

8-1-1990

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Recommended Citation

Rosemary E. Mullaly, *Food Labeling Regulations for Nutrition and Irradiation in the EEC*, 13 B.C. Int'l & Comp. L. Rev. 429 (1990), <http://lawdigitalcommons.bc.edu/iclr/vol13/iss2/7>

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Food Labeling Regulations for Nutrition and Irradiation in the European Economic Community

I. INTRODUCTION

Until recently, each nation in the European Economic Community (EEC or Community) had separate laws and standards for food labeling.¹ Lack of uniformity in labeling laws prevents the free flow of food throughout the Community.² The free movement of goods requires uniform food standards for the whole internal market.³ The Commission of the European Communities (Commission) proposed directives addressing the labeling of food for nutrition⁴ and the use of irradiation treatment.⁵ The Single European Act (SEA), amending the Treaty of Rome's

¹ The first major Community legislation on the food labeling was Directive 79/112. Directive 79/112, Council Directive of 18 December 1978 on the Approximation of Laws of the Member States relating to the Labelling, Presentation, and Advertising of Foodstuffs for Sale to the Ultimate Consumer, 22 O.J. EUR. COMM. (No. L 33) 1 (1979), 2 Common Mkt. Rep. (CCH) ¶ 3,353 (1984) [hereinafter Directive 79/112].

² See, e.g., Directive 79/112, *supra* note 1, at 1. Directive 79/112 indicates that the purpose of the legislation is to eliminate "differences which exist at present between the laws, regulations, and administration provisions of Member States on the labelling of foodstuffs imped[ing] the free circulation of these products and can lead to unequal conditions of competition." *Id.*

³ Single European Act, Feb. 17, 1986, 29 O.J. EUR. COMM. (No. L 169) 1, 3 Common Mkt. Rep. (CCH) ¶ 20,045 (1987) [hereinafter SEA], *amending* Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11, art. 100A [hereinafter EEC Treaty]. "The Council shall, acting by qualified majority on a proposal from the Commission in co-operation with the European Parliament and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provision laid down by law, regulation, or administrative action in Member States which have as their object the establishment or functioning of the internal market." *Id.*

⁴ Proposal for a Council Directive (EEC) of 7 October 1988 on the Introduction of Compulsory Nutrition Labelling of Foodstuffs Intended for Sale to the Ultimate Consumer, COM(88) 489 final, 30 O.J. EUR. COMM. (No. C 282) 8 (1988) [hereinafter Proposed Directive on Compulsory Nutrition Labeling of Food]; Proposal for a Council Directive (EEC) of 7 October 1988 on Nutrition Labelling Rules for Foodstuffs Intended for Sale to the Ultimate Consumer, COM(88) 489 final, 30 O.J. EUR. COMM. (No. C 282) 10 (1988) [hereinafter Proposed Directive on Labeling Format].

⁵ Proposal for a Council Directive of 9 December 1988 on the Approximation of the Laws of the Member States Concerning Foods and Food Ingredients Treated with Ionizing Radiation, COM(88) 654 final, 30 O.J. EUR. COMM. (No. C 336) 7 (1988) [hereinafter Proposed Directive on Radiation Treatment].

(EEC Treaty) article 100A,⁶ and the 1985 White Paper⁷ guided EEC harmonization of the member states' food labeling laws.

The proposed directives on nutritional labeling and use of irradiation treatment will have a significant impact on exporters and importers of food in the Community if approved by the Council of the European Communities (Council). Part two of this Comment discusses the treaty sources for harmonization of food laws and their importance for the completion of the internal market. In addition, it describes how the United States, faced with a similar situation, met its need for uniform food laws. Part three outlines uniform standards for labeling for nutrition and labeling for use of irradiation in the Community. Part four assesses the impact these proposed directives will have on the Community and on nonmember states. The Comment concludes that the proposed directives will require that manufacturers provide consumers not only with wholesome food but also with much needed information about that food. These requirements strike a delicate balance between the desire for consumer safety and the interests of the food production industry.

The proposed directives may require nonmember states, like the United States, to use new labeling procedures. Nutritional labeling for exported food most likely will not cause difficulty for U.S. exporters since U.S. nutritional labeling regulations are substantially similar to the proposed EEC requirements.

U.S. exporters of irradiated food will probably have difficulty gaining access to member state markets which prohibit irradiation treatment if the Community does not adopt the proposed directive on irradiation treatment. Even if the Community does adopt the proposed directive on irradiation treatment, U.S. exporters, relying on differing U.S. regulations, may have difficulty complying with proposed irradiation use and labeling requirements.

II. FREE MOVEMENT OF EEC AND U.S. GOODS

A. *Need for Community Action*

Scientific development coupled with a heightened awareness of the need for fitness generated a consumer interest in nutrition.⁸

⁶ SEA, *supra* note 2, at 8, art. 18.

⁷ Completing the Internal Market, White Paper from the Commission to the European Council, COM(85) 310 final, at paras. 1, 65; Annex at 1, 17 [hereinafter White Paper].

⁸ *Commission Report on Proposed Directive on the Introduction of Compulsory Nutrition Labelling*

Manufacturers capitalize on this consumer interest by labeling a product with nutritional information.⁹ Since economic incentives exist to provide information, national governments regulate industries to assure that wholesome food and understandable, accurate information reaches consumers.¹⁰

Prior to EEC legislation on food labeling, products that were manufactured for export had to meet both the standards established by national law and also the laws of the importing country enforced at the border.¹¹ Individual member state standards varied considerably and dual compliance produced increased manufacturing costs. In addition, some member states created excessive restrictions which increased the cost of goods thereby frustrating the creation of a common market for products. The existence of these barriers forced manufacturers to focus on national rather than Community markets. These regulations hindered the international competitiveness of the EEC food industry.¹²

The EEC Treaty prohibits national measures which excessively and unjustifiably restrict the free movement of goods.¹³ The 1985 White Paper calls for the elimination of barriers created by national product regulations and standards.¹⁴ In accordance with EEC Treaty and White Paper measures, the Commission proposed standards for food labeling regarding nutrition¹⁵ and the use of irradiation treatment.¹⁶ In order to arrive at a standard for nutrition and irradiation treatment labeling, the Commission

of Foodstuffs Intended for Sale to the Ultimate Consumer and Proposed Directive on Nutrition Labelling Rules for Foodstuffs Intended for Sale to the Ultimate Consumer, COM(88) 489 final, at 2-3 [hereinafter *Commission Report on Nutrition Labeling*]. For the WHO/FAO Codex Alimentarius study on nutrition adopted by the Codex Commission which includes all member states, see Draft Standard For Labelling of Prepackaged Foods, ALINORM 85/22, App. III; Draft Guidelines for Nutrition Labelling, ALINORM 85/22, App. II; see also Council Resolution of 7 July 1986 on a Programme of Action of the European Communities Against Cancer, 29 O.J. EUR. COMM. (No. C 184) 19 (1986).

⁹ *Commission Report on Nutrition Labeling*, *supra* note 8, at 3.

¹⁰ *Id.* at 3-4. The following member states have labeling legislation: the United Kingdom, Denmark, Germany, and the Netherlands. *Id.*

¹¹ *Processed Food Products*, 2 Common Mkt. Rep. (CCH) ¶ 3,341.01 (1979).

¹² White Paper, *supra* note 7, at para. 60.

¹³ EEC Treaty, *supra* note 3, at art. 32. "In their trade with one another Member States shall refrain from making more restrictive quotas and measures having equivalent effect existing at the date of the entry into force of this Treaty." *Id.*

¹⁴ See *id.* at para. 65.

¹⁵ Proposed Directive on Compulsory Nutrition Labeling of Food, *supra* note 4; Proposed Directive on Labeling Format, *supra* note 4.

¹⁶ Proposed Directive on Radiation Treatment, *supra* note 5.

considered the burden placed on manufacturers,¹⁷ the benefits consumers gain from receiving wholesome food as well as accurate information about that food, and the need for uniform regulation among the member states.

B. *U.S. Uniform Food Laws*

Federal legislation in the United States which requires uniform food laws among states exemplifies the present situation in the EEC. Prior to any substantive federal regulation of the food industry in the United States, individual states enacted food laws to protect their citizens from adulterated food and fraudulent nutritional labeling claims.¹⁸ As with individual member state legislation in the Community, the laws passed by the U.S. states lacked uniformity.¹⁹ Each U.S. state passed laws dictated by the capabilities of its food industry and the needs of its citizens. As a result, some states had neither laws nor law enforcement. Other states had strong laws and rigorously enforced those laws.²⁰ Thus, some food would meet the standards of one state and not meet another state's standards. Lack of uniformity between food laws created burdens on interstate commerce.²¹ As a result of these economic burdens, Congress developed a federal regulatory scheme to govern the labeling of food products.²²

1. U.S. Nutritional Labeling

The Federal Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are responsible for regulating nutritional

¹⁷ For example, the Commission considered the ability of the small manufacturer to comply with the nutrition labeling directive. Instead of requiring the manufacturer to actually test the product sold, it could use data compiled on the ingredients. Proposed Directive on Labeling Format, *supra* note 4, at art. 5(7).

¹⁸ Nyberg, *The Need for Uniformity in Food Labeling*, 40 FOOD DRUG COSM. L.J. 229, 233 (1985).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.* at 229-30.

²² Congress gave the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) primary statutory authority to regulate the labeling of food sold in interstate commerce. *Id.* at 230. For the proposition that federal labeling requirements preempt state requirements, see *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977). Permitting the state requirements to take precedence would defeat Congress' intent to promote interstate commerce by food labeling uniformity.

labeling of food in the United States.²³ Congress enacted statutes and regulations to guide the FDA and the USDA in this regulatory function.²⁴ According to U.S. regulations, nutritional labeling is voluntary except where manufacturers advertise, make nutritional claims,²⁵ or add nutrients to the food.²⁶ When manufacturers add nutrients, make claims on the label, or advertise food, this subjects the label to nutritional labeling regulations.²⁷

In situations which give rise to regulation, the United States requires manufacturers to provide consumers with a profile of the nutrients contained in food and the nutritional importance of these ingredients.²⁸ In addition, this regulation states that products are mislabeled not only when there are advertising or labeling mistakes but also when the label or advertisement contains omissions regarding information material to the food.²⁹ The United States also requires data to support label declarations. Every label must be submitted for approval with evidence that the manufacturer derived the information from sound data bases.³⁰ The label must be accurate and periodically verified to insure accuracy.³¹

²³ The FDA has jurisdiction over food labeling under the Food, Drug, and Cosmetic (FD&C) Act of 1938, 21 U.S.C. §§ 301-92 (1982) and the Fair Labeling and Packaging Act of 1966, 15 U.S.C. §§ 1451-61 (1982). The USDA exercises jurisdiction over food labeling under the Meat Inspection Act, 21 U.S.C. § 678 (1982); the Poultry Inspection Act, 21 U.S.C. §§ 301-92 (1982); and the Egg Products Inspection Act, 21 U.S.C. § 1052 (1982). Nyberg, *supra* note 18, at 230.

²⁴ The USDA has not formally set nutrition labeling regulations to guide its supervision of meat and poultry. Houston, *USDA's Regulation of Food Claims*, 40 FOOD DRUG COSM. L.J. 238, 239 (1985). The USDA follows the format provided by FDA regulations. *Id.* The FDA based these regulations on section 201(n) of the FD&C Act. FD&C Act, *supra* note 23, at § 321; see Lister, *Comparison of the U.S. Laws and Regulations Concerning Labeling of Prepackaged Foods Within the Codex Alimentarius Draft General Standards for Labeling of Prepackaged Foods*, 42 FOOD DRUG COSM. L.J. 174, 180 (1987).

The USDA did publish a proposal for nutrition labeling in the *Federal Register* which was never adopted. 39 Fed. Reg. 1606-14 (1974) (proposed Jan. 11, 1974); see Houston, *supra* at 239. In 1980, the USDA began to publish the labeling review experts' responses to questions submitted to the USDA by food manufacturers. These policy memoranda resolve certain complex issues not addressed by regulation or policy. *Id.* at 239.

²⁵ Nutrition Labeling of Food, 21 C.F.R. §§ 101.9(h)(9) (1988) [hereinafter Nutrition Labeling].

²⁶ *Id.* at § 101.9(a)(2).

²⁷ *Id.* at § 101.9(a).

²⁸ When a manufacturer submits a label to the USDA for approval, supporting information from sound data bases must accompany it. Houston, *supra* note 24, at 240.

²⁹ Lister, *supra* note 24, at 180.

³⁰ Houston, *supra* note 24, at 240.

³¹ *Id.* at 243.

The FDA developed the specific format for nutritional labeling.³² Nutritional information proved a valuable tool for marketing food in the United States because of increased understanding by the scientific community and consumers of the relationship between nutrition and health. In order to make sure manufacturers were not using this tool to mislead consumers, the FDA format requires clear statements of nutritional value to alleviate difficulty in identifying the nutritional qualities of food purchased.³³

Once manufacturers make nutritional claims, the U.S. standard requires the listing of every nutrient making up 2 percent of the U.S. recommended daily allowance (USRDA) for that product.³⁴ The standard also requires labeling of food characteristics in the following order: average serving size; serving per container;³⁵ information about an average serving for caloric content, protein content, carbohydrate content, fat content, amount of protein, vitamins, and minerals described in USRDA percentages; and sodium content.³⁶

The United States addresses the needs of manufacturers that may not have the resources or the desire to make extensive labeling claims by providing an abbreviated label form.³⁷ The United States allows use of the short form when it determines that the labeling does not compromise the consumer interest in accurate and clear information. The short form requires only information on calories, protein, carbohydrates, and fat per average serving.³⁸ Thus, the U.S. scheme strikes a balance between consumer safety and the limitations of the food industry.

2. U.S. Irradiation Labeling

The FDA publishes regulations dealing with the production, processing, and handling of irradiated food.³⁹ Food irradiation

³² Nutrition Labeling, *supra* note 26, at § 101.9(a)–(h).

³³ *Id.* at § 109.9(c).

³⁴ *Id.* at § 101.9(c)(7)(i); *see also* Lister, *supra* note 24, at 182.

³⁵ Nutrition Labeling, *supra* note 26, at § 101.9(b).

³⁶ *Id.* at § 101.9(c)(3)–(8).

³⁷ Houston, *supra* note 24, at 239.

³⁸ *Id.*

³⁹ Sources of Radiation Used for Inspection of Food, for Inspection of Packaged Food, and for Controlling Food Processing, 21 C.F.R. § 179.21 [hereinafter Sources of Radiation].

is a physical method to process and preserve food comparable to heat treatment or freezing. The food producer exposes food to X-radiation or electron beams emitted from various sources in specialized facilities. If manufacturers practice food irradiation under proper conditions, evidence shows that it presents no known danger to consumers.⁴⁰

The FDA created strict standards for the use of irradiation treatment. The regulations imposed by the FDA indicate permissible types of radiation.⁴¹ In addition, the regulations limit the allowed radiation dosage⁴² and limit use of irradiation only to control certain food impurities.⁴³ The FDA requires notice of the irradiation treatment to consumers. Regulations require that retail packages of irradiated food have a logo printed on the label along with the statement "treated with radiation" or "treated by irradiation."⁴⁴ Food containing a single irradiated ingredient does not need to meet these labeling requirements.⁴⁵

In order to supervise this type of food treatment, the FDA requires irradiation of food to conform to a scheduled process as indicated by the FDA.⁴⁶ This scheduled process for food irradiation is a written procedure that ensures that the irradiation is adequate to achieve its intended effect on a product. A qualified person having expert knowledge in irradiation processing for that specific food and for that specific treatment must verify the scheduled process and submit it for agency approval.⁴⁷

⁴⁰ New Developments, *Controls on Irradiation of Foodstuffs Will Protect and Inform Consumers*, [1985-1988 Transfer Binder] Common Mkt. Rep. (CCH) ¶ 95,020 (1988) [hereinafter *Controls on Irradiation*].

⁴¹ The following are examples of these source limits: sealed tubes producing X-radiation at levels of 300 kilovolts peak or lower; sealed units producing radiation at energy levels of not more than 2.2 million electron volts from isotope Americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, or strontium-90; or sealed units producing neutron radiation from isotope Californium. Sources of Radiation, *supra* note 39, at § 179.21(a)(1)-(3).

⁴² *Id.*

⁴³ The regulations permit use of irradiation treatment for control of *Trichinella spiralis* in pork; growth and maturation inhibition of fresh foods; disinfestation of arthropod pests in food; microbial disinfection of dry or dehydrated enzyme preparations; and microbial disinfection of dry or dehydrated aromatic vegetable substances, culinary herbs, seeds, spices, teas, and vegetable seasonings. Ionizing Radiation for the Treatment of Food, 21 C.F.R. § 179.26(b) (1988) [hereinafter *Ionizing Radiation*].

⁴⁴ *Id.* at § 179.26(c)(1).

⁴⁵ *Id.* at § 179.26(c)(2).

⁴⁶ General Provisions for Food Irradiation, 21 C.F.R. § 179.25(d).

⁴⁷ *Id.*

III. PROPOSED DIRECTIVES

In the EEC, as in the United States, each member state has an interest in protecting its citizens and industries by regulating food production.⁴⁸ Like the United States, the EEC has an overriding interest in the free movement of food products to invigorate the internal market. The need for uniform legislation arises from the Community's commitment to increased economic competitiveness. Diverse food labeling requirements defeat increased economic competitiveness when one member state's law prohibits the sale of another's food.⁴⁹

A. *Nutritional Labeling of Food*

The growing body of scientific knowledge linking diet with health has heightened the European consumer interest in nutritional labeling.⁵⁰ Nutritional labeling is becoming an important marketing tool.⁵¹ European consumers are interested in improving their diets; and therefore, they seek information about the food they eat.

A uniform, accurate, and simple presentation of information serves consumer interests and avoids technical barriers to trade.⁵² The presence of clear information about a product allows consumers to make informed choices—a practice which gives European manufacturers that provide this information a competitive advantage.

The need for uniform nutritional labeling was so crucial to achieve 1992 objectives that the White Paper proposed what has become the Commission's two proposed directives on nutritional labeling of food.⁵³ One proposed directive involves the introduction of compulsory nutritional labeling on certain food intended

⁴⁸ See *supra* notes 2-7, 18-20, and accompanying text.

⁴⁹ See *supra* note 11 and accompanying text.

⁵⁰ *Commission Report on Nutrition Labeling*, *supra* note 8, at 2. "Advances in the field of nutrition science have led to the identification of an increasing number of links between nutrition and health." *Id.*

⁵¹ Proposed Directive on Labeling Format, *supra* note 4, at 10. "[T]he knowledge of basic principles of nutrition and appropriate nutrition labelling of foodstuffs would go a long way in enabling the consumer to make this choice" of one product over another. *Id.*

⁵² *Id.* at 10. "[F]or the benefit of the consumer on the one hand, and to avoid any possible technical barriers to trade on the other, nutrition labelling should be presented in a standardized format applying Community wide." *Id.*

⁵³ White Paper, *supra* note 7, Annex at 17.

for sale to retail consumers.⁵⁴ The other proposed directive deals with the specific labeling format for both compulsory and optional nutritional labeling.⁵⁵

The first proposed directive provides a mechanism for the Commission to require nutritional labeling if it determines that such labeling is imperative.⁵⁶ In order to determine if labeling is imperative for a certain product, food must meet certain criteria. Article 1 of the proposed directive considers "the existence of epidemiological⁵⁷ evidence linking the intake of certain foods or nutrients by the population or by substantial groups thereof to specific diseases . . . [and] the need to improve the nutrition status of the population or substantial groups thereof."⁵⁸ Once the Commission determines a product warrants labeling under these considerations, labeling must conform to the standard format enumerated in the second proposed directive on nutritional labeling.

The second proposed directive requires that the information on a nutritional label follow a standard format.⁵⁹ While Directive 79/112 (the major Community legislation on labeling, presentation, and advertising of food) already prohibits misleading labeling in the Community, this directive does not provide a standard format for nutritional labeling.⁶⁰ Without a clear standard for nutritional labeling, information on labels is often misleading. The second directive's goal is to rectify this situation.

The second proposed directive, however, does not require any nutritional labeling.⁶¹ If manufacturers do not opt to label for nutrition, they are not subject to the proposed requirements. The proposed directive provides for labeling if the first directive makes labeling mandatory for that type of food. In addition, if manufacturers do opt to make a nutritional claim to cater to

⁵⁴ Proposed Directive on Compulsory Nutrition Labeling of Food, *supra* note 4.

⁵⁵ Proposed Directive on Labeling Format, *supra* note 4.

⁵⁶ Proposed Directive on Compulsory Nutrition Labeling of Food, *supra* note 4, at art. 1(2)(a)-(b).

⁵⁷ Epidemiology is defined as "[t]he branch of medicine which investigates the courses and control of epidemics; all the elements contributing to occurrence or nonoccurrence of a disease in a population." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 762 (3d ed. 1976).

⁵⁸ Proposed Directive on Compulsory Nutrition Labeling of Food, *supra* note 4, at art. 1(2)(a)-(b).

⁵⁹ Proposed Directive on Labeling Format, *supra* note 4, at art. 3(1)-(3).

⁶⁰ Directive 79/112, *supra* note 1, at art. 2.

⁶¹ Proposed Directive on Labeling Format, *supra* note 4, at art. 2(1)-(2).

consumer wishes, they must also follow the standard format found in this proposed directive.⁶²

The second proposed directive also requires certain labeling information⁶³ to be in a particular order and in a tabular form.⁶⁴ Nutritional labeling must include information categorized in the following order and relating to energy, protein, carbohydrates, fat, dietary fiber, sugars, and sodium content of a product⁶⁵ per one hundred grams or per one hundred milliliters.⁶⁶ *All* of this nutritional information is compulsory when *any* nutritional claim appears on the label.⁶⁷

Manufacturers may include other information on the label.⁶⁸ Manufacturers may declare vitamins and minerals making up 5 percent of the recommended daily allowances for that item.⁶⁹ In most cases, the second proposed directive does not require additional information. Yet, the directive will require more information, for example, when a manufacturer makes a nutritional claim that a product is high in vitamin C. In this example, declaration of the nutrient would be compulsory.⁷⁰

B. *Use and Labeling of Irradiated Food*

In order to guarantee a high level of protection to consumers and ensure the free trade of irradiated food, the Commission presented a proposed directive on control of irradiation.⁷¹ In order to justify use of food irradiation, manufacturers must show this treatment reduces the incidence of food borne disease, reduces the spoilage of food by arresting decay and killing spoilage organisms, reduces the premature ripening of food, or disinfects food of harmful organisms.⁷² The White Paper envisioned this proposal⁷³ because evidence existed to show that food irradiation

⁶² *Id.* at art. 2(1).

⁶³ *Id.* at art. 3.

⁶⁴ *Id.* at art. 5(8).

⁶⁵ *Id.* at art. 3(1).

⁶⁶ *Id.* at art. 5(2).

⁶⁷ *Id.* at art. 3(3).

⁶⁸ *Id.* at art. 3(2).

⁶⁹ *Id.* at art. 5(4).

⁷⁰ *Id.* at art. 3(3). "The declaration of a nutrient for which a nutrition claim is made is compulsory." *Id.*

⁷¹ Proposed Directive on Radiation Treatment, *supra* note 7.

⁷² *Id.* at 13.

⁷³ See *Controls on Irradiation*, *supra* note 40, at ¶ 95,020 and accompanying text.

under controlled conditions is wholesome⁷⁴ and already existed in certain member states. The Community felt common rules were necessary for irradiation use and labeling.⁷⁵ If certain member states prohibited irradiation while other member states employed this method of food treatment, excessive restriction would frustrate the creation of the common market in food.

The EEC aims to circumscribe the use of irradiation treatment of food in two ways. First, the proposed directive limits the types of irradiation that manufacturers may use,⁷⁶ the types of food that manufacturers may irradiate,⁷⁷ and the dosage of radiation with which manufacturers may treat the food.⁷⁸ Second, the proposed directive provides a mechanism for the oversight of irradiation treatment. The proposal requires member states to designate a competent authority responsible to oversee irradiation treatment.⁷⁹ The authority must grant prior approval for treatment, grant an official reference number, control and inspect treatment, and withdraw or modify its approval when warranted.⁸⁰ The proposed directive sets out the conditions for approval of irradiation treatment of food.⁸¹ According to the proposed directive, the authority may approve food irradiation only if it is a reasonable technological necessity, it presents no hazard to the health of consumers, it benefits consumers, and it does not substitute for health rules.⁸²

C. *Consideration by the Council's Economic and Social Committee*

The Council has not yet adopted the proposed directives.⁸³ On April 26, 1989, the Council's Economic and Social Committee

⁷⁴ *Id.*

⁷⁵ "[D]ifferences between national laws relating to the treatment of foods and food ingredients . . . by ionizing radiation and its conditions of use hinder the free movement of foodstuffs and may create conditions of unequal competition, thereby directly affecting the establishment or functioning of the common market." Proposed Directive on Radiation Treatment, *supra* note 5, at 7.

⁷⁶ *Id.*, Annex II at 11.

⁷⁷ The European Economic Community (EEC) limits irradiation treatment to strawberries, papayas, mangoes, dried fruits, pulses (legumes), dehydrated vegetables, cereal flakes, bulbs and tubers, aromatic herbs, spices and vegetable seasonings, shrimps and prawns, poultry meats, frogs' legs, and arabic gum. *Id.*, Annex I at 11.

⁷⁸ *Id.* For calculation of wholesome dosages, see also *id.*, Annex IV at 12.

⁷⁹ *Id.* at art. 6(1).

⁸⁰ *Id.* at art. 6(2).

⁸¹ *Id.*, Annex V at 13.

⁸² *Id.*

⁸³ 22 BULL. EC 4-1989, point 2.1.28; 22 BULL. EC 5-1989, point 2.1.28.

(Committee), however, delivered an opinion on both proposed directives.⁸⁴ The Committee opinion encouraged discussion among all parties concerned with establishing harmonization of compulsory labeling. The Committee requested the Commission to report on the role of advertising and the impact of labeling. The Committee further asked the Commission to plan a conference for all interested parties on the topic of nutritional labeling.⁸⁵

On May 3, 1989, the Committee delivered an opinion on the proposed directive concerning irradiation treatment.⁸⁶ The Committee did not adopt the proposed legal framework for food irradiation as proposed by the Commission. At this time, the Committee advises only the adoption of the irradiation treatment proposal limited to spices. Therefore, the Council will await conclusive proof from the Commission of the technological necessity and harmlessness of irradiation treatment for food preservation before making a final determination.⁸⁷

The Council has formally adopted Directive 89/395 which amends⁸⁸ major portions of Community legislation on labeling, presentation, and advertising of food.⁸⁹ Unlike the proposed directive on irradiation, Directive 89/395 does not address the legalization of irradiation treatment. This directive merely requires that manufacturers of irradiated food must label it according to one of the specific indications for the treatment listed in the directive.⁹⁰ This amendment extends the labeling requirements to food intended for supply to restaurants, hospitals, and other types of mass caterers.⁹¹ Yet, the amendment postpones a decision on labeling for a single irradiated ingredient until the Community adopts provisions governing irradiation treatment.⁹²

⁸⁴ 22 BULL. EC 4-1989, point 2.1.28.

⁸⁵ *Id.*

⁸⁶ 22 BULL. EC 5-1989, point 2.1.28.

⁸⁷ *Id.*

⁸⁸ 22 BULL. EC 6-1989, point 2.1.20(iii); Directive 89/395, Council Directive of 14 June 1989 Amending Directive 79/112/EEC on the Approximation of the Laws of the Member States Relating to Labelling, Presentation and Advertising of Foodstuffs for Sale to the Ultimate Consumer, 31 O.J. EUR. COMM. (No. L 186) 17 (1989) [hereinafter Directive 89/395].

⁸⁹ Directive 79/112, *supra* note 1.

⁹⁰ Directive 89/395, *supra* note 88, at art. 1(8).

⁹¹ *Id.* at art. 1(2).

⁹² *Id.* at art. 1(11).

IV. POSSIBILITY OF SUCCESSFUL UNIFORMITY

A. *Harmonization of Laws in the Community*

In order to gain acceptance by the member states, the proposed directives must address the reality of the food production industry, assure wholesome food, and protect consumer interest through clear, accurate information. The proposed directives sought compromise in order to assure harmonization. The Commission considered the economic and technical needs of food manufacturers and their ability to comply with labeling requirements.⁹³ Although the directives essentially aim to inform and protect consumers, the Commission provided for the varying capabilities of large and small EEC food manufacturers. Like their larger counterparts, smaller manufacturers wished to reap the benefits derived from nutritional labeling. Requiring detailed nutritional information on a product, however, would prejudice small manufacturers. Many could not afford to do intensive research on the nutritional character of the food they manufacture. The proposed directives permit manufacturers to derive the nutritional values of their product based on calculations of average values of the ingredients from generally accepted data.⁹⁴ To small manufacturers, this means no expensive analysis but merely a calculation derived from acceptable data for the ingredients used in manufacturing the food.

The standard format is limited, and compliance is easy. The Commission only requires listing of the most basic characteristics: energy, protein, carbohydrate, fat, sugar, sodium, and dietary fiber.⁹⁵ The proposed format of the tabular listing creates a clear, uniform presentation of the nutritional information to aid consumers.⁹⁶ If space on the label does not allow for tabular form, the proposed directive permits linear form.⁹⁷ The limited, unified format keeps manufacturers' costs down in compliance with the proposal.

⁹³ Proposed Directive on Radiation Treatment, *supra* note 5, at 7. "[R]ules relating to the use of ionizing radiation for the treatment of foodstuff should take account primarily of human health requirements but also, within the limit required for the protection of health, of economic and technical needs." *Id.*

⁹⁴ Proposed Directive on Labeling Format, *supra* note 4, at art. 5(7).

⁹⁵ See *supra* note 65 and accompanying text.

⁹⁶ See *supra* note 64 and accompanying text.

⁹⁷ Proposed Directive on Labeling Format, *supra* note 4, at art. 5(8).

The Commission did not expose consumers to unhealthful conditions in its efforts to comply with the needs of the food manufacturing industry. The Commission allowed itself the option of mandating nutritional labeling for potentially harmful food even against manufacturers' desires.⁹⁸ Although the format is not detailed, the requirements force manufacturers making nutritional claims to inform consumers that a product is very high in fat or sodium. Hence, manufacturers may not accidentally leave this information off the label while boasting of the product's high protein character.

In the proposed directive for irradiation treatment, the Commission seemed more concerned for consumer safety than the needs of the food production industry. The irradiation labeling requirements set out detailed steps for food treatment.⁹⁹ Since the use of irradiation could become harmful if not closely monitored, the supervisory component of this directive dominates. In order to protect consumers, the proposed directive limits the use of this treatment by requiring limited dosages of radiation, limited sources of radiation, and limited products subject to irradiation.¹⁰⁰ In addition to limiting irradiation use, the proposed directive requires approval of the facility treating and labeling the food for irradiation treatment.¹⁰¹

The requirements established by the proposed directive on irradiation treatment of food reflect less compromise.¹⁰² The lack of concern over the increased cost of compliance to food manufacturers shows that there is a clearly accepted standard beyond which irradiation treatment becomes unwholesome. In addition, other options for food treatment exist. Since not all member states permit use of irradiation treatment, the Commission is trying to establish the highest level of consumer safety standards to assure compliance by those member states that oppose irradiation treatment.¹⁰³

Member state acceptance and compliance with these uniform standards is necessary to reach the overarching goal of an internal market. The Commission required high standards in each of the

⁹⁸ See *supra* notes 56–58 and accompanying text.

⁹⁹ See *supra* notes 76–82 and accompanying text.

¹⁰⁰ See *supra* notes 76–78 and accompanying text.

¹⁰¹ See *supra* notes 79–82 and accompanying text.

¹⁰² See *supra* note 93 and accompanying text.

¹⁰³ See *supra* notes 76–82 and accompanying text; see also SEA, *supra* note 3, at art. 18(2).

proposed directives to assure the health and welfare of consumers in each member state. Adoption of the proposed directives would initially change some member state laws on labeling and treatment of food and, thus, increase compliance costs of manufacturers. The directives' adoption may result in a short-term decrease of production, but it will eventually promote the international competitiveness of the food production industry in the EEC.

B. *U.S. Compliance with EEC Proposed Directives*

The proposed directives on nutritional labeling should not present an obstacle to U.S. food exporters to the EEC. U.S. regulations require U.S. manufacturers to include more information than the EEC will require.¹⁰⁴ Compliance should be easy except for the labeling of dietary fiber required by the EEC. As U.S. food exporters are accustomed to U.S. consumer interest in nutritional labeling, compliance with the dietary fiber requirement should not seem excessively burdensome. Likewise, although U.S. regulations do not require listing dietary fiber, U.S. exporters would merely have to add that information in order to comply.

U.S. regulations, however, provide for an abbreviated format which could cause greater difficulty for U.S. exporters. If U.S. food exporters employ the abbreviated food labels, the label would lack listing of dietary fiber, sugar, and sodium content information as the proposed directive requires.¹⁰⁵ Hence, U.S. manufacturers exporting food into the EEC should not use the abbreviated form and should include dietary fiber on their labels to insure compliance with the EEC requirements.

Community law provides no uniform statement permitting the use of irradiation treatment. The Committee supports only the limited use of irradiation treatment on spices.¹⁰⁶ Member states may prohibit or limit import of any type of irradiated food. Furthermore, no legislation exists which prevents extension of these prohibitions to nonmember state exporters of food to the EEC.

¹⁰⁴ See *supra* notes 34–36, 63–67, and accompanying text.

¹⁰⁵ See *supra* notes 37–38 and accompanying text.

¹⁰⁶ See *supra* notes 86–87 and accompanying text.

If the Commission provides evidence of technological necessity and harmlessness of irradiation treatment for the Council's adoption of the proposed directive,¹⁰⁷ U.S. exporters can easily comply with certain requirements. U.S. manufacturers must first gain approval from the EEC before they can export irradiated goods to the Community.¹⁰⁸ Approval does not present a real obstacle to entry since U.S. exporters already have to file a scheduled process under U.S. regulations.¹⁰⁹ Manufacturers can forward this process to the EEC for approval. Second, labeling for irradiation treatment will not be problematic for U.S. exporters. U.S. regulations already require manufacturers to label for use of the irradiation process.¹¹⁰

U.S. exporters of irradiated food may have difficulty complying with other aspects of the Commission's proposed directive on irradiation treatment of food. The proposed directive on irradiated food provides an exclusive list of the *food* which manufacturers may irradiate.¹¹¹ Manufacturers may irradiate the specific food on the list for any impurities they wish. In comparison, U.S. regulations provide an exclusive list of *impurities* which manufacturers may treat by irradiation.¹¹² U.S. manufacturers may irradiate any food for the specific impurities on the list. If a food, not on the EEC list, happens to have impurities which can be irradiated according to U.S. regulations, manufacturers will still not be able to export to the EEC. Therefore, use of methods other than irradiation to treat food would be better for U.S. exporters, unless they are in the business of exporting the limited types of food for which the EEC permits irradiation treatment.

V. CONCLUSION

The proposed directives balance consumer interest in wholesome food and information about food against the needs and limitations of the food production industry, without compromising consumer safety and while furthering the goals of the EEC.

¹⁰⁷ See *supra* note 87 and accompanying text.

¹⁰⁸ Proposed Directive on Radiation Treatment, *supra* note 5, at art. 8(1). "Irradiated foods may not be imported from a third country unless: they comply with the provisions of this Directive . . . [and the manufacturer] has been officially confirmed . . ." *Id.*

¹⁰⁹ See *supra* notes 46-47 and accompanying text.

¹¹⁰ See *supra* note 44 and accompanying text.

¹¹¹ See *supra* note 77 and accompanying text.

¹¹² See *supra* note 43 and accompanying text.

If the Council adopts the proposed directives, compliance may require new labeling procedures by nonmember states, like the United States. When food manufacturers use the standard U.S. form with the addition of dietary fiber content, nutritional labeling for exported food most likely will not create a large obstacle for U.S. exporters. This is because U.S. regulations are substantially similar to the EEC proposed directive's requirements.

If the the EEC does not adopt the proposed directive on irradiation treatment, U.S. exporters of irradiated food will have difficulty gaining access to member state markets which prohibit irradiation treatment. If the Council adopts the proposed directive, U.S. manufacturers might have difficulty complying with irradiation labeling requirements. Because of the different basic approaches used by U.S regulations and the proposed directive for irradiation labeling, U.S. manufacturers of irradiated food often will be unable to comply with this directive. Therefore, if the Council adopts the proposed directive, U.S. manufacturers would be wise to employ different food treatment for food exported to the EEC than used in the United States.

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