

# Food Allergens and Their Control in 2019 – Where are We Now?

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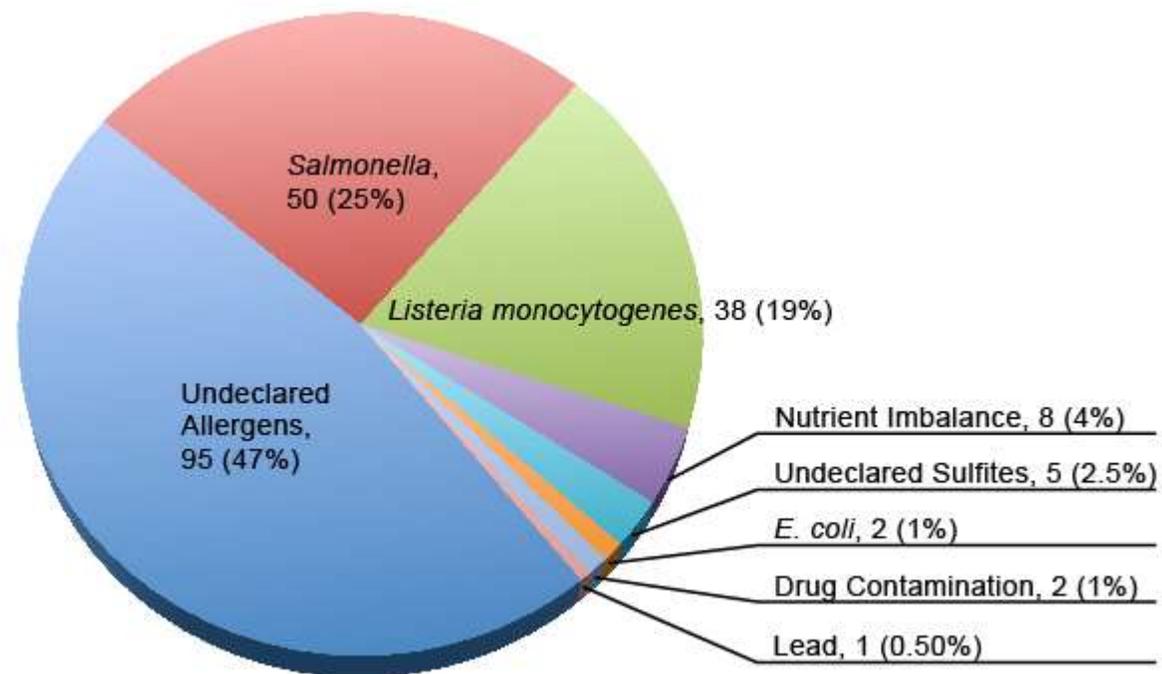
# Food Allergen Concerns

- Food allergens are an increasing food safety issue globally.
- Food allergies affect a relatively small proportion of the population, but an allergic reaction can be life threatening or fatal.
- Food allergen concerns are a common cause of reportable foods and recalls.

# Public Health Aspects of Allergens

- Affect 3-4% of the U.S. population
  - 4-8% of children
  - 1-2% of adults
- Small amounts of food allergens can cause reactions
- Symptoms include hives, swelling (lips, tongue, throat), vomiting, abdominal pain, asthma, wheezing, anaphylaxis, death

# Reportable Food Registry Year 5



# Reportable Food Registry – Undeclared Allergens

Year	Y1	Y2	Y3	Y4	Y5
Number of Reports	69	75	85	88	95
% of total reports	30.1	38.3	37.9	43.6	47.0

# Common Problems Resulting in Undeclared Allergen

- Label printing errors/label review errors
- Incorrect label/ container applied
- Formulation mix up – wrong ingredient used
- Recipe/formulation change but old label used; old labels not purged from the system
- Supplier change in formulation; change in suppliers
- Inadequate cleaning of shared equipment between products with different allergen profiles

## CGMPs & Preventive Controls Rule – 21 CFR Part 117

- Updated CGMPs include many provisions to “protect against allergen cross-contact” and “minimize the potential for allergen cross-contact.”
- Preventive controls - Include procedures, practices, and processes to control food allergens.

# Food Allergen Controls

- Food allergen controls must include those procedures, practices, and processes employed for:
  - (i) Ensuring **protection of food from allergen cross-contact**, including during storage, handling, and use; and
  - (ii) **Labeling the finished food**, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act

# Sanitation Controls

- Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as ...food allergen hazards
  - Prevention of allergen cross-contact from insanitary objects and from personnel and from raw product to processed product

21 CFR part 117

## Determining Appropriate Procedures, Practices, Processes

- FDA will have guidance on preventive controls for food allergens
- Peer-reviewed publications:
  - Deibel, K. et al. 1997. A comprehensive approach to reducing the risk of allergens in foods. *Journal of Food Protection* 60:436–441.
  - Jackson, L.S. et al. 2008. Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations *Journal of Food Protection* 71: 445-458.

# Determining Appropriate Procedures, Practices, Processes

- Existing guidance from experts, e.g.,
  - Food Allergy Research and Resource Program at the University of Nebraska (FARRP): Components of an Effective Allergen Control Plan: A FRAMEWORK FOR FOOD PROCESSORS  
(<http://www.foodallergy.org/file/food-processor-plan.pdf>)
  - Trade association publications, food safety training manuals, extension specialists, consultants

# Guidance from Codex Alimentarius - 2018

- Draft *Code of Practice on Allergen Management for Food Business Operators*
- Addresses allergen management across food chain: primary production, manufacturing, retail/food service

# Primary Production

- Manage to reduce the likelihood of allergen cross-contact/adventitious presence
  - Remove foreign allergenic material to extent possible by cleaning harvested commodities
  - Segregate commodities
  - Clean storage facilities between different commodities to minimize allergen cross-contact
  - Bags used for allergenic commodities should not be used for other commodities

# Establishment: Design and Facilities

- Design space to separate production of foods with different allergen profiles
- Dedicate equipment/processing lines/production areas or separate lines and provide barriers where possible – eliminate cross-overs and contain or shield food

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Control of Operation

- Control allergens by
  - preventing or minimizing the potential for allergen cross-contact
  - ensuring clear, correct information identifying the allergens in food
  - Ensuring that retail and food service establishments are able to communicate the allergens present in the foods they prepare

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Manufacturing Controls

- Review recipes/labels
- Ensure the correct product is packed in correct package
- Production scheduling to accommodate different allergen profiles
- Traffic flow/barriers/shielding to minimize potential for allergen cross-contact
- Dedicated containers/utensils for foods containing allergens
- Control rework
- Review suppliers to address changes that introduce an allergen into an ingredient or with potential for allergen cross-contact

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Retail/ Food Service Controls

- Manage menus (including in-store and on websites) to ensure allergen information is current
- Minimize potential for allergen cross-contact during food preparation, e.g., separate equipment/utensils
- Display foods for purchase in a manner that protects against allergen cross-contact
- Personnel handling product at display and consumer purchase and servers in restaurants should be knowledgeable about the allergens in products or how to obtain that information, especially when food is not labeled

# Establishment: Maintenance and Sanitation

- Adequately clean between foods with different allergen profiles to prevent or minimize allergen cross-contact
- Manufacturers should validate the cleaning process and verify by visual observation and, where feasible, through analytical testing

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Product Information & Consumer Awareness

- Manufacturers – food should bear adequate information to ensure other food manufacturers/processors and consumers are informed about allergens; may include precautionary allergen labeling (truthful, not misleading, not used in lieu of good hygiene practices)
- Retail and food service –
  - foods should bear adequate information to ensure customers are informed about allergens;
  - personnel that serve food should be knowledgeable about the allergens in menu items and preparation practices that may result in cross-contact
  - Signage should request customers make dietary requirements with respect to allergens known.

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Training

- All relevant personnel in a food business should receive food allergen training as appropriate to their job responsibilities
- Training should include, e.g.,
  - General allergen awareness
  - GHPs to prevent allergen cross-contact
  - Procedures for corrective actions when allergen cross-contact or labeling errors are suspected

*Codex Draft Code of Practice on Allergen Management for Food Business Operators*

# Determining Appropriate Allergen Labeling

- Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance
  - <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059116.htm>
- Codex STAN 1-1985 General Standard for the Labelling of Prepackaged Foods
  - <http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/#CODEX%20STAN%201-1985>

# Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

- Established food allergen labeling requirements for packaged foods regulated by FDA and sold in the United States (including foods packaged by a retail or foodservice establishment)
- Designated 8 “major food allergens” for labeling
- Does not apply to major food allergens that are unintentionally added to a food as the result of cross-contact.

# Food Allergens of Concern

- Milk



- Egg



- Crustacea



- Fish



- Peanut



- Soybean



- Tree nuts



- Wheat



# Advisory Labeling

- FALCPA does not address the use of advisory labeling
- FDA "Notice to Manufacturers," June 10, 1996: advisory labeling such as "may contain [allergen]" should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs).
- In addition, any advisory statement such as "may contain [allergen]" must be truthful and not misleading.

# Thresholds

- FDA draft report "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food" was published in the *Federal Register* ([70 FR 35258](#)) on June 15, 2005
- FDA Food Advisory Committee meeting July 13-15, 2005
  - Risk-assessment-based approach is strongest
  - Use in transparent manner with appropriate consideration of uncertainties when sufficient data become available
- To date there are no established thresholds

# Control of Allergens in Retail/Food Service

- FALCPA and FDA Food Code
- FDA Food Code and Allergens
- State and Local Laws and Codes



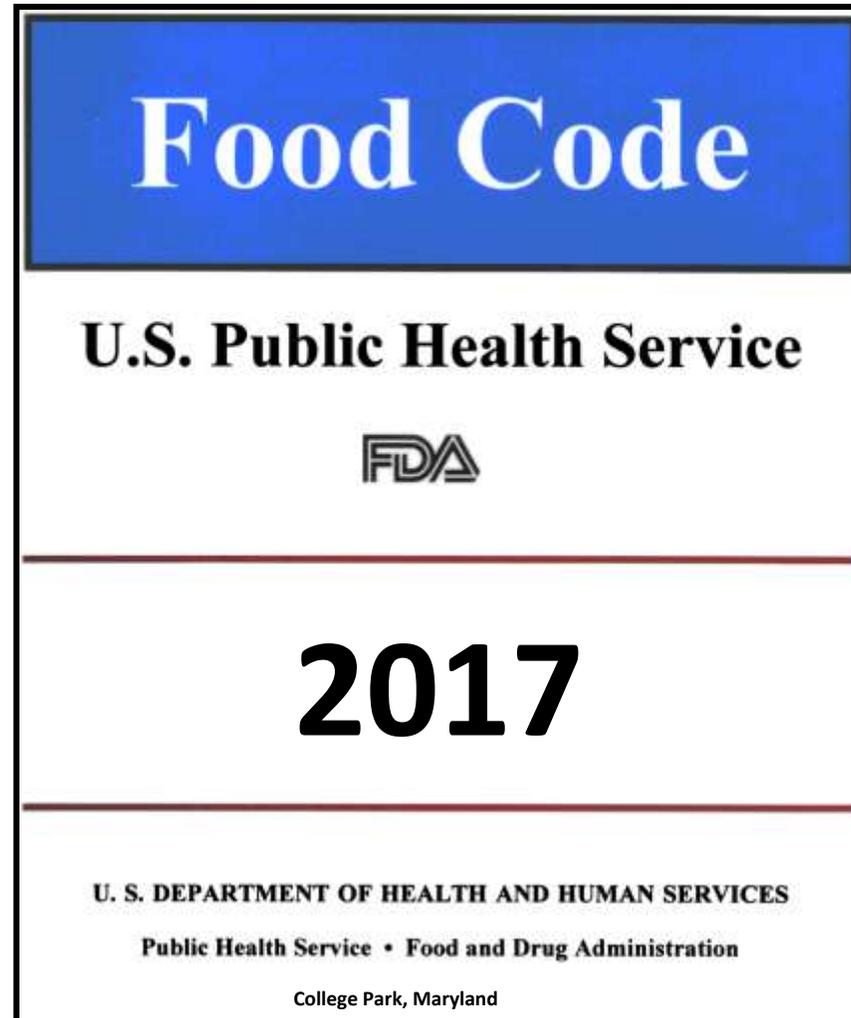
# FALCPA and Foodservice

## FALCPA Sec. 209

“...as part of its efforts to encourage cooperative activities between the States, FDA is directed to, **pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including restaurants, grocery store delis and bakeries, and elementary and secondary school cafeterias.** The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision although cross contact and disclosure at retail is not specified.”

- Model for enforceable regulations for use by food establishments where consumer takes possession of the food
- Available for adoption by local, state, and other jurisdictions; but under no obligation to adopt in full
- Almost every State Code modeled after some version of the FDA Food Code
- 4 –year cycle – 9<sup>th</sup> Edition in 2017

[www.fda.gov/foodcode](http://www.fda.gov/foodcode)





# FDA Food Code

- Encourage effective science-led prevention and uniformity of retail food establishments across US
  - Guides industry training and certification
- Reflects input of Industry, states, local agencies, academia and the public
- Primary Vetting mechanism:
  - Conference for Food Protection (CFP)
    - Biennial Meetings provide forum to recommend changes to the Food Code
    - Next Meeting April 2020 in Denver, Colorado



# FDA Food Code and Allergens

Prior to 2005, no mention of Food Allergens or their control

**Now there is a focus is on Food Allergy Awareness and Labeling of foods intended for customer self-service**

## **2005 Additions:**

- Definition of "major food allergen"
- Person in Charge must be able to demonstrate knowledge of food allergens to the Regulatory Authority
  - describe the foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual.
  - Triggered inclusion of Food Allergen Awareness component into what is required in nationally accredited food protection manager certification programs



# FDA Food Code and Allergens

## 2005 Addition

- Allergen labeling requirements in FALCPA applies to foods “packaged at retail”
  - Food that the establishment packages for customer self-service;
  - FALCPA, like Nutritional Labeling laws, were preemptive anyway but this provides continuity as enforcement vehicle for States and locals
- General information on food allergens and FALCPA added to Annex 4 – *Management of Food Safety Practices*

## 2009 Addition

- Duties of the Person in Charge now include that he/she ensures that “employees are properly trained in food safety, **including food allergy awareness**, as it relates to their duties”

## 2013 Addition

- Mandatory cleaning of surfaces between different animal proteins.

# State & Local Laws and Codes

- Some go beyond the Food Code, but not many
  - Allergen awareness posters in staff areas
  - Posted notifications to customers to alert manager or server of food allergies
  - More specifics about training of managers and/or employees
- Latest data from 2016 showed 36 states had adopted Food Code language in whole, or in part, on allergens



# Pathways Forward

- Encourage research that industry and public health community can use
- Recognize and incentivize industry best practice
- Develop and promote education and training materials that satisfy current requirements
  - Based on best available science
- Potential modifications to FDA Food Code
- Keeping eye on progress made in other sectors

# May is Food Allergy Awareness Month

- CDC and its EHS-Net program partners are sharing some food allergen resources during May:
  - **See CDC EHS-Net Studies on Food Allergies and Restaurants**
    - [How Restaurants Address Food Allergies](#)
    - [Food Allergies: Knowledge and Attitudes of Restaurant Managers and Staff](#)
- FDA collaborates with CDC in the EHS-Net project
- State initiatives

# Summary



- The CGMP & PC requirements in 21 CFR part 117 require firms to address food allergens.
- Implementing these requirements is expected to reduce recalls and to enhance protection of public health.
- Guidance will be forthcoming, but managing food allergens in processing facilities is not a new concept and many resources are available
- The FDA Food Code has provisions addressing food allergen awareness and training of retail food establishment managers and food employees
- There are still states where regulatory language needs to reflect food allergens and their control for the retail level, but educational efforts continue.



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