Term Paper

Food Standards should be Reviewed and Extended

By Monica To

SS 07 ANR – 490 / 811

Food Regulation in the United States

Michigan State University

April 2, 2007

I. Introduction

The U.S. Congress passed the Pure Food and Drugs Act on June 30, 1906 as the first federal food law. Due to the Great Depression and the industrialization of food processing, economic and aesthetic adulteration was common in the American marketplace. Products with distinctive names had legal protection from misbranding and intentional deception of quality and quantity. In the interest of consumers, the Food and Drug Administration (FDA) first introduced food standards to the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938[1]. Such standards contributed to a reference for food manufacturing and labeling to ensure that products sold under specific names have the characteristics expected by consumers. Since then, the list of standards had been expanded from the original list with a few standards on tomato products to over 200 standards after several decades.

This paper will focus on the merits of food standards in consumer protection, industrial fairness, and benefits to international trade, and why they should evolve with the growth of food manufacturing in the United States. Section II will provide a summary of the legislation, current food standards, and the recent modernization. Section III will compare the perspectives of consumers, industry, and government. Section IV will examine the impact of food standards in international trade. Conclusion will be summarized in Section V.

[1]. Food and Drug Administration, FDA Consumer magazine, *A Century of Ensuring Safe Foods and Cosmetics*, available at http://www.fda.gov/fdac/features/2006/106_cfsan.html (last accessed February 26, 2007).

II. Current Standards and Modernization

The intent of food standards is to protect both consumers and the food industry against economic fraud and unfair competition. Whenever a promulgated standard is available, the U.S. law also requires the food to comply with the specifications of the standard in every respect. On the other hand, the regulations also do not permit products that do not confirm to a standard to be represented as the standardized, but to be sold under other non-standardized names.

The Food Safety and Inspection Service (FSIS) and the FDA are the main authorities governing the truthfulness of labels. The FSIS enforces the standards of identity or composition mainly for meat and poultry products, codified in title 9 of the Code of Federal Regulation (CFR). The authorities of the FDA are coded in Section 401 of the FD&C Act, which defines the purpose for the standards of foods as quoted below:

> "**SEC. 401**. [21 U.S.C. 341] Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container."

A. Current Standards

The FD&C Act authorized three kinds of food standards: identity, quality, and fill of container in 21 CFR 130 to 169. Standards of Identity define the food product by its name and any requirement for specific ingredients and the amounts; for example, Sec.

169.140 describes the mandatory and optional ingredients and the corresponding amount permitted to be used in Mayonnaise. These standards also include nutritional requirements, such as vitamin fortification in Enriched Flour as described in Sec. 137.165. Standards of Quality establish minimum quality requirements, such as specifying the minimum levels of the valuable constituents, maximum levels for fillers, or the manufacturing process, such as Sec. 155.191 for Tomato Concentrates. Fill-of-container standards define the net quantity of the product and the measuring methods.

B. Modernization

On December 29, 1995, the FDA published an Advance Notice of Proposed Rulemaking (ANPRM), requesting information on the need to retain, revise, or revoke its food standards of identity regulations and its common or usual name regulations[2]. Ten years later, the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) and the FDA proposed to modernize existing standards or creating new standards, and established a set of general principles for food standards. The adherence to these principles aims at "promoting better honesty and fair dealing in the interest of consumers and protect the public, allow for technological advances in food production, be consistent with international food standards to the extent feasible, and be clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards"[3].

[2] Federal Register: December 29, 1995 (Volume 60, Number 250), *Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations*, available at http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=37647421903+1+0+0&WAISaction=retrieve (last accessed April 1, 2007).
[3] Federal Register: May 20, 2005 (Volume 70, Number 97), *Food Standards; General Principles and Food Standards Modernization*, available at http://www.cfsan.fda.gov/~lrd/fr050520.html, (last accessed April 1, 2007).

This recent revision of the federal regulations has added flexibility to the standards for traditional foods as described in 21 CFR 131 through 169. The 21 CFR 130.10 provides a "general standard of identity" for modified versions of traditional standardized foods. The conditions for such modified versions are listed as follows:

1. Comply with the provisions of the standard for the traditional standardized food except for the deviation described by the nutrient content claim.
2. Not be nutritionally inferior to be traditional standardized food.
3. Possess performance characteristics, such as physical properties, flavor characteristics, functional properties, and shelf life, that are similar to those of the traditional standardized food, unless the label bears a statement informing the consumer of a significant difference in performance characteristics that materially limits the use of the modified food (e.g., "not recommended for baking").
4. Contain a significant amount of any mandatory ingredient required to be present in the traditional standardized food.
5. Contain the same ingredients as permitted in the standard for the traditional standardized food, except that ingredients may be used to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness so that the modified food is not inferior in performance characteristics to the traditional standardized food[4].

The FDA and FSIS Work Group finally adopted the approach to rely on external groups-consumer, industry, commodity, or other groups-to draft recommended revisions to existing Federal food standards but retain the agencies' authority to establish the final food standards. This approach is expected to allow stakeholders to participate in the identification for and the development of new and revised standards, and the elimination of the obsolete ones. To protect consumer interests, this approach also provides a channel for the submission of data to support any claims made in petitions relating to consumer expectations or beliefs.

[4] . Food and Drug Administration, FDA / CFSAN Q & A, *What are the requirements regarding Food Standards?*, available at http://www.cfsan.gov/~dms/qa-ind2d.html (last accessed February 26, 2007).

III. Benefits to Stakeholders

As part of the consultation for public opinion on the need for food standards, the FSIS and FDA received 123 letters in response to the ANPRMS issued in 1995. Most comments supported the concept of food standards, while a few of them requested their elimination, and even less of them were satisfied with the standards as currently written[3].

In general, respondents had a wide range of concerns, including the worry that food requirements may restrict flexibility and the development of novel foods, but the overall benefits to stakeholders outweigh the restriction of rules. The various opinions are summarized into the perspectives of the consumers, industry, and enforcing parties as follows:

A. *Consumer*

Most comments supported the belief that food standards could protect consumers from fraudulent and substandard products. Food standards ensure the uniformity of quality and guarantee the basic nature of the foods. They serve to protect consumers from economic deception, for instance, how much filler can be used to substitute for more valuable ingredients. Standards also help consumers with special dietary needs to know what they are using in the meals, and lessen the burden of relying on nutrition labeling and ingredient declaration. Some commented that the labeling for standardized and non-standardized foods should be equivalent. Furthermore, some emphasized the importance

of allowing consumers to discern differences between standardized product and the modified versions.

B. *Food Service and Manufacturer*

Food standards set the framework for food quality, which allows fairness in competition. They simplify the development of product specifications as the content and quality of certain raw materials are already specified in the legislation, and therefore, Food Service operators and manufacturers are aware of the composition for food preparation. Food standards also provide a universal standard across the country so that manufacturers would not be confronted with different states' requirements. Some comments requested to have simplified, clarified, or more flexible food standards, such as, allowing alternative manufacturing technologies and ingredients that do not alter the basic nature of the food. The industry also prefers to have an evolving set of food standards that can match the continuous development in food processing and packaging technologies[5].

C. *Regulatory Authorities*

In the enforcement point of view, food standards enhance the utilization of resources of the FSIS and the FDA in ensuring foods labels are truthful and not misleading. Federal legislation promotes consistency and uniformity across the country. Not only can they allow the identity and quality of food products to become "measurable", but also they serve as a reference for court cases and the determination whether a violation exists.

[5] . Food and Drug Administration, FDA News Release, *USDA and HHS Propose to Modernize Principles for Food Standards of Identity*, available at http://www.fda.gov/bbs/topics/news/2005/usda_hhs051705.html (last accessed February 26, 2007).

Certain groups also proposed rescinding or modifying standards on a case-by-case basis to allow flexibility and better consideration.

III. International Trade

Internationally, the Codex Alimentarius, established by the World Health Organization and the Food and Agricultural Organization, has set 204 food standards to avoid trade barriers and unnecessary disputes[6]. The United States has adopted such voluntary standards into the legislation. In addition, it has also implemented stricter standards wherever scientific evidence justifies a higher level of protection, resulting more than 280 standards established for dairy, bakery, grain-derived, canned, fish and shellfish, cacao, nut, beverage, sweeteners, and food dressing and flavorings products. Since the U.S. has already had a long history in adopting and enforcing food standards and safety rules, the country can demand and assist developing countries to improve their levels to meet the U.S. standards.

According to the United States Department of Agriculture (USDA) Economic Research Service, population growth, increasing ethnic diversity, and increasing incomes led to an inelastic demand for agricultural imports of prepared and processed foods. The average import prices in the US had been rising steadily from 2001 to 2004 (See Figure 1 below). Imported processed foods contributed to 63 % of US agricultural imports, which

[6] . Food and Drug Administration, FDA Consumer Magazine, *The International Flow of Food: FDA Takes on Growing Responsibilities for Imported Food Safety*, available at http://www.fda.gov/fdac/features/2001/101_food.html (last accessed February 26, 2007).

consisted of standardized and non-standardized products, such as beer, wine, cheese, meat, and snack foods[7].

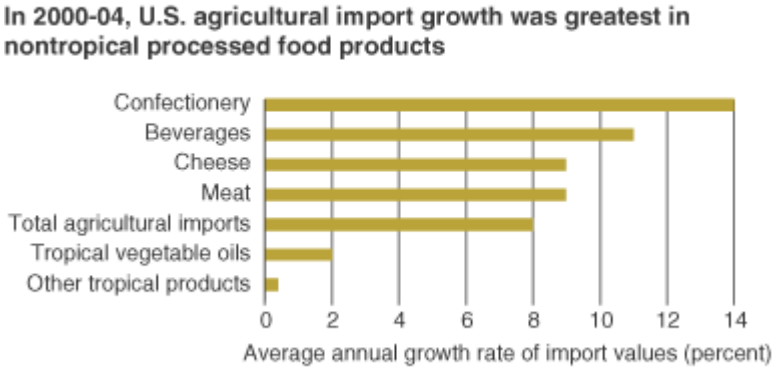

Figure 1 Source: Bureau of the Census.

This growing volume of international trade demands for a global harmonization of food standards. U.S. consumers have expressed that a US food standards system would have better consideration to the American consumer or industry than standards set by international bodies[3]. The establishment of food standards allows the monitoring of imported products quality against domestic food standards for any violation in safety, adulteration, and mislabeling, and also facilitates exports and international markets.

In addition, the emerging trend for novel, organic, and controversial foods also drives for an expansion of standards. For organic foods, the national organic standards established

[7] Alberto Jerardo, United States Department of Agriculture - Economic Research Service, Amber Waves April 2005, *Americans Have Growing Appetites for Imported Foods*, available at http://www.ers.usda.gov/Amberwaves/April05/Findings/GrowingAppetite.htm (last accessed April 1, 2007).

by the USDA in 2000 promoted the growth of domestic organic farm sector, consistency among the states, and the accreditation of over 40 foreign programs[8].

In terms of controversial food items, U.S. farmers have extensively and rapidly adopted genetically engineered (GE) crops since they became commercially available 10 years ago due to the potential higher yields, savings in management time, and lower pesticide costs. Nevertheless, GE crops still have limited acceptance in certain countries, such as the European Union, due to environmental and consumer concerns. Since the US is one of the few countries leading the development and supply of GE crops[9], the American standards and labeling requirement will have impact on other countries.

Currently, food standards are not uniform around the world. Different countries have their own interpretation of common names and the requirements for food labels often reflect the value and the culture of the country. Consider the labeling of wine as an example to compare the legislation in the U.S., the European Union, Canada, and Australia:

A. United States

In the US, wine is defined in the Federal Alcohol Administration Act (FAA Act) as "containing not less than 7 and not more than 24 percent alcohol by volume"[10]. The US

[8] Catherine Greene, AmberWaves April 2006, USDA Economic Research Service, *U.S. Organic Farm Sector Continues to Expand*, available at http://www.ers.usda.gov/AmberWaves/April06/Findings/Organic.htm (last accessed April 1, 2007).
[9] Jorge Fernandez-Cornejo, AmberWaves September 2006, USDA Economic Research Service, *Adoption of Genetically Engineered Crops Continues To Increase*, available at http://www.ers.usda.gov/AmberWaves/September06/Findings/GEcrops.htm (last accessed April 1, 2007).
[10] 27 U.S.C. 211(a)(6)

regulations have specific standards of identity (such as “malt beverage”). With the target of controlling the process as well as the product, there are specific requirements for the definition of the process, such as "dealcoholized", and "alcohol-removed”. Moreover, due to the freedom of speech and enormous amount of advertising in the country, the standards also define claims ("non-alcoholic" is not equivalent to "alcohol-free") and the use of them[11].

B. European Union

In general, the European Union has less stringent rules for food standards. There are mandatory specific requirement for allergen, beef, egg, genetically modified, organic, etc[12]. For wine, however, there is a detailed specification outlined in the Council Regulation (EC) No 1493/1999[13]. The labelling is different from the US requirements[14], and wine has a different definition as “the product obtained exclusively from the total or partial alcoholic fermentation of fresh grapes, whether or not crushed, or of grape must”[15]. The US - EU Wine Agreement limits the use of “table Wine” and traditional expressions for only the ones produced by the EU. The EU prohibits the use of any geographical indications that the EU considers proprietary and any reference in descriptive text to EU quality wines.

[11] Food and Drug Administration, Compliance, Sec. 510.400 *Dealcoholized Wine and Malt Beverages - Labeling (CPG 7101.04)*, available at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg510-400.html (last accessed April 1, 2007).
[12] Europa, Food Labelling - Community Legislation, available at http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm (last accessed April 1, 2007).
[13] Europa, SCADPlus: Wine, available at http://europa.eu/scadplus/leg/en/lvb/l60031.htm (last accessed April 1, 2007).
[14] USDA Foreign Agricultural Service, *Gain Report E36067: EU-25 Wine EU Wine Labeling Requirements 2006*, available at http://www.fas.usda.gov/gainfiles/200604/146187574.pdf (last accessed April 1, 2007).
[15] Council Regulation (EC) No 1493/1999

C. Canada

In Canada, the standard for wine is coded under the Food and Drugs Regulations Section B.02.100[16]. Wine is defined as "an alcoholic beverage that is produced by the complete or partial alcoholic fermentation of fresh grapes, grape must, products derived solely from fresh grapes, or any combination of them" with a list of specific requirements. The standard specifies the process, ingredients, and compositional requirements. The legislation also contains other types of wines under B.02.101 to B.02.107, with varying details.

D. Australia

Australia has standards for certain food groups, such as cereals, meat, egg, fish, fruits and vegetables, and dairy products, etc.[17] Wine means "the product of the complete or partial fermentation of fresh grapes, or a mixture of that product and products derived solely from grapes"[18]. The labeling of wine mostly concerns about the alcohol content, its declaration[19], and is much simpler in comparison to that of the countries mentioned above.

[16] Department of Justice - Canada, Food and Drug Regulations, available at http://laws.justice.gc.ca/en/ShowFullDoc/cr/C.R.C.-c.870///en (last accessed April 1, 2007).
[17] Australia New Zealand Food Standards Code, available at http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm (last accessed April 1, 2007).
[18] Australia New Zealand Food Standards Code Standard 2.7.4 Wine and Wine Products, available at http://www.foodstandards.gov.au/_srcfiles/fsc_2_7_4_Wine_prod_v78.pdf (last accessed April 1, 2007).
[19] Australia New Zealand Food Standards Code Standard 2.7.1 Labelling of Alcoholic Beverages and Food Containing Alcohol, available at http://www.foodstandards.gov.au/_srcfiles/Standard_2_7_1_Alc%20label_v64.pdf (last accessed April 1, 2007).

V. Conclusion

Food standards should be reviewed periodically in order to keep pace with globalization, the constant launching of new food products, and the technological advancement in food processing and packaging. The historical use of food standards in the U.S. has proven the effectiveness of a framework to protect the general public from economic fraud and adulteration, to aid the food industry, and to enhance enforcement action by regulators. Such standards can also be expanded to novel and controversial foods to facilitate global commerce. In this modern world, a growing legal reference is advantageous all the stakeholders as everyone prefers to make informed choices, and more importantly, to maintain the public trust towards the American food supply.