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The Food Label and the Right-to-Know

FREDERICK H. DEGNAN*

I. INTRODUCTION

As this article is being written, thousands of tons of corn and soybeans are poised for delivery to the countries of the European Union (EU).¹ The distribution of the commodities has been delayed as the EU attempts to resolve whether and, if so, how the commodities should be labeled.

The soybeans at issue are from a new variety that have been genetically engineered to enhance resistance to the herbicide glyphosate. The corn variety has been genetically engineered to enhance resistance to the European corn borer. Prior to marketing their products, the companies developing the new commodity varieties consulted with the U.S. Food and Drug Administration (FDA) regarding safety and propriety of use. For both products, teams of FDA experts reviewed summary data and evaluated the scientific issues. The FDA teams included experts in chemistry, molecular biology, toxicology, human and animal nutrition, environmental science, and the regulation of food ingredients. According to these experts, the information submitted by the companies adequately addressed the fundamental questions about the nature of the molecular alterations at issue, product safety, composition, and wholesomeness.² Based on this information, FDA found no reason to disagree with the developer's determinations that neither product is significantly altered from varieties of soy and corn with long histories of safe use, and that both products are safe for introduction into the marketplace.³

In FDA's view, no material difference in nutrition, composition, or safety exists between the modified commodities and their traditional counterparts. In fact, meaningful arguments can be made that, by virtue of the technology employed, genetically modified plants are safer than their traditional counterparts in light of the precision and specificity that can be accomplished with current genetic technology. In light of the foregoing, FDA has concluded that there is no reason to label the commodities in any way that would distinguish them from their traditional counterparts.⁴

In spite of the FDA precedent, EU members find themselves stalemated in an effort to create their own labeling framework for such products. The EU's regulatory slate is comparatively blank in the field of biotechnology — this presents a unique opportunity to tailor regulatory requirements closely to the needs of the time and to find a sensible balance between the concerns of industry, government, science, and the public. Accomplishing that balance, however, has been difficult. Moreover, constructing a policy from a blank slate to achieve such balance inevitably involves consideration of the inherently conflicting perspectives that accompany food biotechnology, in general, and labeling,

* Mr. Degnan is a Partner at the law firm of King & Spalding, Washington, DC. Some of this article is derived from a project collaborated on in 1993 with Richard A. Merrill, Esq., Covington & Burling, and Jess H. Stribling, Esq., King & Spalding, for a client. This article also contains excerpts from a speech on international labeling issues given by Mr. Degnan at the 1st Annual European Food Law Update Conference, sponsored by European Document Research, Washington, DC (Oct. 29-30, 1996).

¹Peter Fritsch, *Huge Biotech Harvest is a Boon for Farmers*, WALL ST. J., Oct. 24, 1996, at A1.

² *FDA Evaluation of Bioengineered Soybean and Corn Varieties*, FDA TALK PAPER, T96-68, AT 2-3 (Oct. 7, 1996).

³ *Id.* at 3.

⁴ *Id.*

in particular. At the heart of the controversy is what is commonly referred to as the "consumer right-to-know" perspective. And, at the core of this perspective is the notion that the public has a basic right to know any fact it deems important about a food or a commodity before being forced to make a purchasing decision.

The consumer right-to-know concept is, of course, not limited to the EU. The Codex Alimentarius Commission is struggling with the same concepts in connection with the labeling of genetically engineered food. In fact, "green" or consumer right-to-know interests pervade any number of global regulatory issues. In the United States, the consumer right-to-know impetus is clearly evidenced in aspects of California's Proposition 65 warning requirements⁵ and the aborted efforts of the State of Vermont to require manufacturers to identify products that were or might have been derived from dairy cows treated with a genetically modified growth hormone used to increase milk production.⁶

In the face of numerous consumer right-to-know initiatives, FDA's regulation of the food label has remained unaffected. This article will focus on FDA's longstanding regulation of the food label and Congress' limitations on the agency's ability to require information to appear thereon. The premise of the article is that those limitations were the product of foresight and, over the years, have resulted in a rational system of food labeling that serves the interests of the public by guaranteeing that consumers have the essential information they need to choose foods wisely. Efforts to broaden the permissible scope of required information beyond what is essential represent a dramatic departure from a history of regulation dedicated to ensure that consumers are meaningfully informed about the food they buy.

II. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT HAS BEEN CAREFULLY CRAFTED TO LIMIT THE AMOUNT OF INFORMATION THAT CAN BE REQUIRED TO APPEAR ON THE FOOD LABEL

Since 1906, FDA has regulated the food label. Without question, FDA's current labeling authority is more complex than that with which its predecessor agency was invested in 1906.⁷ Section 8 of that early act focused on the misbranding of food; it was not about requiring important information to appear on the food label, rather, its purpose was to prevent consumers from being deceived by what sellers said about their food. Simply put, the section forbade the sale of any food labeled in a false or misleading manner.⁸

The framers of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)⁹ confirmed the wisdom of the general prohibition in section 8 against false or misleading representations in labeling. In fact, Congress adopted essentially the identical language in section 403(a) of the 1938 Act¹⁰ and concluded that the prohibition against false and misleading representations was meant to be comprehensive in character.¹¹ Moreover, Congress recognized that "the labels of food . . . are not considered . . . to be the proper

⁵ See Safe Drinking Water and Toxic Enforcement Act, CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (West 1992 & Supp. 1995).

⁶ See *infra* notes 52-57 and accompanying text.

⁷ See Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768.

⁸ Pub. L. No. 59-384, § 8, 34 Stat. at 772.

⁹ Pub. L. No. 75-717, 52 Stat. 10440 (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)).

¹⁰ Pub. L. No. 75-717, § 403(a), 52 Stat. at 1047 (codified at 21 U.S.C. § 343(a)).

¹¹ S. REP. NO. 361, 74th Cong., 1st Sess. (1935); reprinted in A LEGISLATIVE HISTORY OF THE FEDERAL FOOD DRUG AND COSMETIC ACT 244 (Charles Wesley Dunn 1938).

media for making any representations . . . which are not in accord with the facts."¹²

The framers of the 1938 Act, however, were not content with prohibiting false and misleading labeling — regardless of how comprehensive the prohibition. They introduced a new notion in product labeling, such that labels were required to include certain items of information deemed essential to the consumer. The Act required the identification of the ingredients used to fabricate the food; the prominent, clear declaration of the net weight of the contents of the food; the name and address of the manufacturer or responsible party of the food; and a precise statement of the identity — the name — of the food.¹³

In addition to these narrow but fundamental requirements, Congress enacted section 201(n), which amplifies the general prohibition against false and misleading labeling found in section 403(a). Section 201(n) provides as follows:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.¹⁴

The language gives FDA the authority to require additional key information to appear on the food label if such a requirement is necessary to prevent consumers from being misled. The wording of the section, however, reveals that Congress was concerned that this provision be applied carefully and with good judgment. Section 201(n) does not say that FDA may require food labels to include whatever information the agency deems to be "material." Rather, in strictest terms, the authority provided under section 201(n) is conditional in nature — a seller may be required to reveal only those facts that are material in light of the seller's own representation about the food. At the heart of this notion is the ability to require a seller to balance its own representations about a food. Also under section 201(n), FDA can require the disclosure of facts that are material to the "consequences" of consuming a food — i.e., the possible adverse effects that could arise.

The clear import of section 201(n), therefore, is that labeling may be misleading not only because of what it says but because of what it fails to say. Although the omission of a "material" fact from labeling may misbrand a product, there is no precise definition of what constitutes a material fact. Trivial or insignificant facts about a product, however, are not material.

FDA has creatively relied on sections 403(a) and 201(n). In its original 1973 nutrition labeling regulations, the agency reasoned that any meaningful claim related to the nutritional aspects of a food required a manufacturer to comply with complete nutrition labeling, and that the failure to provide such a complete nutrition profile would be tantamount to an omission of material fact.¹⁵ Notably, however, the requirement was

¹² *Id.*

¹³ See 21 U.S.C. §§ 301, 343(e), (g), (i) (FDCA §§ 1, 403 (e), (g), (i)).

¹⁴ *Id.* § 321(n) (FDCA § 201(n)).

¹⁵ Final Rule, Nutrition Labeling, 38 Fed. Reg. 2125 (Jan. 19, 1973); additional modifications, 38 Fed.

conditional and could be invoked only in the presence of a statement regarding an aspect of the nutritional value of a food.

The agency also has relied on the second component of section 201(n) to require that the label of a product identify the presence of an ingredient or ingredients that may adversely affect a consumer. Thus, the agency has required declarations identifying the presence of ingredients possessing the potential to cause adverse reactions in consumers with sensitivities to such ingredients.¹⁶ Similarly, the agency has required a declaration of the presence of phenylalanine in diet soft drinks containing the artificial sweetener aspartame because infant phenylketonurics are born with a natural metabolic defect that requires avoidance of exposure to phenylalanine.¹⁷

The agency, on rare occasions, also has used section 201(n) to require warnings on the food label. A recent example of this involves the fat substitute "olestra." Human dietary studies established that olestra has the potential to cause abdominal cramping and loose stools in some individuals, and it inhibits the body's absorption of certain soluble vitamins and nutrients.¹⁸ As a result, FDA not only required manufacturers who use olestra to add essential vitamins to the product but also to label products with the following "boxed" warning: "This product contains olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some added vitamins and other nutrients. Vitamins A, D, E and K have been added."¹⁹ The approval of olestra was supported by over 150 studies and 150,000 pages of data.²⁰ Unlike other food additive approvals, extensive human data were submitted in support of the approval of olestra (normally laboratory animal data provide the basis for food safety decisions). These data, in the agency's view, documented the "materiality" of the consequences some consumers of olestra might suffer. A similar warning is required to appear on products containing the artificial sweetener sorbitol.²¹

The agency has a long history of expressly avoiding the imposition of warnings for ingredients that can cause only mild idiosyncratic responses in consumers, on the rationale that such a warning would over-expose consumers to warnings and decrease the effectiveness of such warnings. This is consistent with the prevailing case law, which supports the conclusion that section 201(n) may require affirmative label disclosure of facts necessary to protect consumer health.²²

In only one case, involving food irradiation, has FDA relied on sections 403(a) and 201(n) to require the disclosure on the food label of a processing technique applied to food.²³ Although the comments FDA received regarding its initiative expressed concern about the safety of irradiation, the requirement was not based on fears about safety.²⁴ Instead, the agency concluded that irradiation could cause changes in the flavor or shelf-

Reg. 6951 (Mar. 14, 1973).

¹⁶ See, e.g., 21 C.F.R. § 74.705(d)(2) (1996) (requiring the declaration of yellow No. 5).

¹⁷ See *id.* §§ 105.66(b)(2), 172.804(e)(2).

¹⁸ See H.H.S. News, Jan. 24, 1996, at 2.

¹⁹ *Id.*

²⁰ *Id.*

²¹ 21 C.F.R. § 184.1835(e).

²² Courts have sustained a seller's obligation to disclose the fact that its food contained the poisonous substance monochloroacetic acid (*United States v. 12 Bottles of Esterex* (not reported) (E.D. Mo. 1946)); declared misbranded a food whose label omitted any warning about likely allergic reaction (*Kellogg Co. v. Mattox et al.*, 763 F. Supp. 1369 (N.D. Texas 1991)); and upheld FDA's required warning about the hazards of low calorie protein-based diets (*National Nutritional Foods Ass'n v. Novitch*, 589 F. Supp. 798 (S.D.N.Y. 1984); *National Nutritional Foods Ass'n v. Young*, 598 F. Supp. 1107 (S.D.N.Y. 1984).

²³ 51 Fed. Reg. 13,376 (Apr. 18, 1986); 21 C.F.R. § 179.26(c).

²⁴ 51 Fed. Reg. at 13,376.

life of the finished foods and that these changes could be significant and material in light of the consumer's perception of the foods as unprocessed.²⁵ The agency stated, "in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed."²⁶ The limits to the agency's requirement are significant: FDA did not require irradiated ingredients to be specially labeled. No meaningful evidence existed that irradiation of an ingredient would or could affect the characteristics of a multiple-ingredient food in a significant way. Moreover, a fabricated food — one consisting of more than one ingredient — obviously is processed, thereby ensuring that consumers would not be misled on the issue of whether a product is fresh or processed.

Section 403(i) of the Act requires that a food or food ingredient bear its common or usual name. The legislative history reveals that the purpose of this requirement was to limit the practice of using a high-sounding name for a product composed largely of common, inexpensive ingredients.²⁷ In developing regulations to implement this provision of the Act and to respond to consumer complaints and confusion about products with uninformative names like "seafood cocktail," the agency articulated the standard that a common or usual name should reflect the reasonable expectations of consumers.²⁸ Accordingly, agency regulations provide that the common or usual name of a food or food ingredient must accurately identify the product in as simple and direct terms as possible.²⁹ The focus of these regulations is on communicating the essential nature and attributes of the food at issue. Thus, products named "seafood cocktail" were required to contain seafood, in fact, and to bear labeling identifying the percentage by weight of seafood in the product.³⁰

The agency has relied on sections 201(n) and 403(i) to provide consumers with information about the source of a given food. This required information also has been limited to that necessary to accurately identify the basic nature (including value) of the food³¹ or to reveal information which, for cultural or religious reasons, is critical to know before purchasing.³² There are any number of situations, however, in which the agency has decided that source information is not a necessary part of the common or usual name of a food or is not material within the meaning of section 201(n).³³ The controlling factors in agency decisionmaking in this area have been that required information must be key to identifying 1) the basic nature of a food or 2) the serious health consequences that can accompany its use.

III. THE NUTRITION LABELING AND EDUCATION ACT AND THE NEED TO COMMUNICATE ESSENTIAL NUTRITION-BASED INFORMATION

²⁵ *Id.* at 13,389-90.

²⁶ *Id.* at 13,390.

²⁷ See David Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. (1939).

²⁸ See 38 Fed. Reg. 6964 (Mar. 14, 1973).

²⁹ 21 C.F.R. § 102.5.

³⁰ *Id.* § 102.54.

³¹ For example, gluten, the principal protein component of corn endosperm and of wheat, must be identified as either "corn gluten" (21 C.F.R. § 184.1321) or "wheat gluten" (21 C.F.R. § 184.1322). This declaration is material for those with celiac disease who suffer serious reactions when exposed to wheat gluten.

³² Applying this rationale, FDA has contended that the declaration of the source of protein in protein hydrolysates is necessary. 56 Fed. Reg. 28,592, 28,596 (June 21, 1991).

³³ See *id.* at 28,603.

The passage of the Nutrition Labeling and Education Act of 1990 (NLEA) added a fifth required piece of information to the food label: complete nutrition labeling.³⁴ The NLEA imposes additional requirements on a manufacturer who wants to make nutrition-related claims about its product.³⁵ In this context, the Act simply codifies specific requirements that could also have been imposed under section 201(n). Reduced to simplest terms, the NLEA reveals a strong congressional desire that the food label convey meaningful nutrition information about foods in a simple, clear, consistent format. The goal of the NLEA reforms remains the same as the fundamental goal of the 1938 Act: the communication of essential information to enable consumers to choose foods more wisely.

This goal can be achieved only if consumers understand and use the information on food labels. In passing and implementing the NLEA, Congress and FDA, respectively, have recognized that the educational potential of the food label is limited and, as a result, the label should contain the essential information about the identity and nutritional quality of food and that this information should be conveyed in the most economical fashion. The NLEA was not designed just to require new information on food labels, but rather to require meaningful information that consumers need to choose foods wisely. To this end, consider that while the NLEA specifies the nutrients for which information must be provided in nutrition labeling, section 403(q)(2)(B) gives the agency authority to exclude any nutrient from the declaration requirement, despite its presumptive public health importance, when the agency finds that the information "is not *necessary* to assist consumers in maintaining healthy dietary practices"³⁶

In the course of formulating its nutrition labeling regulations, FDA faced real choices about the information, and the level of detail, it would require. In its proposal, the agency acknowledged that nutrient information previously required in labeling but currently of no "pressing public health importance" had to be excluded to ensure that critical messages about calories, cholesterol, fat, protein, and carbohydrates were meaningfully conveyed to consumers.³⁷ When it adopted final rules excluding numerous declarations, FDA emphasized that "[N]ot all information related to maintaining healthy dietary practices can be included on the food label Not only would space constraints not allow for this, but *the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance*"³⁸

Throughout its NLEA rulemaking, FDA acknowledged the difficult trade-offs it was forced to make to ensure that essential information about foods was conveyed in a fashion that consumers could use. The agency noted, for example, that although the NLEA requires health claims to contain sufficient information to be understood by consumers in the context of a total daily diet, "there is a limit to the amount and complexity of information that can be presented in a health claim" that can be reasonably understood and used by consumers.³⁹

The agency recognized that a similar choice was necessary when it required nutrient declarations to be made on the basis of only one set, rather than multiple sets, of Reference Daily Intake values for persons over four years of age:

³⁴ Pub. L. No. 101-535, § 2, 104 Stat. 2353 (codified at 21 U.S.C. § 343(q)(1)).

³⁵ *Id.* § 3, 104 Stat. at 2357 (codified at 21 U.S.C. § 343(r)).

³⁶ H. REP. NO. 101-538, 101st Cong., 2d Sess. 18 (1990) (emphasis added).

³⁷ 55 Fed. Reg. 29,487, 29,492 (July 19, 1990).

³⁸ 58 Fed. Reg. 2079, 2107 (Jan. 6, 1993) (emphasis added).

³⁹ *Id.* at 2510.

Because of space constraints on the food label — a problem that is becoming ever more compelling given the mandatory requirement for nutrition labeling on most foods — FDA does not believe that a viable option exists other than to develop a single set of label reference values for most consumers of the general food supply.⁴⁰

Clearly, the NLEA as conceived by Congress and as implemented by FDA, cannot be characterized as consumer right-to-know legislation. To the contrary, by its very terms the NLEA rigidly controls the nature of information to be provided on the food label, and FDA has crafted its regulations to convey essential information economically to the exclusion of other important but not critical information. As articulated above, the overriding purpose of this initiative is to ensure that consumers have the essential information to enable them to choose foods more wisely.

IV. FDA'S LABELING POLICY FOR FOOD PRODUCTS OF BIOTECHNOLOGY

It is in the foregoing legal context that FDA created its labeling policy for food products of biotechnology.⁴¹ The agency's policy is firmly rooted in the science of biotechnology and the FDCA's requirements. To this end, an implicit component of the policy is the fact that foods developed through biotechnology are not inherently dangerous and should be regulated like ordinary foods unless a new plant variety differs from its traditional counterpart to such an extent that the common or usual name no longer applies, or unless it presents a safety issue about which consumers must be informed. The policy also recognizes that the method of development of a new plant variety has never been considered the kind of information that must be disclosed on the label of food derived from plants. The policy is grounded expressly in the legal limitations that have been placed on FDA's authority to require information on the food label.

Consumer and public interest groups disagreed with the agency's approach, and argued that labeling should be required to distinguish genetically engineered foods, food ingredients, and additives from other products. At the heart of these arguments was the notion that genetic engineering techniques are fundamentally different from traditional methods of genetic modification. In light of these perceived differences, consumers and public interest groups were concerned that unexpected or unintended adverse changes in the composition of the food or food ingredient as a consequence of genetic engineering might cause some foods to be unsafe.

In response, FDA has taken the view that safety issues involving food biotechnology can be resolved reasonably and that only when a specific transfer has been shown to give rise to a safety concern should labeling be required.⁴² The agency has underscored that it is widely recognized in the scientific community that the use of modern methods of biotechnology does not present unique risks or hazards.⁴³

While the scientific community has embraced the use of genetic engineering, consumers generally are not well informed about the use of these new food product technologies and often are uneasy about alterations of the traditional food supply. FDA recognizes that firms using genetic engineering have an interest in educating the public

⁴⁰ *Id.* at 2213.

⁴¹ 57 Fed. Reg. 22,984 (May 29, 1992).

⁴² *Id.*

⁴³ *See, e.g.*, Labelling of Foods and Food Ingredients or Additives Produced Through Biotechnology, Discussion Document Prepared by the U.S. Delegation to the Codex Alimentarius Commission (1995).

about their products so as to build consumer confidence. The agency has subscribed to the dual view, however, that not only is such information not required under the Act but also, to serve their essential purpose, labels cannot be cluttered with complex or subordinate messages.

This concern about collateral information extends even to information that cannot be required, i.e., to voluntarily labeled information. In the case of the labeling of milk derived from cows that had been treated with recombinant bovine somatotropin (rBST), the agency provided "interim guidance" that cautioned that even truthful information could mislead consumers.⁴⁴ Accordingly, the agency's interim guidance emphasized that if voluntary labeling is to be employed, misleading implications must be avoided and the information presented must appear in its proper context.⁴⁵ Thus, FDA considers voluntary representations with regard to the presence or absence of genetic modification in a food to be potentially misleading, and the agency has said these must be crafted with care and caution.⁴⁶

V. THE INTERNATIONAL SCENE: CONSUMER RIGHT-TO-KNOW ISSUES AND THE FOOD LABEL

In 1988 the Council of the European Communities began to implement what it hoped would be a comprehensive framework for regulating products of biotechnology. Because the European Community's (predecessor to the EU) regulatory slate was comparatively blank in the field of biotechnology, a "unique opportunity existed to tailor regulatory requirements closely to the needs of the time and find a sensible balance" among the concerns of industry, government, science, and the public.⁴⁷ Accomplishing that balance has been difficult. Addressing risk and perceived risk in a way that satisfies the perceptions and values of all interested parties is never easy. Moreover, constructing a policy from a blank slate inevitably involves consideration of the inherently conflicting perspectives that accompany food biotechnology, in general, and labeling, in particular.

Although not without controversy, the task of implementing a labeling policy has been far easier here in the United States. Instead of having to create new policy, the task confronting U.S. regulators, the industry, and the public has involved evaluating the new biotechnology-derived food products in light of existing labeling authority found in the FDCA. The Act's guidance has infused federal decisionmaking regarding the labeling of genetically modified foods. In this context, the most important thing to note about that authority is that the Act contains no general authorization to require food labels to bear whatever information some consumers might wish to know. In fact, as explained above, the Act has been carefully assembled by Congress and implemented by FDA over the years to limit the amount of information that can be required to appear on the food label.

No such commanding or authoritative guiding criteria exist in the EU. Instead, the EU is trying to accomplish a democratic compromise among the industrial, scientific, and public sectors in an effort to create a rational labeling structure. This is consistent

⁴⁴ See Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that have not been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).

⁴⁵ *Id.* at 6280.

⁴⁶ For a further discussion of issues related to voluntary labeling see section VIII, *infra*.

⁴⁷ Int'l. Env't Rep. (BNA), No. 3, at 172 (Mar. 9, 1988) (quoting Stanley Clinton Davis, EC Envtl. Aff. Comm'r). See also Valerie Szcapanik, *Regulation of Biotechnology in the European Community*, 28 LAW & POL'Y INT'L BUS. 617, 618 (1993).

with the Single European Act,⁴⁸ which requires the EU to consider the economic and social development of the European community as a whole, as well as the balanced development of its regions, in any effort to craft and develop environment-based guidance and legislation. The conflicting viewpoints on whether and how to label products of biotechnology, however, have, at times, appeared irreconcilable.

The current status of the EU's proposed regulation on novel foods reflects the tensions of diverse viewpoints. The European Commission, the Council of Ministers, and the European Parliament have disagreed over the appropriate form labeling of novel foods should take.⁴⁹ The Parliament has taken the view that the presence of a genetically modified organism should be noted clearly on product labeling in every case regardless of its impact or materiality on the food itself. The Council offered the contrary view that it was whether the nature of the foodstuff itself was affected that should be the key consideration for product labeling, not how the product was processed. The Commission espoused a view similar to that followed in the United States, and focused on informing consumers about meaningful differences between modified and traditional foods.

The issue in the EU appears not to be *whether* to have labeling on products of biotechnology, but rather *how* to label. In the absence of any guiding, objective criteria like those found in the FDCA, wagers or predictions about the likely ultimate outcome of the EU regulatory process would be foolhardy. It would be helpful if guiding principles could be developed and followed (much the way the guiding principles of the FDCA have been followed by FDA in the United States), and on this front, the Codex experience could provide a helpful reference point.

VI. CODEX AND RELATED DEVELOPMENTS

The Codex Alimentarius Commission is confronted with the same clash between the "consumer right-to-know" and the "material, meaningful information" labeling philosophies. What may help Codex avoid the EU's dilemma is its adoption of "the four points of science."⁵⁰ These standards place a premium on the value of scientific objectivity. As FDA has argued in its position papers to Codex, consumer right-to-know standards are more subjective than objective, and if permitted to govern labeling initiatives, they could interfere with consumers' abilities to purchase foods wisely.⁵¹ Stated more bluntly, consumer right-to-know considerations are, for the most part, unscientific. The four points of science might well serve as support (as the FDCA has in the United States) to add objectivity (e.g., considerations of materiality) to the process of resolving the proper role of food labeling. The Codex Executive Committee has ordered the Secretary to draft guidance regarding food labeling. A resolution could come in Ottawa at Codex's April 1997 meeting.

⁴⁸ Single European Act 1987 O.J. (L 169).

⁴⁹ Regulatory authority in the EU is shared by the Commission (the EU's managing executive body), the Council (made up of representatives from EU member states) and the Parliament (directly elected by citizens of the EU). The Commission is the most powerful — any legislative measure must be based on a proposal by the Commission. The Council has the authority (under the Treaty of Rome) to adopt important Commission proposals. The Parliament has an active and influential, but largely advisory, role. In the "conciliation" process, however, the Parliament possesses what amounts to veto power over certain important legislation. For a detailed discussion of the interplay between these bodies, see George A. Berman, *Regulatory Cooperation Between the European Commission and U.S. Administrative Agencies*, 9 ADMIN. L.J. 933 (1996).

⁵⁰ See Codex Discussion document, *supra* note 43, at 6.

⁵¹ *Id.*

VII. INTERNATIONAL DAIRY FOODS V. AMESTOY: THE RIGHT NOT TO LABEL

The notion of essentiality that characterizes the Act's provisions regarding what may or may not be required to appear on the food label was reinforced recently in a decision of the U.S. Court of Appeals for the Second Circuit, finding that a Vermont State law requiring certain information to appear on a food label violated the First Amendment to the U.S. Constitution. The case, *International Dairy Foods et al. v. Amestoy et al.*,⁵² involved rBST, a synthetic growth hormone that increases milk production by cows. In 1993, FDA approved the use of rBST in dairy cows and, in the process, concluded that dairy products derived from herds administered rBST are indistinguishable from products derived from untreated herds.⁵³ The agency also concluded that because there was no material difference between milk and milk products from supplemented and unsupplemented herds, the Act provided no basis upon which to impose such a labeling requirement.⁵⁴ The agency made this decision despite heavy pressure from consumers and state officials that milk and milk products from supplemented herds be so labeled. The State of Vermont subsequently enacted a statute requiring that "if BST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."⁵⁵

Dairy manufacturers challenged the law and its implementing regulations, arguing that the law infringed their constitutional right not to speak. In response, Vermont asserted a state interest: the demand of its citizenry for such information. With "reluctance," the Second Circuit concluded that consumer interest alone was not sufficient to justify requiring a product's manufacturer to publish the functional equivalent of a warning about a production method (recombinant DNA engineering) that has no discernible impact on a final product.⁵⁶ The court noted that, were consumer interest alone sufficient to impose such a labeling requirement, there would be no end to the information that states could require food manufacturers to disclose:

For instance, with respect to cattle, consumers might reasonably evince an interest in knowing which grains herds were fed, with which medicines they were treated, what the age at which they were slaughtered. Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial government concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.⁵⁷

The court, thus, concluded that consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement. The decision is in complete harmony with the framework embodied by sections 403 and 201(n) and by FDA's long history of implementing that authority in the interests of requiring only meaningful, essential information to appear on the food label.

⁵² 92 F.3d 67 (2d Cir. 1996).

⁵³ 58 Fed. Reg. 59,946 (Nov. 12, 1993).

⁵⁴ 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

⁵⁵ See *International Dairy Foods*, 92 F.3d at 69.

⁵⁶ *Id.*

⁵⁷ *Id.* at 73.

VIII. VOLUNTARY LABELING AND OTHER EFFORTS TO EDUCATE THE CONSUMER

Obviously, a real distinction exists between imposing a requirement that certain information appear on the food label and merely allowing truthful and nonmisleading information to appear on the food label. The distinction is critical. Whereas consumer curiosity is not a basis for requiring information to appear on a food label, consumer curiosity may be a very compelling encouragement to manufacturers, processors, and distributors to voluntarily provide truthful, nonmisleading information that the consumer — for whatever reason — is interested in knowing about the food he or she purchases.

Although conceptually sound, a “voluntary” labeling initiative also may have the potential to mislead consumers. For example, in the area of genetically engineered foods, touting a food as not being the subject of recombinant DNA technology may leave the misimpression on the part of the uninformed consumer that the labeled food is somehow safer or better than its genetically manufactured counterpart, or that somehow the use of genetic engineering techniques adversely affects the character, quality, or nature of the food. Such voluntary representations must be able to withstand scrutiny under the standard adopted by the Supreme Court over seventy years ago for evaluating the propriety of information voluntarily placed on the food label:

The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. *It is not difficult to choose statements, designs and devices which will not deceive.* Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. *The statute applies to food, and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is.*⁵⁸

This test applies to “labeling” as well and, thus, governs promotional and display materials accompanying the sale of food.

Labeling has the potential to serve a valuable educational purpose for food, particularly foods about which there is a good deal of consumer confusion and interest. The difficulty, of course, with any type of educational labeling effort is to ensure that labeling conveys complete, nonmisleading information in an easily comprehensible manner. One area in which the agency and industry together have focused on this task involves “health claims.” Unfortunately, industry and the agency alike generally have found it difficult to craft health claims that are not “wordy” and that concisely convey essential information.⁵⁹

In sum, vehicles exist to communicate the information to consumers they desire, but great care must be taken in developing the message to be conveyed. Moreover,

⁵⁸ United States v. 95 Barrels of . . . Apple Cider Vinegar, 265 U.S. 438, 442-43 (1924) (emphasis added).

⁵⁹ See Labeling: General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2509-11 (Jan. 6, 1993); Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims, 60 Fed. Reg. 66,206, 66,215-23 (Dec. 21, 1995).

manufacturers generally cannot be compelled to provide such information. In fact, manufacturers generally are free from requirements that would force them to reveal information on the food label or related labeling that is not essential to the fundamental purpose of the food label.

IX. CONCLUSION

Some — perhaps many — consumers will always desire more information than is required about the food they eat. The FDCA resolves this tension by requiring the food label to contain only that information deemed essential to help consumers choose foods wisely. The Act leaves the information not deemed essential to be voluntarily communicated by those responsible in the food chain for the production, distribution, or marketing of food. The Act, however, places reasonable constraints on how such voluntary information is communicated. The concern is apparent: information should be clear and unambiguous. Comparative information should not distort the characteristics, value, or nature of the foods among which consumers must choose. Manufacturers, distributors, and marketers are free to withhold a wide variety of information from consumers.

To critics, the limited scope of what may be required on the food label appears flawed. Regardless of one's perspective, reflection reveals a system of regulation in which the hard choices regarding what is essential and what is not already have been made. Congress, over decades of regulation of the food label, has concluded consistently that the central purpose of the food label — i.e., to meaningfully inform, warn, and instruct — must be accomplishable. FDA has implemented this statutory charge effectively and, through extensive NLEA regulations in particular, has made the food label an information source of real public health significance. This has honed agency efforts to prevent other information from interfering with the consumer's ability to use and understand what is required to appear on the food label. Simply put, although consumer interest in receiving information is important, consumer interest alone is not enough to justify requiring that such information be included in food labels. The value judgments implicit in the statutory design contemplate that not only misleading information, but also information that is collateral and unnecessary or that crowds out or overshadows more important information, is not fundamental and, in the long run, can be at odds with what the Act establishes as the consumer's most basic right — the right to be able to choose food wisely.