

FOOD LABELING FOR THE 21ST CENTURY:



A Global Agenda for Action

A Report by the
Center for Science in the Public Interest

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Center for Science in the Public Interest

The Center for Science in the Public Interest (CSPI), a non-profit consumer organization with offices in the United States and Canada, was formed in 1971. CSPI's twin missions are to conduct innovative research and advocacy programs in the areas of health and nutrition and to provide consumers with current, useful information about their own health and well-being. CSPI is supported by more than 1,000,000 subscribers to its
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TABLE OF CONTENTS

Page No.

| | |
|---------------------------------------------------------------------------------------------------------------------------------|----|
| TABLE OF CONTENTS | I |
| INTRODUCTION AND SUMMARY | 1 |
| I. QUANTITATIVE INGREDIENT DECLARATIONS | 3 |
| A. The Need for Quantitative Ingredient Declarations (QUID) | 3 |
| B. Examples of QUID Labeling | 4 |
| 1. European Union | 4 |
| 2. Thailand | 5 |
| 3. United States | 5 |
| 4. Codex | 6 |
| C. Recommendations for QUID Labeling | 6 |
| II. FRESHNESS DATING | 8 |
| A. The Need for Freshness Dating | 8 |
| B. Examples of Freshness Dating Requirements | 9 |
| 1. European Union | 9 |
| 2. Japan | 9 |
| 3. Canada | 9 |
| 4. United States | 9 |
| 5. Codex | 9 |
| C. Recommendations for Freshness Dating | 10 |
| 1. Freshness dates should appear on all perishable food products and most non-perishable food products | 10 |
| 2. Freshness dates should be clearly and uniformly disclosed on food labels | 11 |
| III. NUTRITION LABELING | 12 |
| A. The Need for Nutrition Labeling | 12 |
| B. Examples of Nutrition Labeling Requirements | 13 |
| 1. European Union | 13 |
| 2. Canada | 13 |
| 3. United States | 14 |
| 4. Codex | 16 |
| C. Recommendations for Nutrition Labeling | 16 |
| 1. Nutrition labeling should be mandatory for all foods | 16 |
| 2. Nutrition labeling should include all nutrients for which national public health authorities have made recommendations | 17 |
| 3. Nutrition information should be based on serving sizes | 18 |

| | | |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 4 | Serving sizes should represent the amount of food customarily consumed and should be standardized within food categories so that consumers can easily compare different products | 19 |
| 5. | Nutrition information should be expressed in a way that is meaningful and useful to the average consumer | 20 |
| IV. | LABELING OF FOODS POSING HEALTH CONCERNS | 22 |
| A. | The Need for Labeling of Foods Posing Health Concerns | 22 |
| 1. | Health risks posed by food ingredients | 22 |
| 2. | Health risks posed by additives | 22 |
| B. | Examples of Labeling Requirements for Ingredients and Additives Posing Health Concerns | 24 |
| 1. | United States | 24 |
| 2. | Canada | 27 |
| 3. | European Union | 28 |
| 4. | Codex | 28 |
| C. | Recommendations for the Labeling of Food Ingredients and Additives that can Cause Adverse Health Reactions | 28 |
| V. | DECLARATIONS REGARDING METHODS OF PRODUCTION | 30 |
| | Part One: The Labeling of Irradiated Foods and Food Ingredients | 31 |
| A. | The Need for Labeling of Irradiated Foods | 31 |
| B. | Examples of Irradiation Labeling Requirements | 32 |
| 1. | United States | 32 |
| 2. | Canada | 32 |
| 3. | European Union | 33 |
| 4. | Codex | 33 |
| C. | Recommendations for Labeling of Irradiated Foods | 33 |
| | Part Two: The Labeling of Genetically Engineered Foods and Food Ingredients | 34 |
| A. | The Need for Labeling of Genetically Engineered Foods | 34 |
| B. | Examples of Labeling Requirements for Genetically Engineered Products | 36 |
| 1. | United States | 37 |
| 2. | European Union | 39 |
| 3. | Australia and New Zealand | 41 |
| 4. | Japan | 42 |
| 5. | Codex | 42 |
| C. | Recommendations for Labeling of Genetically Engineered Foods and Ingredients | 44 |
| | Part Three: Labeling of Organic Foods | 44 |
| A. | The Need for Regulating the Labeling of Organic Foods | 44 |
| B. | Examples of Labeling Regulations for Organic Foods | 46 |
| 1. | European Union | 46 |
| 2. | United States | 46 |

| | |
|--------------------------------------------------------------------------------------|-----------|
| 3. Canada | 47 |
| 4. Codex | 47 |
| C. Recommendations for Labeling..... | 48 |
| Part Four: Labeling of Foods Meeting Religious Dietary Specifications | 48 |
| A. The Need for the Labeling of Foods Meeting Religious Dietary Specifications | 48 |
| B. Labeling Requirements for Kosher and Halal Foods | 49 |
| 1. United States | 49 |
| 2. Codex | 49 |
| C. Recommendations for Labeling..... | 50 |
| CONCLUSION | 51 |

INTRODUCTION AND SUMMARY

Consumers need more complete and accurate information about the food they eat. This is particularly true in developed countries where food has often been processed and packaged before it is sold, making traditional assumptions about food quality and nutrition either difficult or impossible to make.¹ Many nations have long required that food labels disclose the name of the food, as well as the ingredients, the net quantity of contents, and the name and location of the manufacturer. More recently, some countries have instituted or are considering new requirements for the disclosure of additional information pertaining to ingredients, product quality, nutrient content, production methods, and more information about substances that may cause adverse health effects. No single nation, however, requires food labels to disclose complete information in all of these areas. The disclosure of such information would assist consumers in making fully informed purchasing decisions and maximizing marketplace competition.² In some cases, such information is also necessary for consumers who wish to improve or protect their health.

This report surveys recent developments in food labeling disclosure requirements around the world.

- Chapter I discusses quantitative ingredient declarations. These declarations go beyond the traditional list of ingredients by disclosing the percentage of key ingredients that foods contain so that consumers can make informed purchasing decisions.
- Chapter II discusses nutrition labeling requirements. These requirements disclose the amount of important nutrients in food products. Without information on the nutritional composition of foods, it is extremely difficult for consumers to select foods in accordance with dietary recommendations.
- Chapter III discusses requirements for dating of food products. Dating requirements inform consumers about the freshness of food products and the time beyond which a food begins to lose its nutrients and deteriorate.
- Chapter IV discusses labeling of ingredients or additives that may cause adverse health reactions in sensitive individuals. Food labels need to conspicuously disclose the presence, and in some cases the amount, of certain ingredients and additives, such as caffeine or monosodium glutamate, so that sensitive individuals can avoid or limit their intake of those substances.
- Chapter V discusses a variety of labeling requirements concerning how a food has been produced. Such requirements disclose whether a food was irradiated, contains genetically engineered ingredients, is organic, or was produced in accordance with religious laws. This information may be important to consumers for a variety of reasons.

These topics are not intended to represent a complete list of all possible food labeling reforms. They do represent, however, some of today's leading controversies in the area of food labeling regulation.

Each chapter discusses the need for a particular type of information to be disclosed on food labels. These discussions are followed by a brief survey of current regulatory policies of various developed countries, as well as an explanation of any applicable standards of the Codex Alimentarius Commission (Codex).³ Each chapter concludes with recommendations for action by national regulatory authorities.

As nations strive to harmonize food labeling requirements on an international basis,⁴ efforts should be made to ensure that requirements are harmonized in an “upward” direction and reflect regulatory policies that best provide consumers with the information they need to make informed purchasing decisions. Because some nations already require the disclosure of some of the information discussed in this report, countries should learn from one another and incorporate the best requirements from around the world into their national regulatory programs.

The United States, for example, should adopt plans for requiring quantitative ingredient labeling and freshness dating as required in Europe. The U.S. should also adopt more informative disclosure requirements for the labeling of production processes. In turn, the EU should consider requirements for mandatory nutrition labeling. All nations should proceed with improved disclosure requirements for the labeling of ingredients or additives that may cause adverse health effects.

The Codex Alimentarius Commission could help facilitate such developments by increasing efforts to ensure that international standards are based on the premise of “upward harmonization.” International trade agreements encourage nations to support food labeling standards developed by Codex and to adopt such standards as domestic requirements.⁵ Thus, Codex has a special role to play and should take the lead in ensuring that nations learn from one another and that food labeling standards are upgraded to world-class levels that embody the best consumer protection requirements from around the globe.

The development of such standards would help raise consumer protection standards in all countries and would discourage trade disputes in which one nation argues that another nation’s consumer protection requirements are too extensive and constitute an illegal trade barrier.⁶ This effort would help further Codex’s mission and will, hopefully, drive Codex’s agenda for the 21st century.

CHAPTER I: QUANTITATIVE INGREDIENT DECLARATIONS

A. The Need for Quantitative Ingredient Declarations (QUID)

Most, if not all, developed countries require packaged multi-ingredient foods to be labeled with an ingredient list. Typically, ingredients must be listed in descending order of proportion by weight in the food. However, this requirement does not provide consumers with full information. Some nations have determined that consumers also need information about the percentage of ingredients contained in a particular food. Disclosures requiring such information are referred to as quantitative ingredient declarations (QUID).

QUID informs consumers if a particular ingredient is present in a significant amount. For example, the first ingredient of a product might be listed as water. Simply listing ingredients in order of predominance does not inform consumers whether water comprises closer to 30% of the product or 90% of the product. But QUID informs consumers exactly how much water the product contains, enabling them to make more educated purchasing decisions.

QUID is necessary for consumers to compare the relative amount of ingredients between seemingly similar products. For example, two different brands of spaghetti sauce may both list the first two ingredients as water and tomatoes. Yet one brand may contain 50% water and 40% tomatoes, while the other brand may contain 70% water and 20% tomatoes. Since this difference is not detectable from the ingredient list alone, QUID is necessary to indicate clearly the proportion of ingredients in the products, allowing consumers to select the food with the greater amount of desirable ingredients.

Furthermore, QUID is essential to rectify misleading claims on food labels. Many labels imply, through words or pictures, that the food contains significant amounts of meat, fruits, vegetables, or whole grains — yet those ingredients may be present in only trivial amounts, if at all. For example:

- In Canada, a bottle of Libby's Strawberry Real Fruit juice contains more water and sugar than fruit juice. Based on the name, consumers might logically assume that the beverage contains 100% fruit juice, when in fact it contains only 21% fruit puree.
- In the United Kingdom, the main ingredient of a product called "Minced Meats" is chicken. A 1997 survey revealed that 92% of shoppers were misled by the name of this product.⁷
- In the United States, the front label of Kellogg's "Nutri-Grain Cereal Bars" states that the bars are made with "whole-grain oats" even though the bars actually contain more enriched white flour than whole oats. Based on this claim, many consumers might assume that the bars are a good source of whole grains.

QUID reduces the likelihood that consumers will be misled by better indicating the actual amount of ingredients in those foods. Moreover, requiring food companies to disclose the relative quantity of ingredients also enhances competition, which will result in better products. In sum, QUID provides consumers with the information they need to make informed purchasing decisions, decreases the probability that consumers will be duped by exaggerated claims and provides manufacturers with the incentive to increase the quality of food products.

B. Examples of QUID Labeling

1. European Union

The European Union (EU) has taken the lead in this area by issuing a directive requiring QUID for many foods.⁸ The EU's 1997 directive requires QUID "where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer."⁹ For example, the amount of strawberries in "strawberry yogurt" and the amount of vegetables in "spring rolls" must be disclosed.¹⁰

QUID is also required "where the ingredient or category of ingredients concerned is emphasized on the labelling in words, pictures or graphics."¹¹ For example, if a food is described as "made with butter" or features pictures of strawberries on the label, the amount of those highlighted ingredients must be disclosed.¹²

The quantity of an ingredient must also be stated "where the ingredient or category of ingredients concerned is essential to characterize a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance."¹³ This provision applies when the composition of products that are marketed under the same name vary from one Member State to another.¹⁴

The EU directive requires that the quantity indicated be expressed as a percentage and correspond to the quantity of the ingredient or ingredients at the time of use.¹⁵ This information "shall appear either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient or category of ingredients in question."¹⁶ When the declaration accompanies the product name, it is not required that the declaration be on the principal display panel or that the lettering be of a particular size. It is sufficient that the information be provided with the product name anywhere on the label, as long as the information is easily visible, clearly legible, and indelible.¹⁷

QUID is not required for ingredients that are used in small amounts for the purposes of flavoring,¹⁸ natural constituents of foods (such as caffeine in coffee) when present in their natural proportions, or ingredients mentioned in the name of a food that have not been used in the manufacture or preparation of that food.¹⁹ Members of the EU must comply with this directive no later than February 14, 2000.

The following food labels illustrate the use of QUID labeling.²⁰

2. Thailand

The EU's directive on QUID labeling represents a major development in food labeling requirements for fully developed countries. Thailand, however, had required full percentage ingredient labeling of food products more than a decade ago. The Thai regulation requires that the percentage of each essential ingredient contained in products sold directly to consumers be disclosed on the label.²¹ This requirement goes beyond the EU directive as the percentage of every major ingredient must be disclosed. The following pages contain labels illustrating Thailand's percentage ingredient labeling requirement.

3. United States

In contrast to the EU and Thailand, the U.S. basically requires only that ingredients be declared on food labels in descending order of predominance by weight.²² In a few situations, a percentage ingredient disclosure is required. Under U.S. law, beverages that purport to contain fruit or vegetable juice must list the percentage of juice that the beverage contains, peanut spreads must indicate the percentage of peanuts in the spread; olive oil blends must indicate the percentage of olive oil contained in the blend; and seafood cocktail must include the percentage of the seafood ingredients present in the cocktail.²³ While the U.S. Food and Drug Administration (FDA) encourages food companies to voluntarily provide percentage ingredient labeling on all foods, few if any have done so.²⁴ However, American-based food companies doing business in Thailand and other countries where quantitative ingredient disclosures are required do routinely provide such information to consumers.

The U.S. FDA clearly has the authority to require QUID to remedy misleading labeling practices. First, U.S. FDA regulations require that the common or usual name of a food accurately identify or describe the basic nature of the food or its characterizing properties or ingredients.²⁵ Moreover, U.S. FDA regulations require that the common or usual name of a product shall include the percentage of any characterizing ingredient when

this percentage has a material bearing on product or consumer acceptance, or when the labeling creates an erroneous impression that such ingredient is present in an amount greater than is actually the case.²⁶ However, the agency has declined to use this authority to require QUID to clarify misleading labeling practices.

4. Codex

Codex standards require the declaration of the percentage of ingredients whenever the food label places special emphasis on the presence or low content of a “valuable and/or characterizing” ingredient.²⁷ However, a reference in the name of a food to a particular ingredient does not in itself constitute “special emphasis,” nor is percentage labeling required merely if a reference is made to an ingredient that is used in a small quantity or only as a flavoring.

C. Recommendations for QUID Labeling

Ingredient labeling regulations around the world should be upgraded to reflect the best aspects of the EU’s QUID requirements and Thailand’s percentage ingredient labeling regulations. Food labels should not only list all ingredients, but should also state the percentage of all major ingredients, i.e., those that comprise 5% or more of the total weight. The percentages for those ingredients should be included with the ingredient list.

In addition, ingredient labeling requirements should incorporate some of the theoretical aspects of U.S. regulatory requirements that could help prevent deceptive label claims. Thus, if any ingredient appears in the name of the food or is highlighted on the label through words or pictures, the percentage of this ingredient should also be listed in immediate conjunction to such statements or pictures. For example, a product called “Blueberry Waffles” should disclose the percentage of blueberries contained in the product in immediate conjunction to the name. Similarly, a bread that claims to be made from “natural whole grain goodness” should disclose the percentage of whole grains in the product. The percentage declaration should be located in immediate proximity to the name or claim in which the ingredient is mentioned or implied and should be in type no less than one-half the size of that name or claim. It is essential that the disclosure be included near the claim, rather than the ingredient list, as consumers may base their purchasing decisions on claims made on the front label without consulting the list of ingredients.

In sum, nations should build on progress being made by the EU and the example set by Thailand and provide consumers with better information about the ingredients contained in food products. As consumers

around the world come to depend more and more on pre-packaged processed food items, such information becomes increasingly important.

CHAPTER II: FRESHNESS DATING

A. The Need for Freshness Dating

Most developed countries (with the notable exception of the United States) require that a date appear on food labels, which usually represents the time after which the food manufacturer cannot guarantee the freshness of its product. An example of a freshness date may be “Best if used by June 1, 1998” or “Use before March 3, 1999.”²⁸ Exact requirements for freshness dating vary. Some countries require dates on products with a shelf life of 90 days or less while others require dates on most pre-packaged foods including frozen items.

Freshness dates primarily provide consumers with a means to judge the quality of a food product by determining when it was produced or how long it has been on store shelves. As international trade in food increases and foods are transported over greater and greater distances, the disclosure of such information becomes increasingly important.

Surveys show that consumers want freshness dates on food labels. According to one recent U.S. survey, consumers place a high priority on purchasing dairy, bakery, deli and other foods that are at their peak freshness.²⁹ Another survey in the United States found that one of the top ten reasons cited by consumers for selecting a supermarket is the number of products having freshness dates.³⁰

A survey conducted by New Zealand’s Ministry of Health in 1995 determined that freshness dates were the most frequently scrutinized element on food labels.³¹ In fact, more than three-quarters of the respondents said that they always or often look at the freshness date at the time of purchase. Moreover, 91% said they wanted freshness dates on all or some longer-life foods, and 77% wanted freshness dates for longer-life frozen foods.³² At the time of the survey, New Zealand only required date-marking for foods with a shelf life of less than 90 days.³³

Freshness dating may also play a role in matters concerning nutrition and food safety. Every food has a shelf life — even frozen foods deteriorate over time.³⁴ As a food ages, it loses some of its nutrients. While nutrient loss varies greatly depending on the nutrient, the food, and storage and handling conditions, freshness dates, nevertheless, serve as a valuable guide for consumers.³⁵

B. Examples of Freshness Dating Requirements

1. European Union

The EU requires many types of foods to indicate the “Date of minimum durability,” which is usually expressed as “Best before ...” or “Best before end of ...” followed by the date until which the food will keep its “specific properties when properly stored.”³⁶ Foods that are highly perishable must have “Use before” followed by the date after which the product should not be used.³⁷ Furthermore, storage directions must be placed near the freshness date if this information is needed to maintain freshness for the specified period.³⁸

2. Japan

In 1995, Japan began enforcing a new date-marking system that requires food labels to have either a “Best before” date or an “Expiry of consumption” date, with the latter being used for those foods whose quality changes rapidly and should be consumed soon after manufacture.³⁹ The law applies to all foods, including raw, processed, dried, canned and frozen foods.⁴⁰ In the case of those products bearing “Best before” dates, the date is not meant to be the last day to eat the product, but rather it is to be used as a guideline for consumers.

Before 1995, Japan’s requirements were less helpful to consumers because either the pack date, or the date the food was produced, could be printed on labels. Japan changed its law in 1995 so that consumers would have a better understanding of how to use date markings on food labels.

3. Canada

Canada requires a “Best before” date on all pre-packaged foods with a durable life of 90 days or less, with the exception of prepackaged fresh fruits and vegetables, vending machine foods, individual portions of food served by restaurants and airlines, and donuts.⁴¹ The Canadian regulations define the “Best before” date as the period throughout which a food will retain its taste, nutritional value, and normal wholesomeness when properly stored.⁴²

Foods that are packaged at retail and have a durable life of 90 days or less may be labeled with either a durable life date and any necessary storage instructions or with a packing date and durable life information. This information may be placed on the label or on a poster by the food.⁴³

4. United States

In contrast to the European Union, Australia, New Zealand, Canada and Japan, the United States does not have any type of national requirement for freshness dating. In 1976, the U.S. FDA contemplated requiring

some type of date marking system as a way to improve food labeling,⁴⁴ but no such requirement was ever instituted.⁴⁵ Furthermore, only fourteen U.S. state governments require freshness dates to appear on some products.⁴⁶ Several of those states follow the guidelines provided by the U.S. National Conference on Weights and Measures (NCWM), an organization that has developed model open dating regulations. The NCWM's model regulations call for date labeling of pre-packaged perishable foods and for optional date labeling of non-perishable pre-packaged foods.⁴⁷

The absence of a national freshness dating requirement in the U.S. is somewhat ironic considering that U.S.-based multi-national companies, such as Nabisco and General Mills,⁴⁸ routinely provide freshness dates on various products sold outside the U.S. while failing to provide that information on the same products sold to consumers within the United States. Examples of U.S. food products that carry date marks when sold outside the U.S., but that fail to carry such information when sold in the United States, are depicted on the following pages.

5. Codex

Codex standards provide that the “Date of minimum durability” be declared, which consists of the day and month for products with a minimum durability of not more than three months, and the month and year for products with a minimum durability of more than three months.⁴⁹ If the product needs special storage conditions in order to preserve the food, these instructions must be placed on the label.⁵⁰

The date shall be preceded by the words “Best before” where the day is indicated or “Best before end of” in all other cases.⁵¹ The date must be in an uncoded numerical form; however, the month may be displayed by letters in those countries where such use will not confuse the consumer.⁵²

C. Recommendations for Freshness Dating

1. Freshness dates should appear on all perishable food products and most non-perishable food products

Many of the countries that have freshness dating requirements exempt certain categories of foods. However, manufacturers should be required to place freshness dates on all perishable products and most non-perishable products. Even canned foods that have a very long shelf life need freshness dates because they can still lose nutrients over time.⁵³ And even for foods that do not lose nutrients, consumers often wish to buy and eat more recently produced food products.

2. Freshness dates should be clearly and uniformly disclosed on food labels

The types of dates that appear on packages, and the nomenclature used to describe such dates, vary greatly. Some countries describe freshness dates as “expiration” dates, whereas other countries refer to them as “dates of minimum durability.” Some U.S. manufacturers place freshness dates on their products that explain the meaning of the date, but other manufacturers just place a date by itself with no explanatory information. In some cases, codes that only the manufacturer or retailer can decipher are used in place of dates. Furthermore, even an actual date by itself is of little use to consumers because it could indicate the date the food was packed (pack date) or the date by which the retailer must sell the food (sell-by date).

A national U.S. survey discovered that most Americans are confused about expiration dates that appear on foods.⁵⁴ Two-thirds of Americans think that the date on cans (e.g., “DEC 04” or “December 4, 1997”) denotes the last day the food can safely be sold; another third believe that the date is the last day that the food can be safely eaten. However, the date generally refers to food quality, not safety.⁵⁵ In order to avoid confusion over the meaning of dates, freshness date markings need to be accompanied by appropriate explanatory terminology.

In sum, labels on all perishable and most non-perishable foods should bear a date marking that is clearly legible and easy to understand. All freshness dates should have accompanying explanatory information, such as “Best before (date)” or “Use before (date).” Freshness dates should be easy to locate on the label and should appear in a uniform place, preferably the principal display panel. Where the validity of the date mark of a food depends on its storage, storage instructions for that food should accompany the freshness date. Both Codex and the EU require that storage instructions accompany the freshness date if the validity of the date is contingent on how the product is stored.

The U.S., in particular, appears to be lagging behind many other developed countries of the world in this area of food labeling regulation. American consumers deserve the same information that is routinely provided by U.S. based food companies to consumers in other parts of the world. The U.S. government should bring its regulatory standards in line with those of other developed countries and require the disclosure of such information in the U.S.

CHAPTER III: NUTRITION LABELING

A. The Need for Nutrition Labeling

When societies become more affluent, traditional dietary patterns often change as consumers begin to rely increasingly on pre-packaged processed foods. As a result, diets often become higher in calories, fat, saturated fat, refined carbohydrates, and sodium. Diets high in calories, fat, and sodium are associated with the increased prevalence of heart disease, diabetes, obesity, hypertension, and some cancers.⁵⁶ Not surprisingly, diet related diseases are widespread in many developed countries.

Cardiovascular disease is the leading cause of morbidity and premature death in developed countries and is responsible for more than 12 million deaths each year — almost one-quarter of deaths worldwide. Cancer is the second highest cause of death in most developed countries.⁵⁷ Hypertension, a leading risk factor for heart disease and stroke, affects about 20% of adults in most countries.⁵⁸ The number of people suffering from diabetes is projected to be more than double from about 135 million to 300 million by 2025.⁵⁹

Health authorities worldwide recommend that people eat a healthful diet to reduce their risks of serious health conditions. But if consumers are to make dietary adjustments, they must be able to make informed decisions when selecting foods. Nutrition information is important for consumers who are trying to follow a healthful diet and is absolutely essential for consumers who are medically advised to select foods based on their nutrient content. However, only two nations, the United States and Israel, have mandatory nutrition labeling requirements, and thus, most consumers do not have the information they need to put official dietary recommendations into practice. Given the prevalence of diet-related diseases, nutrition labeling is a public health necessity.

Evidence shows that nutrition labeling is very useful in helping consumers to select more healthful foods. In the U.S., where nutrition labeling is required on almost all food products, a 1997 survey found that 54% of American consumers said they almost always read the nutrition label when buying a food for the first time.⁶⁰ Twenty-eight percent of those reading the nutrition label said they stopped buying a food product because of something they read on the label, and 25% started buying and using a certain item after examining the label.⁶¹

These changes in consumer purchasing decisions have been sufficient to spur competition on the basis of nutrition, which even benefits consumers who do not read labels. Since nutrition labeling has been mandatory

in the U.S., companies are marketing many more low and reduced-fat foods.⁶² Thus, requiring companies to analyse and disclose the nutrient content of their products may motivate them to improve the nutritional quality of their foods.

B. Examples of Nutrition Labeling Requirements

1. European Union

In the European Union, nutrition labeling is voluntary unless a nutrition claim appears on “labeling, in presentation or in advertising, with the exclusion of generic advertising.”⁶³ This standard has been established by a directive that has been implemented by most of the Member States.⁶⁴

When nutrition labeling is provided, the nutrients listed must consist of either group one (energy value, protein, carbohydrate, and fat) or group two (energy value, protein, carbohydrate, sugars, fat, saturated fat, fiber, and sodium). When a nutrition claim is made for sugars, saturated fat, fiber, or sodium, the group two nutrients must be listed. Nutrition information may also include the amounts of one or more of the following: starch, polyols, monounsaturated fat, polyunsaturated fat, cholesterol, and select minerals and vitamins.⁶⁵ The amount of nutrients must be expressed per 100 grams or 100 milliliters, but they may also be expressed per serving, provided that the number of servings contained in the package is stated.⁶⁶

Nutrition information must be presented together in one place on the label in tabular form, with the numbers aligned if space permits. Where space does not permit, the information must be presented in linear form. Nutrition information must be printed in “legible and indelible characters in a conspicuous place.”⁶⁷

Below is an example:

[INSERT SAMPLE EUROPEAN LABEL]

2. Canada

Canada has recently begun a review of its nutrition labeling requirements.⁶⁸ Presently, nutrition labeling is not mandatory. A food label is only required to divulge nutrition information when a nutrition claim is made on the label or in advertising.⁶⁹ Only the amount of the nutrient for which the claim is

made must be disclosed.⁷⁰ However, companies may also voluntarily list other nutrients as desired.

When nutrition information is provided, it must be based on one serving. The serving size must be reasonable, i.e., “an amount of food which would reasonably be consumed at one sitting by an adult.”⁷¹ Although the *Guide to Food Labelling and Advertising* sets forth suggested serving sizes for use in nutrition labelling, the serving sizes are voluntary and expressed in ranges for many foods.⁷² For example, the suggested serving size for vegetable oil is 5-10 milliliters. Thus, manufacturers have the flexibility to determine the serving size for a given product, and therefore the serving size upon which nutrition information is provided.

Currently, Canadian regulations do not require that nutrition information be provided in any particular format. Although a “standardized presentation format” of nutrition information has been set forth in the *Guide to Food Labelling and Advertising*, that format is voluntary and only consists of the heading (“Nutrition Information”), a statement of the serving size, the “core list” of nutrients (energy, protein, fat and carbohydrate), and optional nutrient declarations given equal prominence in a standardized order.⁷³ That information must be provided in both English and French. The prescribed format does not include specifications regarding type style and spacing. Moreover, the nutrition labeling format may appear on any part of the label, except the bottom of the container.⁷⁴ Below is an example of a food label using this format:

[INSERT SAMPLE CANADIAN LABEL]

Health Canada, however, has commenced a comprehensive review of these requirements. The Canadian initiative aims to increase the availability of nutrition labeling, improve its usefulness, and broaden public education on its use.⁷⁵

3. United States

The United States is one of only two countries that routinely require nutrition information on food labels.⁷⁶ In the United States, nearly all packaged foods have been required to provide nutrition information

since 1994.⁷⁷ The following nutrition information must be listed: calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron. These nutrients reflect current U.S. public health concerns and recommendations.⁷⁸

Nutrients must be expressed in terms of the amount per serving. Serving sizes are defined by law and based on an amount of food customarily consumed per eating occasion.⁷⁹ As a result, serving sizes reflect typical eating patterns and are uniform across product lines so that consumers can easily compare the nutritional qualities of similar products.

Nutrients must also be expressed in terms of a dietary reference value called the Percent Daily Value.⁸⁰ For vitamins and minerals, the Percent Daily Value represents the contribution that one serving of food makes toward the Reference Daily Intake that the U.S. Food and Drug Administration has established for each of those nutrients. For total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the Percent Daily Value represents the contribution that one serving of food makes toward the Daily Reference Value established for each of those nutrients.⁸¹ For example, the Daily Reference Value for sodium is 2,400 milligrams. Thus, a food that contains 1,200 milligrams of sodium per serving has a Percent Daily Value of 50%. Percent Daily Values help consumers eat healthfully by explaining the role of individual foods in the context of their total daily diet.

Nutrition information must be provided in a distinctive, easy-to-read format that enables consumers to quickly locate and read the nutrition information on the label. FDA regulations contain detailed label format requirements that specify where and how the nutrition information must be displayed.⁸² To enhance legibility, the regulations stipulate many graphic requirements including easy-to-read typeface, upper and lower case letters, bold lettering, large type size, and spacing between letters and lines. The following is a sample U.S. label:

[INSERT SAMPLE U.S. LABEL]

4. Codex

The *Codex Guidelines on Nutrition Labeling* state that nutrition labeling should be mandatory for foods for which nutrition claims are made, but should be voluntary for all other foods.⁸³ When a nutrition claim is made, the following nutrients must be provided: energy, protein, carbohydrate (excluding dietary fiber), fat, any other nutrient for which a claim is made, and “any other nutrient considered to be relevant for maintaining a good nutritional status, as required by national legislation.”⁸⁴ Vitamins and minerals that are present in significant amounts may also be listed — but only those for which recommended intakes have been established and/or which are of nutritional importance in the country concerned.⁸⁵

Nutrition information should be expressed per 100 grams, per 100 milliliters, or per package if the package contains only a single portion. This information may be stated per serving provided that the number of servings contained in the package is listed. The *Codex Guidelines* do not specify how or where the nutrition information should be displayed on the label. The Codex Committee on Food Labeling is considering whether to expand the required list of nutrients to include fiber, sugars, sodium and saturated fat.

C. Recommendations for Nutrition Labeling

1. Nutrition labeling should be mandatory for all foods

Nutrition labeling should be mandatory for all packaged foods⁸⁶ — and should be required regardless of whether a nutrition claim is made. Consumers must have complete nutrition information for all foods in order to make informed purchasing decisions, to compare the nutritional value of different foods, and to select foods in accordance with the dietary advice of health authorities.

Nutrition information should also be provided for both processed and raw foods, such as seafood, poultry, and meat.⁸⁷ Because raw foods are a substantial part of consumers’ diets, it is imperative that nutrition information be provided for these foods — especially meat — which adds a significant amount of fat and saturated fat to consumer’s diets.

Less extensive requirements for nutrition labeling, such as those that are merely triggered when a food company makes a nutrition claim, do not adequately address these needs. Before the U.S. required nutrition information on all food labels in 1994, the FDA merely required that nutrition information be provided when a company made a nutrition claim about a product. Under this system, about 60% of foods in the U.S. carried

nutrition information, but the prevalence of such information was not equally representative among food categories. For example, while about 100% of breakfast cereals provided nutrition labeling, only about 31% of carbonated soft drinks provided such information.⁸⁸ Thus, consumers in the U.S. were often provided with nutrition information on relatively healthful foods such as breakfast cereals, but did not receive such information on foods with high sugar or calorie content. The U.S. experience prior to 1994 indicates that partial requirements for nutrition labeling do not provide consumers with adequate information.

2. Nutrition labeling should include all nutrients for which national public health authorities have made recommendations

Consumers need information to make food choices on all nutrients that may affect the incidence of diet related diseases. Accordingly, nutrients for which national and regional public health authorities have made recommendations should be disclosed.

For example, public health concerns in the U.S. are focussed on over-consumption rather than under-consumption of particular nutrients. Thus, the U.S. food label emphasizes the amounts of nutrients, such as fat and saturated fat, that are related to chronic diseases, such as cancer, heart disease, and obesity.⁸⁹ Other nutrients, such as niacin, riboflavin, and thiamin are not required to be listed. However, countries in which deficiency diseases are a concern should require the disclosure of these vitamins or minerals.

Mandatory requirements for complete disclosure of a comprehensive list of relevant nutrients is also necessary to prevent consumer deception. The experience of some developed countries that have permitted partial nutrient disclosures shows that when food manufacturers are allowed to list selected nutrients and not required to list the amount of other important nutrients, consumers may be misled about a food's overall nutritional value. In such situations, food manufacturers may list the content of nutrients that make the food appear healthful but are not required to disclose the fact that the food may be high in undesirable nutrients.

For example, the nutrition information provided on the label of Campbell's V8 Cocktail sold in Canada reveals that it has little fat and is a good source of vitamins A and C. However, the label fails to disclose that V8 is high in sodium.⁹⁰ That information is important for consumers who are trying to follow a healthful diet and is absolutely essential for consumers who are medically advised to limit their sodium intake. Similar problems occurred in the U.S. before 1994 when comprehensive labeling requirements became mandatory. Thus, it is imperative that foods be required to list nutrition information for *all* essential nutrients.

ADD PICTURE

3. Nutrition information should be based on serving sizes

Nutrition information should be expressed in terms of the amount of nutrients per serving, rather than per 100 grams or other standard unit. Providing nutrition information in terms of a standard unit is likely to confuse and mislead many consumers.

For example, the EU directive (based on the Codex standard) requires nutrition information to be expressed per 100 grams or 100 milliliters, which makes it very difficult for consumers to determine the nutrient value of the portion of food that they actually consume. Consumers would have to know how many servings of food are in 100 grams and then multiply or divide accordingly. Moreover, providing nutrition information in terms of a standard weight is also likely to mislead consumers about the food's nutritional value in comparison with other foods. For instance, foods that are typically consumed in small amounts, such as Parmesan cheese, may appear to be relatively high in certain nutrients when compared with foods, such as cottage cheese, that are typically consumed in larger amounts.

A U.S. FDA survey revealed that the per-serving standard was preferred by the majority of consumers, food and nutrition professionals, and food industry representatives.⁹¹ Providing nutrition information on the basis of serving sizes allows consumers to determine the nutrient value of the serving of food they actually consume and make nutritional comparisons among different foods.

4. Serving sizes should represent the amount of food customarily consumed and should be standardized within food categories so that consumers can easily compare different products

Serving sizes should represent the amount of food that people typically consume to ensure that food companies do not use an unrealistically small or large serving size to favorably portray the nutritional composition of their products. The serving size should also be standardized within food categories to enable consumers to easily compare different products.

In Canada, the *Guide to Food Labelling and Advertising* sets forth recommended serving sizes that provide ranges, and which does not facilitate inter-brand comparability. As a result, serving sizes are determined by individual manufacturers and may vary significantly among brands within a given food category. Thus, it can be difficult for consumers to make meaningful nutritional comparisons among similar products.

For example, in Canada, Kraft Peanut Butter lists the amount of nutrients present in *one* tablespoon of peanut butter, while President's Choice Peanut Butter uses a serving size of *two* tablespoons. To compare nutrition information between those two products, Canadian consumers must double the numbers listed on the Kraft label or halve the numbers on the President's Choice label.

Comparing nutrition information between Mazola and President's Choice oils sold in Canada is even more difficult as the information is based on serving sizes using two different units of measurement. Nutrition information for Mazola Oil is based on a serving size of two *teaspoons* while President's Choice bases this information on a *one-tablespoon* serving.

Mazola Oil

President's Choice

Canadian consumers would have to know that there are three teaspoons in one tablespoon and then multiply and/or divide accordingly to make the appropriate comparisons.

Without standardization, consumers can easily be misled about a food's nutritional value and may have difficulty in making meaningful comparisons among foods. Thus, it is essential that serving sizes are standardized and that they represent the amount of food people typically consume at one sitting.

5. Nutrition information should be expressed in a way that is meaningful and useful to the average consumer

Merely listing the amount of nutrients per serving does not help consumers understand how those nutrients contribute to the optimal amount one should eat per day in order to maintain a healthy diet. For example, a food label may disclose that a serving of a food contains 1,600 milligrams of sodium, but a consumer may not know if 1,600 mg of sodium in one serving is high or low.

In the U.S., nutrition information is not only provided per serving, but it is also expressed in terms of a Daily Reference Value. This reference value helps consumers understand how a serving of a food fits into a healthful daily diet. Putting the 1,600 milligrams of sodium in the context of a desirable daily goal of no more than 2,400 mg enables consumers to recognize that a serving of the food provides more than half the maximum daily recommended intake of sodium.

Before nutrition labelling became mandatory in the U.S., the U.S. Food and Drug Administration found that many Americans could not specify the recommended intakes for some nutrients, such as sodium, even when those interviewed indicated that the nutrient was important to their health and that they were concerned about their intake of the nutrient.⁹² Similarly, a recent survey for the British Heart Foundation found that 65% of shoppers did not know the maximum amount of fat that men should consume in one day.⁹³ Thus, it is not only essential that all foods provide nutrition information, but it is also imperative that this information is provided in a context that is meaningful to consumers.

National governments should conduct research to determine how nutrition information should be disclosed. Formats that communicate to consumers the relative contribution that a portion of a food contributes to the maximum or minimum amounts of a nutrient that should be consumed per day to maintain good health should be favored over formats that merely disclose the amount of nutrients in a standard measure of the food.

Because dietary problems differ among various regions of the world, specific nutrition labeling requirements may never be able to be harmonized internationally. However, a basic requirement for mandatory nutrition information based on these principles should be instituted globally because consumers in all countries need such information to protect their health and reduce their risk of disease.

CHAPTER IV: LABELING OF FOODS POSING HEALTH CONCERNS

A. The Need for Labeling of Foods Posing Health Concerns

It is well known that certain foods and additives can cause severe health problems, even death, if ingested by individuals who are allergic or otherwise sensitive. Consequently, it is important that foods be labeled so that consumers can easily determine whether a product has an ingredient or additive that may be hazardous to their health.

Some food additives, while not allergenic, can cause other types of adverse reactions in some individuals. For instance, monosodium glutamate (MSG), caffeine,⁹⁴ and olestra are examples of additives that can cause health problems — sometimes severe health problems — in sensitive individuals.

The ingredients and additives discussed in this chapter illustrate some of the more well-known substances posing health concerns. These examples demonstrate the need for national regulatory authorities to adopt comprehensive label disclosure policies so that sensitive individuals can identify offending substances and avoid food products that may cause health problems.

1. Health risks posed by food ingredients

There are a variety of health problems that can be caused by the ingestion of certain foods. Food allergies involve the body's immune system, which recognizes a reaction-provoking substance — an allergen — as foreign and produces antibodies to attack the offending substance.⁹⁵ For instance, one may experience swelling of the lips, hives, rashes or eczema on the skin, or wheezing or other respiratory problems.⁹⁶ The severity of health problems varies with the individual, substance, and amount ingested.

The most common causes of food allergies in children include soy, cow's milk, eggs, and wheat. In adults, however, tree nuts, fish, shellfish, and peanuts are the most common causes.⁹⁷ Peanuts are just one of several allergens that can cause anaphylaxis, which is an extreme, life-threatening allergic reaction. Symptoms can appear in as little as five to fifteen minutes, but life-threatening symptoms may progress over several hours.⁹⁸ Some individuals have died from anaphylactic shock by ingesting as little as one-fifth to one-five-thousandth of a teaspoon (1g to 1mg) of the offending food.⁹⁹

Another type of sensitivity is called a food intolerance. Food intolerances can take many forms and are not well understood. They may result from the body's inability to digest adequately a portion of a particular

food, sometimes as a result of an enzymatic deficiency.¹⁰⁰ Some individuals with food intolerances can eat a modest quantity of the offending food without uncomfortable symptoms resulting. For instance, many consumers are lactose intolerant, but they are still able to consume milk and milk products in small amounts.¹⁰¹

Because some individuals experience health problems as a result of ingesting certain food ingredients, efforts should be made to inform consumers of potential sources of such food ingredients. The disclosure of the presence of such ingredients in a food product is therefore appropriate.

2. Health risks posed by additives

Food additives may also cause allergic and other types of adverse reactions.¹⁰²

Monosodium glutamate (MSG) is an example of an additive that can cause food sensitivity reactions in some individuals.¹⁰³ It is often added to foods to enhance their flavor. In 1992, the U.S. FDA contracted with the Federation of American Societies for Experimental Biology (FASEB) to review studies on the health effects of MSG and hydrolyzed protein products as food ingredients.¹⁰⁴ The FASEB report found that although most individuals are not affected by even high levels of MSG consumption, a small segment of the population does experience adverse effects. Individuals with “MSG symptom complex”¹⁰⁵ may experience burning sensations of the back of the neck, forearms, and chest, headache, broncho spasms and other symptoms.¹⁰⁶ Those symptoms can severely decrease the quality of life of individuals who unexpectedly and/or frequently experience them. Reports suggest that those symptoms are related to the amount of MSG consumed.¹⁰⁷ Individuals with severe, poorly controlled asthma may be at particular risk.¹⁰⁸

Caffeine is a substance that has physiological effects that can cause adverse reactions in some individuals. Caffeine is a natural component of coffee, tea, and chocolate (and coffee-flavored desserts such as ice cream). It also is added to carbonated soft drinks, such as Coca-Cola and Pepsi, and more recently to bottled waters and fruit-flavored soft drinks. (Some non-prescription drugs contain caffeine in doses similar to that found in beverages.) The amount of caffeine in various processed foods, such as orange soda or coffee-flavored yogurt, is often unpredictable.

Many epidemiological studies have examined the effects of caffeine on several aspects of reproduction with some of the studies indicating that caffeine consumption has adverse effects on fertility and fetal development.¹⁰⁹ Studies suggest that daily doses of 100 to 300 mg of caffeine (the amount found in one to three cups

of coffee) increase the time it takes for a woman to conceive. Similar doses of caffeine have also been found to adversely affect fetal growth.

In addition to its effects on women of childbearing age, caffeine can affect the general population. A stimulant of the central nervous system, caffeine is the most widely consumed psychoactive drug in the world¹¹⁰ and is the only drug that is widely added to processed foods.

Caffeine is addictive and can cause physical dependence in those who regularly consume it.¹¹¹ Those who abruptly stop consuming caffeine after a long period of use can expect withdrawal symptoms, which include headaches, sleepiness, lethargy, and irritability.¹¹² In addition, caffeine can cause restlessness, nervousness, insomnia, gastrointestinal disturbances, and cardiac arrhythmia in even those who regularly consume caffeine.¹¹³ In children, caffeine can cause anxiety and restlessness,¹¹⁴ and high consumption of caffeinated sodas by children may contribute to poor diets. For example, children who drink more soda consume less calcium.¹¹⁵

B. Examples of Labeling Requirements for Ingredients and Additives Posing Health Concerns

1. United States

- **Labeling of ingredients**

The FDA has no formal definition of “allergen,” but it gives as examples those foods that are most likely to cause serious allergenic responses (e.g., legumes, such as peanuts and soybeans; wheat; tree nuts; fish; crustacea; mollusks; milk; and eggs).¹¹⁶ While U.S. law requires a listing of most ingredients in a food, there are exemptions from the ingredient labeling requirements that have contributed to some reports of adverse health reactions by consumers.

One of the exemptions applies to ingredients that are present at insignificant levels and do not have a functional or technical effect in the particular food.¹¹⁷ Such ingredients are referred to as incidental additives and include substances that are present in a food as a result of being a component of an ingredient in a food. However, if a component of an ingredient has the same effect in the finished food as it would if consumed independently, then the ingredient is not an incidental additive and its use should be declared on the label.¹¹⁸

Nevertheless, some manufacturers neglect to list such ingredients. The FDA recently issued a Notice to Manufacturers that reminded companies of the importance of properly interpreting the agency’s exemption for

the labeling of incidental additives. It explained that “when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product) the ingredient is not an incidental additive and its use must be declared on the label.”¹¹⁹

Some manufacturers also are incorrectly interpreting what FDA regulations term an “insignificant level” of a substance. Studies have shown that even trace amounts of certain substances can cause adverse reactions in some consumers; consequently, even very small amounts of the substance are significant and should thus be listed in the ingredient declaration.¹²⁰

The use of single production lines for different food products can inadvertently contaminate a food product with an unexpected ingredient. An example of such cross-contamination might be the presence of peanut oil in a food that is not supposed to contain peanuts, but that was produced on a production line that was previously used to manufacture peanut butter.

Some manufacturers have voluntarily labeled their products with the statement “may contain _____,” with the name of the potentially allergenic substance following so that consumers can be alerted to the possible contamination of the food. While that action is meritorious, the FDA has stressed that informational statements should not replace good manufacturing practices (GMP) and that manufacturers should take the necessary measures to eliminate cross-contamination.¹²¹

The FDA is closely monitoring the response of food companies to the agency’s Notice to Manufacturers regarding allergen labeling and evaluating adverse reaction reports.

Because there have been recent incidents of adverse reactions to foods containing allergenic substances that were improperly omitted from the ingredient declaration, the FDA may take more formal action to clarify its regulations so that food manufacturers fully comprehend when they need to declare allergenic food ingredients.¹²²

- **Labeling of additives**

In the U.S., FDA regulations require most additives to be listed in the ingredient list. But this requirement sometimes fails to adequately protect consumers. MSG provides a good example of this problem.

MSG must be declared in the ingredient statement by its common or usual name when it is added to a food.¹²³ MSG also must be declared in the ingredient statement when it has been added indirectly as part of another ingredient that contains MSG.¹²⁴ Nevertheless, a loophole exists in this disclosure requirement because

foods that contain certain other sources of free glutamate do not have to declare their presence. For example, free glutamate can be added to food in the form of hydrolyzed vegetable protein. Under current labeling regulations, only the ingredient containing the free glutamate needs to be declared in the ingredient statement by its common or usual name.¹²⁵ The presence of free glutamate does not have to be disclosed.

Most consumers are not aware that certain ingredients, such as hydrolyzed vegetable protein, contain free glutamate; moreover, they do not realize that free glutamate is, for sensitive individuals, essentially equivalent to MSG. Consequently, it is likely that some individuals are suffering adverse health effects from consuming foods that contain hidden sources of free glutamates.

As a result of recent consumer requests to require the labeling of the presence of free glutamate in finished foods, the FDA published an advance notice of proposed rulemaking (ANPR) and requested comments as to how the labeling of free glutamate should be accomplished.¹²⁶

The ANPR discussed two possible ways that free glutamate could be labeled. One way is to require all foods that have 0.4 g or more of free glutamate per serving to have a label stating the amount of free glutamate.¹²⁷

The ANPR noted another labeling method that would take into account consumers who ingested larger than average serving sizes. For instance, if products need only be labeled if they have 0.4 g or more of free glutamate, then foods that have just under 0.4 g of free glutamate would not have to bear quantitative labeling; consequently, consumers who eat twice the usual serving size would not be informed that they were eating large amounts of free glutamate. Therefore, a labeling threshold of 0.2 g of free glutamate would provide an additional margin of safety.

CSPI has recommended that the FDA require quantitative labeling on foods that contain at least 0.2 g of free glutamate and additional disclosures on foods that contain at least 1g of free glutamate. CSPI also urged the FDA to permit “No MSG” claims on food labels only in cases where the food does not contain other sources of free glutamate. After reviewing comments on the public record, the FDA is expected to propose a regulation detailing disclosure requirements for free glutamate.

FDA’s treatment of caffeine is another example of the inadequacy of U.S. labeling requirements for additives¹²⁸ that may cause adverse health reactions. U.S. FDA regulations only require that the presence of caffeine be labeled if it does not naturally occur in a food product.¹²⁹ FDA regulations do not require the

disclosure of caffeine in foods that naturally contain it, such as coffee, tea, or coffee-flavored ice cream or yogurt. Furthermore, FDA regulations do not require that the amount of caffeine be disclosed, even though the FDA has advised pregnant women to consume little or no caffeine.¹³⁰ In 1997, the FDA received a citizen's petition from CSPI requesting mandatory quantitative labeling of caffeine content. The American Medical Association pledged to work with the FDA to require the disclosure of the caffeine content of foods containing added caffeine.¹³¹ It is not clear what action the FDA will take.

2. Canada

The Canadian *Food and Drug Regulations* require almost all prepackaged foods to have a complete list of ingredients and components (ingredients of ingredients) which include any substances that performs a function in, or has any effect on, that food.¹³² However, special rules apply to such foods as butter, margarine, flour and rice.¹³³

In an attempt to improve upon this policy, the Canadian Food Inspection Agency has recently issued an allergy information letter to food manufacturers.¹³⁴ The information letter was accompanied by a report¹³⁵ listing those "foods and their derivatives" that should always be declared on food labels by their specific common names. This list includes peanuts,¹³⁶ tree nuts, sesame seeds, milk, eggs, fish, shellfish, crustaceans, soy, wheat and sulfites. To further assist consumers in making safe food choices, the information letter encourages manufacturers to identify the plant source of ingredients, such as hydrolyzed plant proteins, starches, modified starches and lecithin (e.g., hydrolyzed soy protein, wheat starch, modified wheat starch, and soy lecithin). The Canadian government is distributing the information letter and report to food manufacturers, distributors, and importers to encourage the voluntary labeling of food ingredients known to cause serious allergic reactions when present in prepackaged foods.

The information letter also encourages manufacturers to develop "allergen prevention plans" to prevent cross contamination and improper labeling. Canada encourages precautionary labeling such as "may contain peanuts" but has informed manufacturers that such labeling must not be used as a substitute for good manufacturing practices.¹³⁷

Furthermore, claims that a food does not contain or has no added MSG when in fact the product has other sources of free glutamates (i.e., hydrolysed vegetable protein, soya sauce or autolysed yeast extracts) are considered misleading and deceptive.¹³⁸

Canada also has a policy whereby any claim made regarding the absence or non-addition of an ingredient or substance to a food must meet certain thresholds.¹³⁹ For example, there is no tolerance for allergens, so if a product has even a minute trace of peanuts, then the product cannot declare the absence of peanuts. “Food hypersensitivity agents,” however, must be at levels of physiological insignificance (e.g., 10 ppm for sulfites) in order to make a claim of the absence of such agents.

3. European Union

The European Union is considering a directive that would require that certain substances “which are recognized scientifically as being the source of allergies or intolerances be included in the list of ingredients and not qualify as exceptions...”¹⁴⁰ This proposal is based on the Codex proposed draft amendment to the Codex General Standard for the Labeling of Prepackaged Foods, *infra* page 57, except that the EU also requires sesame seeds to be included in the list of ingredients.¹⁴¹

4. Codex

Codex has a proposed draft amendment to the Codex General Standard for the Labeling of Prepackaged Foods that would require foods and ingredients that are known to cause “hypersensitivity” to always be declared.¹⁴² The draft proposes that the following foods and additives always be declared: cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, or their hybridized strains and products of these); crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products (lactose included); tree nuts and nut products; and sulfite in concentrations of 10 mg/kg or more. The Codex proposal exempts components constituting less than 5% of the food from disclosure requirements so long as such components are not food additives which serve a technological function, known allergens, or ingredients associated with intolerances.¹⁴³

C. Recommendations for the Labeling of Food Ingredients and Additives that can Cause Adverse Health Reactions

National regulatory authorities should consider a continuum of labeling requirements for the disclosure of all ingredients and additives with special attention paid to substances that can cause adverse health problems. At a minimum, all ingredients and additives should be clearly disclosed. Governments should also endeavor to advise consumers of the presence of processing aids, accidental contaminants and other substances that are capable of causing adverse reactions.

Ideally, additives that can cause serious reactions should be banned. In cases where ingredients or additives are considered essential, but can cause severe or life threatening reactions, labels should include appropriate cautionary statements. For example, if governments do not ban high levels of sulfites, labels should advise consumers that sulfites may cause life threatening anaphylactic shock. Providing cautionary statements on products will educate consumers and may discourage the use of substances that are harmful to various segments of the population. The following is an example of a manufacturer who has included special labeling disclosure regarding the presence of peanuts and almonds.

In some cases, the amount of the ingredient or additive capable of causing adverse health reactions should also be disclosed when the incidence and/or severity of adverse reactions are dependent on the amount of the ingredient or additive consumed. For instance, one person may be able to consume up to 500 milligrams of free glutamate without having any adverse effects, but another person might have adverse effects after consuming less than 20 milligrams. Listing the amount of free glutamate in foods would allow such consumers to regulate their intake and make appropriate purchasing decisions.

Caffeine represents another example where quantitative disclosure would be useful for consumers. Caffeine is a drug, the effects of which, are dose dependent. If the amount of caffeine was disclosed on the labels of caffeine containing foods, consumers could better manage their caffeine intake.

The amount of these and other ingredients and additives that pose adverse health effects based on the quantity consumed should be disclosed in appropriate measures in the ingredient list next to the name of the substance. Quantitative disclosure of such substances would allow consumers to choose those products that have the least amount of the ingredient or additive that they are trying to avoid. In turn, such disclosure requirements would give manufacturers an incentive to lower the amounts of such substances in food products.

In sum, a comprehensive framework for ingredient disclosure requirements would provide peace of mind to individuals who suffer from food allergies or other sensitivities, reduce health care costs, and possibly save lives. National regulatory authorities should adopt a comprehensive regulatory scheme for disclosing such information in a consistent manner.

CHAPTER V: DECLARATIONS REGARDING METHODS OF PRODUCTION

The food industry increasingly is embracing new technologies to produce and process food. Technologies such as irradiation and genetic engineering, according to their proponents, will help make food safer, increase production, and even end world hunger.¹⁴⁴ While some consumers welcome the use of these new technologies or are just indifferent, others oppose their use and seek to purchase food that is produced using more traditional methods. Consumer interest in purchasing food products produced in traditional manners, for example, has led to an increased demand for organic foods and foods meeting centuries-old religious requirements such as kosher or halal.

Disclosures regarding methods of production are necessary for those consumers who wish to select or avoid a particular food because of how it was produced. Because the method of producing a food is most often not apparent from examining the food itself, food labels must provide this information.¹⁴⁵ If a food has been irradiated or produced with genetically engineered ingredients, that fact should be clearly indicated on the label. If a food claims to be in compliance with rules for organic agriculture or with specific religious practices, the definition of those terms should be clear and consistent.

The disclosure of such information is necessary to permit consumers to exercise free choice in the marketplace and “vote with their pocketbooks,” which is essential in a free market economy. If consumers are not given adequate information, then they cannot make informed purchasing decisions, and producers cannot respond with the types of products that consumers want to purchase. Not surprisingly, the most common rationale for disclosure laws, therefore, is economics — they improve market efficiency.¹⁴⁶

The disclosure of information regarding methods of production is also necessary to fulfill what has been called the consumers’ “right to know.” The consumers’ right to information was recognized by the General Assembly of the United Nations in its Guidelines for Consumer Protection. The guidelines are intended to provide “[a]ccess of consumers to adequate information to enable them to make informed choices according to individual wishes and needs.”¹⁴⁷ The guidelines urge governments to “encourage all concerned to participate in the free flow of accurate information on all aspects of consumer products.”¹⁴⁸

The U.N. guidelines were inspired by the pronouncement of U.S. President John F. Kennedy that consumers have “the right to be informed.” In his landmark message to Congress in March 1962, President Kennedy defined this right as not only encompassing the right of the consumer “to be protected against fraudu-

lent, deceitful, or grossly misleading information, advertising, labeling, and other practices,” but also the right “to be given the facts he needs to make an informed choice.”¹⁴⁹ Each subsequent U.S. President has endorsed this right,¹⁵⁰ and it continues to be a major element of the United Nations Guidelines for Consumer Protection.

This chapter will examine these principles in reference to requiring disclosure requirements for four different food processing and production methods that are currently the subject of debate. These methods include food irradiation, genetic engineering, organic food production, and methods used to produce foods in accordance with religious dietary requirements.

Part One: The Labeling of Irradiated Foods and Food Ingredients

Irradiation involves exposing foods to ionizing radiation — gamma rays from radioactive isotopes or machine-produced, high-energy electrons and x-rays.¹⁵¹ Irradiation can retard spoilage and kill microorganisms that can contaminate meat and poultry.¹⁵² Food irradiation has been approved by over 40 countries and has been endorsed by the World Health Organization and the Food and Agriculture Organization.¹⁵³ However, the practice is not accepted by some consumers who wish to avoid eating irradiated foods for nutritional, environmental or other reasons.

A. The Need for Labeling of Irradiated Foods

Irradiation can cause significant nutrient losses in foods. For example, studies of the effect of irradiation on thiamine levels in fresh foods, conducted under a variety of conditions, show nutrient losses ranging from approximately 10 to 50 percent over a dose range of 0.6 to 7.3 kGy.¹⁵⁴

Irradiated foods may also taste different than non-irradiated foods. Some studies have found that irradiation can create off-flavors and odors in beef and chicken.¹⁵⁵ Therefore, labeling is also necessary to inform consumers about possible taste differences in irradiated foods.

Some consumers may wish to avoid purchasing irradiated foods because of environmental and worker safety concerns. The U.S. Nuclear Regulatory Commission has recorded 54 accidents at 132 irradiation facilities worldwide since 1974.¹⁵⁶ If irradiated foods are clearly labeled, consumers can “vote with their pocket-books,” refrain from purchasing such foods, and help discourage a technology that they oppose.

Consumer surveys throughout the world show that consumers have consistently demanded that irradiated food be labeled as such.¹⁵⁷ In Britain, a national opinion poll found that 95% thought all food, including foods

that contain irradiated ingredients, should be labeled.¹⁵⁸ In a public opinion poll conducted in the United States, 92% of those surveyed said that foods should be labeled if they have been irradiated.¹⁵⁹ For whatever reason, consumers have a right to make an informed choice when deciding whether to purchase and consume irradiated foods.

B. Examples of Irradiation Labeling Requirements

1. United States

The use of irradiation was first approved by the U.S. Food and Drug Administration¹⁶⁰ in the early 1960s to control insects in wheat and wheat flour and to prevent sprouting in white potatoes. U.S. growers and manufacturers have not used either application because less expensive and easier-to-use chemicals are available. Subsequently, irradiation was approved to kill microorganisms in vegetable seasonings, to sterilize trichinae in infected pork, to delay ripening and sprouting in fresh fruit and vegetables, to control salmonella and other pathogens in poultry,¹⁶¹ and to kill disease-causing microorganisms in red meat.¹⁶²

In the U.S., all FDA-regulated packaged foods that have been irradiated must be labeled with the international symbol for irradiation and the words “treated by irradiation” or “treated with radiation.” Irradiated foods that are not in package form must display the required logo and phrase with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation.¹⁶³

U.S. regulations do not require that products containing irradiated ingredients be labeled. The treatment of irradiated ingredients under U.S. law is in marked contrast to those of many developed countries and is inconsistent with Codex standards. Furthermore, under pressure from the food industry, in 1997, the U.S. Congress mandated that the required irradiation disclosure for FDA regulated food products be reduced in size. The required disclosure on such foods must now be no more prominent than the food’s ingredient listing.¹⁶⁴

2. Canada

In Canada, irradiation has been approved to inhibit sprouting on potatoes and onions, to control insects in stored flour, wheat, and whole wheat flour, and to kill microbes in spices and dehydrated seasoning preparations.¹⁶⁵

Any irradiated food that is prepackaged must contain the international symbol on its principal display panel. The outer diameter of the symbol must be no smaller than the height required for the declaration of net

quantity of the package. Foods that are not prepackaged must display a sign that carries that symbol immediately next to the food. The symbol must be no less than 5 centimeters.

In addition, one of the following statements must appear in close proximity to the symbol: (1) “treated with radiation”; (2) “treated by irradiation”; or (3) “irradiated.” Any irradiated food that is an ingredient or component of a prepackaged product that constitutes 10% or more of the prepackaged product must be included in the list of ingredients and preceded by the statement “irradiated.”¹⁶⁶

3. European Union

The European Union authorizes the use of irradiation only if it can be demonstrated that there is a reasonable technological need, if the use of irradiation presents no health hazard, if it is of benefit to the consumer, and if it is not used as a substitute for good hygiene, good manufacturing, or good agricultural practices. Furthermore, irradiation may only be used to reduce the incidence of food-borne disease by destroying pathogenic organisms, to reduce spoilage of foodstuffs, to reduce loss of foodstuffs by premature ripening, germination or sprouting, or to rid foodstuffs of organisms that are harmful to plants or plant products.¹⁶⁷

The EU requires irradiated foods to bear the words “irradiated” or “treated with ionizing radiation” on the label. If an irradiated product is used as an ingredient, the same words must accompany the designation of ingredients.¹⁶⁸

4. Codex

The Codex standard for irradiated foods requires such foods to be labeled with a written statement indicating that the food has been irradiated. This statement must be placed in close proximity to the name of the food.¹⁶⁹ The use of the international food irradiation symbol is optional, but when it is used, it must also be in close proximity to the name of the food. When an irradiated product is used as an ingredient in another food, this must be declared in the list of ingredients. When a single-ingredient product is prepared from a raw material that has been irradiated, the label of the product shall contain a statement indicating the treatment.

C. Recommendations for Labeling of Irradiated Foods

Any foods, or any foods containing ingredients, that have been treated by irradiation should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If

the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale.

The U.S. government, in particular, should revise its regulatory standards to provide consumers with the level of protection accorded by the EU, Canada, and Codex standards. U.S. requirements in this area fall below those of many other developed countries and should be upgraded to world class levels. The U.S. should expand its disclosure regulations to require labeling of foods that contain irradiated ingredients. The U.S. should also reverse recent legislation that tends to obscure the irradiation disclosure by requiring that it appear in small print.

In addition, national regulatory authorities should take steps to ensure compliance with labeling regulations. Since there is no reliable post-treatment technique for detecting irradiation, it is imperative that treatment plants are consistently inspected to guarantee that dosage and labeling requirements are followed. Moreover, control over imported foods is particularly difficult, as importing countries must rely on the integrity of exporting governments and the effectiveness of their monitoring systems.¹⁷⁰ Thus, governments should work together to ensure that imported foods are also labeled reliably and consistently.

Part Two: The Labeling of Genetically Engineered Foods and Food Ingredients

Genetic engineering is a process by which deoxyribonucleic acid (DNA), the genetic material inside the cells of living organisms, is manipulated to block or add desired traits to an organism. Plants, animals, bacteria, and other life forms that have been subjected to such processes are referred to as genetically modified organisms (GMOs) or as transgenic. For example, tomatoes can be produced with delayed ripening ability so that they will stay fresher longer, corn can be grown so that it is resistant to insect borers, and soybeans can be made resistant to herbicides.

A. The Need for Labeling of Genetically Engineered Foods

Consumers may want to know whether a food product contains genetically engineered ingredients for a variety of reasons. Some consumers may perceive such foods as better than their conventional counterparts because of considerations relating to taste, cost, convenience or other factors. Other consumers may hold contrary views. The labeling of genetically engineered foods is necessary to permit all consumers to exercise free choice in the marketplace. If consumers are not given adequate information, then they cannot make in-

formed purchasing decisions and producers cannot respond with the types of products that consumers want to purchase.

Those consumers who wish to avoid purchasing genetically engineered foods may wish to do so for several reasons. First, some consumers may have safety concerns about genetically engineered foods. It is possible, for example, that a gene for an allergen could be transferred from one food to another food to which a consumer would not normally be allergic.¹⁷¹ Without proper labeling, consumers would not know whether a genetically engineered food contains an allergen.

Some segments of the food industry argue that companies can effectively screen for allergens. However, the report of the 1996 Joint FAO/WHO Consultation states

“[u]nfortunately, reliable models for the assessment of the allergenicity of genetically modified foods do not presently exist, although the development of such models is to be encouraged.”¹⁷² In light of this problem, appropriate labeling of genetically engineered foods is essential.

Other consumers have broader concerns about the safety of genetically engineered foods. While there is no evidence that genetically engineered foods are unsafe, some consumers remain skeptical. For instance, many Europeans feel betrayed by their government’s handling of the bovine spongiform encephalopathy (BSE — “Mad Cow Disease”) crisis.¹⁷³ In Great Britain, 24 people died after they apparently ate meat from tainted cows.¹⁷⁴ The European Commission’s handling of the outbreak was criticized by the European Parliament and undermined consumer confidence. With such actual food safety disasters in recent memory, many consumers are suspicious of new food technologies that governments and experts claim to be unquestionably safe.

Second, some consumers may be concerned about adverse effects that genetically engineered crops may have on the environment. The production of genetically engineered foods raises ecological concerns including damage caused by cross-pollination and unwanted pesticide and herbicide tolerance.¹⁷⁵ For example, in 1996, cotton that was genetically engineered to contain the naturally-occurring insect toxin from *Bacillus thuringiensis* (Bt) failed to protect against bollworms and other insect pests. This suggests that “widespread use of the Bt gene, particularly at moderate levels, might induce selection for Bt-resistant insects. Such an event would destroy the use of this toxin for sustainable agriculture systems in which it has been a mainstay.” There have also been reports of recombinant oilseed canola plants passing their gene for herbicide resistance to rapidly producing weeds.¹⁷⁶

In light of these and other environmental concerns, some consumers do not want to purchase genetically engineered products. However, if food products containing genetically engineered ingredients are not appropriately labeled, consumers will not have sufficient information to exercise free choice, and market forces will not be able to operate properly.

Third, some consumers want to know for philosophical, ethical, or religious reasons whether a food product contains a genetically engineered ingredient. Consumers may object to the development and use of genetic engineering because they fear that it could be misused in the future for other purposes. For example, some European consumers object to the use of genetic engineering based on historical experience during World War II when the Nazis conducted experiments in an attempt to create a superior Aryan race.¹⁷⁷ Others object on more general grounds to a technology that, in theory, could eventually be applied to humans. Furthermore, some Jews and Muslims, who do not eat certain foods such as pork, fear that genes from a pig could be inserted without their knowledge into a plant or animal that is part of their traditional diet. In addition, some Muslims, who do not eat insects, may be concerned that insect genes could end up in other foods.¹⁷⁸ Would the use of a protein derived from insects prevent Muslims from eating a genetically modified food? Religious leaders and their followers must answer such questions, but they cannot begin to even address these issues if they do not know which products are affected.¹⁷⁹

Surveys show that consumers in various countries around the world want labeling advising them whether food products have been genetically modified. A survey of American consumers conducted by Novartis, a Swiss-based company that is the world's largest agribusiness, chemical, and pharmaceutical firm, found that 93% of those surveyed want genetically engineered foods to be labeled.¹⁸⁰ That figure is consistent with survey results that show that European consumers also strongly favor labeling of genetically engineered foods.¹⁸¹

Novartis began labeling its genetically modified corn in 1996 and has urged its customers to label their products as coming from genetically engineered seeds. Wolfgang Samo, head of agribusiness at Novartis has stated that “[g]enetically enhanced products are overall superior to conventional ones. Industry should have many reasons to label them If we believe in the right to choose for consumers, the industry cannot reasonably argue against labels facilitating this choice.”¹⁸²

B. Examples of Labeling Requirements for Genetically Engineered Products

The EU leads the world in developing labeling regulations designed to let consumers know whether

foods contain genetically engineered ingredients. The U.S. strongly opposes such labeling requirements except in cases where a new product is essentially created or where a known safety hazard (e.g. allergenicity) is created by transferring the genes of one organism to another. The Codex Alimentarius Commission is presently considering two conflicting recommendations for labeling that reflect the differences between the U.S. and the EU. The conflict between the EU and the U.S. over the labeling of genetically engineered products has been called “the battle royale” of the 21st century world agriculture by U.S. Agriculture Secretary Dan Glickman.¹⁸³

1. United States

Genetically engineered foods and food ingredients are widely sold in the United States. They include canola, corn, cottonseed oil, potatoes, soybeans, tomatoes, and cheese-making enzymes (chymosin). Transgenic ingredients occur in products ranging from soy-based baby formulas to corn chips.

The U.S. FDA does not generally require the labeling of food produced through genetic engineering.

Labeling is required in only two situations:

- The food differs so much from its traditional counterpart that the “common or usual name” no longer applies to the new food; or
- A safety or usage issue exists to which consumers must be alerted, e.g., an allergen is present in a food, or the food no longer functions during food preparation like its traditional counterpart.¹⁸⁴

When labeling is required, it need not mention that the product has been genetically modified — it must only state the relevant change. For example, the FDA would require a label declaration if a tomato has had a peanut protein introduced into it, and the introduced protein could cause an allergic reaction. In such cases, however, the label would only need to indicate the presence of peanuts — not the fact that it was genetically altered.¹⁸⁵

The FDA has defended its policy by claiming that its statutory mandate, the Federal Food, Drug and Cosmetic Act (FDCA), “does not require disclosure in labeling of information solely on the basis of the consumer desire to know.”¹⁸⁶ In comments addressing a Codex Alimentarius proposal on labeling genetically modified foods, the U.S. explained its position:

The United States is mindful of the contention by some that mandatory labeling of all genetically engineered foods is within the concept of consumers’ right to know. The United States has long supported the inclusion in food labeling of information related to dietary guidance (such as nutrient values) and information relating to economic value (such as quantity of contents). However, under current United States’ laws and policy, consumers’ right-to-know does not automatically extend to mandatory disclosures on food labels beyond relevant information on

health, safety, altered nutritional composition, required handling and conditions of use. We are also aware that various groups have raised issues characterized as ‘ethical concerns.’ The United States believes that consumers should have access to information on bioengineered foods and that manufacturers ought to provide such information. There are a number of means of providing such information, other than labeling. Providing such information on the label would be highly impractical and unequitable in that the difficulties and costs in applying such labeling to commingled commodity products and to processed foods containing such ingredients from many different sources would be substantial and would be borne by all consumers regardless of the level of their own concerns and without providing any greater assurance of safety.¹⁸⁷

The U.S. discourages voluntary labeling of foods that do not contain genetically modified organisms on the grounds that such labeling can be potentially misleading. Although there is no official policy statement governing the use of phrases such as “contains no genetically engineered material,” an Interim FDA Guidance Policy on the voluntary labeling of milk and milk products from cows that have been treated with Recombinant Bovine Somatotropin (rBST) indicates that such statements must be carefully crafted to avoid implying that products produced without bioengineering are safer or of higher quality than those produced with bioengineering. FDA stated that “such misleading implications could best be avoided by the use of accompanying information that puts the statement in a proper context.” In the case of rBST-treated milk, FDA explained that a “proper context” could be achieved in a number of ways, including a statement that “no significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.”¹⁸⁸

The American position has been criticized both in the U.S. and abroad. Critics have pointed out that in some cases, the U.S. does require labels to indicate a food production method or process, such as “frozen,” or “from concentrate.” The U.S. also requires food labels to disclose whether added colors and flavors are “natural” or “artificial.” These critics have pointed out that there are ample grounds for considering the process of biotechnology “a material fact” — which triggers labeling requirements under U.S. law.¹⁸⁹

The policy of the FDA is often viewed as being inconsistent with requirements in other parts of the world. In the fall of 1997, the FDA hosted visitors from eight countries — all of whom were interested in the agency’s biotechnology policy. According to an unnamed FDA official, the journalists among the visitors wanted to get the “straight scoop as to why the U.S. is out of step with the rest of the world” on this issue.¹⁹⁰

The U.S. remains under pressure to label genetically engineered food. For example, in May 1997, 24 major European food retailers urged the U.S. food industry to develop a system for segregating and labeling genetically modified corn and soybeans exported to the EU. The retailers cautioned U.S. seed developers,

farmers, and traders that European consumers demand such labeling to enable them to make informed purchasing decisions.¹⁹¹

Recently, Monsanto, the leading U.S. agricultural biotechnology company, has dropped its opposition to labeling requirements issued by the EU. This change in corporate policy is significant considering that the U.S. government has strongly objected to the EU's labeling requirements as unjustified. Although Monsanto has now agreed to comply with those requirements, the company claimed that segregating genetically modified soybeans in the U.S. commodity chain is not viable.¹⁹²

2. European Union

The EU is at the forefront of developing labeling standards for genetically engineered foods. On May 15, 1997, the EU's Novel Food Regulation, 97/258 EC, went into effect, the first European act setting forth specific labeling requirements for genetically engineered food products. The regulation "requires that consumers be informed of differences between a new product and existing equivalent products. This requirement refers to the differences resulting from the use of biotechnological processes including the presence of 'live' and/or processed GMOs."¹⁹³

Much confusion has arisen in the EU over how to interpret the novel food law and how it will be implemented.¹⁹⁴ On July 22, 1997, the EU Commission sought to clarify how the laws will be interpreted and enforced by issuing a policy statement enunciating principles that will be contained in future legislation. In its statement, the Commission indicated that it will prepare draft legislation based on the following principles:

- "labeling of products consisting of, containing or derived from GMOs throughout the food chain;
- labeling intended to give consumers clear, honest and neutral information about the GMO origin of products, facilitating choice for consumers without stigmatizing modern biotechnology, scaremongering or raising doubts about the safety of products;
- a system which is science-based in order to ensure enforceability (for domestic and imported products alike), and to limit the scope for fraud (through the possibility of verification);
- labeling which can co-exist with different existing labelling frameworks, such as that foreseen by the Novel Foods Regulation;
- an approach which is simple and not unduly costly for operators to comply with and one which minimizes uncertainty;
- an approach that is in accordance with the Community's international obligations and which does not impose mandatory segregation of production, transport and distribution lines on operators but only proportionate labeling requirements;

- a coherent and flexible framework to determine the precise labeling rules with a clear proactive role for the Community.”¹⁹⁵

The Commission agreed that:

- products without GMOs can be marketed without any labeling. Voluntary labeling of products of certified non-GMO origin should be facilitated;
- for products known to be of GMO origin, mandatory labeling (e.g., “this contains”) should be required;
- in cases where material of GMO origin cannot be excluded but where no evidence of the presence of such materials is available, mandatory labeling (e.g., “this may contain”) should be required.¹⁹⁶

Because genetically engineered maize (corn) and soybeans were not covered by the Novel Food Regulation, the Commission adopted Regulation 1813/97, which became effective November 1, 1997. This regulation provides for detailed labeling requirements to be imposed for these products at a later time.

On February 25, 1998, the EU Commission formally proposed for Council consideration a regulation to replace 1813/97 that would set detailed labeling procedures for foods derived from genetically modified corn and maize. The proposal was important because it is the most detailed blueprint for a labeling scheme that the EU has issued to date, reflecting the policy enunciated in the July 1997 statement.

Under the proposal, products containing soy or maize products whose genetic modification can be confirmed through DNA or protein testing will be subject to the following requirements:

- If the food consists of more than one ingredient, the words “produced from genetically modified soya” or “produced from genetically modified maize” must appear in the ingredients list in parentheses following the name of the relevant ingredient. For products that do not contain a list of ingredients, those words must appear clearly on the labeling.
- An ingredient of a compound ingredient that is derived from genetically engineered corn or maize must be mentioned in the final product labeling.
- The use of the terms “may contain” or “may have been produced from” genetically modified _____ must be used if there is no evidence that the ingredients have been genetically modified but evidence of such modification cannot be excluded.¹⁹⁷

The proposal was approved recently by the European Parliament in May with minor amendments.¹⁹⁸ Council approval is expected shortly.

The Bureau Europeen des Unions de Consommateurs (BEUC), a European consumer advocacy organization, has criticized the proposal for relying on DNA or protein testing to determine whether consumer products are to be labeled. BEUC believes that because many ingredients are processed in such a way that the

modified DNA and new protein will not be detectable, few products will be required to be labeled. BEUC instead advocates that “business-to-business” information be used, with each entity in the production chain passing on information about product origin in an “audit trail.” The group stated that testing for genetic material should be done on raw materials as they enter the country, when testing is more accurate. In the alternative, produce with a certificate of origin from a certified laboratory indicating that it does not contain GMOs would be acceptable. BEUC also criticized the “may contain” labeling option as fostering consumer uncertainty.¹⁹⁹

3. Australia and New Zealand

On February 24, 1998, the Australia New Zealand Food Authority (ANZFA) published a proposal to require labeling of genetically engineered products where the products are not “substantially equivalent” to traditional foods. Unlike the EU requirements, the use of genetic engineering does not automatically mean that a food product is “not substantially equivalent” to its traditional counterpart. Unlike the U.S., however, the Australian proposal does not discourage negative claims (i.e. that foods do not contain products of a GMO).²⁰⁰

The proposal creates three categories of food, only one of which requires food labeling.

Category 1 is comprised of “[f]oods produced using gene technology that are not substantially equivalent to their existing conventional counterparts and which contain new or altered genetic material.” The category includes foods that are altered in their composition, allergenic properties, nutritional value, or end use. Examples include capsicum (hot or sweet peppers) modified to contain enriched vitamin A and C content, and tomatoes modified to be sweeter. Labeling would be required for such products. The label would be required to state the biological origin and nature of the characteristic or property modified.

Category 2 is comprised of “[f]oods produced using gene technology that are substantially equivalent to their existing conventional counterparts whether or not they contain new or altered genetic material.” Foods that contain new or altered genetic material could include tomatoes genetically modified to be insect resistant and potatoes genetically modified to reduce their susceptibility to browning and bruising. Foods that do not contain new or altered genetic material could include: sugar from sugar cane genetically modified to be resistant to viruses or cotton seed oil from cotton genetically modified to be insect resistant. Category 2 foods would not require labeling.²⁰¹

Category 3 is comprised of foods produced without using gene technology. Such foods may be labeled as containing no GMOs so long as it can be substantiated.²⁰²

The Australian Consumers Association (ACA) issued a statement that ANZFA “betrayed” consumers. ACA stated, “[t]he Authority has not kept faith with consumers. Consumers simply do not consider [that] genetically modified foods *can* be equivalent to conventional ones. This ruling denies their right to know about the *process* used to produce their food.”²⁰³ ACA explained that consumer surveys have shown that up to 90 percent of Australians want labeling for all genetically modified foods. The group, however, was pleased with the provision permitting manufacturers to indicate that their products do not contain genetically modified organisms.

4. Japan

Although Japan has issued Guidelines for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques, it has not yet issued guidelines on labeling genetically modified organisms. Currently, a legislative subcommittee and the Advisory Committee on Food Labeling at the Ministry of Agriculture, Forestry and Fisheries are discussing labeling issues. When the deliberations by the two bodies are completed, the government will present its position.²⁰⁴

5. Codex

The Codex Committee on Food Labeling will discuss two alternative recommendations for the labeling of foods obtained through the use of biotechnology in May 1998,²⁰⁵ reflecting the fundamental disagreement between the U.S. and the EU over “whether to apply specific labelling requirements to genetically modified products which are different from conventional products or to apply them to all genetically modified foods irrespective of their characteristics.”²⁰⁶

The first proposed recommendation reflects the position of the U.S. It states:

“When a food or food ingredient obtained through biotechnology. . . is no longer substantially equivalent to the corresponding existing food or food ingredients as regards

- composition
- nutritional value
- intended use

the characteristics which make it different from the reference food would be clearly identified in the labeling.”

The second proposal reflects a position more akin to that of the EU. It states:

All foods that are or contain genetically modified organisms shall be labeled. Foods that are produced from genetically modified organisms but do not contain them shall always be labeled, if natural variations considered, an adequate analysis demonstrates that they differ from equivalent conventional foods.

The presence of any substance[s] that are absent in existing equivalent foods and may have implications for the health of certain sections of the population and/or are the subject of ethical objections shall be indicated in the label.²⁰⁷

Two alternatives regarding the labeling of known allergens created by the use of bioengineering are also being considered by Codex. The first recommendation is to discourage the marketing of foods containing potential allergens. The second approach is to declare the presence of an allergen in any food or food ingredient produced through biotechnology. If adequate information about allergens cannot be provided through labeling, food containing an allergen should not be marketed.

The introductory comments to those recommendations appear pessimistic that a proposal will be adopted any time soon. They stated that “the Committee may wish to recognize that the positions are too different at this stage to establish international recommendations which would be generally acceptable and defer action until further information is available which could lead to consensus on these issues.”²⁰⁸

The Codex Executive Committee at its 43rd session stated that “while consumers may claim the right to know whether or not foods had been prepared by biotechnology, it also notes that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling.”²⁰⁹ However, the consumer’s need for adequate information in order “to make informed choices according to individual wishes and needs” has been recognized by the UN General Assembly in its Guidelines for Consumer Protection.²¹⁰ Moreover, the provision of such information is necessary to permit market forces to operate properly, *supra* page 61. Ensuring fair trade practices within the food industry is one of the primary purposes of the Codex Alimentarius, and the importance of labeling standards as a means to prevent deceptive trade practices by food companies is specifically recognized by the Codex Executive Committee.²¹¹ Thus, regardless of how the Commission views the consumers’ right to know doctrine, any action taken by Codex in this area should be consistent with its responsibilities to ensure fair trade practices.

C. Recommendations for Labeling of Genetically Engineered Foods and Ingredients

Consumers need to know the process by which a food was produced so that they can make informed purchasing decisions and exercise choice in the marketplace. Such requirements are necessary to ensure fair trade and allow free market forces to function properly. Thus, national regulatory authorities should require, to the greatest extent possible, that genetically engineered foods be labeled. Furthermore, authorities should also allow labels to say that foods are not genetically engineered, or do not contain genetically engineered ingredients, without burdensome qualifying statements. An important issue still to be resolved concerns the circumstances under which foods that *may* contain genetically engineered ingredients should disclose this fact on the label. The EU's implementation of its regulation will, hopefully, provide guidance on this issue.

Part Three: Labeling of Organic Foods

Organic food is one of the fastest growing segments of the food industry. In the United States, the size of the organic industry has risen from \$78 million in 1980 to \$3.5 billion in 1996.²¹² The market for organic foods in the EU was valued at \$1.7 billion in 1990 and has been projected to grow at a rate of 25% per year.²¹³ Japan's retail sales for 1994 were estimated to be \$688 million.²¹⁴ In Canada, 1995 retail sales were estimated at \$50 million and are expected to grow by 15 to 25 percent per year.²¹⁵

Some restaurants are beginning to use organic produce and other ingredients. In the U.S., the National Restaurant Association reports that organic menu items are offered in 57% of restaurants with per person checks of \$25 or more.²¹⁶ Japanese family and fast-food restaurants are taking advantage of the organic boom by adding such products to their menus. Higher-priced restaurants in Japan even serve organic wine.²¹⁷

Some major corporations are also beginning to add organic lines. For example, Heinz Co. now markets the Earth's Best line of organic baby food products.²¹⁸ In Japan, Mitsubishi Corp. has entered the organic market for environmental as well as business reasons.²¹⁹

A. The Need for Regulating the Labeling of Organic Foods

Consumers purchase organic foods for a variety of reasons. Some consumers believe that organic foods are of higher quality and taste better. Others favor organic foods because they want to protect the environment or are concerned about the risks that pesticides and other agricultural chemicals pose to farm workers.

Although more consumers are buying organic food, there is worldwide confusion over what the term “organic” means. Without a standard definition (and reliable enforcement), the word “organic” may, as a practical matter, provide consumers with little useful information.

Presently, a plethora of private entities for certifying organic products has created considerable confusion and controversy. For example, 27 individual U.S. state governments have organic certification laws.²²⁰ Editorials in Japan have called on the government to establish a certification system for products labeled as organic because “fake products are commonly sold.”²²¹

One of the best general definitions of “organic” was recommended by the U.S. National Organic Standards Board in April 1995. This definition incorporates language from the Codex Alimentarius Draft Guidelines for organically produced foods:

Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony. . . .The principal guidelines for organic production are to use materials and practices that enhance the ecological balance of natural systems and that integrate the parts of the farming system into an ecological whole. Organic agriculture practices cannot ensure that products are completely free of residues; however, methods are used to minimize pollution from air, soil and water. Organic food handlers, processors and retailers adhere to standards that maintain the integrity of organic agricultural products. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people.²²²

The following general conditions are among those that usually must be met for the production of organic foods:

- Synthetic pesticides, fertilizers and additives are not permitted.
- Soil is fertilized using composed plant and animal wastes, organic soil enrichers, mineral sprays and green manure. Green manure includes crops such as peas, beans and clovers which are planted in alternation with the primary crop to boost the nitrogen content of the soil.
- Insect pests are controlled through alternating crops, releasing competitive or sterile bugs, and by the use of sexual attractant traps, microbes and soap or vegetable sprays to reduce spores and eggs.
- Weeds are controlled through planting and trimming methods, rather than by chemical intervention.²²³
- Foods are not subjected to high-tech processing methods such as irradiation or genetic engineering.
- Meat and dairy products must be produced without the use of synthetic growth hormones such as rBGH or the use of antibiotics. Animals must have access to the outdoors and must be fed organic feed.²²⁴

Unfortunately, those presumptions may not be satisfied unless the use of the term “organic” has been

clearly and consistently defined and enforced. Without appropriate regulations, such as those adopted by California and certain other U.S. states, consumers have no assurances that organic foods have been produced in accordance with their expectations. The need for regulations is particularly important since consumers may pay up to twice as much for organic foods as conventional foods.

B. Examples of Labeling Regulations for Organic Foods

1. European Union

The EU permits the use of the term “organic” on raw foods meeting specified rules of production.²²⁵ The rules are set out in Article 6 and Annexes I and II to the regulation and detail general principles for organic production and specific methods and products authorized for use in soil conditioning and fertilization.²²⁶

The EU permits the use of the term “organic” on processed foods (the rules do not cover livestock) where “at least 95% of the ingredients of agricultural origin of the product are, or are derived from” products produced in accordance with Article 6.²²⁷ The product may indicate that it contains organic ingredients where “at least 70% of the ingredients of agricultural origin are, or are derived from” products produced in accordance with Article 6. Products that are marketed as organic or made with organic ingredients may not be subject to ionizing radiation.²²⁸ Genetically modified micro-organisms may only be used if they are specifically approved.²²⁹

2. United States

The U.S. FDA currently allows the use of the word organic on most food labels, but the USDA has withheld approval for the use of organic labeling of meat and poultry.²³⁰ Because of the lack of national standards, 27 state governments have adopted standards governing the production or handling of organic food.²³¹ Thus, food that is considered organic in one state may violate the organic standard of another state. There are currently 33 private and 11 state certification agencies with their own standards and identification marks.²³² That inconsistent and confusing patchwork of standards in the U.S. is a disservice to consumers and has impeded the growth of the industry.

In 1990, the U.S. Congress directed the USDA to develop a national standard for organic foods. After seven years of delay, USDA finally proposed a national organic standard for both raw and processed foods.²³³ Under the USDA proposal, raw foods could be labeled as “organic” if they were produced according to a set of principles restricting the use of pesticides, fertilizers, synthetic growth hormones, and antibiotics. Processed

foods could be labeled “organic” or “made with certain organic materials” based on the percentage of organic materials in the product. Processed foods containing at least 95% organic materials may be labeled organic. Processed foods with less than 95% but at least 50% organic ingredients may be labeled as “made with certain organic materials.”

The original USDA proposal permitted foods to be labeled organic if, among other things, they contained genetically modified organisms (GMOs), were irradiated, or were fertilized with sewage sludge. The USDA was bombarded with a record number of negative public comments (more than 200,000). U.S. Secretary of Agriculture Dan Glickman promised that the final regulation would delete these provisions. However, other aspects of the USDA proposal remain controversial, and a national consensus-based U.S. standard for organic food has not yet been developed.

3. Canada

Currently all food products labeled “organic” are produced and handled according to the certification requirements of an independent organic certification body.²³⁴ Foods that are labeled organic but fail to meet this certification requirement may be deemed misleading and deceptive under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*. The food label must indicate the name or number of the certifying agency. Food ingredients may be designated as organic only if they have been certified as such. The term organic is not synonymous with terms such as “pesticide free.”²³⁵

Although organic production in Canada is currently controlled by independent organic certifying agencies, the Canadian Organic Advisory Board will soon issue new standards for organic labeling. The Board is proposing to exclude foods that have been irradiated, genetically engineered, or grown using sewage sludge as fertilizer, and to exclude meat from animals that have been given antibiotics to stimulate growth. The standards will be voluntary at first, but may become law at a later date.

4. Codex

Codex is in the process of developing guidelines for the production and marketing of organic foods. “Draft Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods”²³⁶ are nearing completion. The draft guidelines set out a comprehensive framework for organic regulation including rules of production, lists of approved substances for treating plants and animals, inspection and certification systems, and other matters. With respect to label claims, the draft guidelines provide that manufacturers may

refer to multi-ingredient processed products as organic if 95% of the ingredients are organic. Products containing between 70 and 95% organic materials may state that they contain organic ingredients. Materials and/or products produced from genetically modified organisms are specifically excluded from the guidelines.²³⁷ Irradiated products are also excluded.

C. Recommendations for Labeling

In general, organic foods should not be permitted to contain more than five percent artificial ingredients or preservatives or be produced with the aid of synthetic pesticides or fertilizers, synthetic growth hormones, or antibiotics. Foods that contain between 70% and 95% organic ingredients should be permitted to state on the front label “Made with ___% organic ingredients.” The percentage of organic ingredients should be clearly disclosed in direct conjunction with the claim.²³⁸

Consumers expect that products that are labeled “organic” are not produced with high-tech processing techniques such as irradiation or genetic engineering. Thus, the organic label should not be permitted on products that have been irradiated or that contain genetically modified organisms.

Because it is impossible for consumers to distinguish organic products from conventionally produced products, they must rely on verification methods, such as certification by public or private entities and audit trails. Thus, national regulatory authorities should establish accreditation programs to certify that organic products and products containing organic ingredients are produced in accordance with national regulations. Organic certifiers should be subject to strict controls to ensure their objectivity in evaluating organic products. Organic producers should be inspected at regular intervals.

Part Four: Labeling of Foods Meeting Religious Dietary Specifications

A. The Need for the Labeling of Foods Meeting Religious Dietary Specifications

Internationally, many consumers demand foods produced in accordance with two of the most widely observed religious laws — kosher foods produced under Jewish dietary laws and halal (lawful) foods produced under Islamic law. Although many consumers buy such foods to follow their religious beliefs, many non-Jews and non-Muslims buy such products for other reasons.

According to a survey of American kosher food buyers, more than a third believe that “kosher is better;”²³⁹ twenty-nine percent are Jews, 19% are Muslims and Seventh-Day Adventists, and 16% are vegetarians

or lactose-intolerant. By the year 2007, the kosher food industry is expected to reach 36 million U.S. buyers, of whom 44% are expected to be Muslims and 37% to be vegetarians.²⁴⁰

Both Jewish and Muslim dietary laws forbid the eating of certain foods, including pork. The laws require animals to be slaughtered as quickly and as painlessly as possible so that the animal does not suffer. While kosher meat is generally taken from the front quarters of an animal, Islamic law permits the use of the entire carcass, as long as it is wholesome and properly slaughtered.²⁴¹

Jewish law prohibits consumption of meat and dairy products together, and dishes, cutlery and cooking equipment for each type of product must be kept separate at both the manufacturing and consumption stages. Manufacturing equipment must be dedicated to processing only kosher foods. Products that contain neither meat nor dairy products (e.g., vegetable products, some baked goods, some soups) are considered “pareve” and may be consumed with either meat or dairy products. Pareve products are often purchased by vegetarians and those with milk allergies.

B. Labeling Requirements for Kosher and Halal Foods

1. United States

Recently, as part of an initiative to “reinvent government” and cut down on the number of government regulations, the U.S. FDA revoked an official policy statement governing kosher labeling that had appeared in the U.S. Code of Federal Regulations since 1957.²⁴² The FDA claimed that its policy would be more appropriately reissued as a Compliance Policy Guide, which the agency defines as “an FDA informal guidance document.”²⁴³ While the FDA has withdrawn its formal policy statement, it has not yet reissued the statement as a Compliance Policy Guide. The revoked guidelines provided that:

The term *kosher* should be used only on food products that meet certain religious dietary requirements. The precise significance of the phrase “kosher style” as applied to any particular product by the public has not been determined. There is a likelihood that the use of the term may cause the prospective purchaser to think that the product is “kosher.” Accordingly, the Food and Drug Administration believes that use of the phrase should be discouraged on products that do not meet the religious dietary requirements.²⁴⁴

The U.S. has no policy regarding halal and has no plans to develop one.

2. Codex

In response to the expanding demand for halal products and rapidly increasing trade in such products, Codex Alimentarius approved new guidelines for the use of the term.²⁴⁵ The guidelines were opposed by the U.S. food industry. The Grocery Manufacturers of America (GMA) criticized the plan to issue guidelines,

stating that: “GMA believes that [the commission’s] scientific principles reinforce the view that cultural/religious factors should not play a role in the development of Codex guidelines/recommendations. . . . Religious authorities having the necessary [expertise] should be the ones to develop and issue such guidelines for the use [of the term] by food manufacturers.”²⁴⁶

In issuing the guidelines, Codex explained that:

The guidelines are of a general nature in order to allow for minor differences of interpretation according to the different Islamic schools of thought, and it is recognized that they are subject to the interpretation of the appropriate authorities of the importing countries. However, the certificate granted by the religious authorities of the exporting country should be accepted in principle by the importing country, except when the latter provides justification for other specific requirements. The guidelines define criteria for the use of “halal,” lawful and unlawful sources of food, general requirements for slaughtering and processing, packaging, storage and transport of foods claimed to be “halal.”²⁴⁷

Significantly, the guidelines provide that “claims on *halal* should not be used in ways which would give rise to doubt about the safety of similar food or claims that *halal* foods are nutritionally superior to, or healthier than, other foods.”²⁴⁸

C. Recommendations for Labeling

National regulatory authorities can help facilitate consumer choice and protect consumers from unfair trade practices by working with religious authorities and developing enforcement standards for the labeling of foods meeting religious dietary specifications. Although religious authorities must be the ones who will ultimately determine whether products should be certified as kosher or halal, government authorities can prosecute the fraudulent or misleading use of such terms on package labels.

In nations such as the United States, where the Constitution requires the separation of church and state, guidelines must be carefully drafted to ensure that there is a neutral regulation aimed at preventing fraud in the sale of food. As the U.S. Court of Appeals has stated:

The city [or other government authority] can prevent fraud in the sale of kosher food in a less restrictive and neutral manner by simply requiring that any vendor engaged in the sale of kosher food state the basis on which the food is labeled kosher Anyone offering for sale food marked [kosher] when the product had not in fact been approved by the relevant authority could be convicted of consumer fraud without any intrusion into the internal affairs of the Jewish faith, and without requiring the involvement of adherents of Orthodox Judaism interpreting a city ordinance.²⁴⁹

Unfortunately, the U.S. has moved in the opposite direction and is attempting to diminish its activity in this area. The U.S. should reexamine its policy and consider adopting the Codex standard for halal foods.

CONCLUSION

Food labeling regulations represent a valuable tool to improve consumer decision making in the marketplace and provide incentives to producers to improve product quality.²⁵⁰ Although some countries have required the disclosure of greater information about ingredients, nutritional composition, product quality, health effects, and production methods, no single nation has required disclosure of complete information in all of these areas. As national governmental authorities proceed with international harmonization of food labeling regulations, efforts should be made to ensure that new requirements are based on the premise of “upward harmonization.” Such requirements should reflect regulatory policies from around the world that best ensure that consumers are provided with the information they need to make informed purchasing decisions.

The United States, for example, should require quantitative ingredient labeling and freshness dating as required in Europe. The U.S. should also adopt more extensive disclosure requirements for the labeling of production processes including irradiation and genetic engineering. In turn, the EU should consider requirements for mandatory nutrition labeling. All nations should proceed with improved disclosure requirements for the labeling of ingredients or additives that may cause adverse health reactions.

Codex could help facilitate such developments by establishing international standards that are based on the premise of “upward harmonization.” The development of such standards would raise consumer protection standards and discourage trade disputes in which one nation argues that another nation’s consumer protection requirements are too strict and constitute an illegal trade barrier.²⁵¹

Codex should increase efforts to help nations learn from one another and take the lead in ensuring that food labeling requirements are upgraded to world-class levels that embody the best labeling provisions from around the globe. Such efforts would further Codex’s mission and will, hopefully, drive Codex’s agenda for the 21st century.

¹ Julie A. Caswell, *Uses of Food Labeling Regulations*, Organization for Economic Cooperation and Development (OECD) Working Papers, Volume V (1997) No. 100.

² *Id.*

³ The Codex Alimentarius Commission, a subsidiary body of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), develops international food safety and quality standards.

⁴ For a general discussion of international harmonization, see Scott H. Jacobs, “*Cooperation for an Interdependent World: Issues for Government*,” in REGULATORY CO- OPERATION FOR AN INTERDEPENDENT WORLD,

15-46 (1994).

⁵ See, e.g., Uruguay Round Agreements Act, Pub. L. No. 103-465 (codified as amended at 19 U.S.C. §§ 3501 *et seq.* (1994)).

⁶ Product labeling and related health and safety regulations can be challenged as a barrier to trade under the Agreement on Technical Barriers to Trade and/or the Agreement on the Application of Sanitary and Phytosanitary Measures.

⁷ CO-OP, *THE LIE OF THE LABEL* 6 (1997).

⁸ See Directive 97/4/EC of the European Parliament and of the Council amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, Article 1 (January 27, 1997).

⁹ *Id.* at Article 7(2)(a).

¹⁰ Ministry of Agriculture, Fisheries and Food, *Draft Guidance Notes*, July 1997, United Kingdom, Sec. 13 & 15 (hereinafter *Draft Guidance Notes*). The guidance notes are for purposes of providing informal, non-statutory guidance on QUID and should not be taken as an authoritative statement or interpretation of the law.

¹¹ Directive 97/4/EC at Article 7(2)(b).

¹² *Draft Guidance Notes*, *supra* note 10, at Sec. 16.

¹³ Directive 97/4/EC at Article 7(2)(c).

¹⁴ *Draft Guidance Notes*, *supra* note 10, at Sec. 18.

¹⁵ Directive 97/4/EC at Article 7(4).

¹⁶ *Id.* at Article 7(5).

¹⁷ *Draft Guidance Notes*, *supra* note 10, at Sec. 41.

¹⁸ Directive 97/4/EC at Article 7(3)(a).

¹⁹ *Draft Guidance Notes*, *supra* note 10, at Sec. 41.

²⁰ France has already implemented QUID legislation, see Co-op, *supra* note 7, at 4.

²¹ OFFICE OF AGRICULTURAL AFFAIRS OF THE USDA/FOREIGN AGRICULTURAL SERVICE, THAILAND: FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS (Fairs) 9 (July 1997).

²² 21 C.F.R. § 101.4(a)(1) (1997). However, ingredients present in amounts of 2 percent or less by weight do not need to be listed in descending order of predominance, but may be listed at the end of the ingredient statement following an appropriate quantifying statement, such as “Contains 2 percent or less of.” *Id.* at § 101.4(a)(2).

²³ *Id.* at §§ 101.30, 102.23, 102.37, 102.54.

²⁴ See 58 Fed. Reg. 2865 (1993).

²⁵ 21 C.F.R. § 102.5(a) (1997).

²⁶ *Id.* at § 102.5(b).

²⁷ CODEX ALIMENTARIUS COMMISSION, *Codex Alimentarius Vol. 1, Section 5.1* (1995).

²⁸ Freshness dates are not absolute; the food may still be edible or taste good beyond the date that appears on the package. However, if a product is not stored properly, it may become stale even before the given freshness date.

²⁹ Stephen Dowdell, *Looking for a Date*, SUPERMARKET NEWS, June 17, 1996, at 27. American Consumers were surveyed for Supermarket News by the American Research Group, Charleston, South Carolina. Respondents were questioned about preferences and shopping habits regarding produce, meat, seafood, dairy, bakery and deli items. Responding to the question of which food qualities they considered most important when choosing where to shop, they said freshness was the most important, backed if possible by a sell-by date.

³⁰ Ryan Mathews, *Are Supermarkets Missing the Boat?*, PROGRESSIVE GROCER, Apr. 1997, at S39.

³¹ *N.Z. Survey Assesses Consumer Attitudes toward Food Labels*, WORLD FOOD CHEMICAL NEWS, Apr. 3, 1996, at 11. According to the Australia-New Zealand Food Authority, “[d]ate marks were the most widely recognised, frequently used, and highly valued label elements tested.” AUSTRALIA-NEW ZEALAND FOOD AUTHORITY, DEVELOPMENT OF JOINT AUSTRALIA-NEW ZEALAND FOOD STANDARDS AS PART OF THE PROCESS OF THE REVIEW OF THE FOOD STANDARDS CODE, DATE MARKING OF PACKED FOOD, FULL ASSESSMENT REPORT PROPOSAL P139, February 1998, at 8 (hereinafter *ANZFA Report*).

³² *N.Z. Survey Assesses Consumer Attitudes toward Food Labels*, WORLD FOOD CHEMICAL NEWS, Apr. 3, 1996, at 11.

³³ *ANZFA Report*, *supra* note 31 at 10.

³⁴ Telephone interview with Robert Gravani, Professor of Food Science at Cornell University (Dec. 19, 1997).

³⁵ In most cases, out-of-date foods are still safe to eat. There have been reports of incidents, however, that

implicate the sale of out-of-date foods with safety concerns. *See, e.g.,* Polly Graham, *Horror in Store: The Mirror Investigates Scandal of Old Food for Sale*, THE MIRROR, Sept. 18, 1997, at 6. Such reports may indicate that in some cases, date marking may serve an important food safety function.

³⁶ 1979 O.J. (L33) 7. The EU policy covers all “foodstuff,” but does not require the following foods to have a freshness date: fresh fruits and vegetables, including potatoes which have not been peeled, cut, or similarly treated; wines; beverages containing 10% or more by volume of alcohol; bakers’ or pastry-cooks’ wares that are normally consumed within 24 hours of their manufacture; vinegar; cooking salt; solid sugar; and confectionery products consisting of flavored and/or colored sugars.

³⁷ *Id.*

³⁸ *Id.*

³⁹ JAPANESE AGRICULTURAL STANDARD, LABELING SYSTEMS FOR PROCESSED FOODS IN JAPAN: AN OVERVIEW 6 (Mar. 1995).

⁴⁰ *Id.* at 8-9, 15-16.

⁴¹ AGRICULTURE AND AGRI-FOOD CANADA, GUIDE TO FOOD LABELING AND ADVERTISING, Sec. 2.10 (Mar. 1996) (hereinafter *Canada Guide*).

⁴² *Id.*

⁴³ *Id.* at Sec. 2.10.2.

⁴⁴ 44 Fed. Reg. 75,990 (1976).

⁴⁵ Infant formula, however, does require freshness dates to appear on each bottle. 21 C.F.R. § 107.20 (1997). This subsection requires that all infant formula have a “Use by __,” date, the blank to be filled with the month and year that the manufacturer, distributor or packer of the infant formula has found that the formula will contain the same quantity of each nutrient that is on the label and will be of an acceptable quality.

⁴⁶ NAT’L CONFERENCE ON WEIGHTS AND MEASURES, SUMMARY OF STATE LAWS AND REGULATIONS IN WEIGHTS AND MEASURES, UNIFORM LAWS AND REGULATIONS 4-6 (Sept. 1996).

⁴⁷ *Id.* at 119-120.

⁴⁸ These companies voluntarily provide freshness dates on some of their products but fail to provide dates on other items sold in the U.S.

⁴⁹ Codex General Standard for the Labelling of Prepackaged Foods, Codex Alimentarius Volume 1A, Sec. 4.4.7.1 (1995). Codex does not require certain foods to have freshness dates. These foods are the same foods that the EU does not require to have freshness dates, except Codex exempts one additional food item: chewing gum. *Id.* at Sec. 4.7.1(vi).

⁵⁰ *Id.* at Sec. 4.4.7.2.

⁵¹ *Id.* at Sec. 4.4.7.1(iii).

⁵² *Id.* at Sec. 4.4.7.1(v).

⁵³ For instance, after one year, canned vegetables that are stored at 65° F (18° C) lose approximately 10% of their vitamin C; at 80° F (27° C), canned vegetables can lose as much as 25% of their vitamin C. Audrey D. Hylton, *Take Stock of Kitchen Cupboards*, THE PLAIN DEALER, Feb. 5, 1997, at 1E.

⁵⁴ *Food Poisoning: A Third of the Nation Tempts Fate When They Eat Take-Out According to Prevention/NBC Today - Weekend Edition National Survey*, PR NEWSWIRE, July 21, 1997 (available in NEXIS Library).

⁵⁵ *Id.*

⁵⁶ For example, studies have demonstrated that diets high in saturated fat and cholesterol tend to increase the risk of heart disease. High-fat diets have been associated with an increase in the risk of cancers to the colon, rectum, prostate, and endometrium. The connection between high-sodium diets and hypertension is also well-supported.

⁵⁷ *See* World Cancer Research Fund & American Institute for Cancer Research, *Food, Nutrition and the Prevention of Cancer: a global perspective* (July 1997).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ FOOD MARKETING INSTITUTE AND PREVENTION MAGAZINE, SHOPPING FOR HEALTH 1997 15 (1997).

⁶¹ *Id.* at 18-19.

⁶² More than 2,000 new low-fat or reduced-fat products were introduced in 1996. That number has almost tripled since 1993, the year before nutrition labeling became mandatory in the U.S. New Product News, *Products Bearing Health Claims, 1989-1996*.

⁶³ Council Directive 90/496/EEC, 1990 O.J. (L276) 40, at Art. 2 [hereinafter *Directive 90/496*].

⁶⁴ Marsha A. Echols, *The International Tower of Babel: The Small Business Perspective*, 51 FOOD & DRUG L.J. 175, 181 (1996).

⁶⁵ *Directive 90/496* at art. 4. The following minerals or vitamins may be listed: vitamin A, vitamin D,

vitamin E, vitamin C, vitamin B6, vitamin B12, thiamin, riboflavin, niacin, folacin, biotin, pantothenic acid, calcium, phosphorus, iron, magnesium, zinc, and iodine. *Id.* at Annex.

66 *Id.* at art. 6.

67 *Id.* at art. 7.

68 *See, e.g.* BUREAU OF NUTRITIONAL SCIENCES, HEALTH CANADA, NUTRITION LABELLING: DISCUSSION PAPER (March 26, 1998).

69 Food and Drug Regulations (FDR), Sec. B.01.300. When a nutrition claim is made on a food label, the nutrient declaration must appear on the label. When a nutrition claim is made in an advertisement, the required nutrient declaration must be in the advertisement or on the label. *Id.* at Sec. B.01.304.

70 *Canada Guide, supra* note 41 at Sec. 6.1.4 (Mar. 1996). However, when a claim is made for a fatty acid or cholesterol, the four components of fat (polyunsaturates, monounsaturates, saturates, and cholesterol), and total fat, must be listed. *Id.* at Sec. 6.2.3. When a nutrition claim is made for potassium *or* sodium, both sodium *and* potassium must be listed. Sec. 6.2.5. If the food is for “special dietary use,” its energy value, protein, fat, and carbohydrate content must be disclosed. (A “food for special dietary use” is a food that has been specially processed or formulated to meet the particular requirements of a person in whom a physical or physiological condition exists as a result of a disease, disorder or injury; or for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods. Foods described as “carbohydrate-reduced,” “sugar-free,” “calorie-reduced,” “energy-reduced,” “low in energy,” “low-calorie,” “low-sodium,” and their synonyms must meet the requirement for foods for special dietary uses.) FDR, Division 24.

71 *Canada Guide, supra* note 41, at Sec. 5.6.

72 *Id.*

73 *Id.* at Sec. 5.1.3. Other nutrients may be listed as desired or as required if a nutrition claim is made.

74 FDR at Sec. B.01.310.

75 Health Canada, *Nutrition Labelling: Health Canada Announces a Review* (March 1998).

76 Israel also requires nutrition labeling on foods. Letter from P. Ketsch, Ministry of Trade (Feb. 10, 1998) (on file with author).

77 Nutrition Labeling and Education Act of 1990, P.L. 101-535, 104 Stat. 2353 (1990). Although nutrition labeling is required for almost all packaged foods, there are several exceptions: plain coffee and tea; some spices, flavorings, and other foods that contain no significant amounts of nutrients; ready-to-eat food prepared primarily on site, such as deli and bakery items; restaurant food; bulk food that is not resold; and food produced by small businesses. Foods in small packages do not have to have nutrition information on their labels unless they make a nutrition claim. However, they must carry a telephone number or address consumers can use to get required nutrition information. 21 C.F.R. § 101.9(j) (1997). Nutrition information is voluntary for raw fruits, vegetables, fish, meat, and poultry. 21 C.F.R. § 101.44 (1997), 9 C.F.R. §§ 317.345, 381.445 (1997).

78 Vitamins such as thiamin, riboflavin, and niacin are not required because deficiencies of these vitamins are no longer considered significant public health problems. However, manufacturers may list these and other nutrients if they choose, subject to certain conditions. FDA Consumer, *Focus on Food Labeling* 12 (May 1993).

79 21 C.F.R. § 101.9(b)(2) (1997).

80 21 C.F.R. § 101.9(c)-(d) (1997).

81 21 C.F.R. §§ 101.9(c), 101.9(d)(6) (1997).

82 21 C.F.R. § 101.9(d)-(f) (1997).

83 Codex Guidelines on Nutrition Labelling, Codex Alimentarius Vol. 1A, Sec. 4.2, 3.1 (1995).

84 *Id.* at Sec. 4.2, 3.2.1. In addition, when a claim is made regarding the amount and/or type of carbohydrate, the amount of total sugars should also be listed. Where a claim is made regarding the dietary fiber content, the amount of dietary fiber should be declared. *Id.* at Sec. 4.2, 3.2.2. When a claim is made regarding the amount or type of fatty acids, the amount of saturated fatty acids and polyunsaturated fatty acids should be declared. *Id.* at Sec. 4.2, 3.2.3.

85 *Id.* at Sec. 4.2, 3.2.4-3.2.5. Five percent of the recommended intake (of the population concerned) supplied by a serving should be taken into consideration in deciding what constitutes a significant amount. *Id.* at note 1.

86 Once nutrition information is required for all packaged foods, governments should consider mechanisms for requiring nutrition information for all foods sold in restaurants. Because restaurant foods — unlike most packaged foods — do not provide an ingredient list nor indicate how they were prepared, the nutritional value of such foods is especially difficult to assess. In the U.S., restaurant foods are exempt from nutrition labeling requirements. Restaurants are only required to provide nutrition information for foods for which health or nutrition claims are made. Moreover, only nutrition information that pertains to the particular claim is required to be provided, and it need only be provided upon request. 21 C.F.R. § 101.10.

87 In the U.S., raw fruits, vegetables, fish, poultry, and meat are exempt from nutrition labeling requirements. Instead, the FDA and USDA have established a voluntary nutrition labeling program for these foods. Under these programs, at least 60% of retailers must provide nutrition information or else the agencies will make nutrition labeling mandatory. 9 C.F.R. §§ 317.343, 381.443(2) (1997); 21 C.F.R. § 101.43 (1997).

88 Tom O'Brien, Center for Food Safety and Applied Nutrition, Food and Drug Administration, *Status of Nutrition Labeling of Processed Foods: 1995 — Food Label and Package Survey (FLAPS)* (Aug. 26, 1996) 14.

89 However, it should be noted that the U.S. does not require the disclosure of *trans* fatty acid content, despite the fact that an increasing body of evidence suggests that *trans* fatty acids raise blood cholesterol levels, increasing the risk of coronary heart disease.

90 According to the manufacturer, the Canadian product contains 730 mg of sodium in a one-cup serving (more than one quarter of a day's worth, based on the U.S. labeling standard).

91 INSTITUTE OF MEDICINE, NUTRITION LABELING: ISSUES AND DIRECTIONS FOR THE 1990s 214 (1990) (citing J.T. HEIMBACH, R.C. STOKES, NUTRITION LABELING FOR TODAY'S NEEDS: OPINIONS OF NUTRITIONISTS, THE FOOD INDUSTRY, AND CONSUMERS (1981)). This preference was based on the belief that it would be less useful to consumers to have the nutrient content of all products calculated against a standard weight, which would often be greater or smaller than a usual serving. *Id.*

92 Christine J. Lewis & Elizabeth A. Yetley, *Focus Group Sessions on Formats of Nutrition Labels*, 92 J. AM. DIET. ASSOC. 62 (1992).

93 Chris Mihill, *Shoppers "Confused" by Nutrition Labels on Food*, THE GUARDIAN, June 30, 1997, at 8.

94 U.S. Food and Drug Administration, *FDA Consumer* (May 1994).

95 *Id.*

96 *Id.*

97 *Id.*

98 Harrison's Principles of Internal Medicine, (13th ed. 1994), at 1632. For an example of the impact of such allergies on the individual consumer, see *Peanut Allergy - What You Need to Know*, Allergy Asthma and Immunology Society of Ontario, (visited on March 25, 1998) <<http://www.oma.org/phealth/peanuts.htm>>.

99 *FDA Consumer*, *supra* note 94. See also Katherine Forestier, *One Small Bite Could Be Fatal*, SOUTH CHINA MORNING POST, March 25, 1997, at 24.

100 *FDA Consumer*, *supra* note 94.

101 National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Lactose Intolerance* (April 1994).

102 *FDA Consumer*, *supra* note 94.

103 61 Fed. Reg. 48,102 (1996). MSG is glutamic acid in its salt form, and glutamic acid is a normal component of the human body and some foods. There are two types of glutamate: "free" and "bound." Free glutamate is not "bound" or incorporated into a protein. Free glutamate occurs naturally in certain foods, such as tomatoes, mushrooms, and certain cheeses, but it can also be produced by the hydrolysis of proteins. *Id.* at 48,103.

104 *Id.* at 48,104.

105 *Id.* at 48,105.

106 *Id.*

107 *Id.*

108 U.S. Food and Drug Administration, Monosodium Glutamate (MSG) (August 31, 1995), (visited March 11, 1998) <<http://vm.cfsan.fda.gov/~lrd/msg.tx>>.

109 See W. Srisuphan, M.B. Bracken, *Caffeine consumption during pregnancy and association with late spontaneous abortion*, 154 AM. J. OB. AND GYN. 14-20 (1986); L. Dlugosz *et al.*, *Maternal caffeine consumption and spontaneous abortion: A prospective cohort study*, 7 EPIDEMIOLOGY 250-255 (1996); V. Dominguez-Rojas *et al.*, *Spontaneous abortion in a hospital population: Are tobacco and coffee intake risk factors?* 10 EUROPEAN JOURNAL OF EPIDEMIOLOGY 665-668 (1994); B.G. Armstrong *et al.*, *Cigarette, alcohol, and coffee consumption and spontaneous abortion*, 82 AM. J. OF PUBLIC HEALTH 85-87 (1992); T.R. Martin, M.B. Bracken, *The association between low birth weight and caffeine consumption during pregnancy*, 126 AM. J. OF EPIDEMIOLOGY 813-821 (1987).

110 R.M. Gilbert, *Caffeine Consumption*, in THE METHYLYXANTHINE BEVERAGES AND FOODS: CHEMISTRY, CONSUMPTION, AND HEALTH EFFECTS 185-214 (F.A. Spiller ed. 1984).

111 J.E. James, *Caffeine, health and commercial interest*, 89 ADDICTION 1595-1599 (1994).

112 J.R. Hughes *et al.*, *Caffeine self-administration, withdrawal, and adverse effects among coffee drinkers*

- 48 ARCHIVES OF GENERAL PSYCHIATRY 611-617 (1991); K. Silverman *et al.*, *Withdrawal syndrome after the double-blind cessation of caffeine consumption*, 327 NEW ENG. J. MED. 1109-1114 (1992); M Van Dusseldorp, M.B. Katan, *Headache caused by caffeine withdrawal among moderate coffee drinkers switched from ordinary to decaffeinated coffee: a 12 week double blind trial*, 300 BRITISH MEDICAL JOURNAL 1558-1559 (1990).
- 113 R.R. Griffiths *et al.*, *Low-dose caffeine physical dependence in humans*, 255 JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 1123-1132 (1990).
- 114 G.A. Bernstein *et al.*, *Caffeine effects on learning, performance, and anxiety in normal school-age children*, 33 JOURNAL OF THE AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY 407-15 (1994).
- 115 The average adolescent boy in the U.S. drinks 21 ounces of soda per day and only 10 ounces of milk per day. The average adolescent girl drinks 12 ounces of soda per day and less than eight ounces of milk per day. AGRICULTURAL RESEARCH SERVICE, USDA, FOOD AND NUTRIENT INTAKES BY INDIVIDUALS IN THE UNITED STATES, 1 DAY, NFS Report No. 94-2 (1994).
- 116 57 Fed. Reg. 22,984, 22,987 (1992).
- 117 21 C.F.R. § 101.100(a)(3) (1997). The other is a partial exemption for flavors and spices from the required ingredient list. Under U.S. law, those items can be disclosed on the ingredient list collectively. Hence, consumers cannot determine whether a product contains a specific flavoring or spice that may cause them to suffer an adverse reaction, except in cases where the FDA has required that a particular substance be specifically listed. The FDA recently adopted a regulation requiring that any protein hydrolysate used as a flavoring be disclosed. The food source from which the protein was derived must also be listed. 21 C.F.R. § 101.22 (h)(7) (1997).
- 118 U.S. Food and Drug Administration, Notice to Manufacturers, Label Declaration of Allergenic Substances in Foods (June 10, 1996).
- 119 *Id.*
- 120 *Id.*
- 121 *Id.*
- 122 *Id.*
- 123 21 C.F.R. § 101.22(h)(5) (1997).
- 124 61 Fed. Reg. 48,102, 48,103 (1996).
- 125 *Id.*
- 126 *See supra* note 124.
- 127 That trigger amount of free glutamate was chosen because the FDA concluded that glutamate-intolerant consumers are at risk if the total amount of free glutamate in a meal is equal to or greater than 2.4 g. If one assumed that meals consist of approximately six servings, then each serving should contain no more than 0.4 g of free glutamate.
- 128 Similar issues regarding the labeling of caffeine content are also raised when caffeine occurs naturally in foods.
- 129 21 C.F.R. § 101.100 (1997); 21 C.F.R. § 101.4 (1997).
- 130 FDA Office of Public Affairs, *Caffeine and Pregnancy*, Department of Health and Human Services Publication No. (FDA) 81-1081.
- 131 Resolution passed by the American Medical Association, Annual Meeting, June 22, 1997, House of Delegates resolution No. 523 (A-97).
- 132 FDR at Sec. B.01.008, B.01.009(3) and *Canada Guide* at 2.8.2. Exceptions from labeling requirements are provided for the ingredients of colors, flavors, spices, flavor enhancers, and hydrolyzed plant protein. However, salt, glutamic acid or its salts, potassium, aspartame, and peanut oil in any form must be declared. FDR, at Sec. B.01.009(2)(3) and (4).
- 133 FDR, at Sec. B.01.009(1).
- 134 *See* Government of Canada, Canadian Food Inspection Agency, *Labelling of Foods Causing Allergies and Sensitivities* (Apr. 7, 1998).
- 135 Government of Canada, Canadian Food Inspection Agency and Health Canada Committee, *Proposed Labelling of Foods Causing Severe Adverse Reactions in Canadian*, Food and Drug Regulations Review Project 19 Consultation (Apr. 7, 1998).
- 136 Peanut oil, hydrogenated or partially hydrogenated peanut oil, and modified peanut oil must appear in the ingredient list of any food that has an ingredient, preparation, or mixture that is not normally required to list its ingredients.
- 137 *Supra* note 134.
- 138 *Canada Guide*, *supra* note 41, at 4.2.4.4.
- 139 *Canada Guide*, *supra* note 41, at 4.2.4.

140 EU, Draft proposal for a European Parliament and Council Directive amending Directive 79/112/EEC (January 16, 1998).

141 *Id.*

142 Proposed Draft Amendments to Codex General Standard for the Labeling of Pre- Packaged Foods (at Step 5 of the Procedure), Codex Alimentarius, Alinorm 97/22A, Appendix IV, at Sec. 4.2.1.3 (1997).

143 *Id.*

144 Peter Scher, Deputy U.S. Trade Representative, remarks at the 1998 Ceres Conference on “Politicizing Science: What Price Public Policy?” (Georgetown University Center for Food and Nutrition Policy) (April 4, 1998).

145 Caswell, *supra* note 1.

146 See Caswell, *supra* note 1; Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California’s Proposition 65*, 23 Ecology L.Q. 302, 313 (1996)

147 United Nations, Resolution Adopted by the General Assembly, Annex Guidelines for Consumer Protection, Apr. 16, 1985, at II. (c), *reprinted in, Consumer Law in the Global Economy National and International Dimensions* (Iain Ramsay, ed. Dartmouth Pub. Co., Ltd. 1997) at 372.

148 *Id.* at 375 (III. B.21).

149 President John F. Kennedy, Message Relating to Consumers’ Protection and Interest Program (March 15, 1962) at 2.

150 For example, in his address marking National Consumer Week in 1994, President William J. Clinton recognized the importance of the consumer right to know. He stated, “What has come to be called the Consumer Bill of Rights has evolved as our marketplace has evolved. At present, it includes: ‘The Right to Information’ — the right to have full and accurate information upon which to make free and considered decisions and to be protected against false or misleading claims.” William J. Clinton, Proclamation, National Consumers Week, 1994.

151 Rosanna Mentzer Morrison, *Food Irradiation Still Faces Hurdles*, Food Review (Oct.- Dec. 1992) at 11-12.

152 International Consultative Group on Food Irradiation, Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, *Facts About Food Irradiation* (May 1991).

153 P.J. Skerrett, *Food Irradiation: Will It Keep the Doctor Away?* TECHNOLOGY REVIEW (MIT), Nov. 21, 1997.

154 62 Fed. Reg. 64,107, 64,114 (1997).

155 Other studies, however, have found no such effects. Rosanna Mentzer Morrison, et al., *Irradiating Ground Beef to Enhance Food Safety*, Food Review (Jan.-Apr. 1997) at 34.

156 Susan Meeker-Lowry & Jennifer Ferrara, *Meat Monopolies: Dirty Meat and the False Promises of Irradiation*, Food & Water, at 25.

157 Tony Webb, Tim Lang, Kathleen Tucker, FOOD IRRADIATION: WHO WANTS IT? 53 (Thorsons Publishers, Inc. 1987) (*citing* Titlebaum, Dubin, and Doyle. *Will Consumers Accept Irradiated Foods*, Journal of Food Safety, 5, 219-228 (1983)); See also Bruhn, Schultz, and Sommer, *Attitude Change Toward Food Irradiation Among Conventional and Alternative Consumers*, Vol. 40, Food Technology 86 (Jan 1986); Survey conducted by UK Consumers’ Association, London (Nov. 1986).

158 *Food Irradiation*, Omnibus Research by Marplan Ltd. Conducted for the London Food Commission, London (January 1987).

159 Bruskin/Goldring Research, (Irradiation Telephone Survey for the Center for Science in the Public Interest) (June 1996) (on file with author).

160 Under U.S. law, irradiation is considered to be a food additive and, as such, must be approved by the FDA. For both meat and poultry irradiation, the FDA approves its use at set levels, while USDA is responsible for labeling requirements and other implementation issues.

161 Rosanna Mentzer Morrison, *Food Irradiation Still Faces Hurdles*, Food Review (Oct.- Dec. 1992) at 13.

162 62 Fed. Reg. 64,107 (1997).

163 21 C.F.R. § 179.26(c) (1997). The USDA has similar labeling requirements for poultry products (9 C.F.R. § 381.135) and is currently preparing a proposed labeling regulation for meat products.

164 Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 306 (1997).

165 FDR at Sec. B.26.003.

166 *Id.* at Sec. B.01.035.

167 European Commission, Official Journal of the European Communities, C389/36, 41, Common Position (EC) No. 46/97, Foods and Food Ingredients Treated with Ionizing Radiation, Directive 97/C 389/02, December 22, 1997, Annex I.

- 168 *Id.* at Article 6.
- 169 CODEX ALIMENTARIUS COMMISSION, Codex Alimentarius Vol. 1, Section 5.2.
- 170 Consumers International Briefing Paper; American Dietetic Association Statement (citing M.H. Stevenson, *Identification of Irradiated Foods*, Food Technology, 1994 48(5) 141- 144.)
- 171 Julie A. Nordlee *et al.*, *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 New Eng. J. Med. 688-92 (1996).
- 172 JOINT FAO/WHO CONSULTATION, BIOTECHNOLOGY AND FOOD SAFETY, FAO FOOD AND NUTRITION PAPER No. 61 14-15 (1997).
- 173 *See, e.g.*, Marion Nestle, *Food Biotechnology: Labeling Will Benefit Industry As Well As Consumers*, NUTRITION TODAY, Jan./Feb. 1998, at 10; Tassos Haniotis, First Secretary (Agriculture) European Commission Delegation to the U.S., speech presented at The Integrated Crop Management Conference, *The Economics of Agricultural Biotechnology: Differences and Similarities in the US and EU*, (Ames, Iowa) (Nov. 17-18, 1997, <<http://www.eurunion.org/news/speeches>>.
- 174 U.K. Department of Health, (visited Apr. 6, 1998) <<http://www.coi.gov.uk/coi/depts/GDH/GDH.html>> (monthly Creutzfeldt-Jakob Disease Figures).
- 175 Nestle, *supra* note 173 at 6, 8.
- 176 *Id.* at 8-9.
- 177 *See* Nestle, *supra* note 173, at 10.
- 178 *See* Letter from Margaret Mellon, Director of Agriculture and Biotechnology, Union of Concerned Scientists, to the Editor of N.Y. Times (June 4, 1997) (on file with author).
- 179 Vegans and vegetarians have similar concerns about consuming any plant products that contain genetic material from animals.
- 180 Brian Williams, *Firm's Stance on Labeling Genetically Engineered Food Continues to Spark Debate*, THE COLUMBUS DISPATCH, Feb. 27, 1997, at 2C. Significantly, the survey also showed that 71% feel bioengineered food is very safe and that 73% prefer bioengineering to pesticides as a means of increasing crop production. *Id.* Surveys cited by certain segments of the U.S. food industry tend to show less demand among Americans for labeling of genetically engineered foods. International Food Information Council, U.S. Consumer Attitudes Toward Food Biotechnology, (Survey conducted by Wirthlin Group Quorum) (March 1997). Survey results can be influenced by how the labeling question is posed to respondents.
- 181 Stefan Flothmann, Greenpeace Germany, remarks at the 1998 Ceres Conference on "Politicizing Science: What Price Public Policy?" (Georgetown University Center for Food and Nutrition Policy) (April 4, 1998).
- 182 Williams, *supra* note 180, at 2C.
- 183 *European Stance on Labeling Genetically Modified Crops Prompts Farm Chemicals Association Response*, Food Labeling & Nutrition News, Jul. 17, 1997, at 11.
- 184 57 Fed. Reg. 22,984 (1992).
- 185 *Id.* at 22,987, 22,991.
- 186 FDA, *FDA's Policy for Foods Developed by Biotechnology*, FDA Education/Compliance Program: 1995, <<http://vm.cfsan.fda.gov/~lrd/biome.html>>.
- 187 Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling, *Implications of Biotechnology for Food Labelling, Governments Comments*, Additional Comments from U.S.A. (Ottawa, Canada) (May 14-17, 1996).
- 188 59 Fed. Reg. 6,279, 6,280 (1994).
- 189 Under U.S. law, a food is "misbranded" if its "labeling is false or misleading in any particular." 21 U.S.C. § 403(a) (1997). In determining whether labeling is false or misleading, the FDA must consider representations actually made as well as "the extent to which the labeling or advertising fails to reveal facts material in the light of such representations" 21 U.S.C. § 201(n) (1997). *See* Consumers Union and Mother & Others for a Liveable Planet, comments to the U.S. Delegation to the Codex Committee on Food Labelling (Oct. 9, 1997).
- 190 *Labeling of Biotech Foods Highlighted by FDA's Foreign Visitors*, WORLD FOOD CHEMICAL NEWS, Oct. 15, 1997, at 12.
- 191 *EU Approves Labeling Rules for Genetically Modified Products*, WORLD FOOD CHEMICAL NEWS, June 25, 1997, at 18.
- 192 *Monsanto changes stand on labeling genetically modified food in the EU*, FOOD LABELING AND NUTRITION NEWS, May 13, 1998, at 10.
- 193 European Commission, Memo/97/110, *Labelling of Genetically Modified Organisms*, Dec. 18, 1997, at 4.

- 194 E.g., Gillian Handyside, *EUR: EU Gnawed by Worries Over Genetically Changed Foods*, AAP Newsfeed, Jan. 11, 1998 (available in NEXIS file) (“Faced with criticism from consumers, environmentalists and industry, the European Union is trying to turn its hotch-potch of rules on genetically modified crops and foodstuffs into something resembling a coherent policy.” The Novel Foods Regulation has been characterized as resulting in “a plethora of convoluted regulations, only some of which dovetail, and a great deal of confusion, consumer concern and delays for industry seeking product approval.”).
- 195 European Commission, *Broad Orientation for an Extended Community Labelling System for GMO Products* (July 22, 1997).
- 196 European Commission, *The European Commission Agrees on an Orientation for Labelling of GMO Products*, press release (July 25, 1997).
- 197 Proposal for a Council Recommendation concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.
- 198 *European Parliament Approves Plans for Labeling GM Foods*, FOOD REGULATION WEEKLY, May 18, 1998, at 19.
- 199 BEUC’s comments on the proposed Commission Regulation concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, BEUC/002/98 (Jan. 6, 1998).
- 200 ANZFA, Statement of Reasons, Proposal P97, For Recommending, Standard A18, Food Produced Using Gene Technology (Feb. 25, 1998).
- 201 ANZFA, *Australia New Zealand Food Authority Makes Recommendation to Health Ministers on Regulation of Foods Produced Using Gene Technology*, press release and information sheet (Feb. 24, 1998). The proposal rejected mandatory labeling for food that was “substantially equivalent” to traditional food because it could not be justified on the basis of sound scientific principles; it is not necessary to protect public health and safety; it is more restrictive than necessary; it is not practicable; and it is too difficult to enforce. Proposed Standard A18, Draft Variation to the Food Standards Code (Australia, New Zealand). See ANZFA Statement of Reasons, *supra* note 200.
- 202 ANZFA Press Release and Information Sheet, *supra* note 201.
- 203 Australian Consumers Association, *Consumers Betrayed by Ruling on Gene Foods*, press release (Feb. 25, 1998).
- 204 Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labeling, *Proposed Draft Recommendations for the Labelling of Foods Obtained Through Biotechnology*, CX/FL 98/8 (Government Comments of Japan).
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- 206 Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling, 26th Session (May 26-29, 1998) (Ottawa, Canada), *Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology*, CX/FL 98/8, at Part B (2).
- 207 *Id.*
- 208 *Id.* at B(1).
- 209 Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Report of the 43rd Session of the Executive Committee (June 4-7, 1996) Alinorm 97/3, paragraph 29.
- 210 United Nations, Guidelines for Consumer Protection, Article 3© (United Nations Publications, New York) (1986).
- 211 See Alinorm 97/3, *supra* note 209.
- 212 62 Fed. Reg. 65,850, 65,856 (1997).
- 213 *Id.* at 65,959 (citing William Tate, *Organic Produce in Europe*, The Economist Intelligence Unit Special Report No. 2128. London: Business International Limited (1991)).
- 214 *Id.* at 65,856.
- 215 Anna Kohn, *Natural Growth: Organic Produce is Becoming Part of the Mainstream Food Chain as Consumers Question Whether ‘Safe’ Levels of Pesticides are Really as Safe as We Think*, THE FINANCIAL POST LTD., Mar. 1, 1998, at 38.
- 216 Cathy Hainer, *Organics cropping up everywhere. Natural superstores cater to families hungry for chemical-free food*, USA TODAY, Oct. 7, 1997, at 8D.
- 217 Sei Sasaki, *Organic foods starting to outgrow niche as more consumers look for such products, more companies see them as business opportunity*, THE NIKKEI WEEKLY, Nov. 10, 1997 (available in NEXIS Library,

News, Non-U.S. file).

218 See Hainer, *supra* note 216.

219 See Sasaki, *supra* note 217.

220 62 Fed. Reg. 65,850, 65,963 (1997).

221 Asahi Shimbun, *Japan Needs System to Certify Organic Products*, ASAHI NEWS SERVICE, Jun. 2, 1997.

222 National Organics Standards Board, Definition of Organic (Apr. 1995) *reprinted in*, Rural Advancement Foundation International-USA, *Toward Organic Integrity: A Guide to the Development of US Organic Standards*, July 1997, at 199.

223 Fresh Fields Whole Foods Market, *Fresh Fields Primer; Organic Food An Introduction to Sustainable Agriculture* (1996); Margaret Wittenberg, Fresh Fields Whole Foods Market, *Everything You Need to Know About Organic* (visited Jan. 30, 1998)

<<http://www.wholefoods.com/wfm/whatsnew/organicquestions.html>>.

224 *Id.* at 2.

225 Council Regulation (EEC) No. 2092/91 (update July 1995).

226 *Id.* at Article 6, Annex I, Annex II.

227 *Id.* at Art. 5.3(a).

228 *Id.* at Art. 5.3(e), Art. 5.5a(f).

229 *Id.* at Annex VI, Sec. A.4.

230 62 Fed. Reg. 65,850, 65,855 (1997).

231 *Id.* at 65,963.

232 *Id.* at 65,856.

233 62 Fed. Reg. 65,850 (1997).

234 See Subsec. 5(1) of the *Food and Drugs Act*, R.S.C. 1985, C.F-27; Sec. 7 of the *Consumer Packaging and Labelling Act*, R.S.C. 1985, c.C-38; *Canada Guide*, *supra* note 41, at Sec. 4.2.9.

235 Although synthetic pest control products are not used in organic agriculture, there may be a carry-over of pesticides from applications prior to the certification period, or spray drift from neighboring fields. In addition, a limited number of pesticides are approved for use in organic production.

236 Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labeling, and Marketing of Organically Produced Foods, *Draft Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods*, Government Comments at Step 6 (France, Japan, Poland, Consumers International) CX/FL 98.4.

237 CODEX ALIMENTARIUS COMMISSION, *Draft Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods*, Alinorm 97/22 A Appendix III at Section 1.5.

238 Some countries, such as the U.S., have made initial determinations not to allow percentage declarations on the principal display panel (PDP) on the grounds that only essential information should be on the PDP.

USDA believes that the percentage of organic ingredients in a product is not essential information.

239 Steve Levin, *New Products Abound at Kosherfest*, PITTSBURGH POST-GAZETTE, Dec. 11, 1997, at G5.

240 *Id.*

241 Mike Dunne, *What the 'Halal' Means: Meat's Guaranteed to meet Muslim Dietary Laws*, SACRAMENTO BEE, Jan. 28, 1998 (available in NEXIS Library, News File).

242 61 Fed. Reg. 29,701, 29,710 (1996), 62 Fed. Reg. 43,071-73 (1997).

243 *Id.*

244 21 C.F.R. § 101.29 (1997) (revoked).

245 Food and Agriculture Organization of the United Nations, *Codex Commission makes major decisions on food claims, hygiene, labelling at Geneva meeting* (July 17, 1997) <<http://www.fao.org/waicent/faoinfo/economic/esn/codex/cacnote.htm>>.

246 *Guidelines for 'halal' term should be developed by religious authorities, not Codex*: Ziller, FOOD LABELING & NUTRITION NEWS, June 6, 1996, at 5.

247 FAO, *supra* note 245.

248 CODEX ALIMENTARIUS COMMISSION, Draft General Guidelines for Use of the Term 'Halal,' ALINORM 97/22 (version submitted by Codex Committee on Food Labelling was adopted without revision).

249 *Barghout v. Bureau of Kosher Meat and Food Control*, 66 F.3d 1337, 1346, n.15 (4th

Cir. 1995).

250 Caswell, *supra* note 1.

251 Echols, *supra* note 64.