B2 Allergens

Definition: An overview of food allergens, including labeling requirements, preventive controls, and societal impact.

Topic Area TLO: Discuss the control of allergens in relation to food safety.

Topic Area ELOs:

- Explain the risks of allergen exposure.
- Identify major food allergens.
- Describe potential routes of allergen cross-contact.
- Use agency resources to evaluate allergen controls.
- Explain allergen labeling requirements.

Unit 1: Foundations

Definition: Food allergens related to food programs.

TLO: Discuss foundational information related to major food allergens.

ELOs:

- Define relevant terminology.
- Differentiate food allergy from food intolerance.
- Discuss the prevalence of food allergy in the United States.
- Identify major food allergens as recognized by FDA and USDA.
- Give examples of foods deemed major allergens in non-U.S. countries.
- Discuss the public health significance of food allergens.
- Describe the symptoms of an allergic reaction.
- Describe the treatment of an allergic reaction.

TLO Behavioral Anchors - not all-inclusive

- The regulator has a knowledge or awareness of the existence of allergens.
- The regulator can define what an allergen is.
- The regulator has a knowledge or awareness of regulations tied to allergens.
- The regulator has a knowledge or awareness that allergens have the potential to cause a health hazard.
- The regulator can give examples of some of the major allergens:
 - a. List the major food allergens
 - b. 8 common allergens
- The regulator has a knowledge or awareness of regulations related to allergens:
 - a. Name the regulation
 - b. Undeclared allergens
 - Recalls
 - c. Animal feed is exempt
 - d. Labeling requirements
- The regulator can discuss the importance of regulating allergens.
- The regulator has a knowledge or awareness of routes of exposure for allergens:
 - a. Hygiene hypothesis

•	Discuss allergens i	n
	relation to recalls.	

Unit 2: Labeling Requirements

Definition: Food labeling requirements pertaining to major food allergens.

TLO: Discuss allergen labeling requirements.

ELOs:

- Discuss the purpose of the Food Allergen Labeling and Consumer Protection Act (FALCPA).
- Give examples of allergen labeling options under FALCPA.
- Give examples of scientific terms vs. plain language.
- Give examples of allergen labeling for tree nuts, fish, and crustacean shellfish.
- Discuss the placement of allergen provisions on food labels.
- Discuss the use of allergen advisory ("may contain") statements.

TLO Behavioral Anchors - not all-inclusive

- The regulator has knowledge or awareness that allergens must be declared on the label.
- The regulator has a knowledge or awareness of which allergens must be declared on the label:
 - a. Big 8 (USA)
- The regulator has a knowledge or awareness of different allergen labeling options.

Unit 3: FSMA

Definition: The provisions of FSMA specifically related to major allergens.

TLO: Discuss the allergen provisions of the Food Safety Modernization Act (FSMA).

ELOs:

TLO Behavioral Anchors - not all-inclusive

The regulator has a knowledge or awareness that because of FSMA, allergens are considered health hazards.

- Discuss "adulterant" in relation to allergens under FSMA.
- Discuss "hazard" in relation to allergens under FSMA.
- Define "food allergen cross-contact".

Unit 4: Control Measures

Definition: Measures by industry to prevent allergen cross-contamination.

TLO: Discuss control measures to prevent allergen crosscontact.

ELOs:

- Define "allergen threshold".
- Define "dedicated" in relation to allergen crosscontact.
- Discuss cleaning methods to remove allergen residues.
- Discuss the role of product changeover in relation to allergen crosscontact.
- Discuss the scheduling of processing runs in relation to allergen cross-contact.

TLO Behavioral Anchors - not all-inclusive

- The regulator has a knowledge or awareness of various control measures.
- The regulator has a knowledge or awareness of control measures utilized to prevent cross-contact.
- The regulator can name several control measures:
 - a. Cleaning
 - b. Sanitizing
 - c. Physical separation
 - d. Dedicated equipment
 - e. Labeling
 - f. Colored coding
 - g. Dedicated facility
 - h. Gloves
 - i. Air flow controls
 - j. Training
- The regulator can explain how control measures prevent cross-contact.
- The regulator can recognize when control measures are not properly implemented.