Basic Labeling Requirements for Food Products Entering Commerce

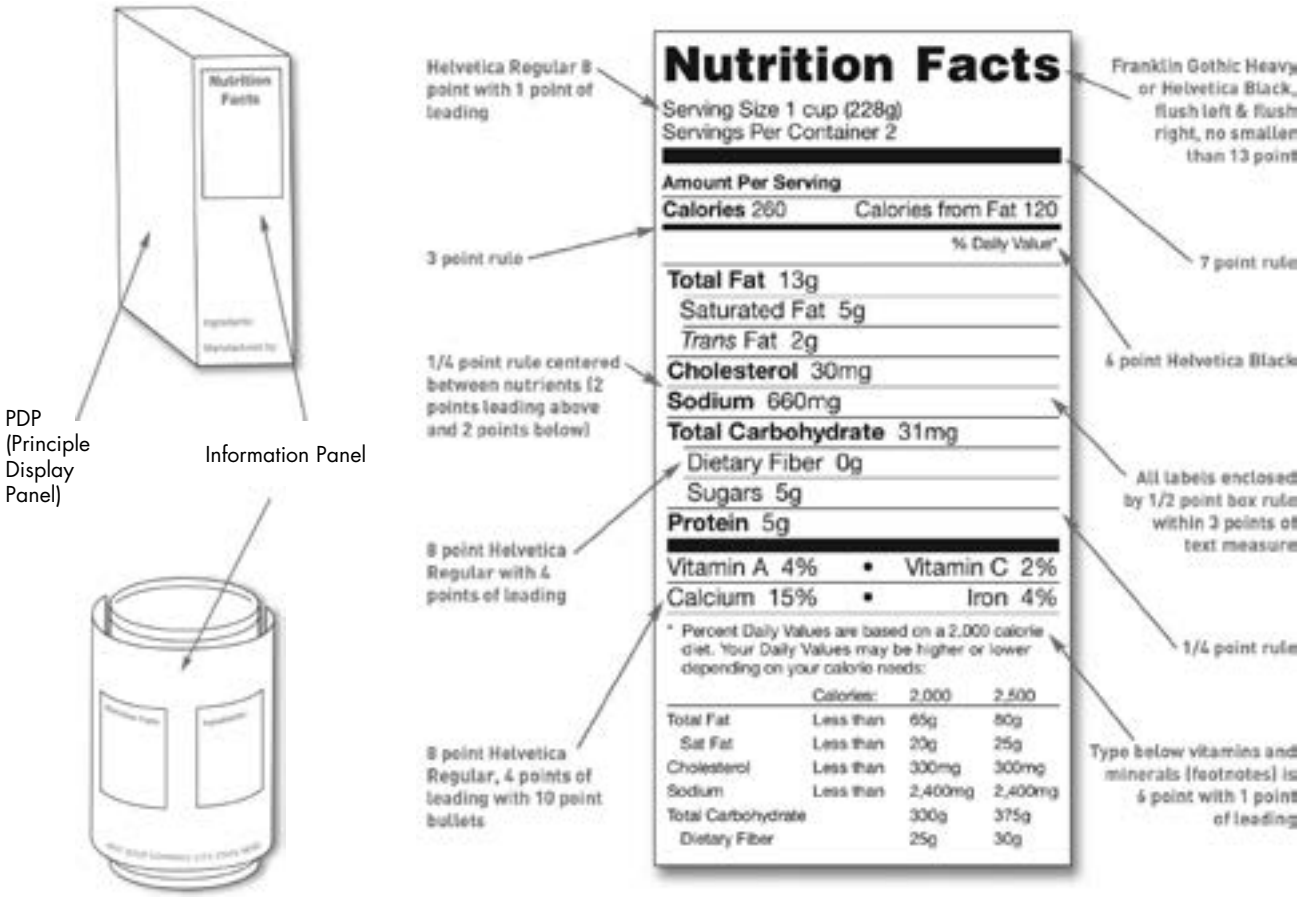
MISSISSIPPI STATE UNIVERSITY EXTENSION

A food label is often a consumer's closest contact to a food manufacturer and only source of knowledge of the product. A label offers assurance of what the product is and some information of how it was produced. Just as a company is represented by the name, it is also represented by the label on its product. Whether FDA or USDA regulates a product, the fundamentals are similar.

Regulation and labeling of food products are handled through two organizations, the United States Department of Agriculture Food Safety Inspection Service (USDA FSIS) and the Food and Drug Administration (FDA). In general, USDA FSIS regulates most meat, poultry, and processed eggs (broken whole eggs, egg whites, egg yolks, dried, etc.), while FDA handles all other food products.

Food labels may have two formats: a principal display panel (PDP) only or a principal display panel and an information panel. If an information panel is used, it is placed to the right of the PDP. See the examples below and on the next page. Nutrition panel examples of various formats with specifics of formatting are also included in this publication. Nutritional information is a required feature on all products unless exempt from the requirement as outlined in Title 21 of the Code of Federal Regulations (21 CFR 101.9 j).

All required labeling must be clearly legible and easily seen. Intervening material that is not required by regulation must not be placed between required labeling features. The name of a product must be in compliance with any standards of identity or common names associated with the product and must be prominent on the label. If the product is not included in either of these standards, then the name must adequately describe and represent the product. Text size must be at least one-sixteenth of an inch, based on the height of the lowercase "o." For specific text size



requirements, see Title 21 of the Code of Federal Regulations (21 CFR 101). If a label includes a foreign language, all required statements must be given in both English and the foreign language. Artwork must accurately depict the product inside the packaging and may not detract from the required label features.

Ingredients are listed in order by weight with the ingredient that weighs the most listed first, followed by the next in descending order, and so forth. The common or usual name of the ingredient must be used unless there is another term given by regulation. If an approved chemical preservative is used in a product, it must be listed in the ingredient statement and followed by the purpose of the preservative such as "mold inhibitor," "to help protect flavor," or similar. Spices added to a product may be declared as "spices," "flavor" or "natural flavor," or "artificial flavor." If an ingredient used in a product includes other ingredients, the sub-ingredients must be listed in parentheses behind the ingredient used in the product, or the sub-ingredients may be listed in order of descending predominance without the name of the ingredient used in the product. An allergen statement must be included if any of the eight major allergens are included in the product ingredients. More information on allergens is presented below.

The net quantity statement must be given in both metric and U.S. Customary System terms. The size of the statement depends on the size of the principal display panel. The quantity stated is the quantity of only the food (not including the packaging), so it should be given in net weight or net volume depending on the type of product.

The name of the manufacturer, packer, or distributor must be clearly defined. If the actual manufacturer is not applicable to the product, a statement such as "manufactured for" or "distributed by" must be used. The street address must be given if the name and address of the business is not listed in a current city directory or phone book. The city, state, and zip code must be included (21 CFR 101.5).

Labeling FDA-Regulated Products

FDA does not require preapproval of food labels. Product labels are monitored through post-marketing checks. A manufacturer, competitor, or customer may request a label review by FDA. In general, FDA regulates all foods other than those containing a significant portion

Nutrition Facts

Serving Size 1 Cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	with 1/2 cup Skim milk
Calories	130	170
Calories from Fat	0	0
	% Daily Value**	
Total Fat 0g*	**0%**	**0%**
Saturated Fat 0g	**0%**	**0%**
Trans Fat 0g		
Cholesterol 0mg	**0%**	**0%**
Sodium 200mg	**8%**	**11%**
Total Carbohydrate 30g	**10%**	**12%**
Dietary Fiber 4g	**16%**	**16%**
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%

* Amount in cereal. One half cup skim milk contributes an additional 40 calories, 65mg sodium, 6g total carbohydrate (6g sugars), and 4g protein.
**Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 12

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Nutrition Facts

Serving Size 1 Tbsp (14 g)
Servings Per Container 64

Amount Per Serving

Calories 130	Calories from Fat 130
	% Daily Value*
Total Fat 14g	**22%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

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

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

of meat or poultry or 100 percent processed egg products. FDA also has authority over exotic species of livestock and poultry, such as deer, elk, and pheasant. The following outlines products that qualify for FDA regulation:

- 3 percent or less raw meat or less than 2 percent cooked meat
- Less than 2 percent cooked poultry [9 C.F.R. § 381.15(a)(1) (poultry)]
- All other food products other than processed eggs
- Seek clarification from FSIS to determine exact legal responsibility.

There are six requirements for an FDA-labeled product:

1. Product name
2. Ingredient list*
3. Allergen labeling* (if applicable)
4. Net quantity
5. Manufacturer name and address*
6. Nutrition labeling*

Items denoted by an asterisk (*) may be placed on the information panel. If there is not a separate information panel, then all information must be displayed on the principle display panel. Products that consumers expect to contain juice must contain a "percent juice" declaration near the top of the information panel.

Labeling USDA FSIS-Regulated Products

FSIS mandates the preapproval of all labels before the product enters the market. FSIS receives approximately 130,000 labels for review and approval annually. There are a few specific circumstances when a preapproved label may be modified and the resulting new label not be resubmitted for approval. Many minor modifications and single-ingredient product labels can be approved by local inspectors and/or through the new generic approval process. However, any type of claim made on the label requires USDA FSIS prior approval. There are eight requirements for an FSIS-labeled product:

1. Product name
2. Inspection legend and establishment number
3. Handling statement
4. Net weight statement
5. Ingredients statement and allergen statement (if applicable)
6. Address
7. Nutrition facts
8. Safe handling instructions for raw products

The principal display panel, the area most likely to be read or viewed on the package, must include the product name, net quantity, inspection legend and establishment number, and handling statement (when applicable). The required area of the principal display panel can be found at 9 CFR 317.2 for meat and 9 CFR 381.116 for poultry (see references section for direct links to these regulations). The information panel may be located next to the principal display panel and may include information such as the ingredients statement, nutrition statement, and manufacturer or distributor name and address. Each of these items must be easily read and understood by the average consumer.

The product name must be prominent and easily seen on the principal display panel. All foods that fall under a standard of identity as stated in 9 CFR 319 (meat) and 9 CFR 381 (poultry) must be clearly labeled as the given name by regulation. In any case, when there is a common or usual name for a product, it must be used to avoid misbranding or misrepresenting the product. Names that include a geographic origin or significance may be included in the product name only when the product is made in the same geographic region. If the product is not made in the geographic area stated on the label, it must include a qualifying statement such as "style" or "type," as well as a statement clarifying where the product was made ("Made in …").

Allergens

There are eight major food allergens that are responsible for 90 percent of food allergies. All allergens and ingredients derived from allergen proteins must be labeled on the food product. Sources of protein must be identified, such as "hydrolyzed plant protein (soy)." All ingredients used in a product formulation must be thoroughly scrutinized, and all ingredients, including allergens, must be listed on the product label. Allergen statements must be addressed in the standard operating procedures (SOPs) or hazard analysis and critical control points (HACCP) program.

1. Milk
2. Eggs
3. Fish
4. Crustacean shellfish
5. Tree nuts
6. Wheat
7. Peanuts
8. Soy

Traceability

All labels/products should include a traceability measure in order to keep record of where each ingredient originated and where the finished product has been shipped. A "one step forward and one step backward" approach has been used in the industry, but with new regulations, such as the Food Safety Modernization Act, and the potential for recalls, it is suggested that food producers and processors maintain records of all ingredients from origin to final consumer sale if possible. A coding system is typically used to verify these traceability records in the case of a recall. FDA has defined three classes of recalls:

- Class I: potential to cause serious health problems or death
  Example: undeclared allergen, pathogen
- Class II: may cause temporary health problem
  Example: non-pathogen, low-risk undeclared ingredient, very small foreign particles
- Class III: unlikely to cause any adverse health reaction
  Example: lack of English language on retail food label, incorrect order of ingredients

Foodsafety.gov includes an updated list of all food-related recalls from FDA and USDA. Media outlets may be used to inform the public of a recall if it is deemed necessary. The role of the governmental agencies during recalls is to oversee the process and verify the adequacy of the recall. Most recalls are voluntary. It is in the producer's best interest to recall all products that could be affected in order to ensure the safety of consumers as well as the financial stability and reputation of the business. New regulations will give FDA and USDA mandatory recall authority.

References

9 CFR 317: ***http://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-part317.pdf.***

9 CFR 319: ***http://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-part319.pdf.***

9 CFR 381: ***http://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-part381.pdf.***

21 CFR 101: ***http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-part101.pdf.***

Food and Drug Administration. (2010). FDA 101: Product Recalls. *Guideline*, (Cdc), 1–2. Available online at ***http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143332.pdf.***

Foodsafety.gov. (n.d.). Recalls & Alerts. Available online at ***http://www.foodsafety.gov/recalls/index.html.***

Hartson & Hogan. (2007). A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products, 1–117. Available online at ***http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES.***

U.S. Department of Health and Human Services. (2013). Food Labeling Guide. Available online at ***www.fda.gov/FoodLabelingGuide.***

Other Resources

AOAC-Approved Labs

Eurofins Labs

Intertek USA Food Testing Services

Mississippi State Chemical Laboratory

Schawk.com

Center for Food Safety and Applied Nutrition. (n.d.). Labeling & Nutrition Guidance Documents & Regulatory Information. Center for Food Safety and Applied Nutrition. Available online at ***http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/***

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