B17 Laws, Regulations, Policies, & Procedures

Definition: Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

Topic Area TLO: Employ legal authorities when conducting regulatory activities.

Topic Area ELOs:
- Discuss legal authorities.
- Differentiate among law, regulations, and ordinances.
- Explain legal authorities to conduct activities.
- Describe administrative protocols.
- Apply authorities to determine compliance.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive

Definition: Base knowledge of laws, regulations, policies and procedures related to feed and food programs.
 	
TLO: Differentiate between laws, regulations, policies, and procedures applicable to regulatory activities.
 	
ELOs:
• Define relevant terminology.
• Explain the significance of key laws.
• Describe the relationship between laws and regulations.
• Describe how administrative protocols support laws and regulations.
• Describe how model codes can be adopted.
	• The regulator can define key terms:
	  a. Laws (acts, statutes, and ordinances), regulations, policies, procedures and authority
	• The regulator can provide an example of each key term.
	• The regulator can identify laws, regulations, policies, and procedures applicable to your agency.
	• The regulator can list the laws, regulations, policies, and procedures pertinent to your position.
	• The regulator can describe how each is developed:
	  a. Authority versus agency requirements (example: Congress gives FDA authority in FD&C Act, FDA promulgates regulations to carry out the law)
	  b. Have awareness of the difference between a law and regulation
	• The regulator can describe the relationship of policies and procedures to laws and regulations.
	  a. Support of regulatory activities (example: relationship of sampling to the law, regulation, policy and procedure)
	  b. Describe when to refer to each one
	  c. Identify regulatory actions your agency may take for non-compliant firms

Unit 2: Constitution	TLO Behavioral Anchors - not all-inclusive
Definition: The system of	

fundamental principles according to which Federal, State and local agencies are governed.
 	
TLO: Describe how constitutional law grants and limits authorities.
 	
   ELOs: - Describe how the federal constitution grants and limits agency powers.   - Describe how state constitutions grant and limit agency powers.   - Explain the difference between State and Federal rights and limits.   - Explain due process.   - Explain individual rights guaranteed by the constitution.   - Describe the separation of powers between the executive, legislative, and judicial branches of government.
	- The regulator has a basic knowledge or awareness of the constitution:
	  a. Define Constitutional law
	  b. Constitution establishes fundamental principles of all laws
	  c. 3 branches of the federal government
	  d. Commerce clause (interstate commerce)
	    ▪ Grants authority and accountability - The regulator has a knowledge or awareness of rights of the individual protected under the Constitution:
	  a. Interpretation of rights example: FD&C Act requires payment for some samples because of the Constitution, other agencies may not
	  b. Food Law and regulations may require owner giving up rights
	  c. Seizures, embargoes, stop sales, inspections - The regulator has a knowledge or awareness of the Federal constitution versus state constitution. - The regulator has a knowledge or awareness of the delegation of authority.

Unit 3: Law	**TLO Behavioral Anchors - not all-inclusive**

Definition: The foundational knowledge of the process by which laws are created and how authority is delegated.
 	
TLO: Discuss how laws determine regulatory authority.
 	
   ELOs: - Describe legislative processes.   - Explain how local
	- The regulator can define regulatory authority. - The regulator can define a law, act/statute:
	  a. Include enforcement authority
	  b. Authority to write regulations - The regulator has a knowledge or awareness of Laws establish and limit regulatory authority:
	  a. Agencies are not able to exceed regulatory authority - The regulator has a knowledge or awareness of which laws provide the authority to do the regulator's job. - The regulator can find where in the law your authority is

ordinances differ from state and federal statutes. • Explain delegation of authority. • Differentiate between statutory and case law. • Explain how law authorizes enforcement actions.	derived from: a. Delegation of authority
Unit 4: Regulation	**TLO Behavioral Anchors - not all-inclusive**

Definition: An administrative act or rule, based on law, prescribed by agency authority.
 	
TLO: Explain how regulations assist agencies to implement laws.
 	
    ELOs:
    • Identify pertinent regulations that are applicable to regulatory programs.
    • Explain the general process by which regulations are developed.
    • Describe the FDA cooperative program model regulations.
    • Describe how regulations are published.
	• The regulator can explain the relationship between a law and regulation:
	    a. What is the difference between a regulation and a law
	    b. Regulations provide information about the implementation of laws
	    c. Laws prevail over regulations
	    d. Regulations are based on the law
	• The regulator has a knowledge or awareness that your agency implements regulations.
	• The regulator can list regulations your agency implements.
	• The regulator can clarify enforcement authority:
	    a. Discretion
	• The regulator can list the information that regulations may provide about implementation of the law:
	    a. Standards
	    b. Who/what is regulated
	    c. Required procedures
	    d. Point of reference
	    e. Minimum requirements
	    f. Clarity
	    g. Required process

Unit 5: Policy	**TLO Behavioral Anchors - not all-inclusive**
Definition: Set of principles formulated or adopted by an agency to influence and determine actions. **TLO:** Describe the purpose of	• The regulator can define a policy. • The regulator can give examples of policies. • The regulator can provide the basis for consistent implementation or application of the law. • The regulator can outline legal requirements in plain

agency policies.
 	
ELOs:
- Describe how policies are developed.
- Differentiate between regulatory and administrative policies.
- Give examples of when a regulatory policy is applicable.
- Give examples of when an administrative policy is applicable.
- Discuss the relationship between policy and procedures.
	language.
	- The regulator can link policies to specific laws and regulations.
	- The regulator can give examples of what agency policies accomplish:
	   a. Provide agency positions/strategy
	   b. Correct an issue
	   c. Address a need
	   d. Emerging technology
	   e. To provide a scientific basis
	- Provide additional information about laws and regulations

Unit 6: Procedures	**TLO Behavioral Anchors - not all-inclusive**

Definition: Providing a standard method for conducting activities.
 	
TLO: Explain the purpose of procedures used in federal, state, and local regulatory programs.
 	
ELOs:
- Describe the process of procedure development.
- Describe the process of procedure implementation.
- Explain the importance of following procedures.
- Explain how procedures are used to obtain compliance.
	- The regulator can define a procedure:
	   a. Series of steps to be followed
	   b. Provides the instruction and/or paperwork to carry out an activity
	   c. Describe how policies will be put into action
	   d. Determines who will do what
	   e. Step by step instructions/guidance
	   f. More detailed than policy
	   g. Identify specific forms or documents
	- The regulator can give examples of procedures used in their agency.
	- The regulator can describe how procedures benefit the agency:
	   a. Improve time efficiency
	   b. Improves sharing of information
	   c. Efficient use of resources

• Give examples of when to use applicable procedures.	

Unit 7: Guidance	**TLO Behavioral Anchors - not all-inclusive**
	
	• The regulator can define what is a guidance document is:
	    a. Interpretation of regulation
	    b. Recommendations, not law or legally binding
	    c. Recommendations or instructions on how to meet agency expectations
	    d. Guidelines to assist in carrying out regulatory requirements
	    e. Regulatory authorities current thinking on a subject or method
	    f. Not mandatory
	    g. Can be used by industry and regulators
	• The regulator can give an example of guidance documents.
	• The regulator can recognize how their agency uses guidance documents.
	• The regulator can describe the relationship of a guidance document to a regulation.
	• The regulator can describe what guidance documents accomplish:
	    a. Support a consistent application of laws, regulations, policies and procedures
	    b. Provide additional clarity for vague or gray areas within the regulations
	    c. Provides historical and scientific background to regulation and policy
	    d. Standardize response to a defined situation
	    e. Explain a complex subject or procedure
	    f. Clarify laws, regulations, policy and procedures, etc.
	    g. Guidance documents often point to additional resources
	    h. Help implement best practices
	    i. Additional information to support and/or complete an activity
	    j. Provide information that can be used to attain and remain in compliance