Anaphylaxis Emergency Plan signed by a medical doctor, describing the individual's specific medical needs

Food Allergy - Prevalence

Food allergies affect **8%** of U.S. children and 10.8% of adults.

1 in 10 adults (26 million) and

1 in 13 children (6 million) have food allergies
- 2 students per classroom, U.S.

Food allergies & asthma in children = **29%**
-Higher risk for anaphylaxis

40% of allergic children allergic to multiple foods

#KnowtheFAACTs

FoodAllergyAwareness.org

Food Allergy - FAACTS

There is **NO cure** for food allergies

Management based on strict avoidance and prompt treatment of accidental ingestions

18% of children reacted while at school

25% of first time severe reactions occur in the school setting

Fatalities have occurred in schools due to delays in properly **recognizing and treating** serious allergic reactions (anaphylaxis)

Anaphylaxis

- **Anaphylaxis** (an-a-fi-LAK-sis) is a severe allergic reaction that is rapid in onset and may cause death.
- Anaphylaxis from food = (within minutes – several hours)
- Death from food = (30 min – 2 hrs. of exposure)
- Approximately 20% of ANA reactions recur within 4-6 hrs (**biphasic reaction**)
- MUST be transported to ER

Allergic Reactions Can Look Like...