Why is Food Labeling Important?
Imagine that you are grocery shopping and want to buy a box of cereal. What are the most important factors (other than price) that influence your decision to purchase a particular box? Which part of the label do you look at first, before making your purchase? The brand name? The claims (e.g., a good source of fiber)? The Ingredient List? Nutrition Facts? Country of origin? Or availability of recipes?

For many, the Ingredient List and the Nutrition Facts panel are key packaging elements. More and more shoppers rely on these elements to understand what they will be eating. Are there any preservatives, artificial sweeteners or colors, or hydrogenated fats in the product? How much fat, carbohydrate and sodium will they consume? Are there any allergens in the product that could affect the buyer?

Food labeling is important—specifically the ingredient/allergen declarations and Nutrition Facts—because they communicate to consumers what they are putting into their bodies. Allergen labeling is critical because millions of Americans have allergic reactions to food. People with diet-related diseases such as diabetes rely heavily on the Nutrition Facts panel because they need to limit sugar intake and count carbohydrates.

What is Involved in Food Labeling?

Mandatory Elements
The food label is more than just the Nutrition Facts, ingredients and allergen declarations; it is everything you see on the package. Food companies are not allowed to put just anything on their product labels. What they put on the label must be truthful and not misleading.

There are regulations governed by the US Food & Drug Administration (FDA) in the Code of Federal Regulations (CFR) on how a packaged food product is labeled—what must be labeled, and what may or may not appear on a label. There are five mandatory labeling requirements:

1. Statement of Identity (Common or Usual Name of the Food); 21 CFR 101.3
2. Net Quantity; 21 CFR 101.105
4. Ingredient List; 21 CFR 101.4
5. Manufacturer’s Name & Address; 21 CFR 101.5
The FDA has established regulations for these labeling elements. For example, as you see in Figure 1, the Name of the Food and the Net Quantity must be printed on the front of the package—known as the Principal Display Panel (PDP)—most easily seen by the consumer at purchase. The Net Quantity must be placed in the bottom 30% of the PDP, in lines generally parallel with the base of the container. The Nutrition Facts panel, Ingredient List and Manufacturer’s Name and Address must either be on the PDP, or if there is not enough space, on the Informational Panel immediately to the right of the PDP.

These three pieces of information (Nutrition Facts, Ingredient List and Manufacturer’s Name & Address) must be placed together on the Information Panel without any intervening material. An example of intervening material would be the UPC bar code (not required by the FDA).

**Nutrition Facts**

Nutrition Facts information must be based on a serving size determined by the Reference Amount of food Customarily Consumed per eating occasion (RACC). Manufacturers must follow the procedures set out in 21 CFR 101.9(b)(2) to determine the serving size of their product. There are rounding rules for declaring calories and each of the 13 core nutrients, plus serving size and servings per container.

The rules are complex, and everything inside the Nutrition Facts panel is regulated. There are highlighting requirements for the heading “Nutrition Facts” and all non-indentated nutrients, type size requirements, hairline rules, and how much space to place between text. Figure 2 provides an example of graphics enhancements used by the FDA for displaying the Nutrition Facts panel.
The Ingredient List

In the Ingredient List, each ingredient must be declared by its common or usual name and in descending order of predominance by weight. There are requirements for declaring preservatives, flavors and spices. For example, an approved chemical preservative must be declared on the Ingredient List by its common or usual name followed by a description of its function (e.g., Ascorbic Acid to Promote Color Retention). Spices, natural flavors, and artificial flavors may be declared on the Ingredient List of the finished product as “spices,” “flavor” or “natural flavor” and “artificial flavor.” However, paprika, turmeric and saffron or other spices which are also colors must be declared as “spice and coloring” unless declared by their common or usual name.

There are provisions for incidental additives, which are food additives/ingredients present in a food at insignificant levels without any technical or functional effect in that food (21 CFR 101.100(a)(3)). Incidental additives are usually present because they are food additives/ingredients of other foods that are incorporated in the finished product. If they meet the definition of an incidental additive, they are exempt from ingredient declaration requirements. A sulfiting agent (e.g., sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite and potassium metabisulfite) is considered an incidental additive only if present at less than 10 ppm in the finished product.

Allergens

Allergen labeling is extremely important. Under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), there are eight major food allergens: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans. An incidental additive loses its ingredient declaration exemption if it contains a major food allergen and must be declared.

Declare major food allergens in one of two ways:

▶ Declare the name of the food source from which the major food allergen is derived on the Ingredient List, e.g., “milk, eggs” or “whey (milk)” and “semolina (wheat)”.

▶ Place the word “Contains” followed by the name of the food source from which the major food allergen is derived, adjacent to or immediately after the Ingredient List in a type size no smaller than that used in the Ingredient List (e.g., “Contains: Wheat, Milk, Egg and Soy”). An important requirement for allergen labeling specifies the type of tree nuts, fish and shellfish included (e.g., cashews, anchovies, shrimp).

The purpose of food labeling regulations is simple and clear: to ensure that foods sold in the US are safe, wholesome, not misbranded and not adulterated. It is important that food and beverage companies understand these regulations and interpret them accurately so that they can produce products and develop labeling that complies fully with FDA regulations. This compliance minimizes legal action and avoids delays in distributing products.
How Can Covance Help?

Covance can assist with your Food Labeling needs:

▶ Developing Nutrition Facts panels based on lab-analyzed data of your products
▶ Developing calculated Nutrition Facts panels based on database analysis of your product formulation or analysis of client-provided documentation
▶ Generating Nutrition Facts panels for baby foods, Dual Nutrition Facts panels (Figure 3) to show two forms of the same food (e.g., cereal “as purchased” and “as prepared with milk”), Aggregate Nutrition Facts panels for outer packages that contain two or more separately packaged foods and Supplement Facts panels for Dietary Supplements
▶ Preparing ingredient statements based on client-provided documentation

The Covance Partnership

We recognize your need for solutions across the lifecycle continuum, from product development to product labeling. Covance offers a wide breadth and depth of services and is committed to your success. Make us your partner for integrated consulting, development, and testing solutions.

Learn more about our food solutions at www.covance.com/foodsolutions