RECENTLY ISSUED PREVENTIVE CONTROLS FOR ANIMAL FOOD RULE DRAFT GUIDANCE FOR INDUSTRY

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Draft Guidance Development Process

- Identified the audience:
  - Animal food facility management and front-line personnel (GFI #235)
  - Human food facilities with by-products for animal food use (GFI #239)
  - Federal and State investigators (Secondary audience)
- Identified the purpose:
  - Serve as a “go to” document for facilities
    - Provide necessary background information for successful implementation of the requirements
    - Clearly explain all of the codified requirements and include additional explanation and examples

Draft Guidance Development Process

- Identified information to be included for each guidance:
  - Important background information to understand and comply with the requirements
  - The regulatory requirements
  - Relevant definitions
  - Explanation and examples for information gaps identified from data from FDA's technical assistance network (TAN) and feed back from outreach activities.

Draft Guidance Development Process

- Identified a consistent format to discuss requirements:
  1. State the regulatory requirement with the citation
  2. Use relevant preamble language to explain the requirement
  3. Add additional explanation or examples for:
     - Provisions that indicate flexibility in the regulatory text
     - Areas requiring more explanation based on the TAN questions received to date

DRAFT GUIDANCE FOR INDUSTRY #235: CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS FOR FOOD FOR ANIMALS

Current Good Manufacturing Practice Requirements (CGMPs)

- Baseline requirements intended to protect animal food from contamination
- Proper implementation will help a facility produce safe animal food
- Need to be flexible to address variety of animal food facilities
- Can support implementation of preventive controls

General Considerations

- Describe how CGMPs provide baseline safety and sanitation standards for manufacturing, processing, packing, and holding animal food.
- Discuss the flexibility in the CGMP requirements to address:
  - the diversity of facilities
  - the wide range of animal food activities
  - the potential safety risks of different animal foods
- Explain how CGMPs relate to the definition of "adulteration" in the Federal Food, Drug, and Cosmetic Act

Applicability

- Who must follow the CGMP requirements
- Who is not subject to the CGMP requirements because:
  - They are not required to register as a food facility, or
  - They are exempted from following the CGMPs by 507.5(h).
- How the CGMPs apply to:
  - Facilities that manufacture, process, pack, or hold human and animal food
  - Facilities also covered by other CGMPs
    - Medicated feed CGMPs (part 225)
    - Low acid canned food (part 113)

Training and Qualifications

- All facilities that must comply with the CGMPs must also comply with the training and qualification requirements of the PCAF rule.
  - Personnel must be qualified to perform their assigned duties.
  - Personnel must receive training in principles of animal food hygiene and animal food safety
    - Related recordkeeping requirements

CGMP Requirements

- Organized by topics.
  - Personnel
  - Plant and grounds
  - Sanitation
  - Water supply and plumbing
  - Equipment and utensils
  - Plant operations
  - Holding and distribution
  - Holding and distribution of human food by-products for use as animal food.

Compliance Dates & Definitions

- Compliance dates for CGMP requirements
- Definitions for small business and very small business
- Appendix with other definitions from the regulation relevant to:
  - Applicability (e.g., farms)
  - CGMP requirements (e.g., undesirable microorganism).

DRAFT GUIDANCE FOR INDUSTRY #239: HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD



General Information

- Explanation and examples of human food by-products for use as animal food
- Discussion of the regulatory status of animal food ingredients
  - Generally Recognized as Safe (GRAS)
  - Food Additive
  - Status of AAFCO definitions
- How to distinguish human food by-products that are not intended for use as animal food

Applicability

- Human food facilities not subject to 21 CFR 507
  - Facilities that are exempt from registration, such as grocery stores and USDA FSIS facilities
  - Other FD&C Act provisions may apply (e.g., adulteration)
- Human food facilities that can follow the limited holding and distribution CGMPs in 21 CFR 507.28/117.95
  - Must meet the conditions in 21 CFR 507.12
- Human food facilities that must follow 21 CFR 507
  - For example because they further manufacture/process the human food by-products for use as animal food

Human Food Facilities that Meet 21 CFR 507.12

- Describes the requirements to meet 507.12
  - Subject to and in compliance with FDA human food safety requirements (in particular, CGMPs)
  - Not further manufacturing/processing
- If these requirements are met, only have to follow the limited holding and distribution requirements in 507.28/117.95
  - (a) Holding
  - (b) Labeling
  - (c) Shipping Containers & Bulk Vehicles

Human Food Facilities Subject to Full Requirements of 21 CFR 507

- Describes the flexibility in 21 CFR 507.1(d) for facilities subject to both parts 117 and 507
- Explains how human food and animal food exemptions are not necessarily the same
  - Ex. Seafood processor exempt from preventive controls for human food, but not exempt for animal food
- Explains expectations for food safety plan for animal food
  - May include in human food safety plan, or may create separate food safety plan
  - Food safety plan should address animal food after it has been separated from human food.
  - Food safety plan must address animal food hazards

Diversion to Animal Food Use Due to Food Safety Concern

- Describes current thinking for handling human food that is rejected because of a human food safety concern, but may be acceptable for animal food use
  - Recommended criteria for evaluation
  - Human food safety concern that is not an animal food safety concern
  - Rework or reprocessing to eliminate the food safety concern
  - Diversion request through district office

Compliance Dates and Definitions

- Explains compliance dates and related definitions
  - Small business
  - Very small business
- Appendix with definitions from the regulation that are relevant to the requirements for human food by-products for use as animal food

Commenting on Draft Guidances

- Can comment on guidances at any time, the docket stays open.
- Comments should be submitted by November 23, 2016 for consideration in finalizing these guidances

Questions

- Use the Technical Assistance Network for specific questions about the requirements http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm