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21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 91N-0219]

RIN 0905-AD08

Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Regulatory impact analysis statement.

SUMMARY: The Food and Drug Administration (FDA) is publishing herein the regulatory impact analysis (RIA) that it has prepared under Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354) on the costs and benefits of the food labeling regulations that 'FDA is currently proposing to amend. FDA is issuing these proposals (published elsewhere in this issue of the **Federal Register**) in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and as part of the Secretary of Health and Human Services' (the Secretary's) food labeling reform initiative. The agency has prepared this comprehensive RIA document for these proposals because, when taken together, they constitute a major rule.

DATES: Written comments by February 25, 1992.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFF-303), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0271.

SUPPLEMENTARY INFORMATION: FDA is publishing herein its RIA of the proposed rules to amend the food labeling regulations. This document analyzes both the costs and the benefits, including the impact on small businesses, of FDA's proposals (published elsewhere in this issue of the **Federal Register**) to reform the food label in response to the 1990 amendments and the Secretary's food labeling initiative. This analysis was prepared by the Economics Section of the Office of Compliance in FDA's Center for Food Safety and Applied Nutrition (CFSAN).

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive RIA that presents the costs and benefits of all of the food labeling proposals taken together. FDA requests comments on the RIA.

I. Introduction

The 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) to expand the coverage of nutrition labeling to all food products (except meat and poultry), produce more ingredient labeling, regulate health claims, and standardize nutrient content claim definitions and serving sizes. The 1990 amendments require that the nutrition information on both the food label and on eating establishment menus be readily understandable by the public. These changes to the food label are the most comprehensive changes to be proposed in 53 years. FDA has proposed implementing regulations for the 1990 amendments and estimated the costs and benefits of the proposed changes and regulatory options within the act. However, even before the 1990 amendments were enacted FDA believed that the food label could be improved and was engaged in proposing a series of similar regulations.

In order to evaluate the need for Federal intervention, FDA examined the market for food label information and found that less than the optimal amount of nutrition information was being produced because consumers cannot, independently, determine the nutritional quality of food, thus leading to insufficient incentives for manufacturers to reveal the nutrient content of their products or produce nutritious food. FDA undertook two studies to determine the costs and benefits of these proposed regulations, by engaging a contractor, Research Triangle Institute (RTI). These studies were done over a period of 3 years under the direction of the Economics Section of CFSAN.

A. Costs of the 1990 Amendments

The cost study consisted of both interviews with food manufacturers and a mailed survey. The result was a generic model which can be applied to any regulation mandating a label change. Categories of costs include administrative, analytical, printing, inventory, and reformulation. Administrative costs are management costs which are often high because of the prominence of the food label as an advertising tool for packaged foods. Analytical costs are costs of testing products for nutrient composition to comply with labeling provisions. Printing costs are the costs of printing new labels which may be either glue-on labels or the food package itself. These costs may include redesign costs where extensive labeling changes are undertaken. In the model, estimates of printing costs take into account normal firm relabeling.

Inventory costs are the costs of disposal of existing labels where firms have inventories that outlast the compliance period, i.e., the period of time between issuance of a final rule and its effective date. Inventories of labels, both glue-on labels and packages, range from only a few months to well over 10 years in the food industry. The last cost category reformulation includes the costs of reformulating products and introducing new ones in response to labeling regulations and market testing those products. No estimate of these costs is given because they depend on marketing decisions and are impossible to predict. Moreover, they do not result directly from these proposed rules. Regardless, FDA expects a substantial benefit to be derived from such reformulations, which are likely to make foods more nutritious. In all cost categories, except administrative costs, the costs of relabeling products produced and labeled in foreign countries cannot be separated from those produced and labeled domestically. Thus, administrative costs considered are domestic costs only, and printing, inventory, and analytical costs are considered multinational.

FDA estimates that about 17,000 domestic food manufacturers and 257,000 labels will be affected by the regulations promulgated in response to the 1990 amendments. In addition, approximately 96,000 food service firms might be required to alter their menus if they are not in compliance with health claims or descriptors regulations. The majority of the costs will occur in the first year. Recurring costs are assumed to continue 20 years into the future and are discounted back to the present at a rate of 5 percent.

The individual regulations may be divided into the following separable categories: (1) Mandatory ingredient labeling for standardized foods and certified colors; (2) "voluntary" (see section III.E. of this document) labeling

of raw fruit, vegetables, and fish; and (3) all other labeling regulations including mandatory nutrition labeling. The first category, mandatory ingredient labeling for standardized foods and certified colors, is separable from the other actions because it will take effect almost 2 years prior to mandatory nutrition labeling. Costs for these provisions, as proposed, are $128 million.

Voluntary labeling of raw fruit, vegetables, and fish is separable from all other provisions of the 1990 amendments because it affects supermarkets, not food manufacturers. Costs have been estimated to be between $117 to $155 million for this provision.

All other labeling regulations will become effective at the same time including percent juice labeling, mandatory nutrition labeling, nutrient content claims definition, health claim labeling, format changes and others. These costs to food manufacturers are estimated to be as high as $1.3 billion, depending on the compliance period chosen.

In addition, there could be costs to some restaurants and other food service establishments to reprint menus not in conformance with nutrient content and/or health claim regulations. For those firms wishing to continue use of these statements following publication of the final rules for these regulations, there could be additional costs of analytical testing and, possibly, nutrition information printing. These costs have been preliminarily estimated to be $116 million.

Total costs of the 1990 amendments, excluding the voluntary supermarket labeling, are approximately $1.5 billion. If the agency opted to allow an additional 6 months or an additional year to the compliance period provided for by the statute, total costs would decrease to $.8 billion and $.6 billion, respectively.

B. Benefits of the 1990 Amendments

The benefits of the 1990 amendments include decreased rates of cancer, coronary heart disease (CHD), osteoporosis, obesity, hypertension, and allergic reactions to food. As consumers are given more informative labeling in a better format, uncertainty over the ingredient and nutrient content of the foods they now eat will decrease and some consumers will select more nutritious, healthier foods. Also, with creation of consistent metrics and definitions such as standardized serving sizes and adjectival nutrient content claim definitions by which consumers can judge the nutritional aspects of foods, manufacturers will compete to reformulate their products into healthier foods. Thus, even those consumers who may be unaware of the diet/health revolution may inadvertently eat a better diet.

The model chosen to estimate these benefits focused on the two largest health problems, cancer and CHD (Ref. 24). This model involved the following three-step estimation process:

(1) Estimate changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases and deaths avoided and the dollar value of such benefits.

The estimate of benefits was obtained from the Special Dietary Alert program (SDA) (Ref. 1), a special program done by FDA in conjunction with Giant Food, Inc., which measures actual consumer response to new nutrition information. Reductions in the amount of cancer cases and early deaths were estimated to occur as a result of reduced total fat intake after a lag of 10 years. CHD reductions were estimated to result from lowered serum cholesterol as a result of decreases in saturated fat and cholesterol intake. Over the 20-year period the regulation is estimated to prevent about 39,100 cases of cancer and heart disease, of which, 12,900 would have resulted in death, yielding 80,900 life-years gained. The monetary value of the benefits (number of life-years saved) of this regulation is estimated to be $3.6 billion (discounted at 5 percent over a 20-year period). Valuing benefits based on the number of lives saved would raise this value to $21 billion (discounted at 5 percent over a 20-year period).

To put these estimates into perspective, the maximum health changes resulting from "perfect" diets were estimated by comparing the average nutrient intake of men and women in the U.S. with Daily Reference Values (DRVs). These numbers were then adjusted to reflect only FDA regulated foods. This estimate is a measure of all potential benefits to be derived from consumers eating a healthier diet while maintaining their current consumption of meat and poultry. The results indicate that if all consumers were to adopt "perfect diets" from FDA-regulated foods, 500,000 cases of CHD and cancer resulting in 213,000 premature deaths would be avoided over the next 20 years.

FDA has determined that these proposed rules are major rules as defined by Executive Order 12291, and have significant effect on a substantial number of small entities as defined by the Regulatory Flexibility Act.

II. Purpose of the Regulatory Impact Analysis

The purpose of this RIA is to determine the economic effects of the proposed rules to amend the food labeling regulations in 21 CFR parts 5, 100, 101, 105, and 130. This analysis is intended to satisfy the requirements of an RIA as specified in Executive Order 12291 as well as the requirements for a Regulatory Flexibility Analysis as specified in the Regulatory Flexibility Act.

Guidance for determining whether these actions constitute a "major" impact under Executive Order 12291 includes the criteria in Section 1b of the Executive Order itself, and informal supplementary guidance provided by The Department of Health and Human Services's (DHHS) Handbook on Developing Low Burden and Low Cost Regulatory Proposals, dated February 1984. Guidance for determining whether this action creates "a significant impact on a substantial number of small entities" includes definitions in section 601 of the Regulatory Flexibility Act (Pub. L. 96-354) and informal supplementary guidance provided by the DHHS Handbook.

FDA requests comments concerning the various considerations and conclusions it used in determining the quantitative or qualitative costs and benefits for this proposed regulation.

III. Description of the Proposed Action

FDA is responding to the 1990 amendments to amend the act. The 1990 amendments provide FDA specific authority to issue regulations concerning food labeling. The rulemaking actions analyzed in this document are as follows:

A. Mandatory Status of Nutrition Labeling and Nutrient Content Revision

These actions require nutrition labeling on most foods that are meaningful sources of nutrients and revise the list of required nutrients and the conditions for listing nutrients in nutrition labeling. The 1990 amendments specify that nutrition labeling shall include information on:

(1) The total number of calories derived from any source, and the number of calories derived from fat;

(2) The amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, total protein, and sodium; and,

(3) Any vitamin, mineral, or other nutrient required to be placed on the label before October 1, 1990:

In response to a Citizen's petition, the agency is also proposing to allow the use of the protein digestibility-corrected amino acid scoring method for foods intended for persons of all ages, except infants.

FDA is further proposing that, when a food contains insignificant amounts of more than one-half the required nutrients, a simplified format shall be used.

B. Revision of Reference Daily Intakes and Daily Reference Values

This action updates the U.S. Recommended Daily Allowances (RDA's) used in food labeling and replaces the term U.S. RDA with Reference Daily Intake (RDI). The agency is also proposing a separate set of DRV's for fat, fatty acids, cholesterol, carbohydrate, fiber, sodium and potassium, substances for which RDAs have not been set.

C. Declaration of Ingredients

FDA is proposing the following changes in regard to the label declaration of ingredients:

(1) Require label declaration of certified food colors;

(2) Require label declaration of all ingredients in standardized foods;

(3) Require that when more than one sweetener is used in a product, all sweeteners be declared together by common or usual names in descending order of predominance by weight, in parentheses in the list of ingredients, following the collective term "sweeteners;"

(4) Require the declaration of all protein hydrolysates by their common or usual name, including the identification of the food source;

(5) Require identification of a caseinate as a milk derivative in foods labeled as nondairy foods; and,

(6) Require that labels bear an explanatory statement that the list of ingredients is in descending order of predominance.

FDA is also proposing two voluntary provisions including:

(1) Provide a uniform format for voluntary declaration of percentage ingredient information, and

(2) Permit inclusion of the food source in the names of several of the sweeteners prescribed by food standards.

The agency is also responding to comments by advising sellers that wax or resin coatings on fresh fruit must be labeled with the specific wax (currently required) name or the proposed collective names. This language emphasizes regulatory enforcement of an existing requirement. FDA advises that the information must be placed in a conspicuous place where the produce is displayed in bulk but retailers are allowed sufficient flexibility to choose the specific location. Producers or distributors are required to supply the information to retailers through labeling accompanying the produce. In the case of resins, a statement of function must appear in the labeling. The 1990 amendments exempt produce sold in small open containers.

D. Percent Juice Labeling

The agency is proposing to:

(1) Require declaration of the total percentage of juice and the percentage of each represented juice on both single and multiple juice beverages;

(2) Require percentages of juice to be expressed in one percent increments. For multiple juice beverages, if manufacturers declare one or more individual juices or picture them on the vignette, or represent their presence in any other way, the percent of these individual juices will have to be identified. If major modifications (i.e., changes in the color, taste, or other organoleptic properties) have been made to a juice to the extent that the original juice is not recognizable, or if its nutrient profile has been diminished, then the juice may not count toward the total percent of juice. FDA believes it is appropriate to include juices with minor modifications such as acid-reduced orange juice. If the beverage contains no fruit or vegetable juices, and either fruit or vegetables are pictured on the vignette or the labeling, or the color or flavor of the product implies that a juice is present, then it must be labeled as containing zero percent juice;

(3) Describe where the percentage label statement must be on the container; and

(4) Provide directions on how to name various classes of juices and juice beverages, e.g., "diluted grape juice beverage."

E. Labeling of Raw Fruit, Vegetables, and Fish

The 1990 amendments require that FDA:

(1) Develop guidelines for food retailers for the "voluntary" nutrition labeling of raw agricultural commodities and raw fish;

(2) Identify the 20 varieties of raw fruit, vegetables, and fish most frequently consumed to which the guidelines apply; and

(3) Define substantial compliance with respect to adherence by food retailers to the guidelines.

F. Serving Sizes

This action will ensure that serving sizes are standardized to reflect the amount of the food customarily consumed. In this action FDA will establish mandatory declarations of serving sizes to be used on the nutrition panel which will reflect either the customary amount consumed, e.g., 6 ounces (oz) or the customary unit of consumption, e.g., a slice of bread.

G. Nutrient Content Claims

This action establishes definitions for and proper conditions for use of terms describing cholesterol content, fat content, sodium content, calorie content, and other nutrient content claims on packaged food labels and on food service establishment menus and menu boards. Also, FDA will establish a procedure for handling petitions for inclusion of a claim in a brand name through informal rulemaking.

H. Nutrition Label Format

The 1990 amendments state that implementing regulations "shall require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." FDA will propose to revise the nutrition label format.

I. Health Claims

FDA is proposing general procedures that cover the regulation of health claims on both packaged food labels and on food service establishment menus and menu boards. The 1990 amendments require that the agency issue regulations in 10 diet/health topic areas determining whether health claims may be made in conjunction with specific food components. In addition, FDA will establish a procedure for handling petitions for new claims.

IV. Market Failure

The *Regulatory Program of the United States Government—1990 to 1991* (Ref. 40) notes that agencies must evaluate the existence of a "market failure" which will be addressed by Government action. According to Leftwich, "A market failure is said to occur when either quantity or quality of a good

produced in an unregulated market differs from what is purported to be the social optimum" (Ref. 2). Because there is no objective standard by which the performance of markets may be compared, it may be more instructive to present a comparison of how freely operating markets respond to various interventions and contrast the respective levels of transactions costs. This "comparative institution approach" (Ref. 3) utilizes a positive analysis to predict the outcomes of different institutional sets of property rights (Ref. 4). In this approach, both the unattenuated market and administrative institutions have strengths and weaknesses. Markets are assumed to be low cost transmitters of information to coordinate economic activity between producers and consumers, thereby lowering "identification" costs. The strength of administrative solutions lies in taking advantage of scale economies to enforce difficult or ambiguous property rights.

When "a large number of people are involved and * * * the costs of handling the problem through the market or the firm are high, governmental administrative regulation should lead to an improvement in economic efficiency" (Ref. 5). That is, "* * * a particular good or service may be available at a fixed cost which, if borne by all of those who benefit from it, would cost no more than each beneficiary would be willing to pay. However, if the beneficiaries are so numerous that coordination among them is expensive, either in terms of locating and exacting payment from class members or in terms of measuring relative benefits and, hence, relative charges to each, then potential buyers may forego, wholly or in part, an otherwise desirable good or service" (Ref. 6). In short, when the transaction costs of effecting a purchase or sale are high, the market may produce costly misallocations and redistributions of social resources. When this occurs, government intervention may produce a superior outcome to the market outcome (Ref. 7).

A more probable market failure in food labeling, however, is the problem of asymmetric information that characterizes a market for "lemons" (Ref. 8). Since consumers cannot judge nutritional quality for themselves, manufacturers are unable to charge a premium for high "quality foods" so that only the foods with the lowest nutritional value are produced and marketed.

V. Economic Impact Analysis

A. Costs of the Proposed Actions

This section describes and estimates the costs of the 1990 amendments. The discussion of costs includes a discussion of sources of data, industries affected, and quantitative estimates of the various requirements. Although most costs are a direct result of specific provisions of the legislation and may not be changed, FDA has cost altering options with respect to the time firms have to comply with mandatory nutrition labeling, whether or not eating and drinking establishments are affected by the regulation, and other, lesser options.

1. Sources of Information

The anticipated cost to manufacturers covered by these regulations was estimated using a compliance cost model for food labeling created for FDA by RTI (Ref. 9). RTI conducted their study of food labeling costs in two phases. In the first phase, RTI discussed actual and hypothetical labeling policies with 30 firms of various sizes and four-digit standard industrial classifications (SICs).

Firms were encouraged to estimate the effort (resource use) and, when possible, the cost to complete different compliance activities. From the information gained in the first phase, RTI was able to produce a model of the cost of food labeling. The first phase also produced information on administrative activities.

In the second phase of the project, RTI and FDA surveyed over 350 firms to collect more printing and label inventory data. The sampling frame defined each target population as all firms within a given industry. Within each target population, the sample was stratified to reflect proportional allocation among four firm size categories: Small (less than (<) 10 employees), medium (10 to 99 employees), large (greater than (>) 99 employees), and unknown size. Firms were strongly encouraged to respond to the survey, but participation was voluntary. RTI used the survey data to update and improve the parameter estimates for the compliance cost model developed during the interview phase of the project.

The source for the estimate of the number of food processing firms is Dun and Bradstreet's Electronic Yellow Pages, which is a comprehensive data base of U.S. businesses. Food manufacturers were identified using the SIC on a four-digit level. These firms were further categorized to exclude those producing only foods regulated by the U.S. Department of Agriculture (USDA) to estimate the number of firms producing food products subject to FDA regulations. Precautions were taken in order to avoid double counting. FDA found there were some problems using this data base, such as a lack of frequent updates. However, the alternative, which is Census data, counts establishments rather than firms. Also, very small firms are not included in the Census. Therefore, FDA found the Dun and Bradstreet data base to be the better choice.

The estimate of the number of products (77,000) was derived from A.C. Nielsen sales data obtained from sampling 21,000 grocery stores with annual sales of more than $4 million each. These stores account for approximately 80 percent of the sales of packaged foods. This estimate of total food products was refined in order to include only those food products affected by FDA regulations (USDA-regulated foods were removed from the estimate). This estimate includes both domestic and foreign products for sale on U.S. grocery shelves. Although food product labels are required to list either the address of the distributor or manufacturer of the food, it is impossible to determine the location (foreign or domestic) of the manufacturer who will bear the four costs (administrative, printing, inventory, and analytical), or some portion of them. The estimate of the number of food labels (defined as stock keeping units (SKUs)) (257,000) was also derived using the data from the A.C. Nielsen data base. This estimate also includes both domestic and foreign labels for sale on U.S. grocery shelves. A separate label is applied to each brand of food in a specific size which may be further divided by flavor, color, etc. Products are also differentiated by distinct recipes and manufacturers. In other words, if a manufacturer produces a strawberry jelly and a grape jelly, he produces two products. If the jellies are each sold in two sizes (32 oz and 16 oz jars), the manufacturer has four distinct labels SKUs. In order to estimate SKUs, it was necessary to estimate the number of both branded and private labels. The latter was accomplished by estimating the relationship between the number of private brand labels and sales of private labeled products.

2. Costs of Compliance

The costs of a labeling regulation are those associated with: (1) Administrative activities, (2) analytical testing, (3) label printing, (4) label inventory disposal, and (5) reformulation (including market testing).

These costs depend on the attributes of the regulation itself and on the characteristics of the industry being regulated. Relevant attributes of the regulation include the scope of the regulation, the intricacy of the regulation, the complexity of the expected label change, and the length of the compliance period. The characteristics of the particular industry that affect the magnitude of the costs include:

(1) Firm size
(2) Label type
(3) Printing process(es)
(4) Normal label redesign frequency
(5) Average label inventory
(6) Average label order and its cost
(7) Number of products

a. *Scope of the regulation.* All food processing industries will be affected in whole or in part by these actions. Table 1, which follows, indicates which industries are affected by the various actions.

An internal review of labeling of standardized foods using the Food Packaging and Labeling Survey (FLAPS) (Ref. 15), showed that in all likelihood, all standardized foods already contain full ingredient labeling. Therefore, for cost estimation purposes, only those products which contain artificial colors will be affected by the ingredient labeling requirements (effective in November, 1991). However, cheese (SIC 2022), ice cream (SIC 2024), and milk (SIC 2026) are exempt from labeling colors.

TABLE 1.—INDUSTRIES AFFECTED BY LABELING REGULATIONS

SIC	Industry name	(Phase I regulations)			(Phase II regulations)
		Standard foods, ingredients, and colors labeling	Percent juice labeling	Raw fruit, vegetables, and fish labeling	Mandatory nutrition labeling, format, nutrient content claims
2021	Creamery butter				X
2022	Cheese, natural and processed				X
2023	Dry, condensed and evaporated milk products.	X			X
2024	Ice cream and frozen desserts				X
2026	Fluid milk				X
2032	Canned specialties				X
2033	Canned fruits and vegetables	X	X		X
2034	Dehydrated fruits, vegetables, and soups	X			X
2035	Pickles, sauces, and salad dressings	X			X
2037	Frozen fruits and vegetables	X	X		X
2038	Frozen specialties	X			X
2041	Flour and other grain mill products	X			X
2043	Cereal and breakfast foods	X			X
2044	Milled rice and byproducts				X
2045	Flour mixes and refrigerated doughs	X			X
2046	Wet corn milling				X
2051	Bread, cake, and related products	X			X
2052	Cookies and crackers	X			X
2053	Frozen bakery products except bread	X			X
2061	Sugar cane mill products and byproducts				X
2062	Refined cane sugar and byproducts				X
2063	Beet sugar				X
2064	Candy and other confectionery products	X			X
2066	Chocolate and cocoa products				X
2067	Chewing gum	X			X
2068	Nuts and seeds				X
2075	Soybean oil mills				X
2079	Edible fats and oils, nec [1]	X			X
2083	Malt and malt byproducts				X
2086	Bottled and canned soft drinks	X	X		X
2087	Flavoring extracts and syrups	X			X
2091	Canned and cured fish and other seafoods				X
2092	Fresh or frozen prepared fish and other seafood.	X			X
2095	Roasted coffee				X
2096	Potato chips and similar products	X			X
2098	Macaroni and spaghetti				X
2099	Food preparations, nec [1] dietary supplements grocery stores.	X		X	X

[1] Not elsewhere classified.

All products which purport to contain fruit or vegetable juices are affected by the percentage juice labeling requirements.

The 1990 amendments specifically exempt certain products from nutrition labeling but not from health claim regulations:

(1) Foods that contain insignificant amounts of all the nutrients and food components required within nutrition labeling (insignificant is defined as that amount which allows a declaration of zero in nutrition labeling);

(2) Foods sold by businesses having annual gross sales of not more than $500,000 or annual gross sales of food of not more than $50,000;

(3) Foods served in restaurants or similar food service establishments and foods that are principally processed and prepared in a retail establishment and are ready for consumption; (FDA may choose to require nutrition labeling with a nutrient content or health claim.)

(4) Foods sold by grocery stores that are offered for sale from self-service salad bars and deli or bakery counters; (FDA may choose to require nutrition labeling with a health claim.)

(5) Foods in small packages (must provide nutrition labeling at point-of-purchase);

(6) Medical foods;

(7) Infant formula;

(8) Foods shipped in bulk form; and

(9) Foods supplied for institutional food service use only.

The 1990 amendments specifically exclude restaurant foods from the requirement for nutrition labeling. However, the agency believes it has the authority to issue regulations requiring restaurants that choose to make health claims or nutrient content claims to adhere to the requirements for such claims, including nutrition labeling. In 1989, there were a total of 536,796 commercial food service establishments (CFEs), as illustrated in table 2 (Refs. 10 and 11). In addition, there were 172,131 institutional and 1,256 military food service establishments. Institutional establishments include employee food service, school and hospital cafeterias, penal institutions, nursing homes, and transportation food service. However, only institutional establishments which actually sell food are potentially affected such that prisons, for example, would not be covered.

TABLE 2.—FOOD SERVICE ESTABLISHMENTS

Eating places	331,926
Drinking places	37,227
Lodging places	27,199
Retail hosts	106,397
Food contractors	15,739
Recreation and sports food service	12, 414
Other (vending/catering/mobile)	5,894
Total commercial food service	536,796
Institutional feeding	172,131
Military feeding	1,256
Total food service establishments	710,183

Nutrient content and health claims regulations applicable to food service establishments would apply to all forms of labeling in those establishments: Menus, signs, and posters. FDA believes that posters and other types of menu boards in restaurants are generally changed frequently, at least every 6 months. FDA requests input as to the validity of this assumption. Assuming menu boards are changed frequently, the cost of changing these items will not be considered in this assessment. This analysis will therefore consider only the cost of the currently proposed regulations on changing printed menus and lighted menu boards using preprinted plastic strips to indicate menu items, and the cost of any implied nutrition testing. Approximately 294,051- CFEs may be assumed to have some sort of commercially printed menu, as indicated in table 3. Not all categories of food service establishments can be assumed to have written menus as many establishments may use menu boards and signs. Although there are no data on the number of food service establishments using written menus, a rough estimate of this number may be generated by listing only those establishments in categories for which it seems reasonable to assume written menus. This has been done in table 2. The number of establishments in each category are taken from "The Food Service Industry: 1989 in Review (Ref. 10). Note that the agency assumes only 36 percent of the total number of limited menu restaurants in 1989 have written menus. This corresponds to the portion of all limited menu restaurants falling into one of the following three categories in 1987:

(1) Table, booth, counter seat with waiter/waitress service;

(2) Take out or drive through; and

(3) Other (Ref. 11).

TABLE 3.—ESTIMATED TOTAL NUMBER OF NONINSTITUTIONAL AND NONMILITARY COMMERCIAL FOOD SERVICE ESTABLISHMENTS HAVING PRINTED MENUS

Restaurants and lunchrooms	160,859
Limited menu restaurants (incl. fast food)	52,658
Bars and taverns	37,727
Lodging places	27,199
Store restaurants	16,108
Total	294,051

One of the most significant developments in the restaurant industry has been the shift toward healthier options on the menu. For example, in 1990, the National Restaurant Association (NRA) found 34 percent of the menus submitted to its annual menu contest have "light and healthy" menu sections, compared to only 12 percent in 1985 (Ref. 12). Similarly, in a survey of its members, the NRA found that 55 percent of respondents "featured or promoted items because of their specific health or nutrition benefit (Ref. 13)." Any nutrient content claim or health claim not in compliance would require a change in the printed menu. If it is conservatively assumed that none are i compliance, then 55 percent is an approximation of the proportion of the total number of menus likely to be affected by the current proposal. There are several potential problems encountered with using this survey to estimate the current use of health claim and nutrient content claims. First, the survey was not designed to be a representative sample of the entire industry, only of the membership of the NRA. Secondly, this approach will not reveal where a single respondent may have had such nutrient content claims c health claims on more than one menu, i.e., on both lunch and dinner menus. Thirdly, it will not reveal which CFEs currently using such terms will be in compliance with regulations governing those claims and nutrient content claims.

Finally, there is no way to determine from the survey which restaurants currently using nutrient content claims and health claims will continue to do sc following publication of the final rules. Firms may discontinue use of these terms both because many recipes and types of nutrient content claims will no qualify under the proposed guidelines, and because of the additional costs of analytical testing. Those firms choosing not to continue to use these terms will have to change their menus, but may no have to undergo nutrient analysis.

Under the preceding assumptions, an estimated 161,728 CFEs will be affected potentially. Assuming, further, that 30 percent of the CFEs under consideratior would normally change their printed menus within the time allowed by the regulation, 113,210 CFEs will have to change their menus involuntarily as a result of the current regulations. FDA recognizes that the above assumptions are speculative and FDA requests information regarding these issues.

To generate a more accurate assessment of the number of firms affected, FDA requests information concerning the proportion of firms using health claims or nutrient content claims with respect to nonmeat and nonpoultry dishes, the number of menus affected, and the number of such firms that are already in compliance with FDA regulations governing those claims and nutrient content claims.

In addition, a certain proportion of those CFEs not using printed menus, but using menu boards, will also be affected Since these menu boards typically do not contain as much information as

printed menus, the agency assumes that a smaller proportion of these establishments use nutrient content and/or health claims. As an example, FDA assumes 5 percent of CFEs using menu boards (i.e., not assumed to have printed menus), or 12,137, use health claims or nutrient content claims.

Although nutrition labeling for fresh produce and fish is "voluntary," it will become mandatory if FDA determines that "substantial compliance" has not been met. Because FDA has determined that it is not necessary that all firms comply for substantial compliance to be achieved, some "free riding" may occur. That is, firms may attempt to rely on their competitors to label, which would lead to a low overall compliance rate. However, because: (1) The grocery industry may wish to avoid mandatory regulations, (2) there is a low minimum compliance cost per firm, and (3) firms may have to label to be competitive, full compliance may occur.

b. *Effective dates.* The 1990 amendments require that final regulations become effective 6 months after the date of promulgation of all final regulations. If no final regulations have issued by November 8, 1992, the proposals are statutorily mandated to be considered final rules on November 8, 1992, with an effective date of May 8, 1993. The 1990 amendments allow the Secretary to delay the effective date of some of the provisions for up to 1 year if he finds that compliance with the new provisions of the act would cause undue economic hardship.

FDA is proposing to make certain of the provisions of the ingredient labeling regulations effective on the same date as the nutrition labeling rule. The exception to this is the provisions for the listing of all ingredients in standardized food and the listing of all FDA-certified colors which must take effect November 8, 1991 (Pub. L. 102-108). Under the provisions of Pub. L. 102-108, those firms whose inventory is depleted between July 1, 1991 and May 8, 1993 are required to revise such labels for their products consistent with the proposal in the **Federal Register** of June 21, 1991 (56 FR 28592). Such firms will bear administrative costs and redesign costs to include color and standardized food ingredient information. There will be no analytical costs, inventory costs or printing costs outside of redesign costs as this additional printing is not prompted by requirements of this regulation.

Table 4 shows the separable proposed regulations for enactment of the 1990 amendments.

TABLE 4.—EFFECTIVE DATES FOR THE 1990 AMENDMENTS

Proposed rule	Optional effective dates		
	[1] 1	[1] 2	[1] 3
Declaration of ingredient/color labeling	[2] 11/91		
Percent juice labeling	5/93	11/93	5/94
Raw fruit, vegetables, and fish	11/91		
Cholesterol free and percent fat labeling	5/93	11/93	5/94
Mandatory status of nutrition labeling and nutrient content revision	5/93	11/93	5/94
Nutrient content claims	5/93	11/93	5/94
Cholesterol, fat, and fatty acid labeling	5/93	11/93	5/94
Lite butter	5/93	11/93	5/94
Nutrient content claim and a standardized term	5/93	11/93	5/94
Serving sizes	5/93	11/93	5/94
Petitions requesting exemption from Federal preemption	[2] 11/91		
Health claims general requirements	5/93	11/93	5/94
State enforcement provisions of 1990 Amendments	11/92		

[1] The 1990 amendments allow the Commissioner of Food and Drugs to delay the effective date beyond Option 1 if there is a "substantial economic burden" on industry to comply with any of these regulations. The effective date in Option 1 is prescribed by the 1990 Amendments and the two alternates are 6 month extensions of that date.

[2] The date when manufacturers affected by these regulations and who reprint their labels must be in compliance with the regulation.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

c. *Administrative costs.* The administrative costs associated with a labeling regulation are the dollar value of the incremental administrative effort expended in order to comply with a regulation. The administrative activities which are anticipated to be undertaken in response to a change in a regulation include: Identifying the underlying policy of the regulation, interpreting that policy relative to the firm's products, determining the scope and coverage related to product labels, establishing a corporate position, formulating a method for compliance, and managing the compliance method.

The magnitude of administrative costs to a representative firm is a function of several variables including the scope and intricacy of the regulation (positive relationship), the number of distinct products, and the length of the compliance period associated with the regulation (inverse relationship). Minor regulations are those which have little if any effect on product composition or

marketability. The compliance method for these regulations is usually straightforward and no testing or reformulation is involved. Conversely, intricate regulations are those that lead to analytical testing and, possibly, product reformulations or discontinuations. Intricate regulations require more administrative effort than minor ones.

In addition, longer compliance periods decrease administrative costs because firm executives might delegate downward decisions that are less immediate. According to RTI, many firms estimate that administrative effort would be twice as high for a 6-month compliance period as for a 12-month period. Similarly, a 24-month compliance period would reduce administrative effort due to a simplified coordination of the compliance process.

Administrative costs also vary with firm size in that larger firms often have a more comprehensive approval process for label changes than smaller firms. In addition, administrative costs have a largely variable component for labeling decisions such that these costs are part variable and part fixed. Larger firms also tend to have more products and more labels or stockkeeping units (SKU's), so that there are more label changes (per dollar of sales) that the larger firms must coordinate. For this RIA, administrative costs associated with intricate regulations are estimated at $9,000 for small/medium firms (less than 100 employees) and $68,450 for large firms. For less intricate regulations, the costs are estimated at $650 for small/medium firms and $6,300 for large firms. These costs have been estimated for domestic firms only as FDA has no information on administrative costs for foreign firms. Total administrative costs also only reflect costs to domestic firms.

Administrative costs for the one-time relabeling changes for listing ingredients on labels for standardized foods and artificial colors on labels for all foods containing them will affect 12,800 firms (of which 1,145 are large (based on Dunn and Bradstreet study)) who will incur administrative costs of $16 million. These will be administrative costs of overseeing redesign only as these costs will only occur to firms who are reprinting labels in the interim period.

Administrative costs for all of the 1990 amendments (mandatory nutrition labeling, format changes, etc.) are assumed to be those associated with intricate regulations for the 8,900 medium and large firms (based on Dunn and Bradstreet study). These administrative activities are valued at $152 million.

FDA estimates that manufacturers of dietary supplements will incur administrative costs of $850 per firm. Costs for these firms will be $138,000.

These costs are additive because firms affected by the ingredient provisions (who reprint labels in the interim period) must also relabel to comply with mandatory nutrition labeling. In sum, these provisions are estimated to impose one-time costs of $168 million.

d. *Analytical testing.* Analytical tests are typically performed by technical personnel employed by firms or at independent laboratories. These costs consist of tests to determine nutrient and food component quantities required by various labeling provisions.

FDA assumes all firms affected by the percent juice labeling requirements will perform analytical testing to determine the °Brix level, which is the level of soluble solids in fruit juice, in their products. This assumption is conservative in that some firms may already perform °Brix analyses and no testing would be needed for 100 percent juice products. In addition, firms that produce more than one-juice mixed juice beverage would only need to test each individual juice once. FDA has no information as to the extent of either of these conditions.

The current total cost of analytical tests to determine the °Brix level in juices and juice products is $17 per product. This figure is based on the pricing schedules of five independent testing laboratories. It is assumed that three analyses are required for the initial data base. Therefore, the cost of analytical testing for percent juice labeling is $51 for each of approximately 3,800 products (A. C. Nielson study) for a total cost of $196,000. The recurring analytical costs are $65,000 every 5 years. Assuming recurring analytical costs continue 20 years into the future, total discounted analytical costs are $343,000 (5 percent discount rate). If discounted at 10 percent, these costs would be $287,000. These costs are also discounted at 10 percent for comparison purposes as, later in the document, the benefits estimate is discounted at 10 percent.

In determining the extent to which firms will incur analytical testing costs as a result of mandatory nutritional labeling, it is important to estimate the number of products/labels which currently contain nutrition information on their labels. The costs of compliance for those firms who have never voluntarily obtained nutrition information will be higher than for those firms who are currently performing some or all of the newly required tests.

Based on the most recent information from the 1988 FLAPS, nutrition-labeled products account for an estimated 61 percent of the annual sales of processed packaged foods. However, this estimate refers not to the percentage of products labeled, but rather to the percentage of the dollar value of packaged foods.

Unfortunately, there is no good estimate of the number of products or labels which currently contain nutrition information on the label although it is certainly less than 61 percent. This is because the FLAPS sample is made up of an equal number of market leader (defined as the top three brands in the survey) and nonleader brands. Although market leader brands may account for 75 percent of sales, they are also approximately 1.5 times as likely to provide nutrition labeling than nonleaders. In addition, there are many more nonleaders in the market than market leaders. Consequently, the percentage of brands currently containing nutrition information on the label is estimated to be 40 percent (Ref. 15).

Some firms that do not currently provide nutrition labeling are nonetheless aware of the nutritional characteristics of their food products with the help of prior nutritional testing. Consequently, less than 60 percent of the products may incur the full cost associated with the analysis. FDA has no direct information to estimate the percentage of firms which may be conducting nutrition testing without labeling this information. However, FDA estimates that 20 percent of all firms are already conducting the newly required nutrient analyses, perhaps in anticipation of the 1990 amendments. For this 20 percent of all firms, no additional testing will be required. Although tests already performed are a sunk or historical cost, their inclusion provides an historical account of the costs of these proposed regulations. A cost that has already been incurred is said to be a sunk or historical cost and is not an economic cost because no choice is associated with it. In addition, 32 percent of the firms (40 percent currently labeling × 80 percent not performing all tests) are performing the currently required tests and will, therefore, incur only the incremental analytical testing costs. The remaining 48 percent are assumed not to be currently testing their products and will, therefore, incur the total cost of a nutritional analysis. All tests include both domestic and foreign firms who sell products in U.S. supermarkets.

The total cost of nutrient testing to ensure compliance with current

regulations is approximately $354 per sample. The cost of that portion of the current tests which will no longer be required (testing for thiamin, riboflavin, and niacin) is $135 per sample. In addition to current requirements, firms will be required to test for cholesterol, fiber, fatty acids, and sugars. These tests currently cost $376 per sample. These figures are based on the pricing schedules of five independent testing laboratories. It is assumed that three analyses are required for the initial data base. The formula for determining initial testing costs for the firms who do not currently test their products is [(354–135+376)×3] or $1785 per product. Incremental initial costs for the firms who perform the currently prescribed testing but do not test for the newly prescribed nutrients will be $723 [(376–135)×3] per product. Total initial analytical costs for mandatory nutrition labeling are $112 million (including historical costs). Firms are assumed to retest once every 5 years on average. These costs are reduced to one-third of the original costs, or $37 million. As stated previously, it is assumed that three analyses are required for the initial data base. Only one analysis is required for subsequent testing. Assuming recurring costs continue 20 years into the future, discounted total analytical costs, again including historical costs, are $195 million (5 percent discount rate). At a 10 percent discount rate, these costs would be $163 million. These costs were calculated by adding costs of three tests in the first year and an additional test in the 5th, 10th, 15th, and 20th years, respectively.

TABLE 5.—ANALYTICAL COSTS OF MANDATORY NUTRITION LABELING

	Percent of all products	Incremental cost per product
Currently testing for all nutrients	20	[1] 0
Currently testing for only required nutrients (currently labeled)	[2] 32	$723 [(376–135)×3]
Not currently testing (not currently labeled)	[3] 48	$1785 [(354–135+376)×3]

[1] Historical cost included in total as $723.
[2] (80 percent×40 percent).
[3] (80 percent×60 percent).

FDA believes the incremental analytical testing costs for manufacturers of dietary supplements would be very small. Due to the nature of the product, FDA believes that full analytical testing is already performed on most dietary supplements. FDA requests information on this assumption.

e. *Printing.* Incremental printing costs depend on the type of printing process(es) used, the complexity of the label change, and the length of the compliance period. Because printing activities are specific to individual labels, computing incremental printing effort on a per-SKU basis is necessary.

There are three printing processes used in the food processing industry. These include lithography, flexography, and gravure. The particular process used will indicate the type of plate or cylinder which will be modified or replaced.

Often referred to as "offset," lithography is the most popular process for glue-applied label printing because of its relative advantages in quality, simplicity, and cost. Approximately 43 percent of all food labels are printed using lithography.

Flexography is acceptable for many products and applications in the food industry. However, because the screen elements on the plates are flexible, vignettes are sometimes printed with ragged, irregular patterns. It is used on approximately 43 percent of food labels.

Gravure is capable of high quality pictorial reproductions, high-color densities, and bright intensive solids because it can deposit thick ink films. However, it does not print type as sharply as lithography or flexography. Gravure is used on 14 percent of food labels.

Flexography and lithography have similar incremental printing costs although lithography is slightly more expensive on average. Gravure is a relatively costly printing process. It is not unusual for the incremental printing cost of a label printed with gravure to be three or four times the cost for the identical change when printed with lithography or flexography.

The complexity of the label change determines the level of effort for artwork (the illustrative and decorative elements of printed materials), stripping or image assembly (the assembly or positioning of negatives (or positives) on a flat prior to platemaking), and engraving (the carving, cutting, or etching into a block or surface used for printing). It also determines the number of plates or cylinders that must be modified or replaced. The most common labeling regulations require lettering changes to an area inside the information panel.

Line copy changes usually affect only one label color (printing plate), and it is unlikely that the services of a label artist will be needed. In most cases, a film assembler and an engraver modify an existing plate or produce a new one.

Despite the similarity and relative simplicity of line copy changes, firms differ in incremental printing effort. If flexography or lithography printing is used, many firms engrave new lettering onto an existing printing plate to save time and resources. Other firms order new printing plates regardless of how minor the line copy change may be. For gravure printing, every label change will result in a new cylinder since modifying gravure cylinders is not possible.

The requirements proposed for listing of ingredients on standardized foods and the listing of colors on labels will result in a relatively simple two-color label change. However, by the second effective date, the entire food label will be redesigned to incorporate all changes. Virtually all food products will be expected to carry revised ingredient labeling, nutrition information, and possibly a new nutrition label format. For those products which do not currently have this information, the current label contents will have to be rearranged in order to make room for the new panels. For those products which currently carry nutrition information, the changes required are so comprehensive that it is assumed that the entire label will be redesigned. In fact, those products affected by the regulations defining various nutrient content claim definitions will incur changes to the principal display panel (PDP) as well as to the information panel. In addition, the format chosen may also cause the PDP to be redesigned, depending on the new size of the nutrition panel.

Complex label changes are influenced by the same variables, but the level of effort required for each printing activity is higher. Any label change affecting the PDP will affect the visual appeal of a label. In such a case, an artist may be used to partially redesign the label. This would frequently affect all colors on the label, resulting in substantial artwork, photography, and engraving to complete the label change.

The length of the compliance period determines the firm's ability to combine planned label changes with mandated changes. The amount of printing costs assigned to a mandated printing change depends primarily on the length of time available to make the change. Label redesigning schedules vary from approximately 4 weeks to longer than 10 years. Most firms redesign food labels at least once every 5 years, with many redesigning branded labels at intervals of less than 1 year. Depending upon the complexity and similarity of planned

and mandated changes, a firm could significantly reduce incremental printing activities by combining both changes.

It is estimated that there are approximately 257,000 food labels currently on the market (based on A. C. Nielsen study). These labels represent both domestic and foreign products. Although products are labeled according to the country of origin, products may be imported and then labeled or exported, labeled in other countries and then reimported or other variations. Such variations make it impossible to distinguish between foreign and domestic firms in terms of bearing the cost of label printing.

Because firms will be able to combine planned and mandated changes for some labels, incremental costs will be incurred for fewer than 257,000 food labels. Using the methodology provided in the contractor's cost study, the cost of printing new labels for the mandated changes which will be effective by at least May 1993 will be $643 million. Printing costs are a function of the number of labels that must be printed, the type of process used for printing the labels, and the complexity of the mandated printing change, i.e., number of colors involved and whether or not the label must be redesigned. The printing activities in response to ingredient labeling (redesign costs only are counted) will cost $112 million.

Printing costs for dietary supplements are expected to be $250 per product. FDA estimates there are approximately 3,400 unique dietary supplement products on the market. This leads to a total printing cost for dietary supplements of $858,000. Thus, total printing costs will be $756 million.

f. *Label inventory disposal costs.* An additional cost category is the label inventory loss associated with the transition from old to new labels. The cost of label inventory loss depends on average label inventory and the length of the compliance period. The key variable in this relationship is average label supply. Label supply differs significantly across industries and firms, but a great deal of variation is sometimes present across product lines within the same firm.

There are many different types of labels, usually classified according to their construction and method of application: preprinted and direct. Preprinted labels are printed on special label paper, cut to size, and applied by machines to the container or package using special adhesives. Direct labels are printed directly on the container or package. Therefore, for certain products, such as canned soft drinks, the label which must be disposed of is actually the container.

As discussed above, the average label supply and length of the compliance period are the most important factors in determining inventory disposal costs. If allowed 2 years, for example, most label inventory will be depleted. Because firms will be able to dispose of inventory prior to making label changes, there will be no incremental inventory disposal costs as a result of the declaration of certified colors and ingredient declaration. However, additional costs of $306 million are estimated to be incurred as a result of the second phase of regulations if a 6-month compliance date must be met. Thus, total costs for inventory disposal of food labels amounts to $421 million. These costs include both domestic and foreign firms.

FDA has no information to determine inventory disposal costs for dietary supplements. We assume firms will be able to use up existing supplies within the 6-month compliance period.

g. *Reformulation.* FDA believes that firms may react to labeling regulations by reformulating existing products or introducing new products. Product reformulation occurs when a firm which must now reveal nutritional characteristics competes to provide more nutritious products for the marginal consumers who drive the market for quality. Many firms conduct market tests before distributing a reformulated or new product. These tests range from small internal taste panels to comprehensive public-use tests.

FDA does not have adequate information to determine the amount of product reformulation that may take place as a result of this regulation. Thus, while some firms may alter marketing techniques and strategies, these costs have not been quantified. Furthermore, these costs are inherently difficult to predict because they depend on future choices made by firms.

h. *Loss of trademark names.* Both the percent juice labeling document and the nutrient content claim definitions document may cause firms to alter names currently trademarked. Under Executive Order 12630, a "takings" analysis would be necessary if, in fact, this constituted a potential taking. These regulations, however, serve to reemphasize existing regulations as to how products may be named. Thus, any firm which will be forced to change the name of its product is now using terms that misbrand its products, and therefore no legal property right exists. Thus, no "takings" analysis is necessary. In the past, FDA resources have been used sparingly to enforce economic deception. Nevertheless, the (illegal) value associated with the trademark name will be lost to the firm when they change the name. Further, losses incurred by producers and consumers based on illegal names should not be counted as a societal loss (Trumbull cites Stigler, Buchanan, and others who argue that criminal gains ought not to be counted as societal gains (Ref. 16)).

i. *Costs to food service establishments.* Potential costs of the nutrient content and health claims regulations to food service establishments include costs of changing menus and menu boards, analytical testing, creating nutrition posters or handouts, and administrative costs.

i. Printed menus. To determine the costs of reprinting menus not in compliance with the proposed rules, the estimated number of CFEs having menus with health promotions and/or nutrient content claims will be allocated across different average cost of meal categories. Different menu printing costs may then be applied to the resulting figures. Within each size category, the least-cost menu printing options are considered, but it should be emphasized that these are lower-bound figures. FDA assumes that CFEs with an average cost per meal of less than $15 use a tripanel fold-out paper menu, which is estimated to cost $2.65 to print (Ref. 17). An eight-page booklet estimated to cost $4.25 to print is assumed for a CFE whose average cost per meal is between $15 and $30. For the high-scale CFE with an average cost per meal above $30, printing a single-color menu is assumed to cost $85 per 8.5x11 inch page. This analysis assumes only two pages and one color. An approximate breakdown of affected CFEs by average cost of meal category is as follows:

TABLE 6.—NUMBER OF AFFECTED COMMERCIAL FOOD ESTABLISHMENTS BY AVERAGE COST OF MEAL

Cost of meal	Affected establishments
<$15	106,242
$15 to $29.99	5,929
$30+	1,039
Total	113,210

Another factor affecting costs is the number of menus that must be printed per CFE. The number of menus that must be printed is a function of the average number of customers. Columns 1 and 2 of Table 7 present the average

distribution of seating capacity in the restaurant industry. These percentages have then been applied to the total number of restaurants in each average cost of meal category. This procedure ignores any correlation between the number of seats and the average cost of meal. That is, the same proportion of establishments with various seat sizes is ascribed to each of the average cost of meal categories. FDA is unaware of any correlation between the average meal cost and the size of an individual restaurant.

TABLE 7.—ESTIMATED NUMBER OF AFFECTED COMMERCIAL FOOD SERVICE ESTABLISHMENTS (BY CHECK SIZE AND SEATING CAPACITY) AVERAGE CHECK SIZE

Seating capacity	Percent	<$15	$15 to $29.99	$30 or more
0 to 100	0.14	14,874	830	145
101 to 150	0.21	22,311	1,245	218
150 to 199	0.18	19,124	1,067	187
200 to 400	0.33	35,060	1,957	343
>400	0.14	14,874	830	145
Total		106,242	5,929	1,039

The next step in computing menu reprinting costs is to calculate the total number of menus that must be reprinted and the cost of changing these menus for each of the three check size categories. For simplicity, the average number of seats within each range is used as a proxy for the number of menus and is multiplied by the number of restaurants within each corresponding check size. The total number of printed menus affected for CFEs is shown in table 8.

TABLE 8.—TOTAL NUMBER OF MENUS AFFECTED

Average number of seats	Average check size		
	<$15	$15 to $30	>$30
50	743,694	41,503	7,273
125	2,788,853	155,636	27,274
175	3,346,623	186,764	32,729
300	10,517,958	586,971	102,861
400	5,949,552	332,024	58,184
Total	23,346,680	1,302,898	228,320

If the average number of seats represents the number of menus that must be reprinted, the total cost of reprinting menus, less administrative cost, is $107 million, as shown below.

TABLE 9.—COSTS OF REPRINTING MENUS FOR CFES

	Average Check Size		
	< $15	$15 to $30	> $30
Total number of seats	23,346,680	1,302,898	228,320
Menu costs	× $2.65	× $4.25	× $175
Subtotals	$61,868,701	$5,537,315	$39,956,044
Total	[1] $107		

[1] Million.

ii. Menu boards. In addition to those CFEs having printed menus, a certain number of CFEs using menu boards are likely to undergo compliance costs as a result of the current proposal. As stated previously, the cost of changing menu boards utilizing separate letters that may be easily affixed or removed will be considered negligible. Thus, only those menu boards using preprinted plastic strips that must be professionally manufactured will be considered. However, FDA requests information on any other sort of menu board or printed menu that may be affected but has not been considered.

Unfortunately, no data are currently available on the percentage of CFEs having this type of menu board, or on the number of items on these boards containing nutrient content claims or health claims. However, a rough estimate of the number of items affected may be possible through the use of reasonable assumptions.

FDA believes the CFEs most likely to have menu boards with either health claims or nutrient content claims are frozen specialty shops such as frozen yogurt shops, some of whose business revolves around the ostensible nutrition advantages of their product.

The assumptions to be made on the number of menu strips affected may be broken down into three parts: (1) The number of establishments in various categories likely to have menu boards with preprinted plastic strips and thus potentially affected; (2) the number of establishments having this type of menu board now using health claims, and (3)

the number of menu strips that must be changed per affected menu board.

With respect to the first issue, the agency assumes that 50 percent of frozen food specialty shops (frozen yogurt and ice cream establishments), and 50 percent of all fast food establishments (including those that have previously been identified as having printed menus), use menu boards with preprinted plastic strips. In addition, as an example, the agency assumes that 10 percent of all other CFEs not previously considered to use printed menus, use this type of menu board.

Next, the agency assumes that 50 percent of the potentially affected menu boards used by frozen food specialty shops will contain either health claims or nutrient content claims. In addition, the agency assumes that 5 percent of all other potentially affected menu boards will have health claims or nutrient content claims. Finally, it will be assumed that an average of two strips must be replaced per affected menu board. Using the previous assumptions as an example, the number of affected menu boards would be as shown in table 10.

TABLE 10.—ESTIMATED NUMBER OF MENU BOARDS AFFECTED, BY TYPE OF ESTABLISHMENT

Limited menu (fast food)	3,657
Commercial cafeterias	37
Ice cream vendors, etc	3,049
Miscellaneous food service	143
Food contractors	79
Retail hosts	451
Recreation and sports	62
Total	7,476

The cost of printing menu board item strips ranges from about $6 to $18 for a small number of strips (about 1 to 10) and from about $1.50 to $4 for a very large number of strips (500) (Ref. 18). Since the cost depends heavily on the number of identical strips printed at one time, an accurate assessment of these costs would entail knowledge of the number of independent and franchise establishments. As a preliminary estimate, the simple average of the range of item strip printing costs noted above, $7.40, may be used. Under the preceding assumptions, the additional cost due to changing item strips on menu boards would be about $111,000.

iii. Analytical testing costs. All firms wishing to use nutrient content claims and health claims must undergo verification testing. Analytical testing represents a cost to all firms using health claims or nutrient content claims on the menu, including those firms who would normally reprint their menus within the allotted compliance period and which were not included above. Although all firms currently using nutrient content and/or health claims will incur printing and administrative costs, not all firms will incur analytical costs. Some firms currently making claims will not continue to use them in the future, as not all menu items will meet the criteria for making claims, nor will all firms wish to bear the additional costs.

iv. Administrative costs. Firms affected by these regulations will also incur administrative costs—the dollar value of the incremental administrative effort expended in order to comply with a regulation. Although FDA has no specific information in regards to the administrative cost per restaurant, FDA estimates the relationship of administrative costs to total costs for those firms' continuing to use nutrient content and/or health claims to be approximately 15 percent of those firms' total printing and analytical costs for labeling regulations (Ref. 9). For those firms choosing to not continue the use of claims, administrative costs are estimated to be 5 percent of total printing and analytical costs applicable to those firms. Therefore, if 20 percent of firms currently making claims continue to use them, total administrative costs will be $9 million. If only 1 percent of firms currently making claims continue to use them, total administrative costs will be $6 million.

v. Total costs to food service establishments. The costs to restaurants of the regulations to define the use of nutrient content claims and health claims include the costs of changing printed menus ($107 million) and menu boards ($111,000), analytical testing costs, and administrative costs ($9 million if 20 percent of firms currently using claims continue to use them, $6 million if only 1 percent). Therefore, this speculative estimate of the total cost to restaurants of these regulations is $116 million if 20 percent of firms currently using claims continue to use them, and $113 million if only 1 percent. These costs must be considered to be preliminary estimates as many of the assumptions are speculative. Within the next year, FDA will prepare a more accurate analysis of the cost of these proposed regulations on restaurants.

j. Total costs of the mandatory regulations. The total costs of the regulations are provided in table 11:

TABLE 11.—TOTAL COSTS OF FOOD LABELING REGULATIONS

[In millions of dollars]

	Phase I	Phase II	Total
Administrative costs[2]	16	161	177
Analytical costs	0	195	195
Printing costs	112	750	862
Inventory disposal costs	0	306	306
Total	128	1,412	1,540

[1] Excludes labeling of raw fruit, vegetables, and fish.
[2] Costs discounted at 5 percent.

3. Raw Fruit, Vegetables, and Fish

The costs of the action to label raw fruit, vegetables, and fish include laboratory testing; data base compilation; administrative costs; and the printing of signs, posters, handouts, etc. Because the regulation is "voluntary," it is impossible to predict the number of firms that will choose to comply although it is suspected that most, if not all, of the supermarkets will comply. If a substantial number (60 percent of all stores evaluated) are not found in compliance within 2 years, the agency will have to issue mandatory regulations. There are 31,000 chain stores and 68,000 independent grocery stores that fall under the compliance guidelines.

Compliance costs will vary depending on the particular medium chosen to convey the nutrition information. The more elaborate the labeling, the higher the cost. Brochures to be handed out, for example, would cost $4,000 to 6,000 per 100,000 brochures (Ref. 19). However, where some stores do choose to offer complicated labeling schemes as a marketing device, that would not necessarily be considered a cost of this regulation. Also, bulk orders by large chain supermarkets are expected to reduce costs substantially.

Comments have indicated to FDA that the average life of a grocery store sign is 6 months with a yearly cost of between $150 and $200 (Ref. 20). Over a 20-year period, if exactly 60 percent of supermarkets included are in compliance, the discounted cost would be between $117 ($150 per year discounted at 5 percent) and $155 million ($200 per year discounted at 5 percent).

Assuming every consumer spends the same for groceries, each store with over $2,000,000 per year in sales would have an average of 6,500 customers who would benefit from the labeling (250,000,000 consumers × 80.5 percent of sales = 203,750,000,203,750,000/31,000

supermarkets=6,574 customers/supermarket). The independent stores, with sales under $2,000,000, would have an average of 150 customers (250,000,000 consumers × 6.6 percent of sales=16,500,000. 16,500,000/110,000 stores=150 consumers per store). If labeling costs $200 per store every year, labeling costs in the smaller stores would be $1.33 per consumer per year.

B. Benefits of the Proposed Option

The proposed labeling changes will benefit consumers by giving them information to refine their food choices for health or other reasons. This section contains a qualitative description of individual benefits to be derived from the implementation of each of the requirements of the 1990 amendments and a quantitative estimate of the requirements as a whole.

1. Qualitative Description of Benefits of Individual Regulations

This section will discuss the qualitative benefits of the individual regulations. The benefits of mandatory nutrition labeling will be discussed quantitatively in the next section.

a. *Labeling ingredients.* i. Sweeteners listed together. A common complaint among consumers is that the ingredient list, in descending order of predominance, may contain multiple sweeteners which appear to represent a small proportion of ingredients. For example, sugar, high fructose corn syrup, and dextrose may be used in a ready-to-eat cereal and appear to make only a marginal contribution to the product based on individual listings in the ingredient list, although, if combined, the list would show the product to have sweeteners as the primary ingredient. People wishing to control their intake of sweeteners for health reasons (e.g., diabetes, obesity) or any other reason will be better able to adjust their food choices to match their preferences as a result of this rule.

ii. Required listing of protein hydrolysates. Because of trade secrets and the complex technical names of flavors, FDA has always exempted flavors from ingredient listings (FDA is also required to exempt flavors by statute). However, that exemption has never been applied to flavor enhancers such as monosodium glutamate (MSG). This rule clarifies the status of protein hydrolysates, such as hydrolyzed vegetable protein and other protein hydrolysates, which contain small amounts of MSG and which act as both flavors and flavor enhancers, by requiring them to be listed. MSG has long been suspected of causing allergic-like reactions such as the "Chinese restaurant syndrome." This regulation will benefit those consumers who wish to avoid "protein hydrolysates."

iii. Required listing of sodium caseinates. Sodium caseinates, which are milk derivatives, are components of "nondairy" creamers. Caseinates are required to be listed by some states. However, for vegetarians, milk protein sensitive individuals, and others such as those attempting to follow religious proscriptions, it is important to know that nondairy creamers may contain a dairy product. Thus, this regulation will require that manufacturers indicate that sodium caseinates are, in fact, derived from milk.

iv. Statement that ingredients are listed in the descending order of predominance. Although FDA's regulation has been in place for a number of years, some consumers still do not understand that products are listed in the descending order of predominance. This required statement will eliminate that confusion.

v. Listing of colors. A listing of colors will provide consumers who are sensitive to them with this information as well as provide information for those who wish to avoid chemical colorants.

vi. Required listing of ingredients in standardized foods. Very little, if any, benefit will be obtained from this provision of the statute because most or all ingredients are currently listed in standardized foods.

vii. Provision of a uniform format for voluntary declaration of percentage ingredient information. Although FDA has declined to require that ingredients be listed by their percentage contribution to a product because of the potential costs of such a requirement (relative to the potential benefits), some manufacturers may choose to make such lists available in response to consumers demand. FDA is proposing a uniform format that manufacturers would use if they did choose to make such a declaration. By providing a uniform format, consumer confusion over multiple presentations would be avoided.

b. *Labeling of percent juice.* Providing consumers with the listing of percentages of fruit juice in various juice beverages will enable them to make choices consistent with their desire to obtain percentages of juice. Consumers have repeatedly asked for this information.

Other benefits include clarifying the regulation that requires consistent naming of products. Some products now marketed are mislabeled under existing regulations by failure to put the names of juices in descending order of weight predominance in the product name. A product containing 80 percent apple juice and 20 percent grape juice, for example, may not be called "grape-apple juice." This regulation restates and reenforces this regulatory principle. This regulation also clarifies the rules by which manufacturers can count a modified juice as "juice." In some cases, manufacturers have modified juice so much that only water and sugars remain.

c. *Labeling of raw fruit, vegetables, and fish.* To the extent that consumers do not now know the nutritional composition of the raw fruit, vegetables, and fish that are proposed to be included among the "top 20," some change in purchase behavior may be expected leading to a healthier diet.

d. *Standardizing serving sizes.* The 1990 amendments direct FDA to standardize serving sizes for individual foods rather than allowing each manufacturer to establish their own serving size.

In the past, manufacturers were free to select their own serving size for purposes of calculating nutrient amounts. Standardization of measurements such as weights and scales dates as far back as 3500 BC (Ref. 21). The benefits of such standardization to buyers are reduced search costs (a transactions cost of using the market) and concomitantly, an increased ability to accurately select product quality consistent with individual desires. In the case of serving sizes, manufacturers may often "game" nutritional labeling by selecting a favorable serving size. An example would be to select a smaller serving size in order to be able to claim that a product was low in fat or sodium. If similar products use different serving sizes, consumers must make the appropriate calculation to compare products. However, many consumers may not notice that different serving sizes are being used, which leads to erroneous impressions of the nutritional quality of the food.

e. *Standardizing adjectives to describe nutrient content.* Because adjectives such as low, high, etc., are a verbal qualitative description of quantitative measurement, these regulations will have similar benefits to standardization of serving sizes.

f. *Revising the nutrition label format.* Several goals will be met by this regulation. The format chosen will be one which consumers desire, find easy to use, and easily understand. Ultimately, if a new format is selected, it will cause some consumers to direct their purchase behavior towards more healthful foods.

g. *Regulating health claims.* The benefit of these proposed regulations is to provide for new information in the market in the form of health claims that are not misleading in the sense that scientific evidence supports them. Although health claims exist on the market now, they have not been legally allowed for food products. FDA has used its enforcement discretion to act against only those claims that were egregiously misleading and, in the case of restaurants, FDA has traditionally left enforcement of health claims to the states. In the past, a food which made a claim relating to preventing, curing, or treating a disease legally became a drug and was subject to drug regulations. Because the regulation of drug products is much more burdensome than that for foods, this acted as a disincentive to making such claims. These regulations will now permit these claims to be made, if precleared by FDA, so that labels for food products as well as menus and menu boards can contain health claims without being subject to drug regulations. The additional benefit to regulating the use of claims by food service establishments is to prevent consumer confusion that may occur if different rules apply to foods from different sources, i.e., packaged foods versus restaurant foods.

Because the costs to food service establishments of analytical testing and nutrition information printing are high per menu item, many food service firms might choose to remove claims from their menus. This would reduce benefits to the extent that claims that are not misleading will be removed. FDA requests information on the number of food service companies that will discontinue the use of nonmisleading health claims because of the burden imposed by the proposed regulations. FDA also requests information on the likely changes in consumer behavior, and health, if this reduction occurs. In particular, how large would the health costs be, estimated on a basis similar to that used for estimating health benefits, of increased labeling? Would any health gains from restaurants which added nutrition information to menus be as large as the losses from restaurants which stopped making only health claims at all? Would the number of truthful health claims on menus grow larger than at present if regulation did not discourage this?

As a component of labeling in general, health claims may be the primary motivating force behind consumer behavior changes (substituting toward more nutritious foods). As such, much of the benefits of the 1990 amendments will depend on how health claims are regulated. If mostly incorrect claims are prohibited, consumers will benefit from only seeing those claims that are correct. On the other hand, if claims that are likely to be true are removed, this will decrease the total benefits of the 1990 amendments as consumers will lose valuable information. However, the opportunity exists for firms to petition the agency to reinstate "true" claims. It is not clear how much consumer changes in purchases for nutrition reasons can be attributed to health claims on the front of the primary display panel versus the nutrition panel on the back of product. Ippolito and Mathios found large changes in both producer and consumer behavior due to changes in health claims (front of label), but were unable to separate out behavior changes due to the presence or absence of nutrition labeling (back of label) (Ref. 22).

2. Labeling Benefits Model

FDA looked at several possible ways of quantifying the health benefits of the 1990 amendments. The preferred method of estimating benefits is to measure actual market prices for the good in question—a willingness-to-pay model. However, the good in this case is information on the food label, which is not directly traded in the market. The market for most consumer information is for consumer durable goods, but studies on these goods do not translate well to food labeling information.

Yet another method of quantifying benefits is to use contingent valuation studies in which consumers are given structured interviews to determine their willingness to purchase a good that is not normally traded in the market. However, the more hypothetical the question, the less incentive respondents have for accurate responses (Ref. 23). FDA believes that questions relating to information which might be supplied on the food label would be too hypothetical.

Because neither willingness-to-pay nor contingent valuation studies would produce estimates of the value of new food label information, FDA decided to use an alternative market approach which projects changes in consumer purchasing patterns. It is expected that most consumers will react to the new labeling by readjusting their prior expectations about the nutritional quality of the food they are purchasing. That is, the information they learn about the amounts of saturated fat, total fat, and other nutrients will alter their food choice to discover which, among other things, ranks nutritional qualities of food. This factor then, in combination with other characteristics of food, will cause some consumers to alter their purchase behavior toward healthier food.

The model eventually chosen was created by RTI for FDA, is entitled "Estimating Health Benefits of Nutrition Label Changes" attempted to estimate health benefits through a three-step process:

(1) Estimate the changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

a. *Estimation of changes in consumer purchase behavior and nutrient intakes.* The magnitude of changes in nutrient intakes will depend on how consumers use the new information to alter their choice of foods. That will, in turn, depend on whether the information is important to consumers, whether it is in a format easy to understand, and how nutrition is valued relative to other food characteristics (taste, appearance, convenience, and price). The change in purchasing behavior that will ultimately lead to a change in nutrient intake is difficult to estimate. What is being projected is the change in purchasing behavior that would come as a result of new, specific, product information about which consumers already have a prior estimation.

There is no situation which exactly corresponds to this particular set of regulations which could serve as a model to estimate this change. However, FDA does have a market study of purchasing behavior change from a similar kind of situation. This study was conducted as a result of a special program done by FDA in conjunction with Giant Food, Inc. This study, entitled the SDA, used special shelf labels to call consumers' attention to various nutrient content claims of food. For example, a flag may have called attention to a product that qualified under FDA guidelines as being "low cholesterol." In addition, a guidebook was offered either free or at nominal charge.

To compute the changes in nutrient intakes for consumers that resulted during this study a four-step method was used:

(1) Identify products with a significant market share change.

(2) Estimate the number of shelf labeled and unlabeled products in each significant product category and the market share changes in each product category from unlabeled to labeled.

(3) Compute estimated changes in consumption of food from SDA categories by using the "Continuing Survey of Food Intakes by Individuals (CSFII)," and SDA results.

(4) Estimate changes in nutrient intakes from product share changes and extrapolate changes to the U.S. population (Ref. 24).

Table 12 shows the estimated nutrient changes (Ref. 24):

TABLE 12.—ESTIMATED CHANGES IN NUTRIENT INTAKES FROM THE "MARKET STUDY"

	Men	Women
Change in fat intake:		
Grams	−1.49	−0.67
Percent	−1.4	−1.1
Change in saturated fat intake:		
Grams	−0.48	−0.16
Percent	−1.3	−0.7
Change in cholesterol intake:		
Milligrams	−0.42	−0.26
Percent	−0.1	−0.1

This estimate may be construed to be a reasonable underestimate of the changes consumers are expected to make for the following reasons: (1) The SDA experiment did not cover as much of the nutritional profile as will be covered by the 1990 amendments; (2) Not all food products were covered by the SDA study; (3) Consumer awareness and concern for total and saturated fat has increased since that study was done (1988) and will likely continue to increase over the next 20 years for which benefits are estimated; (4) No reformulation was likely to take place for this small market; and (5) No estimate was made for substitutions between products (e.g., potatoes to rice).

However, there are some reasons that drive this estimate to overstate change, particularly. First, because this information was in the form of shelf "flags" as opposed to nutrition panel information on the back of packages, consumers are more likely to be drawn to this type of labeling instead of new information on the backs of labels. However, the effect may be mitigated if firms choose to voluntarily use such nutritional "highlight" flags as an extension of nutrition labeling. Also, the allowance of health claims on the front of the package may tend to simulate the effect of shelf flags.

Secondly, no net effects of dietary changes were estimated. For example, if consumers decreased their intake of milk to lower fat intake and replaced it with apple juice, this might cause a calcium deficiency and increased risk of osteoporosis. These net effects are complicated because of the extraordinarily large number of risk items associated with any food.

Thirdly, this study, when applied to the entire population over 20 years, assumes that the purchase behavior shifts observed in the SDA study will be permanent. In fact, many studies have noted transitory shifts in behavior in response to new information. Nonetheless, as diet/health links are strengthened in the next 20 years and awareness of these links increases, FDA expects that these behavioral shifts will be lasting. Finally the nutritional benefits are extrapolated to the U.S. population using a baseline for nutritional consumption that is derived from 1988 data. If in fact, there is a trend toward better diets, and to the extent that the trend continues independently of labeling changes, then this extrapolation will tend to overstate benefits.

The fact that this model neither allowed for substitutions between products nor calculated the net effect of all dietary components has been discussed as leading to either an overestimate or an underestimate of benefits. One problem that occurs now with substitutions between products is that some products as a category are almost entirely unlabeled. Putler and Frazao (1991) find that women trying to decrease their level of fat simply traded one source of fat for another between food groups (Ref. 25). The product groups that were added included the largely unlabeled dairy products and food fats and oils. Thus, labeling of all food products will mitigate this problem.

In terms of the net effects of product substitutions, FDA believes that fat, saturated fat, and cholesterol consumption changes are likely to have the largest nutritional impact on health. Furthermore, health messages will be regulated such that no claim may be made unless the food is within the boundaries for a healthy food in several aspects, i.e., saturated fat, total fat, cholesterol, and sodium. Content claims require disclosure of "negative nutrients in high amounts in close proximity to the claim and claims are prohibited if the food contains 'negative nutrients' in high amounts." It is unlikely that consumers switching to avoid consuming too much of the primary negative nutrients will encounter gross health effects from consuming different nutrients in an alternate food that would offset the benefit of reducing consumption of the primary negative nutrients. Thus, while there may be some net effects that decrease benefits as estimated, this effect is likely to be minimal. Furthermore, as consumers become more knowledgeable over time about the diet/health link, they are likely to make even more judicious diet substitutions.

b. *Estimation of changes in health states.* The next step in estimating benefits is to establish the link between changes in nutrient intakes and reductions in the probabilities of disease. Because this estimate focused solely on changes in total fat, saturated fat, and dietary cholesterol, health changes are only estimated for CHD and cancer. A computer model, developed by Dr. Warren Browner for DHHS, has been used to estimate the relationship of changes between intake of fat and dietary cholesterol and changes in cancer and CHD (Ref. 26).

This model estimates the number of cases and deaths of CHD and breast cancer, prostate cancer, and colon/rectal cancer for a 10-year period. The model is divided by age group, race, and sex and computes the expected difference in rates of death from all causes and death from CHD and the three cancers. Cancer is affected by intake of total fat and is assumed to have a 10-year latency.

For CHD, relative risks are based on logistic regression coefficients obtained from the Multiple Risk Factor Intervention Trial (MRFIT) and Framingham studies, which specify the change in CHD resulting from a change in the level of serum cholesterol (Ref. 27 and 41). Serum cholesterol changes occur as a result of changes in the intake of dietary cholesterol and saturated fat with a 2-year lag. These changes are predicted by the Hegsted equation (Ref. 28). Finally, changes in health states for both diseases were predicted for the next 20 years.

There are factors in the estimation of health effects that lead to both underestimates and overestimates.

i. Underestimates. Consumers' increased knowledge of the ingredient and nutrient composition of foods is expected to lead manufacturers, particularly those who are not now providing nutrition information and who can make low cost reformulations, to reformulate their products to make "healthier" products. An indirect benefit may thus arise as some consumers, who do not search for nutrition, inadvertently obtain healthier (reformulated) food.

Many health conditions besides CHD and cancer may be improved as a result of nutrition labeling. Examples include osteoporosis, hypertension, obesity, and diabetes.

ii. Overestimates. Use of the Hegsted equation may overestimate the possible reduction of CHD. Recent results indicate that Hegsted may have overestimated the effect of dietary cholesterol on serum cholesterol by a factor of between three or four (Ref. 29).

Many of the provisions of the ingredient labeling regulations are directed at food ingredient sensitivities such as the provision regarding caseinate in "nondairy" products.

Table 13 presents the numbers of cases and deaths from cancer and CHD that are predicted to be avoided as a result of the 1990 amendments over a 20 year period:

TABLE 13.—ESTIMATED HEALTH EFFECTS [1]

[Over 20 Years]

Cases avoided	Total annual cases	
Cancer	35,179	500,000
CHD	4,028	514,000
Deaths avoided	12,902	
Life-years gained	80,930	

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer, respectively following a diet change.

c. *Valuation of health state changes.* In order to facilitate comparison of the costs of implementing the 1990 amendments, the changes in health states (benefits) will be valued in dollars. These estimates are valued using several separate techniques which reflect different assumptions about how to estimate reductions in the probability of early deaths. Together they provide a range for the benefits of the 1990 amendments.

i. Medical care costs. Medical care costs are cash outlays for the costs of medical care (cases). The figures presented here overstate the true reduction in such costs as the costs of competing illnesses are not subtracted. That is, even though cancer or CHD may be avoided, another disease may occur such that only net savings should be reported. Because costs of average cases of all other kinds of disease are not very meaningful, gross average medical care cost savings are reported in Table 14 below (Ref 24):

TABLE 14.—AVERAGE MEDICAL CARE COSTS

[Dollars]

	Men	Women
CHD	39,838	34,241
Prostate cancer	26,880	31,782
Colon/rectum cancer	24,055	25,963

Applying these figures to the discounted (5 percent) total number of cases to be avoided over the 20-year period yields a total of $0.6 billion saved.

ii. Willingness-to-pay estimates. Avoided medical care costs undervalue the true benefits of a health care regulation because they do not include productivity losses or pain and suffering losses. A more inclusive method of valuing these losses is to estimate the amount people are willing-to-pay to reduce risk. The willingness-to-pay estimates in this section are values that consumers and workers place on risk reduction. This is different from values people place on label information, which, as discussed earlier, we were unable to directly estimate.

Willingness-to-pay studies have been done for a variety of risk situations including wage differentials between high and low risk jobs, use of seat belts to reduce risk and contingent valuation surveys. These studies reflect the fact that people routinely make decisions to accept or avoid some incremental amount of risk such as choosing between buying an automobile or a motorcycle, climbing mountains or playing softball or being a policeman versus being a secretary. These decisions may either increase or decrease risk.

The results of these studies have often been mislabeled as "value of life" estimates. These estimates represent not the value of a life, but only the value of a reduction in the statistical risk of death. Thus, it is incorrect to say that if a person values a 1 in 100 risk reduction at $10,000, then that person's life is valued at $1,000,000 ($10,000/.01). It will matter, for example, whether the marginal risk is a reduction from 100/100 to 99/100, or from 2/100 to 1/100.

Consequently, statistical willingness-to-pay figures must be understood to reflect only estimated values of marginal changes in the risk of death. It should also be pointed out that the willingness-to-pay figures used here will be applied to changes in risk (from estimated consumer behavior changes) which places additional uncertainty on these numbers.

Analysts have not reached a consensus on the best method of applying a willingness-to-pay estimate to value changes in health states. The studies mentioned above examine consumers' and workers' willingness-to-pay to reduce risk in various situations, from dying immediately of injury to dying of cancer at old age. Some analysts apply a mean figure to value the prevention of early death, others believe it is important to consider only the likely remaining number of life-years. Thus, this analysis will present both figures.

(a) *Remaining life-years approach.* The remaining life-years approach calculates a discounted value per life-year saved from mean values of willingness-to-pay to reduce the risk of death. According to analysts who favor this view, "* * * statistics about life expectancy tell us a great deal more than do stupefying tallies of death." That is, it is the length of life that is considered important, since dying of a heart attack at age 80 is posited to be of less societal concern than dying in a car accident at age 35. Use of these values, life-years saved, implies that it is worth more to society to save 60 years of life than 5 years of life.

In their study, RTI used the relatively conservative value of $1.5 million for the willingness-to-pay figure. Using the expected discounted life-years remaining from age 40, and a discount value of 5 percent, a value of $89,074 per life-year saved is derived. Combining this figure with the discounted number of life-years saved produces a benefits estimate of $3.6 billion ($7.2 billion if $3.0 million is used for the willingness to-pay figure as is done in the next section). If benefits are discounted at 10 percent (for comparison purposes, analytical costs, which extend into the future, were also discounted at 10 percent), benefits become $3.1 billion. Benefits do not decline rapidly with discount rates as the original value of life estimate is unchanged and fewer discounted remaining years of life is offset with a higher value per year.

Benefit estimates in each year are discounted back to the time of this decision because changes in risk for CHD and cancer appear at different, distant points in time. The Office of Technology Assessment has noted that health benefits should be discounted, other things equal, because people prefer health benefits today rather than at a future time (Ref. 31). By discounting these health effects to the present time, the value that consumers place today on future benefits may be estimated. Furthermore, it is necessary to discount

benefits in order to be able to compare them to costs. The higher the discount rate used, the lower the discounted health benefits.

(b) *Mean value approach.* The mean value approach is an alternative approach which applies a mean value to all early deaths, without regard to the average remaining years of life. As this approach is based on revealed market data, it avoids a problem of the former approach in that little empirical evidence is available to estimate how consumers value changes in risk for remaining life-years.

Furthermore, some studies have estimated willingness-to-pay values for reductions in risk of death as high as $8.5 million (Ref. 32). For this approach, FDA has conservatively doubled RTIs estimate and used $3.0 million. Combining the discounted number of early deaths (7,027) with a value of $3.0 million per early death avoided produces a benefit estimate of $21 billion ($10.5 billion if $1.5 million is used for the willingness-to-pay figure as is done in the previous section).

FDA realizes the range of values presented for estimating the benefits of reducing risks to health derive from different methodologies appearing in economic literature. It is not clear whether either methodology is inherently preferable either in general or for this particular set of regulations. FDA requests comments as to either the appropriate measure to use to value reductions in health risks or whether it is appropriate to use both in a range, as has been done here.

As has been noted throughout, FDA believes that the estimate of the health gains derived from the SDA study is probably an underestimate. The two primary reasons for this belief are the fact that no reformulation took place during the SDA study and the quantification of early death benefits leave out quality of life gains from fewer cases of CHD and cancer. Each case of cancer and CHD that does not result in early death still tremendously reduces the quality of life for both the afflicted and those around them.

d. *Perfect diet study.* In addition to estimating the benefits that derived from consumers behavior change, RTI estimated the improvement in risk that would obtain if all consumers were to eat a "perfect" diet. A perfect diet is defined as the average consumer consuming over time the DRV for fat, saturated fat, and cholesterol. This estimate represents a baseline of benefits which could be derived from a diet change made by U.S. consumers, particularly affecting their rates of cancer and CHD. Although not an estimate of benefits of nutrition labeling, the estimates provided in this section help to give perspective to the benefits obtained from food labeling. Other health improvements which might take place from a diet change include diabetes, hypertension, osteoporosis, and obesity. These changes are expected to produce small health benefits relative to CHD and cancer reductions. These risk improvements will be partially obtained by FDA's current effort on the 1990 amendments and may be further obtained by FDA's or any other organization's efforts to influence the nutritional intake of the U.S. diet.

To estimate current nutrient intakes, information on U.S. consumption data was obtained from the 1987 Nationwide Food Consumption Survey (NFCS), a self-reported food intake survey conducted by USDA. Next, average DRVs were compared with actual average intakes to estimate the maximum potential change in nutrient intake. Using the same methodology to extrapolate changes in cancer and CHD that was used in the benefits estimation, it is estimated that 725,000 cases of cancer and CHD are potentially avoidable by U.S. consumers over the next 20 years.

All of the health effects avoided from consumers eating the DRVs for fat, saturated fat, and cholesterol are shown in Table 15 below:

TABLE 15.—MAXIMUM HEALTH BENEFITS FROM DIET IMPROVEMENT [1] OVER 20 YEARS

Cases of CHD and cancer avoided	725,155
Deaths avoided	308,366
Life-years gained	2,280,549

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer respectively following a diet change.

Table 15 showed the maximum possible benefits from dietary changes of all foods U.S. consumers eat. However, because the 1990 amendments point only to FDA regulated products, this maximum change is adjusted downward to exclude changes in the consumption of meat and poultry, since labels for those products are not affected. Meat and poultry represent 33 percent of total fat intake for men and 30 percent for women, and this consumption is assumed to remain unchanged.

TABLE 16.—MAXIMUM HEALTH BENEFITS FROM DIET CHANGES [1] FDA REGULATED FOODS ONLY (20 YEARS)

Cases of cancer and CHD avoided	503,448
Deaths avoided	212,596
Life-years gained	1,565,350

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer respectively following a diet change.

The numbers presented in Table 16 may seem small relative to the overall rates of cancer and CHD in this country. CHD, for example, claims over 500,000 lives per year and cancer approximately 514,000 per year (Ref. 33). However, there are many reasons that food labeling will only make a relatively small impact on these numbers. First, only small percentages of consumers change their behavior in response to new information. Secondly, deaths avoided are net after subtracting increased deaths from other causes. That is, if someone is saved from dying from CHD, he/she may die early from something else. Thirdly, there are competing causes for these diseases.

For cancer, Doll and Peto estimate that approximately 35 percent of all cancers are related to diet (Ref. 34). Yet there are many other dietary factors besides fat which cause cancer, such as natural carcinogens and carcinogens produced by storage or cooking. Similarly, CHD has multiple causes outside of fat intake, including genetic factors, smoking, and diabetes.

i. Consumer behavior. The numbers of life-years that might be gained from a better diet are large, but nutrition competes with other food attributes in determining consumer purchases. Taste, convenience, appearance, brand name, and price are all important in the decision. It is estimated that approximately 45 percent of all consumers are actually aware of labels, read them, and understand them. This estimate is calculated from various consumer studies of label awareness as shown in table 17 below.

TABLE 17.—CALCULATION OF DECISION PROBABILITIES [1] PROBABILITY

Being aware	0.76
Looking for label conditional on being aware	0.85
Reading label conditional on looking	0.92
Understanding the label conditional on having read the label	0.76
Probability of being aware, reading and understanding labels	[2] 0.45

[1] Ref. 24.
[2] Obtained by multiplying the above probabilities.

However, FDA does not assume that 45 percent of all consumers will

presently change their purchase behavior as a result of revised labels. As nutritional awareness expands, the very small percentages of nutrient changes estimated in the SDA study (around 1 percent) should increase as the number of interested consumers increases.

VI. Options Considered

Because much of the 1990 amendments is very prescriptive, FDA has very little flexibility to develop options other than with respect to the compliance period and other options as noted below. Most of the options summarized below and many others of less benefit-cost import are also discussed in the preambles to the various rules.

A. Compliance Period Options

The primary cost option alters the amount of time firms have to comply with mandatory nutrition labeling and other labeling requirements that become effective at the same time. The 1990 amendments allow the Secretary to delay the effective date for nutrition labeling, nutrient content claims, serving sizes, and health claims for up to 1 year if he finds that compliance with these provisions would cause undue economic hardship. The following discussion will provide information on the options of extending the proposed 6-month compliance period an additional 6 months (1-year compliance period) and 1 year (a compliance period of 18 months).

The first option reviewed by FDA is to extend the compliance period for mandatory nutrition labeling, etc. to 1 year (a 6-month extension). Because the length of the compliance period affects all cost categories, except analytical costs, extending the compliance period would result in significant savings. The discounted costs of this option would be $896 million (5 percent discount rate). This amounts to a savings of approximately $644 million. If discounted at 10 percent, the costs would be $872 with a savings of $668 million.

The second option available to FDA, extending the compliance period for mandatory nutrition labeling, etc. to 18 months (a 1-year extension), would result in a savings of $835 million. Total discounted costs of this option are estimated to be $705 million (5 percent discount rate).

The 1990 amendments do not allow the Secretary the option of allowing all label changes to be effective at once (i.e., delay the implementation of ingredient labeling changes until nutrition labeling regulations are final). Nor is it possible to extend the compliance period beyond 18 months.

Extending the compliance period would also reduce costs to food service establishments by allowing firms to incorporate mandated menu changes with normally scheduled changes. However, FDA has no information to quantify the reduction caused by extending the compliance period. Therefore, any comments suggesting an extension of the compliance period for these provisions should include information as to the value to restaurants and other food service establishments of extending the compliance period for these actions.

Table 18 shows the costs and benefits of each of the above options. Benefits will decline by a maximum 2.4 percent with each additional 6 months extension of time to comply, depending on how much relabeling were to take place during that period. Benefits decline only because of discounting (2.4 percent). All benefits will be obtained despite the compliance deadlines. However, because benefits today are preferred to benefits tomorrow, giving firms more time to comply with labeling will delay benefits and reduce them by the discount rate. In fact, this is only true because of the finite 20-year horizon. Benefits will decline slightly if labeling is delayed as more cases should be prevented over an infinite timespan.

TABLE 18.—ESTIMATED COSTS OF THE COMPLIANCE OPTIONS [1] (IN MILLIONS OF DOLLARS OVER 20 YEARS)

Cost type	Option 1	Option 2	Option 3
	6 months	12 months	18 months
Mandatory labeling:			
Administrative	177	93	70
Analytical	195	195	195
Printing	862	600	436
Inventory	306	8	4
Total	1,540	896	705
Benefits [2]	3,600	3,513	3,429

[1] Excludes voluntary labeling of raw fruit, vegetables, and fish.
[2] Estimate based on life-years saved. Excludes regulation of restaurant menus.

B. Options for Ingredients Labeling Provisions

FDA considered options for each of the provisions listed in the ingredients document that were not required by the 1990 amendments. Many of the options considered required more extensive labeling (e.g., source labeling for sweeteners). FDA rejected these options where there appeared to be no market failure. The most important option rejected is the elimination of "and/or" labeling for fats and oils. Because mandatory nutrition labeling allows consumers to discover the nutrients in the products they consume, the need to eliminate "and/or" labeling for fats and oils became irrelevant. Furthermore, because all mandatory ingredients in standardized foods must now be listed, FDA will consider altering current food standards policy.

C. Options for Percentage Juice Labeling Provisions

In the proposed regulation for percentage juice labeling, different options were considered to define the amount of modification that could be made to the juice counted in the percentage juice statement. If the juice has been modified in any way other than concentrating it, it may not be counted in the "contains x percent juice" statement. For example, if the color is removed from grape juice and the resulting modified juice is added to a blend of other juices, it would not be counted as adding to the total percentage juice. The more tightly "modification" is defined, the less incentive to modify the juice. It is not clear how juice products will be affected by this proposal, but other options for the definition of "modification" might allow more modification and still be counted as juice in the percentage statement.

D. Options for Voluntary Labeling of Raw Produce and Seafood

In the voluntary labeling of raw fruit, vegetables, and fish, FDA has chosen the option of allowing virtually any format to comply with this labeling. For sampling to determine compliance, one option considered was to include only large supermarkets with sales of $2 million or more (approximately 31,000 stores). This would have allowed the labeling to reach at least 80 percent of the population. By including firms under $2 million, an additional 6.6 percent of the population is reached by including an additional 68,000 stores. This increases discounted costs over a 20-year period from $54 to 99 million to $117 to 155 million. FDA has also proposed to allow less than 100 percent compliance per store and still be counted as "in substantial compliance." Because costs are relatively fixed, aggregate net benefits decrease with smaller store size and fewer consumers utilizing individual signs.

E. Options for Health Claims

For health claim regulations, FDA is required to process requests for new claims rapidly. The agency has considerable latitude concerning how well specified the supporting data for

either a new general health claim or the use of a claim in a brand name must be. The more completely specified, the lower the likelihood the potential claim will be denied because of small omissions and the higher the cost of preparing the initial request. However, total costs are likely to be higher with repeated submissions. The agency will look closely at this issue.

FDA will also have considerable latitude in choosing levels of disqualifying nutrients with the effect that, any food outside of the boundaries set for the four nutrients of concern (fat, saturated fat, sodium, and cholesterol) will be disqualified from any health claim unless firms petition the agency for an exception. The agency can also choose whether or not it will establish separate procedures and standards for claims for supplements.

The proposed regulation of health claims is different from other regulations proposed under of the 1990 amendments (except the proposed regulation of nutrient content claim definitions) in that the health claims proposal would allow firms to provide additional information where such firms believe that the additional information will benefit the marketing of their products. In determining which claims are to be allowed, the agency has some latitude. That is, the agency must establish what constitutes "significant scientific agreement among experts qualified by scientific training and experience * * *" that the claim is "valid" when determining whether or not a particular health claim will be allowed. The level of stringency that is set for what constitutes significant agreement will affect both "Type I" and "Type II" errors (A Type I error is finding something true when it is false and a Type II error is finding something false when it is true). A Type I error would occur if insufficient stringency were set and a false claim were approved. This would cause consumers to make choices toward foods that might be unwarranted substitutions. On the other hand, if the degree of stringency is set too high, a Type II error may occur in which claims that are true are not allowed. In this case, consumers may not be given valuable information to help them choose foods that contribute to better health.

These decision rules have been considered by two health claims researchers who find that a fixed consensus rule requiring a high level of consensus "assumes the costs of a Type I error (allowing a claim that proves to be false) are far greater than the costs of a Type II error (prohibiting a claim that proves to be true)" (Ref. 35). The authors point out that a consensus rule, if flexible, can be equivalent to an expected value rule.

Other authors have pointed out that a consensus is difficult to determine. An article in the *Journal of the American Medical Association* (Ref. 36) makes the point that consensus may have as much to do with "fashion" in medical theory as with objective measures of the effectiveness of the treatment. The ability to reach a consistent measure of consensus is further hampered by the uneven state of knowledge about diet and health in different areas (Ref. 37). Nevertheless, the 1990 amendments direct the agency to permit claims only if there is significant scientific agreement.

In addition, the agency has discretion with respect to how claims can be worded. If a claim may be applied to a specific brand of food, for example, manufacturers will have a stronger incentive to make such claims. If the claim must apply to a generic food group, a "free ride" problem arises. That is, firms not advertising "free ride" on the advertising of those who do. This leads to suboptimal provision of information as firms are less inclined to provide information when competitors also benefit from that information. Depending on how health claims are structured, "Sellers may also attempt to internalize the benefits of generic information by stating simply that their product possesses the desired attribute (or lacks the undesired ones) without mentioning that all competing brands do too (Ref. 38). However, such a claim may be perceived as either deceptive advertising or spurious product differentiation (Ref. 38). Whether or not a claim may be applied to a specific brand may ultimately depend on whether or not the brand has been manufactured to be different from other foods in the class or whether all foods in the class simply meet the definition for the claim. An example would be a food that has reduced fat because its ingredients are different from other foods in the class, versus a frozen vegetable where all the vegetables meet the definition for the claim. An example would be a food that has reduced fat because its ingredients are different from other foods in the class, versus a frozen vegetable where all the vegetables met the definition for the claim.

F. Options for Serving Sizes

Section 2(A)(i) of the 1990 amendments provides for packaged foods to be labeled with the serving size expressed as either a common household measure (e.g., oz.) or the common household unit of measure that expresses the serving size of the food (e.g., slice of bread). FDA has full flexibility under the law to define what these measures are and all nutrient declarations will follow from these definitions. An alternative divisor that could have been chosen (by Congress) for this purpose would be to express all foods in a single measure, e.g., 100 grams. This type of measure would be useful for making comparisons between food whereas different measures, such as common household serving sizes, must be manipulated in order to make these comparisons. The single measure approach has the additional benefit of not overloading the consumer with too much information. Nevertheless, as different foods are customarily consumed in different amounts, the single measure approach is not consistent with the 1990 amendments.

However, the option of providing information in addition to what is required remains open to manufacturers. Thus, a manufacturer who wishes to provide nutrient content information on a per ounce or per 100 gram basis in addition to the information on a standard serving size basis may do so. This type of information would help improve consumer choices across products and thus improve the total diet. Although this additional information may prove confusing to consumers, normal market forces should dictate when and where it will be useful.

G. Options for Nutrition Labeling in Food Service Establishments

FDA is not compelled by the 1990 amendments to require nutrition labeling for restaurants, even those using nutrient content claims and/or health claims. Thus, one option is to require no nutrition labeling to accompany these terms. Under this option, eating establishments might be able to use computerized data bases to determine if they are within required levels set for disqualifying nutrients. FDA has no information on whether or not such data bases would, in fact, be adequate, nor on the cost of these data bases.

An additional option is to require full nutrition labeling for all restaurants using health claims or nutrient content claims on the menu or elsewhere. Analytical tests for these nutrients, if such testing is required, would cost $1765 per menu item (three samples o. the initial analysis is assumed). Firms would also bear the cost of providing nutrition information to the customer. This information could be on the menu,

a poster or sign, in a notebook, or any other possible form. FDA does not have the information to calculate these costs.

Further, FDA could opt to require an abbreviated form of nutrition information for all restaurants using health claims or nutrient content claims on the menu. Restaurants would be required, for example, to provide information on the amount of calories, total fat, saturated fat, total carbohydrates, protein, sodium, cholesterol, and the nutrient for which the claim is made (if different from the above mentioned nutrients). The cost for nutritional analyses for these nutrients is $661 per menu item (three samples for the initial analysis is assumed).

FDA also has several options regarding which firms should or should not be exempted from any requirement to provide nutrition labeling. The options available are: (1) to require nutrition information in all food service establishments with no exemptions, (2) to exempt small restaurants as defined by sales volume, or (3) to require nutrition labeling only in restaurants that are "chains." FDA has no information to calculate the costs of each of these options and requests comments with such information. Also, any proponents of these options should submit a comment including information concerning the utility of data bases and potential costs.

H. Federalism

Executive Order 12612 requires that a federalism analysis be performed whenever there is a question as to whether or not a Federal solution is mandatory for a particular problem. This analysis should include whether or not to refrain from a Federal standard and encourage States to develop their own policies to achieve program objectives, whether or not to consult State and local authorities for Federal decisionmaking, and whether or not to allow maximum flexibility for enforcement of Federal policies by States and Local governments.

The 1990 amendments direct FDA to provide regulations governing the use of health claims and nutrient content claims for all food for human consumption, including restaurants. However, in addition to regulation directly required by the amendments, FDA is proposing to require some nutrition labeling whenever a health claim or nutrient content claim is used. One option of this regulation is to remand to States or localities the decision as to whether or not nutrition labeling should be required. However, because use of health claims and nutrient content claims in restaurants is required to be regulated by the Federal Government, and because nutrition labeling is only required when triggered by the use of these terms, this action is tied to Federal law. Further, that option would have two drawbacks, however. First, travelers would have difficulty comparing menu items between different localities. Second, the costs of this regulation would be increased as chain restaurants operating in different localities would be forced to print different menus for each locality in which they operate. States and localities have the option of requiring full nutrition and/or ingredient labeling in addition to that required by FDA. If FDA regulates restaurant menus, this may raise a Federalism issue under Executive Order 12612, and the agency welcomes comment on this question.

I. Options for Other Provisions

For other actions such as definitions of nutrient content claim definitions and RDI's and DRV's, FDA will review comments on the proposals relative to definitions of Codex Alimentarius and those adopted by U.S. trading partners to attempt, where possible, to facilitate international trade.

FDA has a number of nutrition panel formats available with potentially different costs for each format. At the time this document was written, no format was chosen. However, one concern may be that the nutrition panel size of one potential format is a 240 percent increase in size over the existing format. For some products, this may cause a more extensive label redesign of the PDP than currently estimated.

VII. International Impacts

In accordance with Executive Order 12291 and other guidance received from the Office of Management and Budget (OMB), FDA has also evaluated the effects on international trade of these regulations. Guidance received from OMB requires agencies to make no explicit distinction between domestic and foreign resources when calculating costs and benefits of regulations.

FDA has evaluated the costs of this regulation to both foreign and domestic manufacturers jointly for all costs except administrative costs. It is likely that administrative costs for foreign firms will equal or exceed those of domestic firms but FDA has no information on either the number of firms or the magnitude of the costs per firm. FDA requests information on these costs.

The United States is a signatory to three agreements that provide for efforts to harmonize, inter alia, food labels bilaterally or internationally (Ref. 39). The Canada-U.S. Free Trade Agreement provides for bilateral harmonization efforts. The two international agreements are the Codex Alimentarius Commission (Codex) and the General Agreement on Tariffs and Trade (GATT). Codex, a subsidiary of the United Nations' Food and Agriculture Organization and the World Health Organization, creates advisory information on food labeling and standards for its 130 member countries with the objective of facilitating international trade while protecting consumers' health. The GATT, an agreement signed by 90 nations, provides a framework for settling trade disagreements and for conducting multilateral trade negotiations, including negotiations on nontariff trade barriers such as inconsistent labeling requirements.

The Treaty of Rome of the European Community (EC) is another international agreement with U.S. trade implications. In working toward harmonization of food labeling requirements for its 12-member countries, the EC Council has adopted a directive on nutrition labeling and is developing another directive on labeling claims.

Despite increased efforts by the United States to consider the food labeling requirements of other countries, complete harmonization of food labeling requirements is often not possible because of differing language requirements or other unique national concerns.

The primary differences between the U.S. proposed regulations and the provisions of Codex, Mexico, Canada, the EC, and other trading partners are that many of the mandatory provisions are voluntary in other countries and some of the voluntary provisions are not permitted in other countries. These regulations will cause foreign firms to have to change their English label to market their food products in the United States. Also, because definitions of some nutrients differ, additional analytical testing and compliance activities may be required; other requirements may simply provide manufacturers incentive for product reformulation. The costs for these foreign firms should be identical to those incurred by domestic firms to meet the requirements of these regulations.

Some of the key differences in FDA labeling rules compared to those of Canada, the EC, or other trading partners, which could contribute to the need for foreign firms to change English food labels or conduct additional product testing are:

(1) *The mandatory status of nutrition labeling.* Most food products FDA regulates must have nutrition labeling, whereas in Canada and the EC nutrition labeling is largely voluntary.

(2) *The expanded required content for nutrition labeling.* Nutrition labeling may be limited in Canada or the EC to the declaration of energy value, protein, carbohydrate, and fat content unless claims are made and additionally, in the case of Canada, when vitamins or minerals are added. In contrast, FDA would require the mandatory listing of a number of additional food components, including saturated fat, cholesterol, complex carbohydrate, sugars, dietary fiber, sodium, two vitamins, and two minerals.

(3) *The expanded optional content for nutrition labeling and RDI's.* Because of the proposed rule's expanded list of RDI's, FDA would permit several vitamins and minerals to be listed that would not be permitted by Canada or the EC and would also permit certain other food components to be declared relative to RDI's. The same food product marketed in the United States, Canada, and the EC might also require different percentages to be listed for some vitamin and mineral content because of differing daily intake reference values.

(4) *The definitions of food components.* FDA would define saturated fat, unsaturated fat, and sugars differently from both Canada and the EC, with implications for the formulation, analytical testing, and labeling of food products. FDA would also define carbohydrate differently from Canada but not the EC by excluding dietary fiber.

(5) *Nutrition label format and terms.* Examples of differences between the United States compared to Canada and the EC would include the permitted use of the aggregate category of unsaturated fat, the less prominent order of listing of protein, and the terms used to describe RDI's.

(6) *The mandatory declaration of nutritional content on a per serving basis expressed in household measures and parenthetically in metric units.* Canada also requires the declaration of nutritional content on a per serving basis in metric units, and permits as well the declaration in household measures (although Canada uses Imperial measures and the United States uses avoirdupois). Unlike Canada, which has established guidelines for ranges for serving sizes to use to declare nutritional content, FDA would require that single regulatory reference serving sizes serve as guidance to declare nutritional content and as the basis for labeling claims. As long as FDA's regulatory serving size falls within the range used by Canada, no trade barriers are anticipated.

Finally, dual declaration of nutritional content on a per serving basis and on a 100 gram (milliliter) basis would be permitted by FDA, Canada, and the EC, although in contrast to the United States and Canada, declaration on a 100 gram (milliliter) basis is required by the EC.

(7) *The voluntary declaration of content claims.* FDA would limit the use of terms for content claims to those defined by regulation, some of which would differ in terminology or definition from those in Canadian regulations or guidelines. The EC does not yet have a directive on content claims.

(8) *The voluntary declaration of health claims.* FDA would allow the use of certain health claims if requirements are met; in contrast, Canada is prohibited by law from allowing claims related to diet and disease on food labels. The EC does not yet have a directive on health claims.

(9) *The voluntary nutrition labeling of raw fruit, vegetables, and fish.* FDA would require an appropriate compositional data base for these products.

As before, all firms wishing to import or export into the United States must have two labels. Importing firms are faced with the same relabeling costs as U.S. firms. In addition, many are likely to have to perform two sets of analytical tests (one additional test must be performed as a result of these proposals) because of different definitions. An example is the use of different definitions for saturated fats (length of the carbon chain). It is unclear how much other countries will follow the United States' lead in changing the food label.

VIII. Summary

Total costs of these regulations have been estimated to be $1.5 billion. These costs include administrative, analytical, printing, and inventory costs, the latter three including costs to foreign firms. Reformulation costs were not estimated. These costs do not include the voluntary labeling of raw fruit, vegetables, and fish.

Benefits are reduced risk of illnesses such as CHD, cancer, obesity, osteoporosis, and allergic reactions to food ingredients. The value of these benefits are estimated to be $3.6 billion. Estimated costs, benefits, and estimated health effects are shown in Tables 19 and 20 respectively:

TABLE 19.—ESTIMATED COSTS OF THE COMPLIANCE OPTIONS

(In Millions of Dollars Over 20 Years)

Cost type	Option 1	Option 2	Option 3
Mandatory labeling	6 months	12 months	18 months
Administrative	177	93	70
Analytical	195	195	195
Printing	862	600	436
Inventory	306	8	4
Subtotal	1,540	896	705
Voluntary Labeling	136	136	136
Total costs	1,676	1,032	841
Benefits [2]	3,600	3,513	[1] 3,429

[1] Benefits are reduced by discounting only because a 20-year time horizon was used.
[2] Estimate based on life-years saved. Excludes regulation of restaurant menus.

TABLE 20.—ESTIMATED HEALTH EFFECTS [1] (OVER 20 YEARS)

	Effective date		
	6 months	12 months	18 months
Cases avoided:			
Cancer	35,179	33,356	31,533
CHD	4,028	3,962	3,896
Deaths avoided	12,902	12,438	11,973
Life-years gained	80,930	75,199	69,468

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer, respectively following a diet change.

FDA has analyzed the total costs and benefits of these proposals and has determined that the costs exceed the $100 million threshold, requiring the agency to declare that these proposals constitute in a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has determined that these proposals will have a significant adverse impact on a substantial number of small entities, including small businesses.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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27. "Multiple Risk Factor Intervention Trial," Multiple Risk Factor Intervention Trial Research Group, *Journal of the American Medical Association*, 248:1465–7, 1982.

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X. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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21 CFR Parts 101, 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169

[Docket Nos. 90N–0361 and 80N–0140]

RIN 0905–AD08 and 0095–AC48

Food Labeling; Declaration of Ingredients and Food Labeling; Declaration of Ingredients, Common or Usual Name for Nonstandardized Foods, Diluted Juice Beverages

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; delay of statutory effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes in the statutory effective date of the ingredient labeling provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in response to an amendment of section 10(c) of the 1990 amendments. FDA published proposed rules to implement the ingredient labeling provisions on June 21, 1991 and July 2, 1991.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF–312), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202–485–0229.

SUPPLEMENTARY INFORMATION: Section 7 of the 1990 amendments modified section 403(i) of the Federal Food, Drug and Cosmetic Act (the act) to require the declaration of all ingredients in standardized foods, the declaration of certified color additives in foods, and the declaration, on the information panel, of the percentage of a fruit or vegetable juice in a food purporting to be a beverage containing fruit or