Allergen Control Strategies

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3-A SSI Education Program
May 18, 2022

food allergy research & resource program farrp

University of Nebraska Lincoln

Why are food allergies an important concern for the food industry?

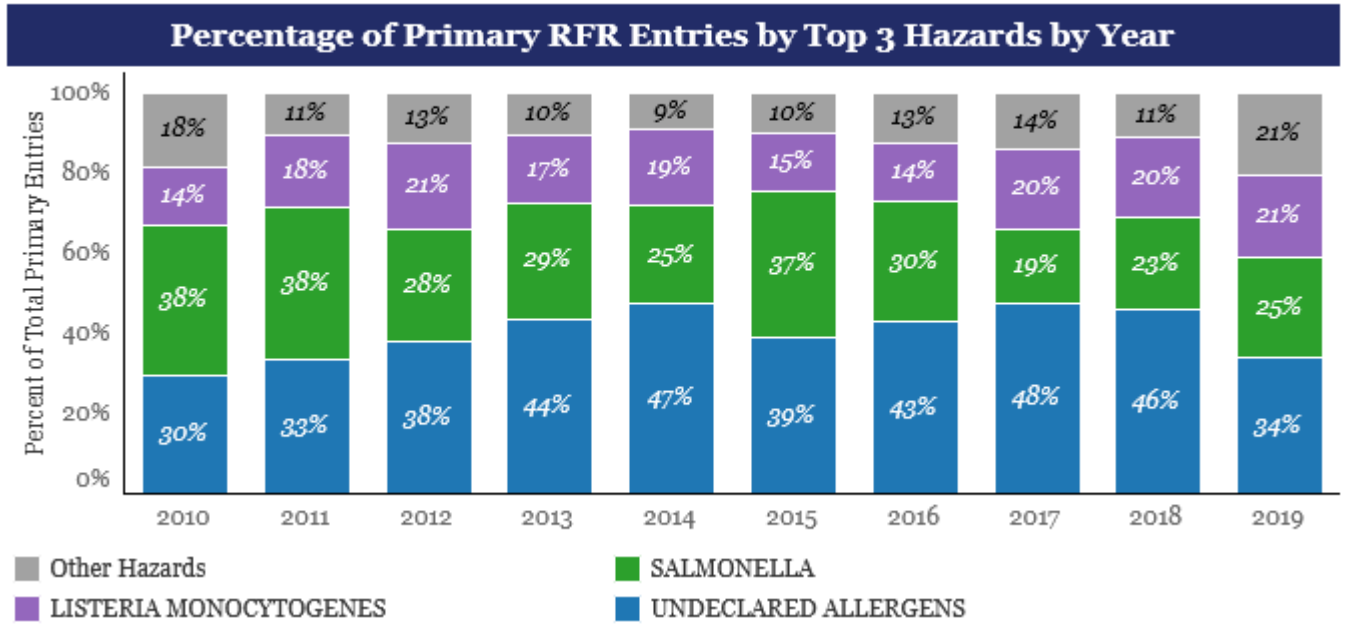
Health Risks

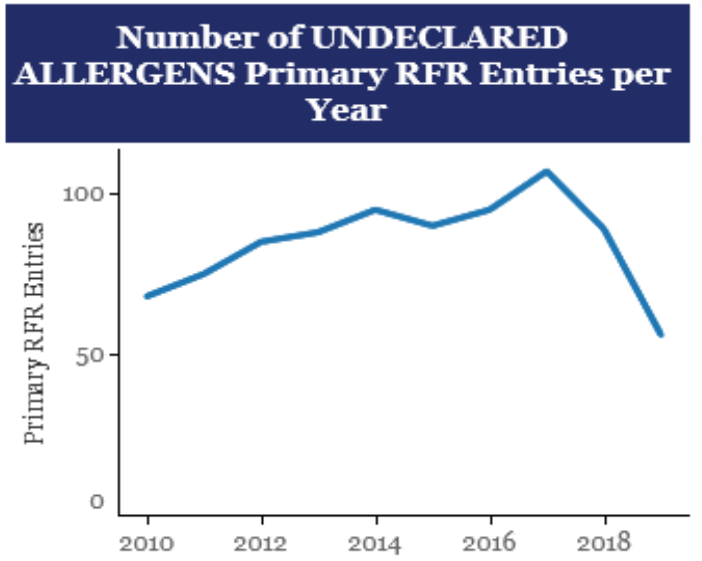
Regulatory Risks

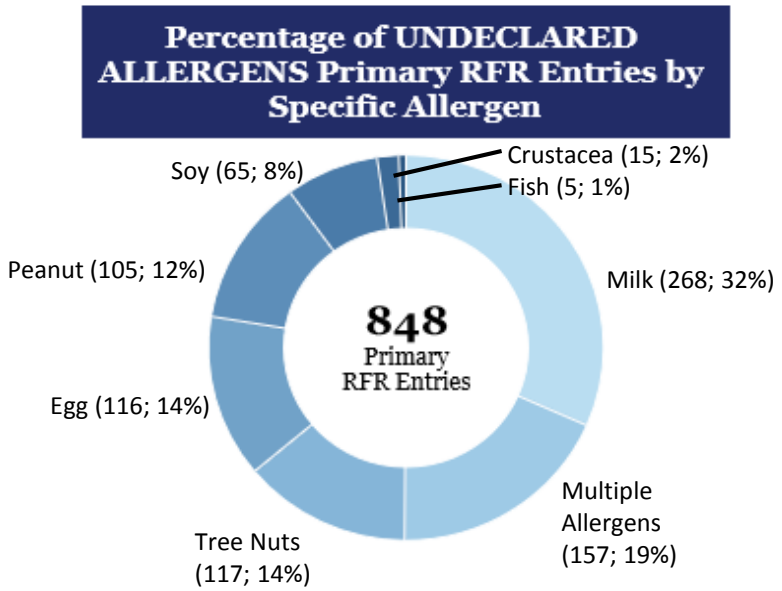
Business Risks

FDA Reportable Food Registry

Data includes entries submitted for RFR Years 1-10 (September 8, 2009-September 7, 2019).

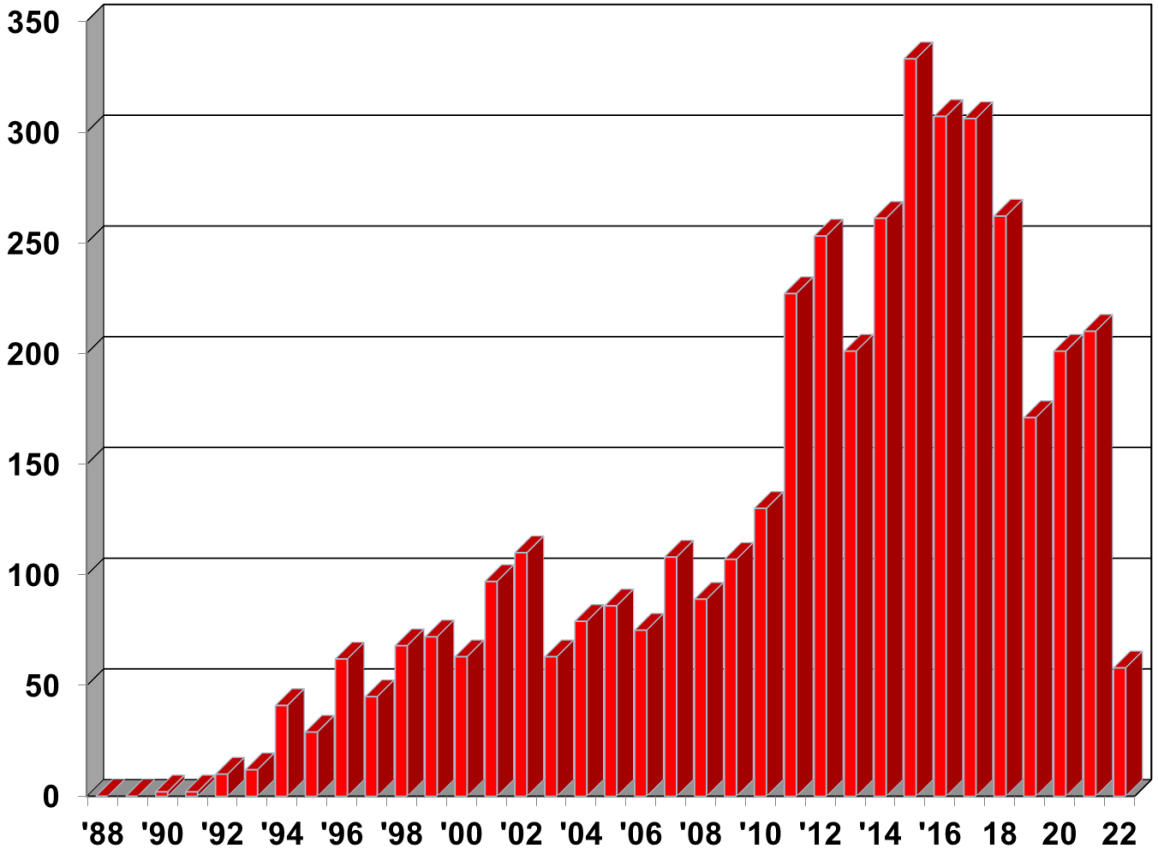






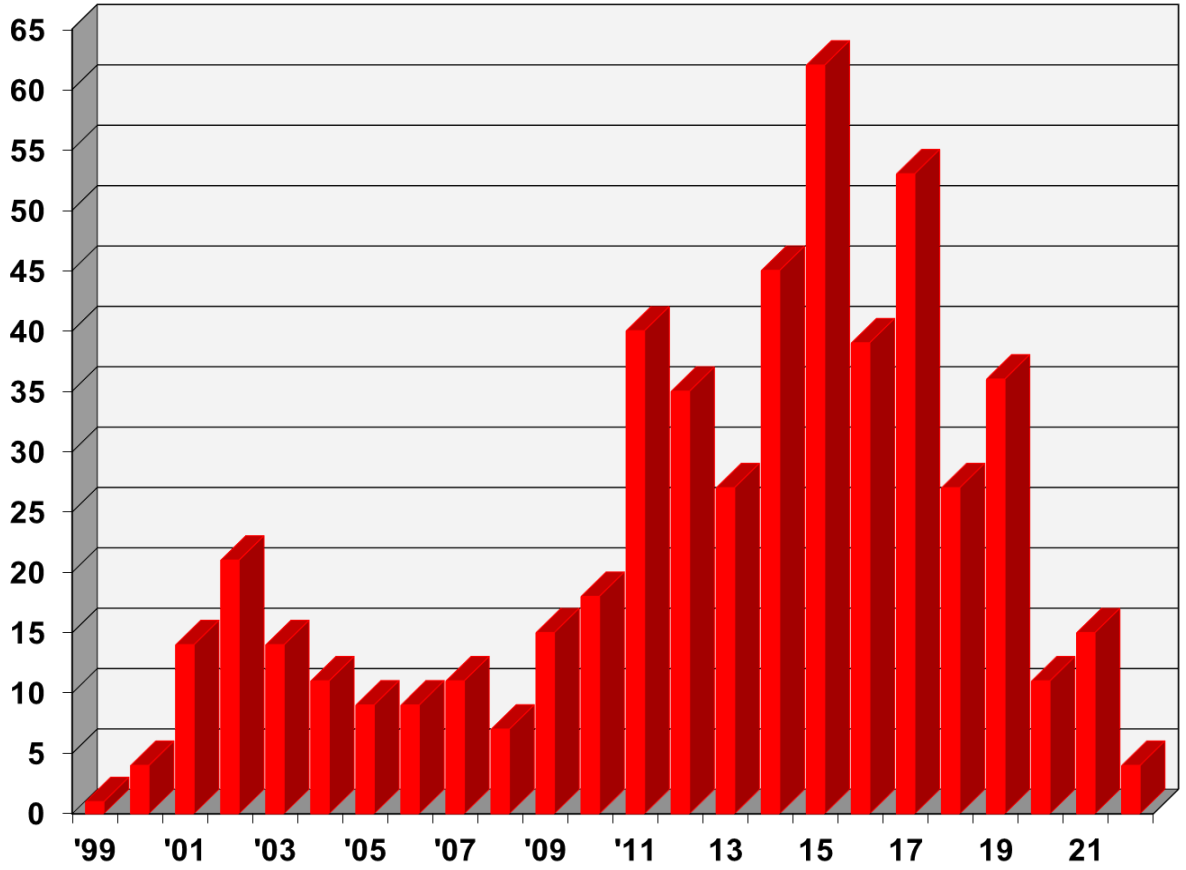
https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard

FDA Food Allergen Recall Incidents: 1988-2022



* Includes FDA recalls & alerts

FSIS/ USDA Food Allergen Recalls: 1999-2022



Food Allergen Recalls: Causes

- Review of FDA allergen recalls FY 2007- FY 2012 (Gendel and Zhu 2013)
  - Identified 732 allergen recalls

TABLE 5. *Distribution of allergen recalls among the major food allergens*

Allergen	Recalls[a]
Milk	296
Wheat	171
Soy	153
Tree nuts	119
Egg	108
Peanut	69
Fish	28
Crustacean shellfish	11
Unspecified	8

[a] A single recall might involve multiple allergens. In those cases, each recall was counted multiple times, depending on the number of allergens involved.

TABLE 4. *Distribution of food allergen recalls among the food categories*

Food	No. (%) of recalls	Recall class (1/2/3)
Bakery	231 (31.5)	144/86/1
Beverages	23 (3.1)	14/8/1
Breakfast cereal	10 (1.4)	5/5/0
Candy	73 (10.0)	46/26/1
Composite	46 (6.3)	31/14/1
Dairy	58 (7.9)	38/19/1
Dressing	59 (8.0)	42/17/0
Imitation milk	5 (0.7)	5/0/0
Meals	14 (1.9)	12/2/0
Other	25 (3.4)	16/9/0
Pasta	13 (1.8)	5/8/0
Produce	10 (1.4)	3/6/1
Salad	5 (0.7)	3/1/1
Seafood	32 (4.4)	22/10/0
Snack	89 (12.1)	55/32/2
Soup	21 (2.8)	12/8/1
Supplement	18 (2.5)	10/7/1
Total	732 (100)	463/258/11

Gendel, S.M. and J. Zhu. Journal of Food Protection, 2013. **76**(11): p. 1933-8.

Food Allergen Recalls: Causes

- Review of FDA allergen recalls FY 2007- FY 2012 (Gendel and Zhu 2013)
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TABLE 6. *The number of recalls involving each of the most frequent food-allergen combinations FY 2007 through FY 2012*

	Bakery	Snack	Candy	Dressing	Dairy
Peanut	10	19	18	0	9
Egg	44	4	6	8	11
Milk	107	41	22	21	13
Soy	36	25	14	21	12
Wheat	58	11	7	17	10
Tree nuts	44	17	20	3	18

TABLE 7. *The number of allergen recalls and the distribution of recall classifications for each root cause FY 2007 to FY 2012*

Root cause[a]	No.	Recall class (1/2/3)
Computer error	21	15/4/2
Cross-contact	52	41/11/0
In process	19	15/4/0
Ingredient mislabeled	26	16/10/0
Knowledge	28	14/14/0
No carry-through	70	39/31/0
No declaration	12	1/10/1
Not updated	22	12/9/1
Omission	191	128/63/0
Other	14	12/2/0
Rework	9	9/0/0
Terminology	85	20/63/2
Unknown	15	15/0/0
Wrong ingredient	31	26/4/1
Wrong label	50	37/10/3
Wrong package	87	63/23/1

Gendel, S.M. and J. Zhu. Journal of Food Protection, 2013. **76**(11): p. 1933-8.

Food Allergen Recalls: Example Causes

Incorrect ingredient statement

- Failure to declare sub-ingredients (e.g. anchovies in Worcestershire)
- Errors at label supplier
- Old labels used with new formulation
- Different product sizes with different allergen profiles

Wrong product in wrong package

- Packaging not changed for subsequent product
- Wrong packaging put onto line

Cross-contact

- Inadequate cleaning
- Pre-op review not conducted correctly

Food Allergen Recalls: Trends

Past Recall Episodes

- 2014-2015: Peanut in Cumin
  - Imported, ground cumin with very high levels of peanut
  - Potentially economically motivated adulteration in overseas supply chain
  - Other cumin sources: potential low-level commodity co-mingling
- 2016: Peanut in Wheat Flour
  - Wheat flour from mill in Georgia with moderate levels of peanut
  - Potential root cause: cross-contact during transportation

Issues

Supplier verification

International supply chains

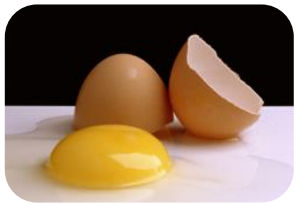
Commodity transportation

Commodity comingling

Common Causes of Food Allergies

~~"The Big 8"~~ **"The Top 9"**

Milk



Egg

Crustacea

Fish

Peanut

Soybean

Tree nuts

Wheat

Sesame

(Jan 1, 2023)

Causative Agents

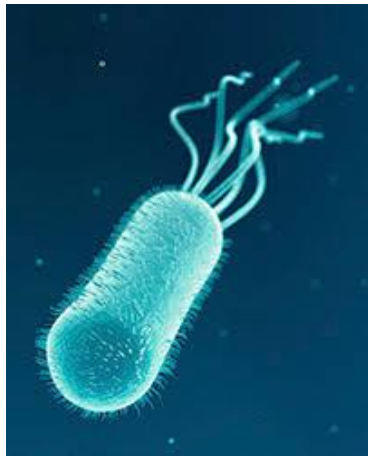
- Naturally-occurring **proteins**

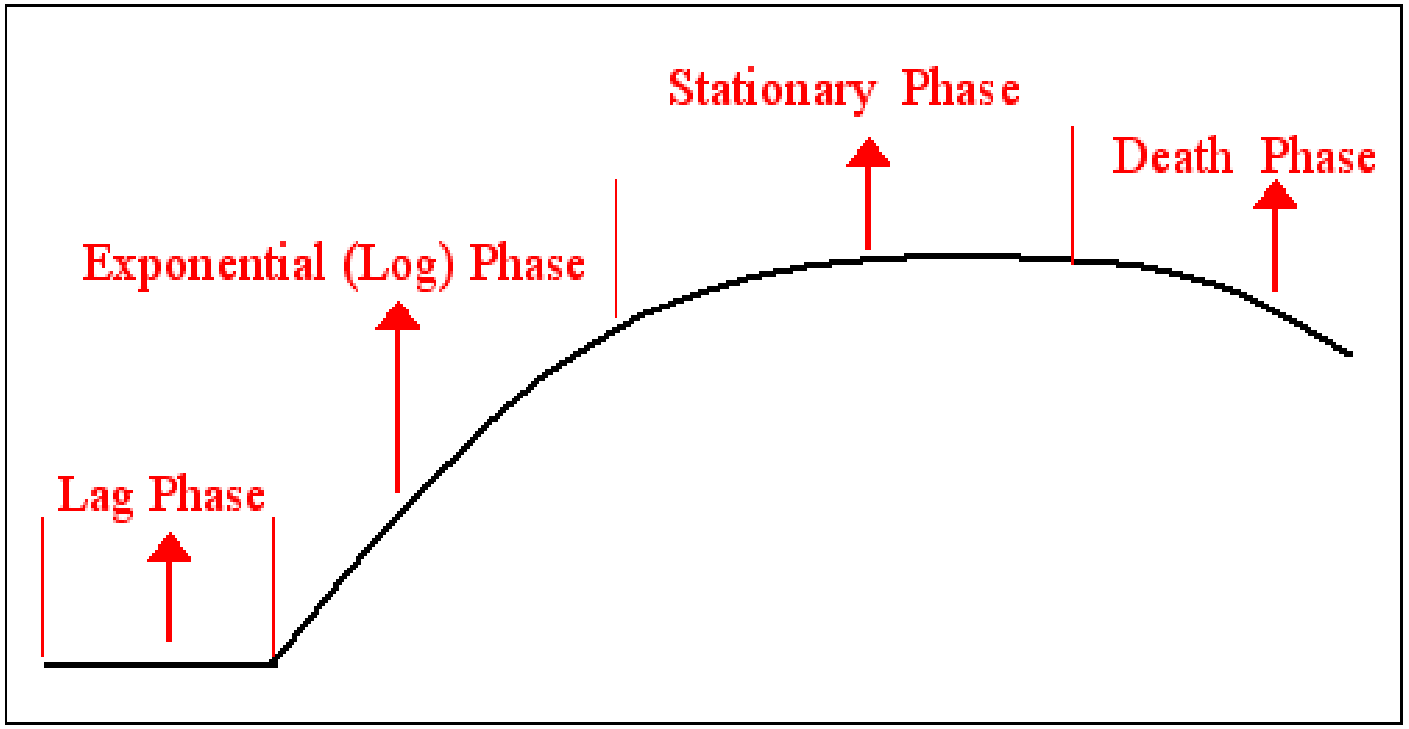
- Heat-resistant
- Resistant to proteolysis
- Resistant to extremes in pH
- Usually, major proteins of the food
- Foods can contain several individual allergenic proteins

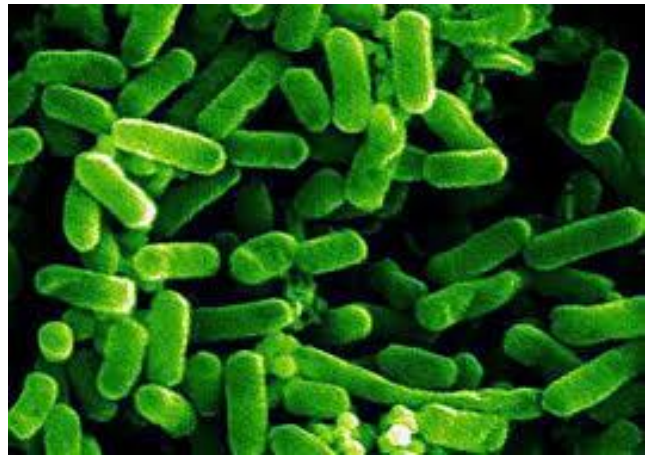
food allergy research & resource program farrp

Microbes ≠ Allergens

- Allergens do not “Grow”

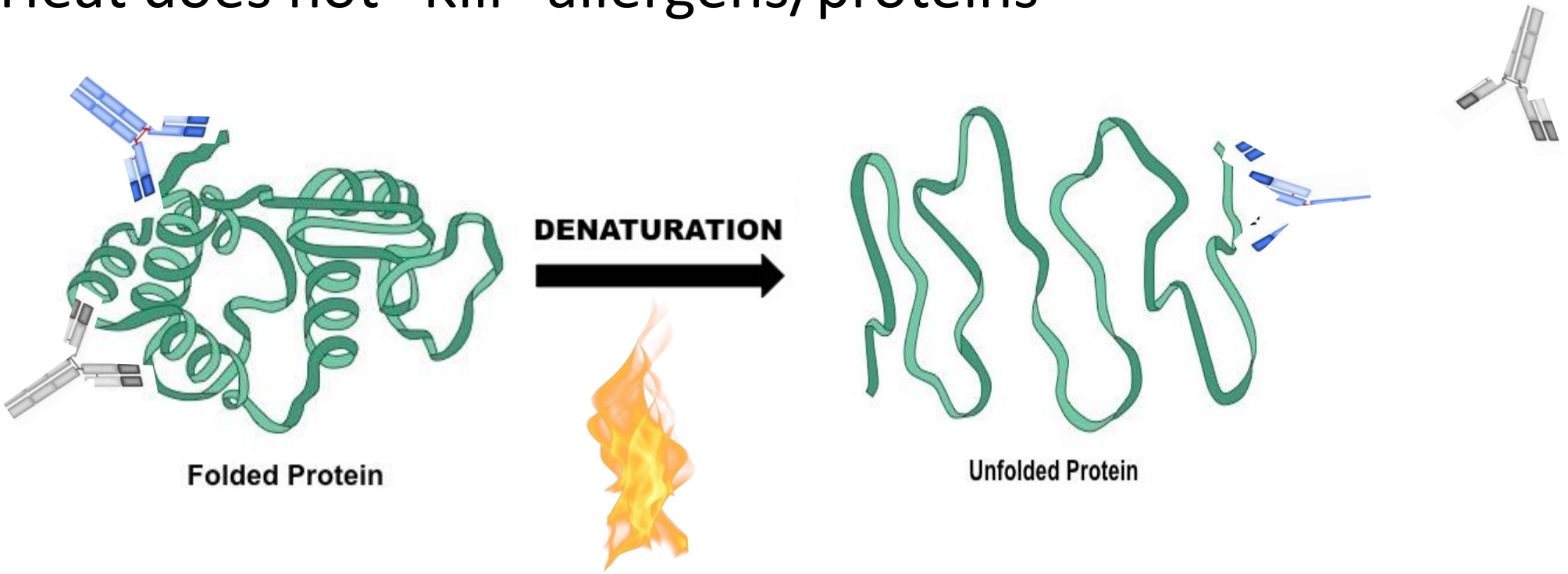




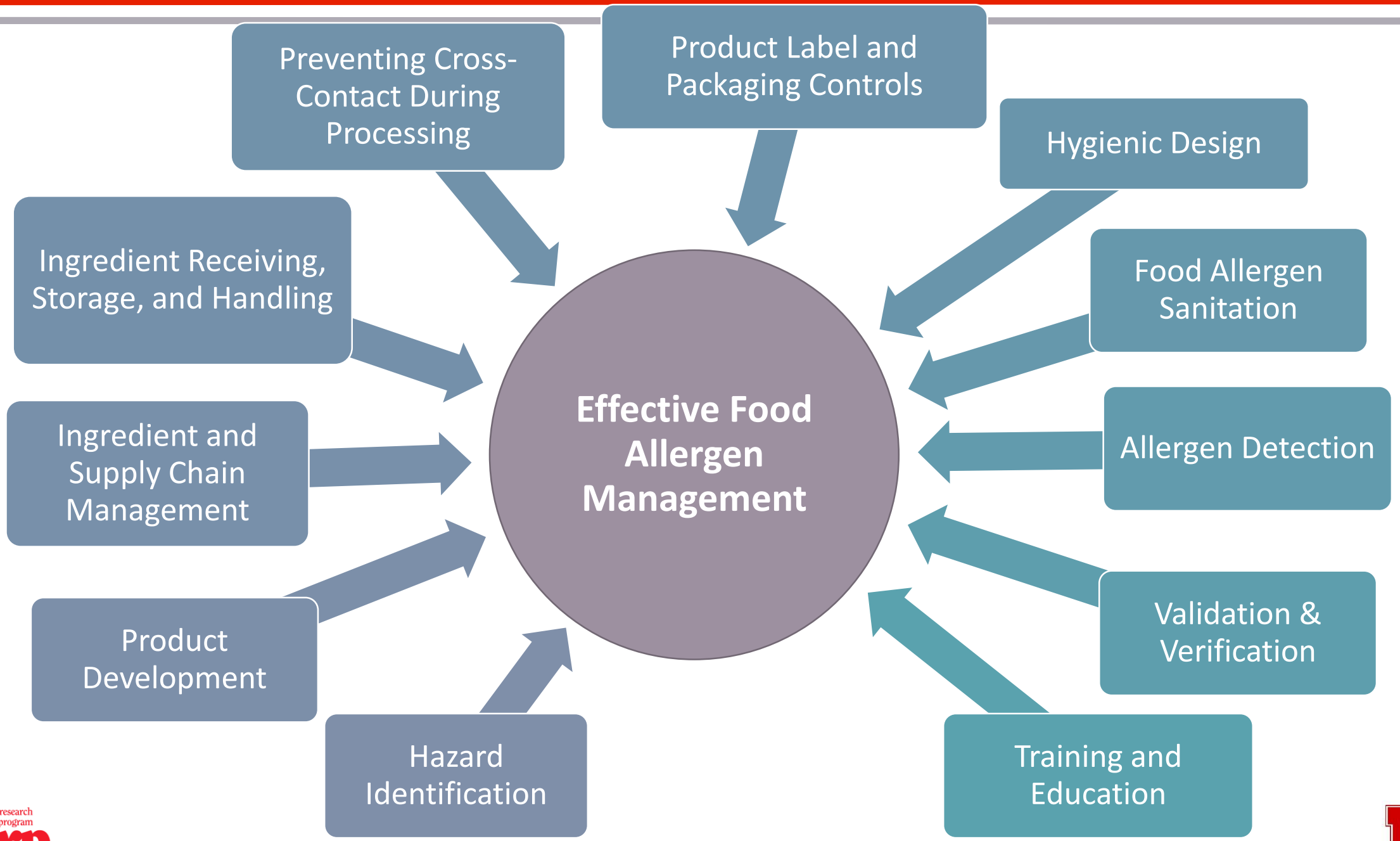


Allergens ≠ Microbes

- Heat does not “Kill” allergens/proteins



Physical removal of allergen residue is critical to minimize allergen cross-contact


Preventing Cross-Contact During Processing
Product Label and Packaging Controls
Hygienic Design
Ingredient Receiving, Storage, and Handling
Food Allergen Sanitation
Ingredient and Supply Chain Management
Effective Food Allergen Management
Allergen Detection
Product Development
Validation & Verification
Hazard Identification
Training and Education

Hazard Analysis and Risk-Based Preventive Controls (HARPC)

- Food allergens are chemical hazards
- If a facility handles any food allergens:
  - Food allergens are almost certainly a hazard requiring control
  - Food allergen controls are applicable
  - A food safety plan is required

- Food allergens can be managed with a combination of GMPs and preventive controls

Food Allergens and FSMA

- **Preventive Controls for Human Food**
- Preventive Controls for Animal Food
- **Foreign Supplier Verification**
- Third Party Accreditation
- **Sanitary Transport**
- Produce Safety
- Food Defense

<u>Preventive Controls and cGMP Rule (21 CFR Part 117)</u>

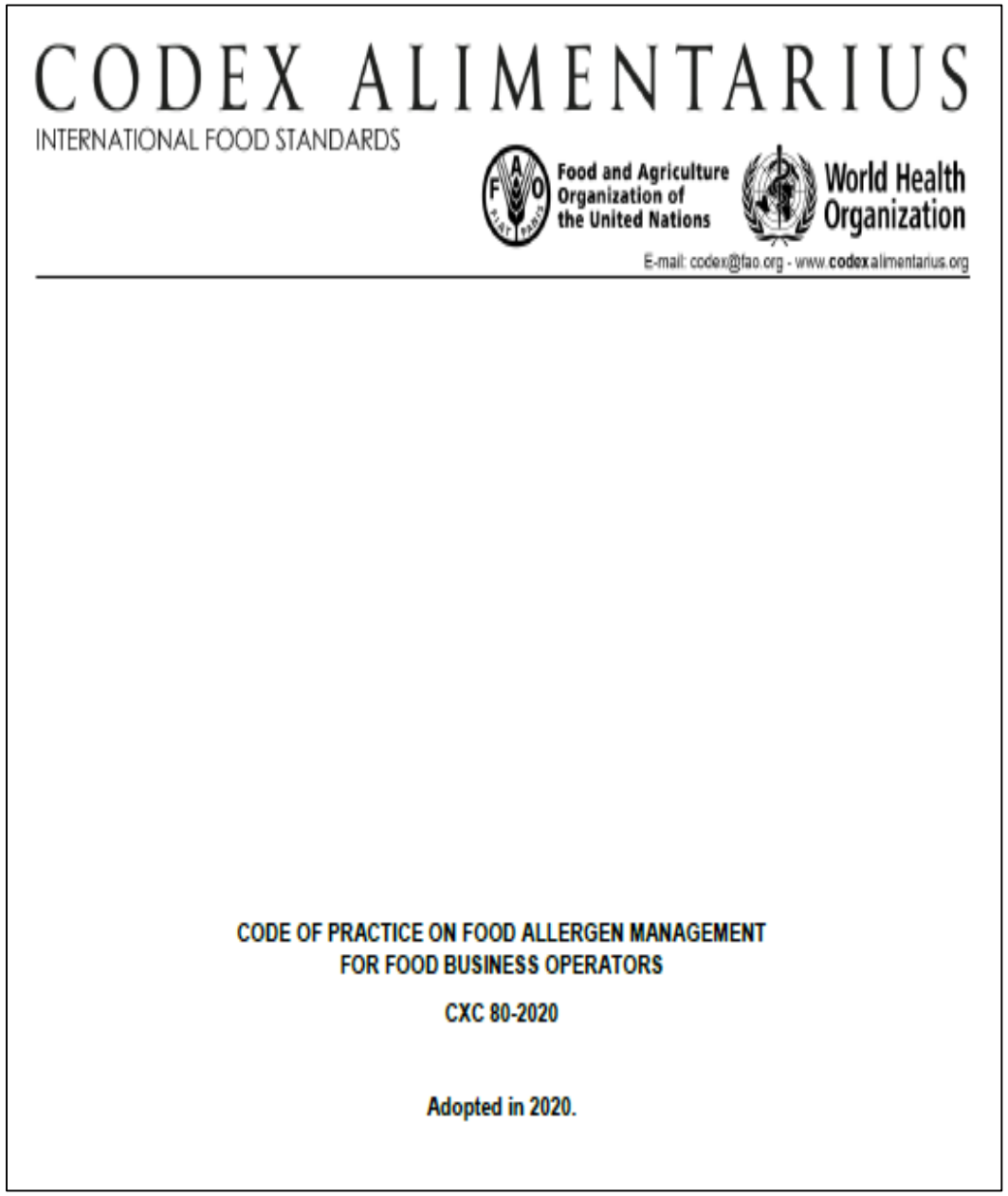
- Updated cGMPs (Subpart B)
- Hazard Analysis and Risk-Based Preventive Controls (Subpart C)
- Supply-chain program (Subpart G)
- Training requirements

<u>Other rules:</u>

- Sanitary transport rule
- Foreign supplier verification program

Updated GMPs & Allergens

Personnel	• Hygienic practices • Outer garments to protect against cross-contact
Plant construction and design	• Operating practices/design: separation of operations • Ventilation to minimize dust which would result in cross-contact
Sanitary operations	• Clean utensils/equipment; storage of clean equipment • Food-contact and non-contact surfaces
Equipment and utensils	• Cleanable and maintained • Seams: smoothly bonded & maintained
Processes and controls	• Raw material and rework storage • Manufacturing, processing, packing and holding conducted to minimize cross-contact
Warehousing and distribution	• Storage and transportation to protect against cross-contact



CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations

World Health Organization

E-mail: codex@fao.org - www.codexalimentarius.org

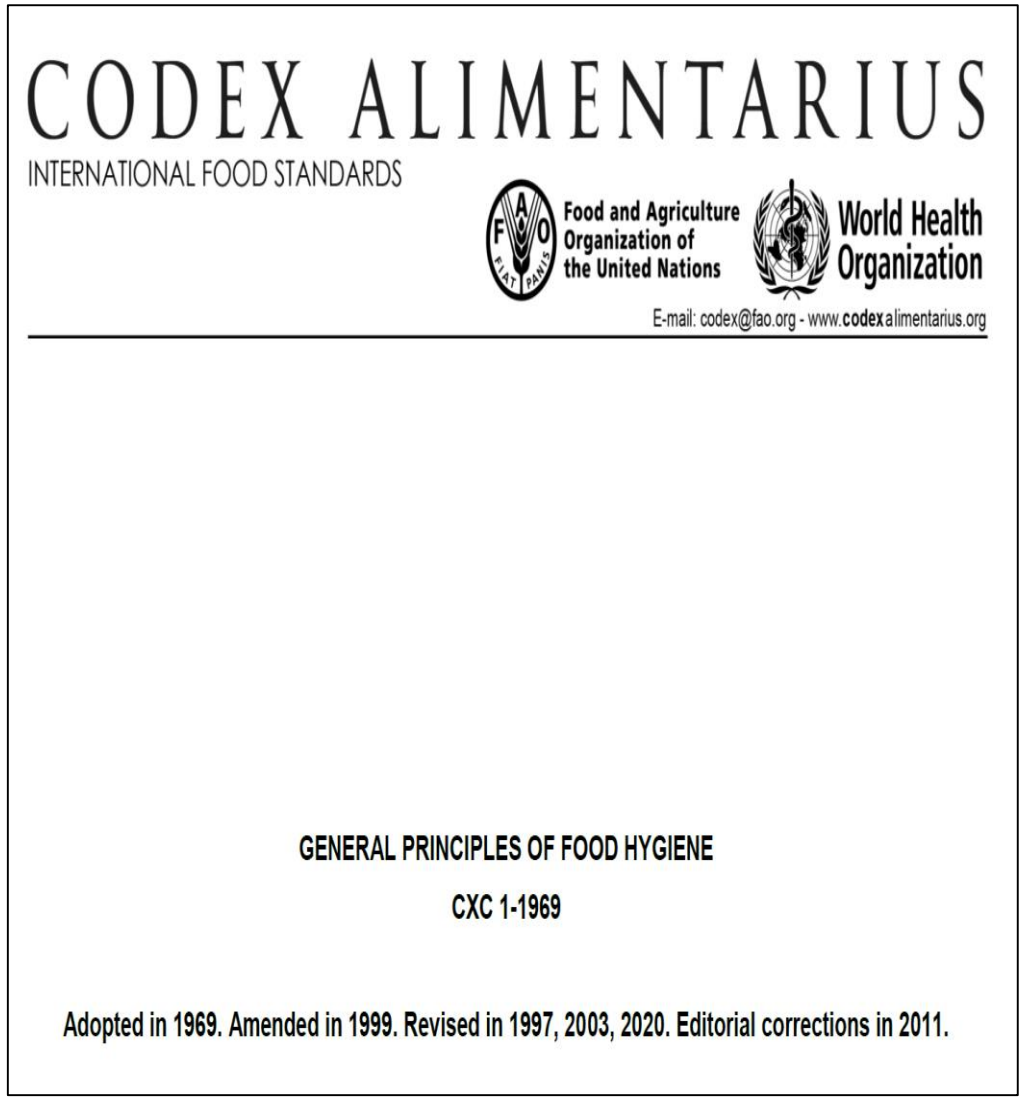
CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

CXC 80-2020

Adopted in 2020.

- **Farm to fork guidance for allergen management**
  - prevent or minimize the potential for allergen cross-contact that is of risk to the consumer with a food allergy
  - prevent or minimize the potential for undeclared allergens being present in a food due to errors arising in the supply chain
  - ensure the correct allergen label is applied to prepackaged foods
  - ensure that accurate information can be provided to consumers at point of sale when the food is not prepackaged

http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf



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GENERAL PRINCIPLES OF FOOD HYGIENE

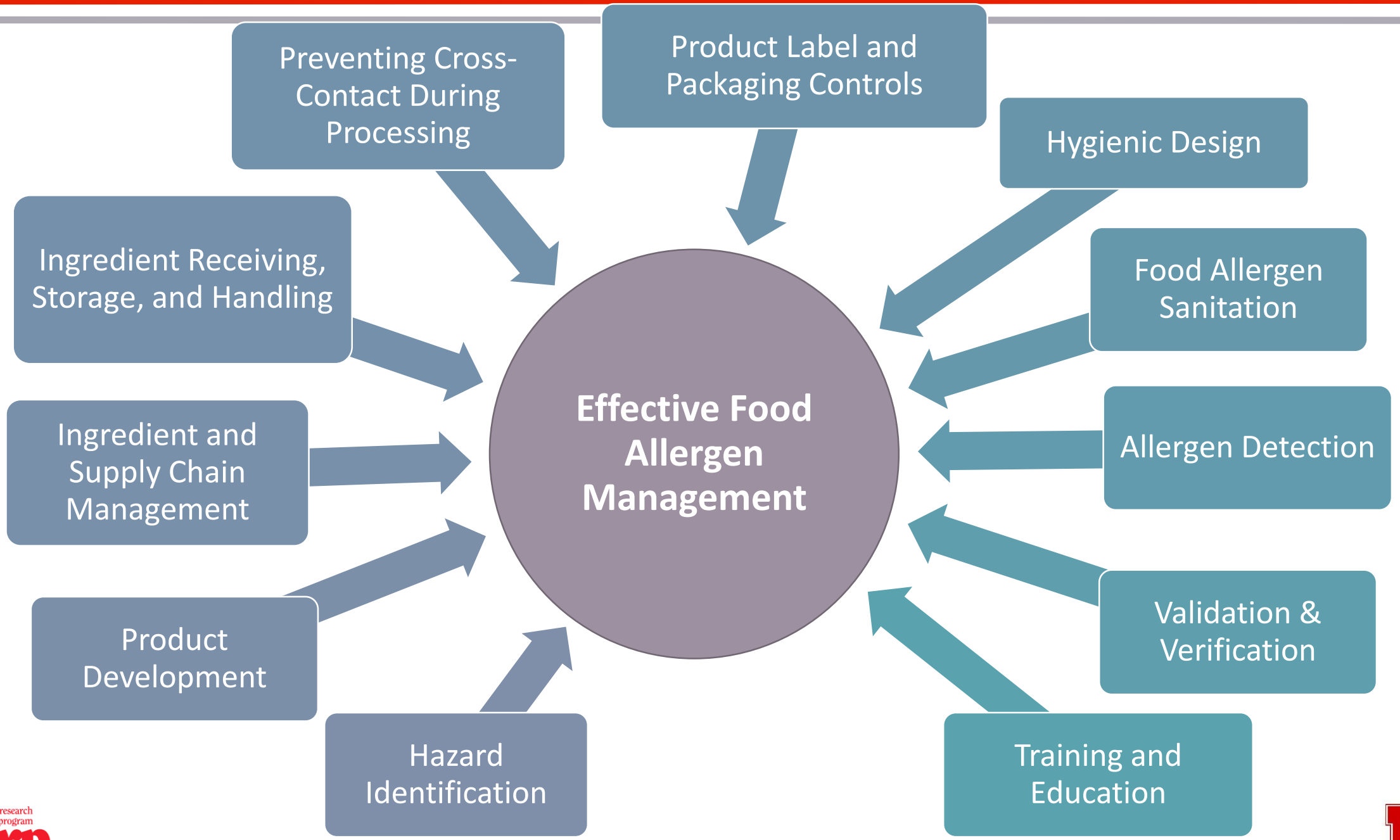
CXC 1-1969

Adopted in 1969. Amended in 1999. Revised in 1997, 2003, 2020. Editorial corrections in 2011.

OBJECTIVES

- The General Principles of Food Hygiene: Good Hygiene Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) System aim to:
  - provide principles and guidance on the application of GHPs applicable throughout the food chain to provide food that is safe and suitable for consumption
  - provide guidance on the application of HACCP principles
  - clarify the relationship between GHPs and HACCP
  - provide the basis on which sector and product-specific codes of practice can be established.

http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf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Training and Education

Allergen Management

Form an allergen control team

Include representatives with a variety of backgrounds and responsibilities:

- Labeling/Regulatory Compliance
- Quality
- Research and Development
- Manufacturing
- Engineering
- Sanitation
- Food Safety

Operations: Allergen Hazard Identification

Allergen Process Map

1

Map the process and track allergens in the facility

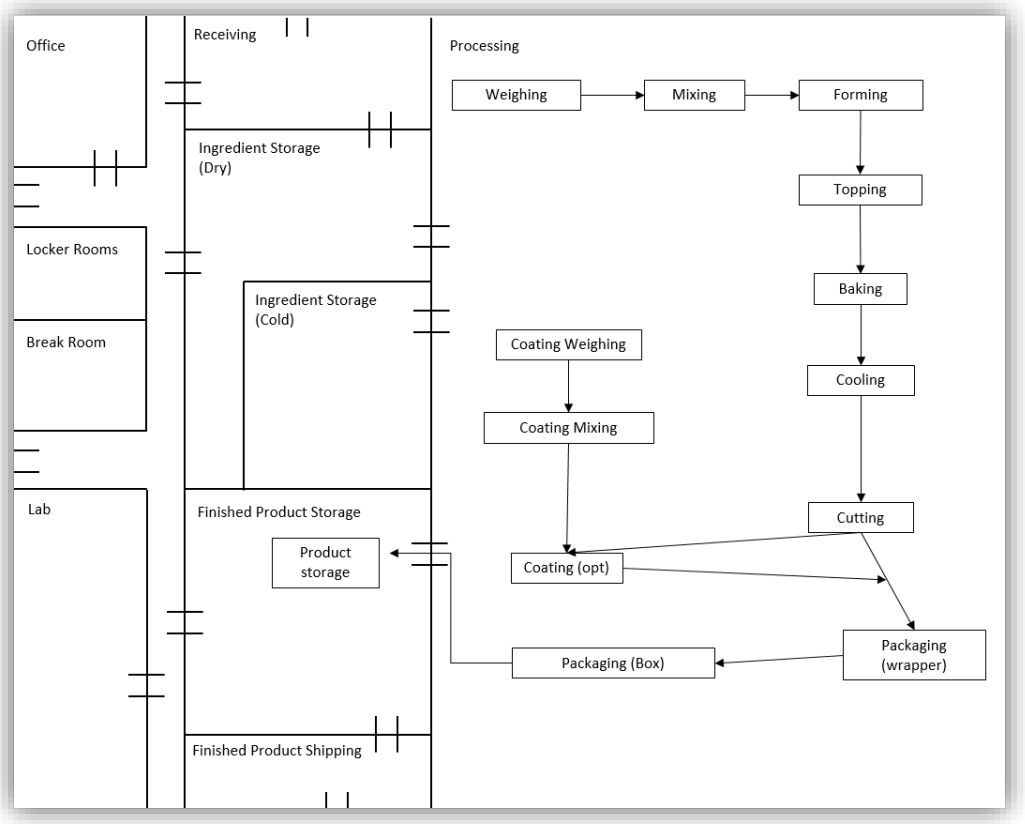
2

Identify where hazards can occur

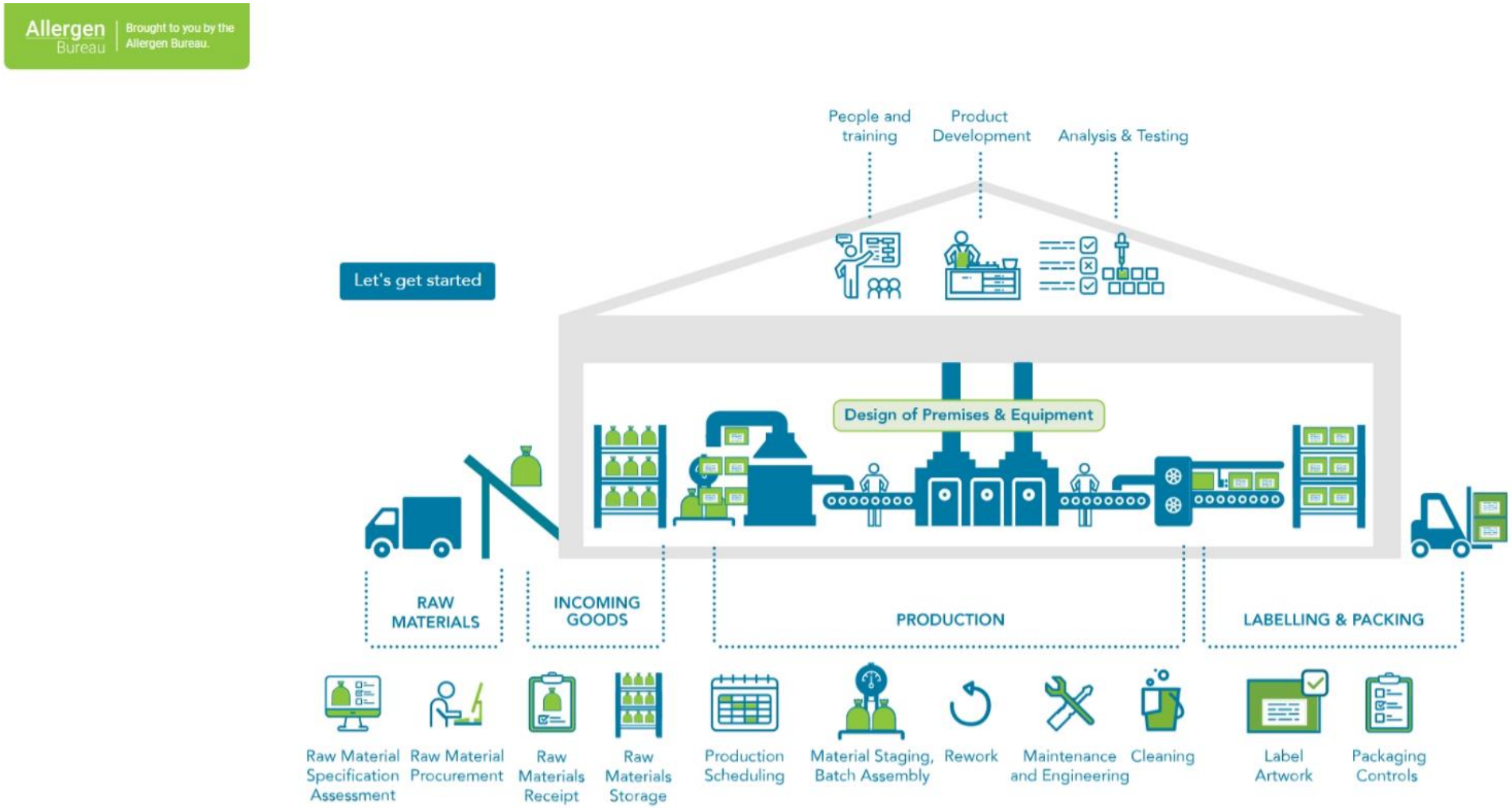
3

Identify where GMPs or preventive controls can be implemented

Identify equipment accessibility and cleanability



Hazard Identification- Tracking Allergens in a Facility



VITAL® Risk Review Tool

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

Know Your Allergens: Allergen Load Considerations

- Some ingredients contain **high** **level of allergenic protein**, for example
  - Casein
  - Gluten
  - Soy flour, soy protein isolate
- Other ingredients contain **modest** **level of allergenic protein**, e.g.
  - Lactose
- Some ingredients contain **low to very low** **level of allergenic protein**, e.g.
  - Soy lecithin
  - Fish oil
  - Butter

Allergen load should be a consideration for allergen storage, product scheduling, and cleaning strategies.

Production/Operations: Allergen Changeover Matrix

Allergen Change Over Matrix		Product After Change Over					
		(milk) A	(peanut) B	(none) C	(milk, egg) D	(egg) E	(none) F
Product Prior To Change Over	(milk) A		Allergen milk	Allergen milk	GMP	Allergen milk	Allergen milk
	(peanut) B	Allergen peanut		Allergen peanut	Allergen peanut	Allergen peanut	Allergen peanut
	(none) C	GMP	Push Through		GMP	GMP	Push Through
	(milk, egg) D	Allergen egg	Allergen milk, egg	Allergen milk, egg		Allergen milk	Allergen milk, egg
	(egg) E	Allergen egg	Allergen egg	Allergen egg	GMP		Allergen egg
	(none) F	GMP	Push Through	Push Through	GMP	Push Through	

Adams T. (2018) Allergen Management in Food Processing Operations: Keeping What Is Not on the Package Out of the Product. In: Fu TJ., Jackson L., Krishnamurthy K., Bedale W. (eds) Food Allergens. Food Microbiology and Food Safety. Springer, Cham. https://doi.org/10.1007/978-3-319-66586-3_7

Labeling & Packaging Considerations

- Most common cause of recalls
  - Incorrect label information
  - Incorrect label applied to product
- Label controls are critical
  - Electronic label version control needed
  - Update vision systems or bar code reader programming if used
  - Visual checks of labels at receipt and before start-up
- Control obsolete label stock
  - Remove or destroyed immediately

Changeover/Cleaning Considerations

Equipment design

- Access and ability to thoroughly clean; no static or hidden areas

Develop and implement clear SSOPs

- Personnel must be trained, dedicated, alert, and thorough
- SSOPs must be clear and easily understood
  - Explain not only ‘How’ but ‘Why Is It Important’

Factors to Consider for Allergen Removal

Allergen and Food Matrix:

- Form of allergen: powder, paste, particulate, liquid
- Food matrix form and properties
  - ➉ Liquid, powder, paste, particulate form of the allergenic ingredient
  - ➉ Dry powder, paste, sticky food product matrices
- Properties of the proteins/matrix
  - Propensity of the proteins to stick to the equipment (e.g. egg albumin after heating)

Equipment:

- Design/accessibility of equipment
- Type of food contact surfaces: stainless steel, plastic, etc.
  - ➉ Finish/texture of the surface
- Where allergens are applied to product in the process

Processing Type and Run Time:

- Heat processing vs. cold processing
- Length of run: potential for residue buildup in Zone 1 and Zone 2 areas

Cleaning Application:

- Type of cleaning application that can be used: wet vs. dry cleaning; automated CIP or COP vs. manual, etc.

Factors to Consider for Allergen Removal: Chemistry of Cleaning

SOIL TYPE

Fats & Oils	Carbohydrates	Proteins	Minerals

MODE OF ACTION

Dissolve	Liquefy	Hydrolyze	Disperse	Emulsify

CHEMISTRY

Alkaline	Acid	Oxidizer	Enzyme	Solvent	Surfactant

- Food processing soils are typically a mixture of soil types
- Soil characteristics vary depending on factors such as processing temperature or time
- Built cleaners better address complex soil challenges

Adapted from slides of H. Hau – Ecolab 2018

Determining the Right Cleaning Method

Wet Cleaning

- Removal of soil/residue with water and chemicals
- Foaming / CIP / COP
- Purge/Push Through (e.g. salt, sugar, flour, hot oil, or first-off food)

Dry Cleaning

- Removal of soil/residue with physical or mechanical action
- Vacuum / brushing / wiping
- Compressed air / CO_2 / Steam (watch out for cross-contact of adjacent lines/area!)
- Pigging
- Purge/Push Through (e.g. salt, sugar, flour, hot oil, or first-off food)

Combination

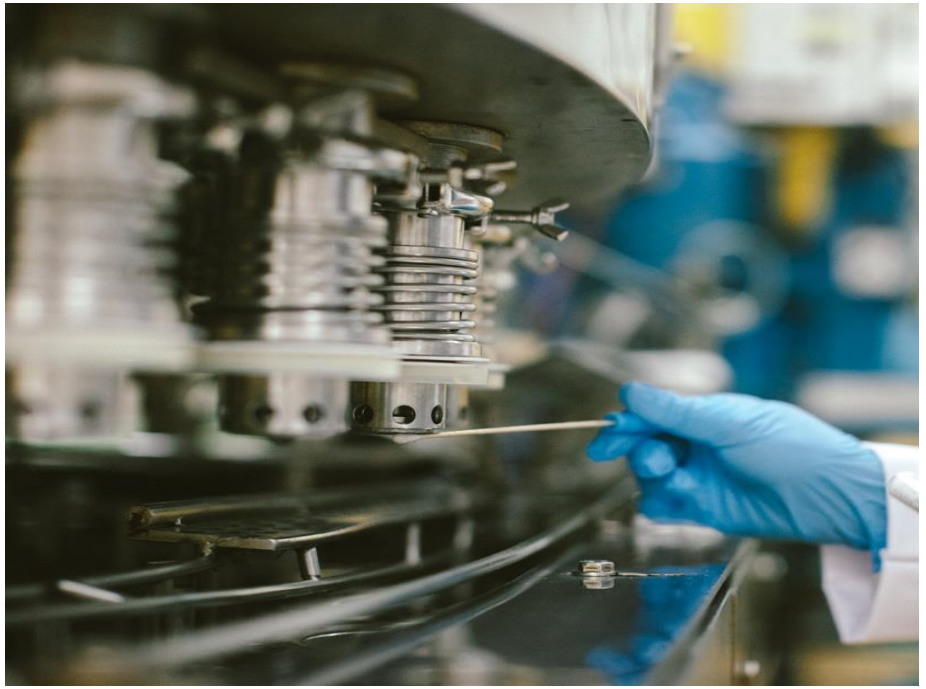
- Dry clean followed by wet (damp) wiping (typically alcohol wipes)

Can it be cleaned – how accessible is the equipment?

- Purge may be the best approach for closed systems (e.g. pneumatic piping)
- Watch out for Zone 2 areas that can harbor particulates

Ensuring That Allergen Residue Has Been Removed

Step 1: Visual Inspection



Step 2: Validation with Appropriate Analytical Tools should be considered

Picking the Best Test Method
General Comments

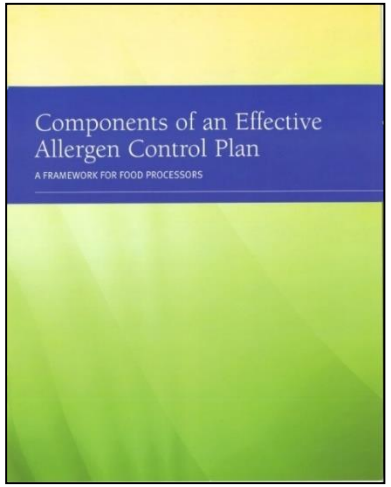
- Recommended to validate removal of allergenic residue using specific ELISAs
  - ATP and general protein tests do not detect proteins from allergenic sources specifically so the effectiveness of these tests ALONE as the sole approach must be carefully examined

- Surrogate testing (protein, ATP) can be helpful in some cases
  - ATP or general protein swabs can provide a good quick check on sanitation effectiveness during routine cleaning

Change Management

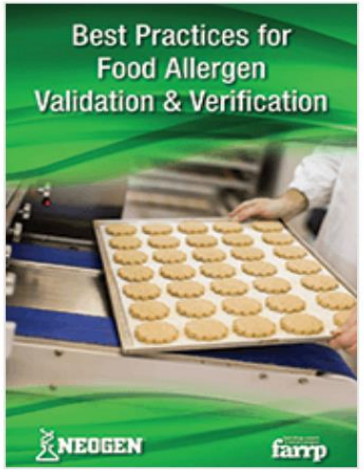
- When ***anything*** changes, then you must re-evaluate the entire allergen control plan
  - Re-Validate by doing a new Quantitative Risk Analysis
  - Does the existing Allergen Control Plan still work with the new conditions?

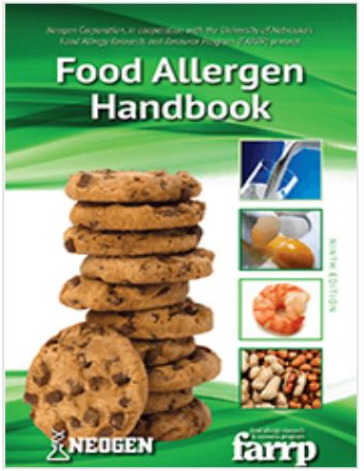
FARRP



English &
Spanish Versions
http://farrp.unl.edu/allergencontrolfi

Neogen

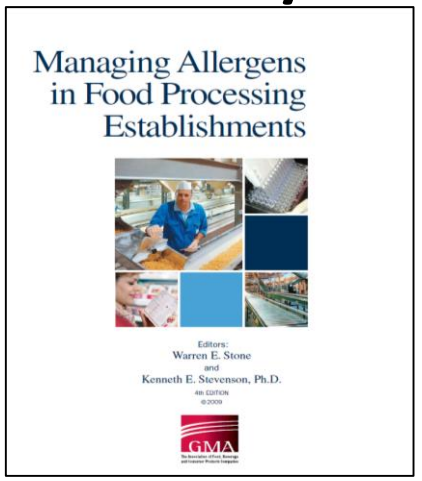




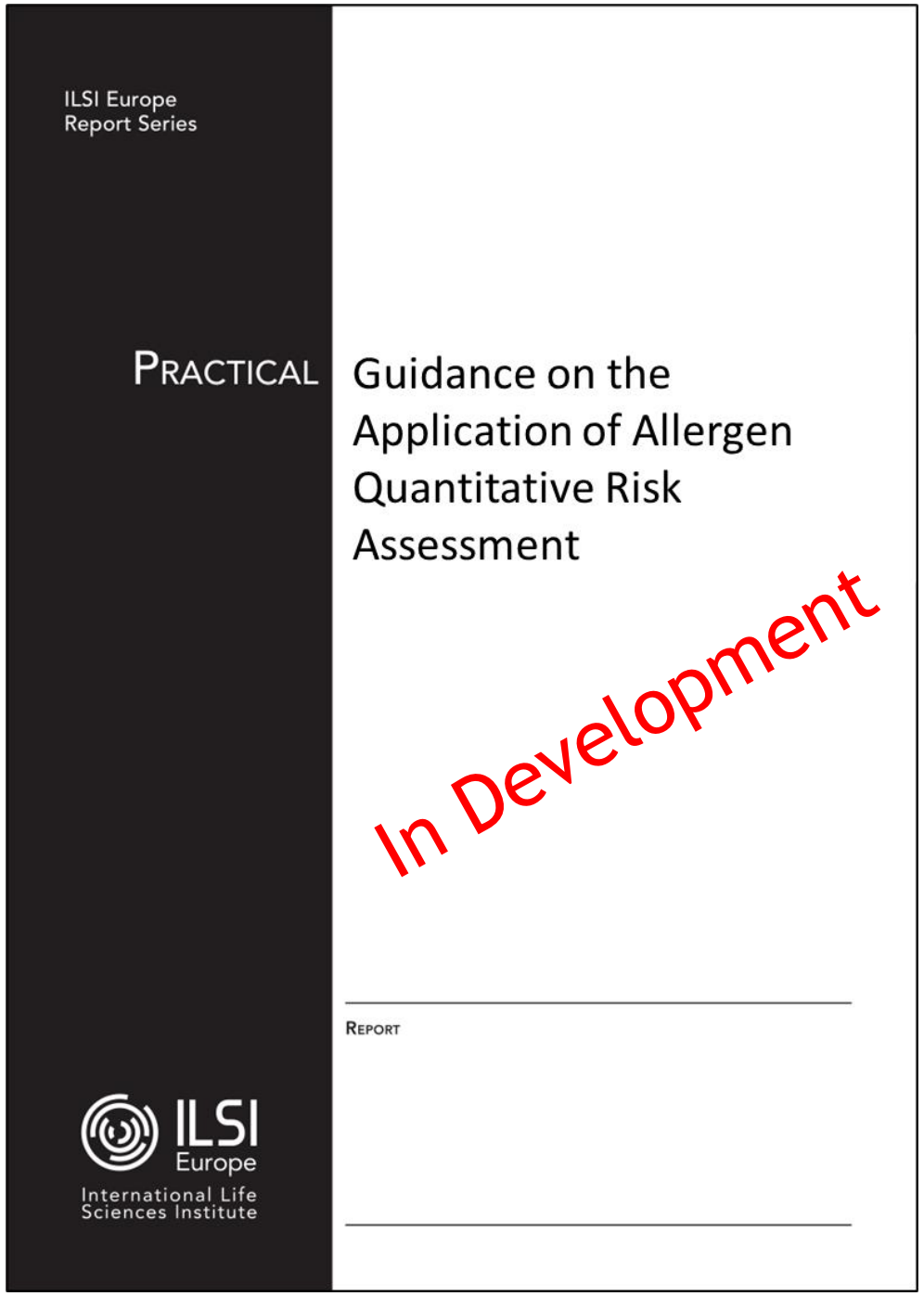
https://www.neogen.com/neocenter/resources/food-allergen-validation-verification-best-practices/

https://www.neogen.com/neocenter/resources/food-allergen-handbook/

GMA/CBA



https://forms.consumerbrandsassociation.org/forms/store/ProductFormPublic/managing-allergens-in-food-processing-establishments



- Introduction
  - What is QRA, why is it needed
  - The place of QRA within allergen management
- Core concepts
  - Example based guidance
  - Sampling and analysis
  - Form & Distribution (eg particulates vs homogeneous)
  - Likelihood & Frequency
  - Carry-over guidance
  - Portion sizes
  - Protein conversion
- Communication across the supply chain
  - Global aspects
  - Information requirements to enable QRA across the supply chain
  - How do you obtain the required information
- Management of operations
  - QRA within allergen control programs
  - Guidance on QRA in site cross contact
  - Guidance on validation
- Management of incidents
  - Guidance to enable capturing the quality of available evidence
  - Guidance on whether a QRA is appropriate and possible
  - Direction on how a QRA for ‘incidents’ should be performed
  - Examples of ‘incidents’ and details of (Q)RA’s performed
- Acceptance by stakeholders
- The future

https://ilsi.eu/scientific-activities/food-safety/food-allergy/

Thank you!

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