Inter-Agency Overlap and Jurisdictional Boundaries

FDLI Food Advertising, Labeling, and Litigation Conference
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FDA Approach/Perspective

- FDA has the authority to regulate "food":
  - (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article

- "Food" includes substances that are also, at least in part, regulated by other agencies, including USDA (namely FSIS), EPA, and FTC

- Lead agency is often dictated by MOU between agencies
- Largely dependent on resources, priorities, authorities, etc.

FDA Approach/Perspective

- Key FDA Offices when Overlap
  - CFSAN – OFAS: food additive and GRAS petitions
  - CFSAN – OFS: pesticide residue monitoring
  - CFSAN – Center Director: mercury in seafood
  - CFSAN – ONFL: advertising/labeling
  - CVM – Division of Animal Feed: food additive and GRAS petitions

** also HHS at Secretarial level

FDA Approach/Perspective

- USDA/FDA – Notable MOUs
  - MOU for procedures when responding to food additive petitions, GRAS notifications, and color additive petitions subject to FDA regulation and intended for use in the production of FSIS-regulated meat, poultry, and egg products (updated 2015)
  - MOU to allow exchange of information between participating agencies of the USDA and FDA related to food safety, public health, and associated regulatory, marketing, trade, and research activities substantially affecting the public health (2012 - indefinite)
  - MOU to facilitate an exchange of information between FDA and FSIS about establishments and operations that are subject to the jurisdiction of both agencies (1999-indefinite)

FDA Approach/Perspective

- USDA/EPA
  - MOU to share non-public information related to the three agencies' respective programs regulating genetically-engineered plants and foods derived from genetically-engineered plants (2011-2021)
  - MOU to improve and sustain federal coordination and collaboration on issues related to pharmaceuticals in drinking water (2012-2017)

- EPA
  - MOU re: regulation of pesticides (1971-indefinite)
    - sharing of food pesticide-related data (2014-indefinite)
  - MOU for regulation of additives to and substances in drinking water

Example: FDA-EPA Fish Consumption Advice

Jointly Issued

- FDA: focus on food safety and nutrition
- EPA: focus on risks from the environment
- Agreement that agencies would have consistent message to help prevent consumer confusion
- Joint advice first in 2001, following two versions of FDA-only advice

Presented by:

Brian Ronholm, Senior Director of Regulatory Policy at Arent Fox LLP

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USDA Food Safety and Inspection Service (FSIS)

- Labeling of FSIS-Regulated Products

Introduction to FSIS

- USDA-FSIS assures that meat and poultry products in interstate or foreign commerce are wholesome, not adulterated, and properly marked, labeled and packaged.
- FSIS is responsible for the development and application of labeling requirements applicable to meat, poultry, and catfish products.
- FSIS develops labeling policy by which it is determined whether a meat or poultry product is misbranded or adulterated.
- This policy within FSIS is administered by the Labeling and Program Delivery Staff (LPDS) within the Office of Policy and Program Development (OPPD).

FSIS-FDA Jurisdiction Determination

- FSIS regulates products containing:

Cooked meat or poultry meat

Raw meat or poultry meat

- FDA regulates “meat flavored” sauces and soups with less than 2 percent meat or poultry meat.

Prior Label Approval

- Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) require food manufacturers to obtain prior approval for labels of meat and poultry products before products can be marketed.
- Prior approval is granted one of two ways:
  - Sketch approval which is approved by the labeling staff.
  - Generic approval which is approved by being in compliance with applicable regulations.

Sketch Approval

- Company submits a printer's proof showing all labeling material, including graphics.
- Must clearly reflect and project the final version of the label.
- Sketch labels are reviewed by labeling staff and either "approved" or "approved as modified."

Generic Approvals

- The approval of labeling or modifications prior approved by FSIS without submitting such labeling for sketch approval.
- Standardized products without special claims, guarantees, or foreign language.
- Single ingredient products without special claims, guarantees, or foreign language.
- Products with contract specification for Federal Government agencies.

Four Categories of Labels Require Review

- Only these four categories of labeling require submission for evaluation by FSIS labeling staff:
  1) Labels for temporary approval.
  2) Labels for products under religious exemption.
  3) Labels for products for export with labeling deviations.
  4) Labels with special statements and claims.

- All other labels that do not fit into one of these categories do not require sketch approval by FSIS labeling staff.

Required Information on a Label

- Up to 8 required features:
  - Product name
  - Inspection legend and Establishment number
  - Handling statement
  - Net weight statement
  - Ingredients statement
  - Address line
  - Nutrition facts
  - Safe handling instructions

Misbranding

- A food is considered misbranded if:
  - Its labeling is false or misleading in any particular way.
  - It is offered for sale under the name of another food
  - It is an imitation of another food without proper labeling.

Product Standards of Identity

- As part of its labeling duties, FSIS promotes and enforces products standards of identity.
- Examples:
  - Ham, ham with natural juices, ham with water added.
  - Hot dogs: maximum 40 percent fat and water.
  - Ground beef: may contain no more than 30 percent fat.
  - Veal cutlet: single slice of veal from the round.

Examples of Special Statements and Claims

- No antibiotics administered or grass fed.
- Gluten free
- Health claims, such as Heart Smart
- Instructional statements, such as For Cooking Only
- All Natural or 100% Natural
- Statements identifying the product as organic
- Claims of the use of non-genetically engineered ingredients

**Small sample list. A complete list that is updated periodically is available on the FSIS website.*

Examples of Generic Approvals Permitted

- “Contains (name of ingredient)” statements
- AMS Grading – Prime, Choice, Grade A
- Flavor profiles – only white/dark meat, made with real cheese
- Environmental claims

**More detailed information available on the FSIS website.*

GROUND BEEF

Ingredients: Beef, salt, pepper, garlic powder

Keep Frozen

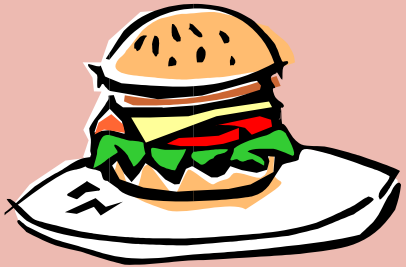
Nutrition Facts

Serving Size: 4 oz. (112g)
Servings Per Container: 4

Amount Per Serving	
Calories 170	Cal. from Fat 70
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 3.5g	**18%**
Trans Fat 0.5g	
Cholesterol 70mg	**23%**
Sodium 75mg	**3%**
Total Carbohydrate 0g	**0%**
Protein 23g	
Iron 15%	

Not a significant source of dietary fiber, sugars, vitamin A, vitamin C and calcium.

*Percent Daily Values are based on a 2,000 calorie diet.



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Frederick, MD 21701

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EST. 38

Net Wt. 16 oz. (1 lb.)

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

Keep refrigerated or frozen.
Thaw in refrigerator or microwave.

Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.

Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

Resources

- The FSIS Food Standards and Labeling Policy Book is available on the FSIS website at https://www.fsis.usda.gov.
- Provides additional guidance regarding FSIS standards outside of the regulations.
- Composite of policy and day-to-day labeling decisions.

Food Advertising, Labeling, and Litigation Conference:

For the Food and Dietary Supplement Industries

Keith Matthews

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EPA and FDA Share Dual Regulation of Food Use Antimicrobial Substances

Food use antimicrobials, depending on intended use and use site, are regulated by EPA under FIFRA and the FFDCA, and by FDA under the FFDCA

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EPA and FDA Share Dual Regulation of Food Use Antimicrobial Substances

- FIFRA – The Federal Insecticide, Fungicide, and Rodenticide Act requires that all pesticide products be registered by EPA
- FFDCA – the Federal Food, Drug, and Cosmetic Act mandates regulation of food additives, and pesticide chemical residues on food

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EPA and FDA Share Dual Regulation of Food Use Antimicrobial Substances

- FDA – Non-pesticide food additives
- EPA – Pesticide chemical residues
- EPA/FDA – Pesticide chemical food additives ~ regulatory jurisdiction depends upon occurrence

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EPA and FDA Share Dual Regulation of Food Use Antimicrobial Substances

FDA defines “food additive” as a substance the intended use of which “results or may reasonably be expected to result, directly or indirectly, either in it becoming a component of food or otherwise affecting the characteristics of food.”

21 C.F.R. 170.3(e)(1)

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EPA and FDA Share Dual Regulation of Food Use Antimicrobial Substances

- EPA regulates pesticides under FIFRA – the Federal Insecticide, Fungicide, and Rodenticide Act

  7 U.S.C. 136-136y.

- Substances intended for sale or distribution as pesticides must be approved ("registered") by EPA prior to any distribution in commerce

- As part of the registration process, EPA considers potential impacts of pesticide residues

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EPA Regulatory Authority re Pesticide Residues in Foods

Section 408 of the FFDCA:

"any pesticide chemical residue in or on food shall be deemed unsafe" unless a tolerance or tolerance exemption is in place.

21 U.S.C. 346a(a)

Standard for a tolerance or tolerance exemption:

"a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

21 U.S.C. 346a(b)(2)(A)(ii)

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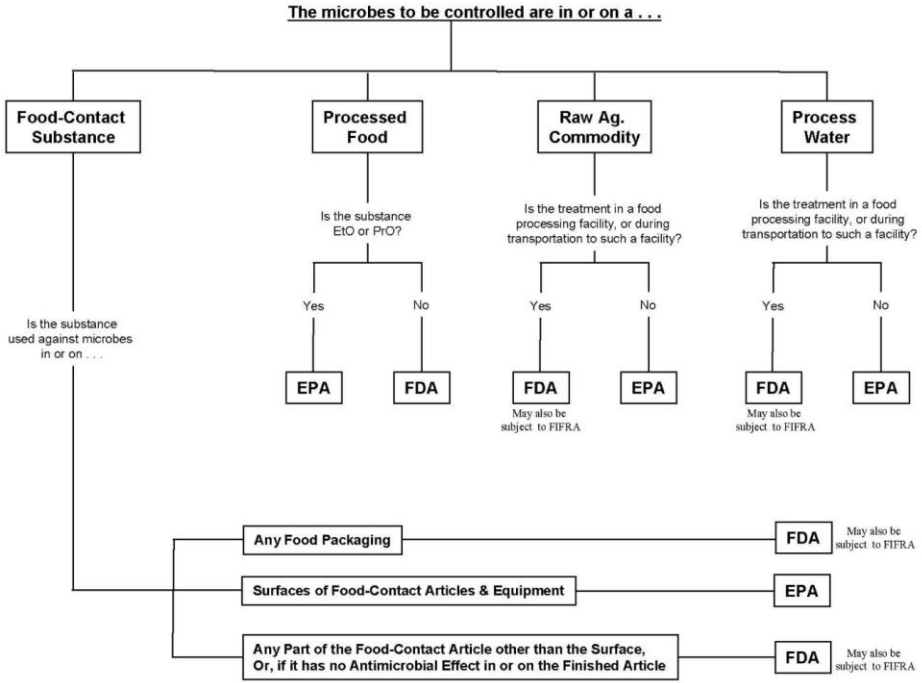
U.S. Food and Drug Administration
Protecting and Promoting Public Health

EPA/FDA Jurisdiction



*A more detailed chart is available at:
http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm

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EPA – FDA Jurisdiction

EPA:

- Raw agricultural commodities
- Surfaces where indirect pesticide exposure may occur
- Direct food contact not in a food processing facility;
- Use of ethylene oxide or propylene oxide on either RACs or processed food anywhere
- Process water not in a food processing facility

FDA

- RACs in a food processing facility
- RACs being transported to a food processing facility
- Food packaging
- Process water in or en route to a food processing facilty

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Questions?

Comments?

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