Food Labeling: FDA and USDA

Food labeling, primarily as a means of consumer protection, is a topic of interest that has evolved from the need to address dynamic challenges stemming from the food industry. In recent years, attention focused on food labeling has exploded with concerns related to nutrition, genetic modification, pesticide and/or additive use, identification of known allergens, product origin disclosure, tracking of products relative to recalls, and more.

Food labels are prescribed in terms of what, where and how the information is presented. Contents of a food label must include name of product, ingredient list, nutritional information, net quantity, allergy information, and contact information (manufacture, packer, and/or distributor).1

The US Food and Drug Administration (FDA): The FDA is the agency tasked with ensuring the safety of domestically consumed foods, which are produced both domestically and internationally. Food safety and labeling requirements are regulated by the Federal Food, Drug and Cosmetic Act (FFDCA) and the Fair Packaging and Labeling Act, which require a standard nutrition labeling system for all foods other than meats and poultry, approximately 80 percent of food sold in the United States. The FDA does not pre-approve producers’ food labels; they establish requirements and guidance for mandated food label attributes.2

The US Department of Agriculture (USDA): The Food Safety and Inspection Service (FSIS), of the USDA, are responsible for the inspections and quality standards for meat and poultry consumables. Unlike the FDA, the FSIS mandates that all labels used for meat and poultry receive pre-approval before they can be used; this amounts to about 60,000 labels per year.3

Legislative History

Early History
The original Food and Drug Act (1906) prohibited misbranding or adulteration of foods in interstate commerce. In a challenge to the Food and Drug Act (U.S. v Johnson), the Supreme Court ruled (1911) that the law did not prohibit false therapeutic claims, just false statements about ingredients. Thus began a steady and gradual increase in the regulation of the food industry, as agencies and Congress responded to (primarily) consumer safety issues. The FFDCA (1938) significantly broadened the reach of the FDA.4 This legislation clearly and broadly stated that food is misbranded if the label contains false or misleading representation.5 The act also authorized standards of identity, quality, and fill-of-container for foods.6

Modern History
1962 **Consumer Bill of Rights** includes the right to safety, the right to be informed, the right to choose, and the right to be heard.\(^7\)

1972 The FDA introduced voluntary nutrition labeling in the reach of this legislation. One caveat to voluntary nutrition labeling was that if a producer added nutrients, or wanted to make nutritional claims, nutrition labels became mandatory.\(^8\),\(^9\),\(^10\)

1990 **Nutrition Labeling and Education Act** requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services.\(^11\) The primary goals of the NLEA are to:

1. Make nutrition information available to assist consumers;
2. Eliminate consumer confusion;
3. Help consumers maintain healthy practices and protect them from unfounded health claims; and to
4. Encourage product innovation\(^12\)

1994 The USDA follows different rules for meat and poultry. In July 1994, “nutrition labeling became mandatory for non-exempt multi-ingredient meat and poultry products... [and] about 40 single-ingredient meat and poultry products came under a voluntary nutrition labeling program.”\(^13\) Because participation in the voluntary program fell below the required 60 percent, the USDA/FSIS had to initiate a final nutrition labeling rule, wherein retailers became required to display easy to read/understand nutrition labels on their meat/poultry products by March 1, 2012.\(^14\)

1997 Among other items, the FDA Modernization Act allows for the regulation of health claims for foods.\(^15\) (See the Health Claims discussion below for more information.)

2004 Food Allergy Labeling and Consumer Protection Act - requires food labels of “any food that contains a protein derived from foods that account for a large majority of food allergies: peanuts, soybeans, cow’s milk, eggs, fish, crustacean shellfish, tree nuts, and wheat.”\(^16\)

**Current Situation**

A driving force behind modern food labeling concerns has been the health industry. As food science has progressed, food choices and consumption quantity have been recognized as key factors in public health. Obesity, heart disease, and diabetes are just a few of the diseases associated with modern eating habits. Health professionals have determined that educating the public on their choices and reducing confusion with regard to food labels is integral to stemming this threat to American’s health and the American economy. There is, however, substantial debate as to what information is appropriate and what method to communicate best serves the interests of stakeholders: consumers and producers. From caloric counts to processing techniques, there
are a number of variables in individual needs and desires when it comes to food labeling. It is important to understand that the food system is very dynamic, as advances are made or new rules are contemplated, there are corresponding costs associated with education, development, implementation and enforcement.

FDA Funding Concern
In 2006, “FDA Commissioner Andrew von Eschenbach asked…the FDA Science Board, to name a subcommittee to weigh whether the agency has the scientific and technologic capacity to support its regulatory mandate.” The report goes on to state that “decades of inadequate funding and growing responsibilities” have resulted in its “[in]ability to keep up with scientific advances…and its information technology systems are obsolete and unreliable.” In terms of food labeling, the agency “does not have enough well-trained scientists” and the “serious deficiencies in its scientific base and organizational structure threaten its ability to meet current and emerging regulatory responsibilities.”

Consumer/Industry Conflict
A number of public interest groups are pushing for legislation on the grounds that consumers have a right to know, especially for perceived health and environmental reasons. In the U.S., a threshold level of one percent GE content is commonly recommended for labeling GE foods; threshold levels range from 0.9 percent in the European Union, to one percent in Australia and New Zealand and five percent in Japan.

Opposition to labeling tends to flow along two paths. The first is that it unfairly stigmatizes a food. The second is that it unfairly penalizes farmers, producers (especially small producers) and retailers who could incur a multitude of additional costs that they will have to pass on to consumers. In addition, the cost to manufacturers is particularly sensitive to the threshold percentage of GMO food content that they are trying to meet. A summarized list of pro/con statements and economic considerations can be found at the Colorado State Extension website.

Legislative Movements
There are several federal food labeling bills that have been introduced in 2013. The Food Labeling Modernization Act of 2013 would grant the FDA additional authority in food labeling, particularly front of package (FOP) and information on the principal display panel (PDP). In April of 2013, HR 1699 and SB809 GE Food Right to Know Acts were introduced in their respective chambers; however, neither was given much chance of getting through committee.

At the state level, there are about 30 states with movements to put mandatory labeling of GE foods to a vote of the people. This June (2013), Connecticut and Maine became the first states to pass a law requiring labels on GM foods. The law will not take effect until four New England states, one of which borders Connecticut, also passes the requirement. The requirement for majority support of a 20 million person population in a geographic region was added to the bill to address concerns about prohibitive costs. In contrast, ballot measures in California and Washington State have recently failed by substantial margins after robust campaigns on both sides.
If labeling legislation passes, then its effect on the labeling system, as a whole, is yet unknown. On one side of the equation are people who say that labels are already too busy to assimilate information effectively and that, with “the percentage of items that contain genetically engineered ingredients in a grocery store ranging from 60 percent to 70 percent,” it may well be more effective to label those foods that do not have GMOs. Michael Pollan (a well-known supporter of organic and local food production), has stated that even though there is no evidence of danger to a person’s health, this is “a fight about transparency - people who want to know where their food comes from should have this information.” In the same NPR segment, David Ropeik (a specialist in risk assessment) stated,

\[
\text{The psychological research...suggests that when you give people choice over risk, they're less afraid of it. Assuming that [the label] was something short of a skull and crossbones, it's likely that many people would accept it and say, "Fine, I'll buy it!"}
\]

A simple GMO label may only tell the consumer that the product, or its ingredients, is the result of genetic modification; it does not tell people how the product was modified. The end result may well be increased costs without educating the consumer with any actionable information. Ultimately, people may become so inured to the label that their buying habits do not change, or they may become even more accepting of GMOs, thereby ending the debate.

**Labeling Terms and Concerns**

The following is a series of topics (alphabetically) that relate to the food label itself.

### Allergy and Gluten Labeling

While there are over 160 known food allergens, the eight covered in mandatory labeling are responsible for 90 percent of documented food allergies and the ones most likely to present severe, life-threatening reactions. Gluten allergies/sensitivities affect 1 in 133 individuals (3 million nationwide). On August 2, 2013, the FDA issued their long-awaited finalized rule for the voluntary labeling of gluten free products.

### Bioengineered Foods (AKA GMOs and GE Foods)

Draft guidance for bioengineered food labeling includes a statement that “each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition...the label of the food must reveal all material facts about the food.” Following are guidelines the FDA provides to demonstrate this concept:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.

- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.
• If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.

• If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

The draft document goes on to give guidance to producers who either want to identify their product as bioengineered, or being made from ingredients that are bioengineered, as well as guidance to those who wish to state their product is produced without bioengineered ingredients. Either option is currently done on a voluntary basis, provided the product is not shown to be significantly different from its traditional counterpart. The following table, from the FDA guidance, provides examples of what would/would not be appropriate labeling for bioengineered foods.

Table 1. Examples of labeling under FDA voluntary guidelines

<table>
<thead>
<tr>
<th>Wording on Label</th>
<th>FDA Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMO free (does not contain genetically modified organisms). OR Not genetically modified.</td>
<td>Not recommended. “Free” implies zero content, which is nearly impossible to verify. “Genetically modified” is an inappropriate term, in that all crop varieties have been modified by plant breeders.</td>
</tr>
<tr>
<td>We do not use ingredients produced using biotechnology.</td>
<td>OK</td>
</tr>
<tr>
<td>This oil is made from soybeans that were not genetically engineered.</td>
<td>OK</td>
</tr>
<tr>
<td>This cantaloupe was not genetically engineered.</td>
<td>May be misleading, because it implies that other cantaloupes may be genetically engineered. Currently, there are no such varieties on the market.</td>
</tr>
<tr>
<td>Genetically engineered.</td>
<td>OK</td>
</tr>
<tr>
<td>This product contains cornmeal that was produced using biotechnology.</td>
<td>OK</td>
</tr>
<tr>
<td>This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat.</td>
<td>OK. The underlined part is mandatory because it indicates a nutritional change. The rest is voluntary under the proposed guidelines.</td>
</tr>
</tbody>
</table>
Ethical/Religious Labeling

For some people, it is important that they eat foods that are processed in a manner prescribed by their culture or faith. The two most used are “kosher” and “halal,” but these are not regulated at the federal level.

Health Claims on Food Labels

Claims made on food labels may have varying degrees of agency authorization. In an effort to respond to this practice the FDA has developed several categories in which health claims fall. In general, health claims characterize the relationship of any substance to a disease or health-related condition (e.g., diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors).

Qualified Health Claims: A qualified health claim is one that the FDA has investigated and added qualifying language to characterize the strength and limitations of the scientific evidence. FDA guidance, to companies that wish to pursue qualified health claims on their products, includes:
1. Identify the relationship between the substance (food, ingredient or component) and the disease, at levels that justify a claim;
2. The health claim (benefit); and
3. Scientific evidence that supports the claim.

From 2002 through 2010, the FDA received 16 petitions for 60 qualified health claims; of these, only 12 claims were approved. The cost to the agency to process the claims was $12.8 million.

Structure/Function Claims: These claims describe the effect that a substance has on the structure or function of the body and do not make reference to a disease. These claims are not pre-reviewed or authorized by FDA. Companies much more frequently pursue structure/function claims because the burden of proof, that the product does not meet the claim, rests on the FDA. Several key factors inhibit the FDA in enforcement of structure/function claims:
1. The lack of adequate funding to provide necessary skill and manpower to inspect the many claims;
2. The agency does not have the legal authority to compel companies to provide proof; and
3. Some claims, such as “immunity” and “attention” do not have outcome measures that can be used to validate the claim.

Nutrient content claims: may be based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences. These claims serve to share a generalized level of a nutrient in a food, such as “free,” “high,” and “low” or with a reference such as “50 percent less fat.”
International Trade and Country of Origin Labeling (COOL)

COOL is a labeling law that requires retailers to provide their customers with information regarding the source of certain foods. This is an issue that is of importance in the growing global food market and supported by both consumer and agricultural advocacy groups. Under COOL, retailers are required to include labels with specific identifying information; for cuts of meat (‘muscle cuts’) it requires location of the three production steps (born, raised and slaughtered), it also prohibits the comingling of meats from more than one country.

COOL is implemented by the Agricultural Marketing Service (AMS) of the USDA. The requirements apply to an estimated 37,000 U.S. retailers. A 2011 audit of the program stated that although the AMS had made significant progress in implementing COOL rules, there has not been vigorous enforcement of retailers who mislabel, fail to label, or keep inadequate traceability records. The AMS acknowledged each of the program deficiencies identified in the audit; their response highlighted the relative newness of the law and budget constraints as key issues, but agreed to continue advancing the implementation of this important tool.

Irradiation

Irradiation has been used for more than thirty years to improve food safety and extend the shelf life of foods by reducing or eliminating microorganisms and insects. The FDA, WHO, CDC and USDA have all endorsed the safety of irradiated foods. The FDA requires the use of the international food irradiation symbol, accompanied with the statement “Treated with radiation” or “Treated by irradiation” on the food label for any food items that are irradiated.

Nutrition

Nutrition is discussed in a separate paper in this Agriculture Update. For purposes of the food label, a Nutrition Facts label is mandatory for most food items. The goal of the label is to help consumers make healthier choices. For more information on the Nutrition Facts label, and specific information for special populations, please see: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm

Organic Labeling

Organic, as an official marketing term, is relatively new in the federal food system; the first accepted standards were adopted in 2000 and went into effect in 2001. The USDA has sole authority for the certification, accreditation, compliance and enforcement of the National Organic Program. Any producer that wants to use the Certified Organic label must comply with USDA standards. It “indicates that the food or other agricultural product has been produced through approved methods that integrate cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. Synthetic fertilizers, sewage sludge, irradiation, and genetic engineering may not be used.”

“All operations [throughout the food system] with more than $5,000 in annual organic sales must be certified.”
Other Common Terms
The following are some labeling terms that the USDA has defined. A more complete and detailed list can be found on their website. The Supplemental Resources section (at the end of this paper) includes more detailed references, including Food Labeling for Dummies, which sorts out some of the complexities of labeling terms for consumers.

| **Table 2. Meat and Poultry Labeling Terms (partial)**
| **Cage Free** | This label indicates that the flock was able to freely roam a building, room, or enclosed area with unlimited access to food and fresh water during their production cycle. |
| **Certified** | Implies that the USDA's Food Safety and Inspection Service and the Agriculture Marketing Service have officially evaluated a meat product for class, grade, or other quality characteristic. If the certification is from a different organization, it must clearly associate the name of that organization. |
| **Chemical Free** | NOT allowed to be used on labels |
| **Free Range or Free Roaming** | This label indicates that the flock was provided shelter in a building, room, or area with unlimited access to food, fresh water, and continuous access to the outdoors during their production cycle. The outdoor area may or may not be fenced and/or covered with netting-like material. This label is regulated by the USDA |
| **Grass-Fed** | Grass-fed animals receive a majority of their nutrients from grass throughout their life, while organic animals’ pasture diet may be supplemented with grain. Also USDA regulated, the grass-fed label does not limit the use of antibiotics, hormones, or pesticides. Meat products may be labeled as grass-fed organic. |
| **Humane** | Multiple labeling programs make claims that animals were treated humanely during the production cycle, but the verification of these claims varies widely. These labeling programs are not regulated under a single USDA definition. |
| **Mechanically Separated Meat** | In 1982, the FSIS determined that mechanically separated meat was safe. In 2004, the FSIS determined that it no longer applied to beef, due to concerns about Bovine Spongiform Encephalopathy, but it could still be used for pork. Pork processed in this manner must be labeled as such. |
| **Mechanically Separated Poultry** | This poultry product has been used since 1969. A final rule, established in 1995, said it would be used without restrictions. However, it must be labeled as “mechanically separated.” |
Concept of Process v. Product

An important concept that is often overlooked in the debate over labeling GE foods (and some other processes, e.g. irradiation) is that when the FDA determined to adopt a “narrow reading of the statute,” they were looking at the product not being substantially different. For some critics, the concern lies more fundamentally with the processes of genetic engineering.

The general definitions section of the FFDCA states that an assessment of an allegedly misleading label should take into account not only the 'representations made or suggested by' the labels text/graphics, but also ‘the extent to which the labeling...fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article...

The process versus product distinction in food labels lies at the heart of the FDA’s resistance to repeated calls for mandatory labeling of foods derived from genetic engineering.

Transparency and Clarity of Information
Hot topic issues tend to fall under the umbrella of transparency in the food supply chain. Much of the discussion in food labeling centers on the consumer’s right (or need) to know on a variety of issues including, but not limited to: health-related, genetic engineering, irradiation, adulterated food products, sustainability, and nanotechnology applications.

There is growing interest in identifying and adopting accepted definitions of terms that are used to market food products. A GAO summary report states, “Research showed, and stakeholders indicated, that consumers find it difficult to understand the differences between health claims with significant scientific agreement and the lower level of scientific support for qualified health claims. Research also showed that consumers find it difficult to distinguish among the many different types of claims on food labels, including health claims, qualified health claims, and structure/function claims.”

The Center for Science in the Public Interest is seeking better rulemaking and enforcement from the FDA on misleading food labels. It is common for companies to place pictures of the product on the label that misrepresent what consumers are getting, despite the fact that the ingredient label is accurate. For example, a box of blueberry waffles that depicts large, plump blueberries while the label reads, ‘artificially flavored blueberry bits.’ According to Michael Jacobson, of the Center for Science in the Public Interest, accuracy in food labels is a low priority for the FDA. FDA staff attorney, Rebecca Goldberg, speaking in a personal capacity, stated that barriers include an alphabet soup of overlapping regulatory agencies as well as First Amendment rights relative to commercial speech.

Future of Food Labeling
The debate over food labeling shows no signs of abating. Consumer groups, the health industry, and niche agricultural groups are mounting pressure on the FDA and state legislators, to bring a cleaner, less confusing, labeling system to the American public. The GAO has determined that the FDA has been challenged with a need to assess relevant evidence of claims made by companies, countered by a lack of legal authority to compel companies to provide such information. The GAO has further determined that the “FDA’s oversight and enforcement efforts have not kept pace with the growing number of food firms…and the FDA has reported that limited sources and authorities challenge its efforts to carry out its food safety responsibilities and impact their efforts to oversee food labeling laws.” The issue of food labeling will continue to evolve as stakeholders continue to work for a balance that best meets the needs of the public in the dynamic food industry.

Recommended Readings


Supplemental Resources


This is a “user friendly” guide to the various terms and claims found on food labels.


Video presentation of the various components and concerns of food labeling (about ¾ down the webpage).


Perspective and information regarding labels in the global perspective.


7 Ibid

9 Ibid, pg. 19.


14 Ibid

15 Ibid

16 Ibid


22 Byrne, P., op cit.


Ibid


44 Ibid.


48 Ibid, p. 25.

49 Ibid, p. 41.


60 Ibid


66 Ibid
