



# Food Labeling Regulation: A Historical and Comparative Survey

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## Introduction

Food labeling had gone through several stages of historical development. Labeling regulations began with regulatory marks, which served as logistical aids to the enforcement of adulteration laws and the levying of duties and taxes on bread. The principle problem of misbranding was the misrepresentation of weight. With minor exceptions, most food was produced locally and consumed locally, so that there was no widespread usage of food labels, and hence no need for extensive regulation of such labels. The industrialization of food production in the nineteenth century made consumers more reliant on food labels as a key source of information in making purchases. Trademarks provided a partial assurance of quality to purchasers, but there was a clear need for regulation to prevent misleading and fraudulent labeling. Once anti-misbranding statutes were passed in the early twentieth century, regulators began to realize the need for more comprehensive regulation including affirmative labeling requirements. At first such affirmative labeling requirements were basics such as weight, the name of the food, and the address of the manufacturer. However, with advances in nutrition science and the realization of the connection between food consumption and long term diseases, affirmative labeling requirements included detailed nutrition information. Today nutrition labeling had become so specific in some countries that it is seen as means to educate the public about nutrition. The latest food labeling regulation dilemma centers around issues of the internationalization of food distribution and creating regulations that are not burdensome for food distributors in many countries, while at the same time maintaining individual regulation in each country that acknowledges that country's cultural preferences with regard to food. And as technology continues to play an increasing role in food production, questions arise as to which technologies are acceptable. Labeling specifying the use of genetically modified organisms

helps consumers exercise preferences with regard to the one new technology, but some, including the FDA, question whether such information should be relevant to consumer decisions. Different countries have come up with different answers.<sup>1</sup>

## **Historical Context: pre-Industrial food distribution and lack of need for labeling**

People in the industrialized world, and to a lesser extent, the developing world, live in an era when most of the food we consume is bought with a label of some sort attached. However, for most of manes history, in a world where rapid transportation was absent, almost all food was made from fresh ingredients, locally produced, locally purchased, and locally consumed.<sup>2</sup> People did not rely on any government inspection service or labeling to ensure the quality of the food they consumed. Rather they identified food tested its quality by looking at it, feeling it, smelling it, and poking at it. In many farming areas, consumers bought or bartered for flour directly from the mill, and thus could see first hand whether it was produced in a satisfactory manner. If people bought rice, flour, or sugar from a store, they could see the shopkeeper fill the bag right before their eyes, so that they had a level of trust in what they were purchasing. This contrasts with pre-packaged goods which deprive the consumer of the opportunity to inspect their weight or quality. Further, people bought bread from local bakers who had incentive to continuously turn out a quality product to maintain good relationships with customers and so maintain consumer demand for their goods. The baker

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<sup>1</sup>This paper seeks to examine food labeling regulations and policies in different jurisdictional and institutional settings as a means to finding system features that are worth adding to American food labeling regime. Further, lawyers recognize more and more the need to analyze the law of multiple jurisdictions simultaneous. When transactions involves movement of goods across many borders, a company has several legal regimes to concern itself with. A comparative approach ensures the smoothest navigation and helps in the design of a system to ensure smoother navigation in the future. After an extensive search of food labeling law, the author concludes that US regulations have long maintained a position at the forefront of food labeling trends, and US regulations are closer to optimal than other country's labeling regulations.

<sup>2</sup>Wilkins, *When and Why Brand Names?*, GEOFFREY JONES AND NICHOLAS J. MORGAN, EDS, ADDING VALUE: BRANDS AND MARKETING IN FOOD AND DRINK, at 18 (1994).

and his shop were guarantor of the breads quality.

This is not to say that man has not found need for labeling and regulation of food, for, in fact, food labeling has deep historical roots.<sup>3</sup>

## Early Food Labeling Regulation:

### branding as a logistical aid to anti-adulteration enforcement

A very interesting predecessor of food labeling existed in Roman time. In the Roman Empire, the rules governing the sale of food were as complex and specific as a modern regulatory statute.<sup>4</sup>The rules prevented fraud by the vendor, but generally relied on the principle of *caveat emptor*. Nonetheless, there a very straightforward system of selling bread on the steps of a city, with the arrangement of the bread as an indicator of the quality of the bread. According to Pliny, on each step a different grade of bread would offered for sale, and the higher the step the higher the grade of the bread and thus the higher the price.<sup>5</sup>This practice was formalized in the Theodosian Code of A.D. 438, which specifically required bread to be sold publicly on the steps rather than secretly by the breadmakers. The code mentions coarse bread and fine bread. <sup>6</sup>The code stated that [t]he transfer of bread from one step to another shall be prohibited, and the

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<sup>3</sup>The history of food labeling regulations in the context of the overall historical development of food regulation is enjoyably retraced in Hutt, Peter Barton and Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L. J. 2 (1984).

<sup>4</sup>*Id.* at 6.

<sup>5</sup>Pliny, NATURAL HISTORY 55 (H. Rachman, Ed. 1949), *cited in* Hutt and Hutt, *supra* note 3, at 6.

<sup>6</sup>C. PHARR, THE THEodosian CODE 418 (1952) *cited in* Hutt and Hutt, *supra* note 3, at 6.

office of the perfect of Annona shall know the severest punishments threaten them if they should permit such transfer to be made throughout the steps.

In medieval and early modern Europe, many types of food were identified by origin, grade, and regulatory marks.<sup>7</sup>In particular, medieval regulators used regulatory or liability marks with bakers to maintain the standards of quality in breadmaking and to prevent extortionist pricing of bread; such regulation of standards and pricing was important to rulers as a way to maintain both support of a populace dependent on bread as a staple and to maintain an effective tax base, since bread was a major article of commerce.<sup>8</sup> In England, the regulatory labeling of bread is traced back to 1203, when King John enacted the Assize of Bread (an assize is an ordinance regulating the price of a given quantity of food). Unfortunately for historians, no copies of the document have survived. In 1266, the Assize was codified by Parliament.<sup>9</sup> Shortly thereafter, Parliament enacted the Statute of the Pillory and Tumbrel to provide punishment for violation of the Assize of Bread and Ale.<sup>10</sup>The statute included one of the earliest historically evidenced example of affirmative food labeling regulation. The assize stated: “And upon every Measure, Bushel, Weight, and also upon every Loaf, the Name of the Owner distinctly written.<sup>11</sup>A later statute required every Baker shall have a Mark of his own for his Bread.<sup>12</sup> The mark became a key regulatory mechanism to assist with enforcement difficulties. The Assize of Bread of 1266 had set prices for different grades of bread. Later amendment added to the list of

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<sup>7</sup>KENNETH F. KIPPLE AND KRIEMHILD CONEE ORNELAS, EDS., CAMBRIDGE WORLD HISTORY OF FOOD 1621 (2000).

<sup>8</sup>SCHECHTER, FRANK I., THE HISTORICAL FOUNDATIONS OF THE LAW RELATING TO TRADE-MARKS, (1925) at 48-49. Wilkins, Mira, *When and Why Brand Names?* in GEOFFREY JONES AND NICHOLAS J. MORGAN, EDS ADDING VALUE: BRANDS AND MARKETING IN FOOD AND DRINK, 17 (1994).

<sup>9</sup>51 Hen. III, Stat. 1 (1266), *reprinted in* D. Pickering, 1 THE STATUTES AT LARGE FROM MAGNA CARTA TO THE END OF THE ELEVENTH PARLIAMENT OF GREAT BRITAIN 34 (1762) (hereinafter cited as Pickering) *cited in* Hutt and Hutt, *supra* note 3, at 14.

<sup>10</sup>51 Hen. III, Stat. 6 (1266), 1 Pickering 47, *cited in* Hutt and Hutt *supra* note 3, at 14.

<sup>11</sup>*Id.* at 14.

<sup>12</sup>Edw. I, c.1-10 (1285/1306), 1 Pickering 390-94.

approved grades of bread, and any bread not in compliance with the standards was viewed as illegal. As the variety of grades and number of prices increased, enforcement became more difficult. Parliament responded in 1749 by enacting a statute requiring bakers to:

fairly imprint or mark, or cause to be imprinted on every loaf so by hum made or exposed for sale, the letters hereinafter mentioned, (that is to say,) upon every loaf exposed to sale as wheaten bread a large Roman W H, and upon every loaf exposed to sale of household bread, a Large Roman H, and every person selling or exposing to sale not marked as aforesaid shall forfeit and pay the sum of 20s. to the informer.”<sup>13</sup>

Labeling regulations were also common at the local level. In London of the fourteenth and fifteenth centuries, each baker was required to have his own seal, and each loaf of bread was required to be labeled using the seal so that its baker could be identified. “Every baker shall have the impress of his seal appearing on his bread, that so the same may be more easily and readily known. And this manner of sealing shall be used in brown bread as well as white.”<sup>14</sup> Other common food products were also subject to label marking regulations in England. Wine was one of the earliest articles of commerce, and because they often were sold far away from where they were produced, there may have been greater danger of adulteration and misbranding than was the case with other food products. Since ancient times, wines have commonly been named after their place of origin. A 1419 proclamation against the adulteration of wine and mixing of wines from different regions,

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<sup>13</sup>22 Geo. II, c. 49 (1749), *reprinted in* C. Walford, *EARLY LAW AND CUSTOMS IN GREAT BRITAIN REGARDING FOOD* 24-25 (1879) *cited in* Hutt and Hutt, *supra* note 3, at 15.

<sup>14</sup>*LIBER ALBUS: THE WHITE BOOK OF THE CITY OF LONDON* (H.T. Riley, Ed., 1861) 308 *cited in* Hutt and Hutt, *supra* note 3, at 20.

required that a wine from one geographical area must be so labeled and could not be mixed with wine from another area.<sup>15</sup> A 1311 London ordinance required of all wine that each turn be marked in front, so that the buyer may readily see the value of the wine.<sup>16</sup> One of the most commonly adulterated food items in England was butter. A 1649 statute regulating the adulteration of butter required every butter packer to place his initials of mark on the container in order to discover and punish any person who violated the regulation.<sup>17</sup> A similar butter statute enacted by Parliament in 1662 sought to trace violators by requiring every butter packer to brand his first initial and full surname on each container of butter he sold.<sup>18</sup>

## Common Law on Misbranding

It is useful to look at English common law regarding misbranding as a tool to understanding the historical evolution towards present day statutes on labeling and misbranding. Sec. 403(a) of the Food, Drug, and Cosmetic Act is substantially the same as the common law concept of misbranding.<sup>19</sup> While branding was common form of statutory regulation in England, there was no cause of action for misbranding at common law, and the very term “misbranding” was unknown at common law. Current dictionaries define the term solely in relation to modern statutory requirements of labeling.<sup>20</sup> Nonetheless, the concept of misbranding

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<sup>15</sup>7 Hen. V (1419), in MEMORIALS OF LONDON AND LONDON LIFE 670 (H.T. Riley ed. 1868) *cited in* Hutt and Hutt, *supra* note 3, at 16.

<sup>16</sup>LIBER ALBUS: THE WHITE BOOK OF THE CITY OF LONDON (H.T. Riley, Ed., 1861) 308 *cited in* Hutt and Hutt, *supra* note 3, at 20.

<sup>17</sup>Act of March 12, 1649, c. 77, *reprinted in* H. Scobell, A COLLECTION OF ACTS AND ORDINANCES OF GENERAL USE 109 (1658) *cited in* Hutt and Hutt, *supra* note 3, at 17.

<sup>18</sup>13 & 14 Car. II, c. 26 (1662), in 8 Pickering 131 *cited in* Hutt and Hutt, *supra* note 3, at 18.

<sup>19</sup>Hutt, P.B., *Criminal Prosecution for Adulteration and Misbranding of Food at Common Law*, 15 FOOD DRUG COSM L.J. 382 fn 6. (1960) (hereinafter Hutt Common Law).

<sup>20</sup>See, e.g., Merriam Webster’s Collegiate Dictionary, 10<sup>th</sup> Ed. 743 (1995), indicating that the word did not become an official word in the English language until the twentieth century.

was prevalent at common law, and there were many reported instances where people sold merchandise falsely representing that it was something other than what it actually was.<sup>21</sup> Because extensive modern food labeling was non-existent in medieval England, false representations were instead usually made by verbal affirmation of use of false weights and measures.<sup>22</sup> Definitions or standards of identity for food did not exist at common law, but standards of weight and measure did exist and were well known. The Magna Carta in 1215 stated: There shall be one measure of wine throughout all our kingdom, and one measure of corn, namely, the quarter of London; and one breadth of dyed cloths, and of russets, and of halberjects, namely two ells within the lists. And it shall be same with weights as with measure.<sup>23</sup>

Almost all misbranding at common law was concerned with false weights and measures or with passing-off of inferior products for superior ones.

Misbranding was characterized at common law as cheating.<sup>24</sup> The great legal scholar Blackstone discussed cheating as follows:

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<sup>21</sup>Hutt, *Common Law*, *supra* note 19, at 382-83.

<sup>22</sup>*Id.* at 383, fn 5.

<sup>23</sup>Barrington, *Magna Charta*, 2d Ed., 1900) at 238. See also McKechnie, *Magna Carta* (2d Ed., 1914) at 356-58.

<sup>24</sup>Hutt, *Common Law*, *supra* note 19, at 390.

Cheating is another offense, more immediately against public trade: as that cannot be carried on without a punctilious regard to common honesty, and faith between man and man. Hither therefore maybe referred that prodigious multitude of statutes, which are made to restrain and punish deceits in particular

trades, and which are enumerated by Hawkins and Burn, but are chiefly of use among the traders themselves. The offense also of [breaking the assise][italics] of bread, or the rules laid down by law, and particularly by statutes 31 Geo. II. c.29, 3 Geo. III. c.11, and 13 Geo. III. c.62 for ascertaining its price in every given quantity, is reducible to this head of cheating: as is likewise in a peculiar manner

the offense of selling by [false weights and measures][italics]; the standard of which fell under our consideration in a former volume. The punishment of bakers, breaking the assise, was antiently to stand in the pillory, by statute 51 Hen. III. st. 6 and for brewers, (by the same act) to stand in the tumbrel or dungcart.... But now the general punishment for all frauds of this kind, if indicted (as they may be) at common law, is by fine or imprisonment....<sup>25</sup>

At common law, offenses which affected individuals merely in their capacity as private citizens were subject only to civil remedies for the damage sustained.<sup>26</sup> Only offenses which affected the public as a whole were subject to indictment. Later cases and commentators unanimously agree that use of false weights and measures was an obvious instance of a public offense, indictable at common law. One commentator stated: But if in any of these cases the cheat be effected by means of false weights or measures, (which are known public tokens) it is then clearly indictable; for these betoken a general design to defraud; they are instruments or tokens purposely calculated for deceit, and by which the public in general may be upon without any imputation of folly or negligence.”<sup>27</sup>In *Roy v. Burgaine* in 1680, the defendant was indicted for selling an unsealed

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<sup>26</sup>Hutt, *Common Law*, *supra* note 19, at 390-91

<sup>27</sup>2 East's P.C. 820 (1803).

measure of ale. The court upheld the indictment as good at common law.<sup>28</sup> Another successful indictment was against John Hill, for selling goods by false weights and measures in a public shop. Pleading (1798), Vol. 6, at 389.

## Early American Food Labeling Regulations

In colonial America, liability marks were used as by municipalities as a means to impose weight and price controls on loaves of bread. In 1646, the General Court of Massachusetts Bay Colony the first recorded Assize of Bread in colonial America.<sup>29</sup> Almost an exact copy of the British Assize of Bread, it too required that every Baker shall have a distinct mark for his Bread. When Virginia passed a law in 1745 regulating the size of flour barrels, it provided that inspector of barrels was supposed to stamp each barrel as first, or second fitness before it could exported.<sup>30</sup> Later such labeling regulations were extended to barrels of pork in 1762 with a regulation requiring an the inspector to stamp every barrel with a letter L for Large, or the letter S [for] small pork.<sup>31</sup> A 1772 amendment of the flour law required every flour inspector to brand every cask of flour with the first letter of the owner's christian name, and with his surname at length, or the name of the said mill, which brand or mark so used, shall be recorded in the court of the county, as well as the quantity of flour, SF for superfine, and F for fine.<sup>32</sup> Other colonies' laws showed patterns very

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<sup>28</sup>1 Sid. 409, 82 Eng. Rep. 1185.

<sup>29</sup>THE LAWS AND LIBERTIES OF MASSACHUSETTS 3 (1648 ed.).

<sup>30</sup>L. Va. 1745, c. 8, s. 5, *reprinted in* W.W.Hening, 1-13 THE STATUTE AT LARGE (1823)(hereinafter Hening).

<sup>31</sup>L. Va. 1762, c. 10, s.2, in 7 Hening 40.

<sup>32</sup>L. Va. 1772, c. 2, s. 2 *in* 8 Hening 512-13.

similar to the Massachusetts and Virginia laws.; New York City used such regulatory marks on bread up until the early nineteenth century.<sup>33</sup> Also during colonial times, flour and pork were also expected to be marked during shipping and before sale in an attempt to grade such products and provide an indicator of quality control.<sup>34</sup> In 1785, Massachusetts may have been the first legislative body in the world to enact a broad food adulteration statute applicable to all food commodities.<sup>35</sup> In the last quarter of the 18th century, many states enacted similarly broad statutes. For example, in 1786, Virginia enacted a broad statute.<sup>36</sup> However, these statutes lacked many affirmative labeling requirements, and not until the twentieth century did affirmative labeling requirements become common place.

### **Industrialization of the Food Production**

The second half of the nineteenth century involved a number of trends coinciding to bring about the industrialization of agriculture. In the US, the West was settled, farm mechanization began, the rise of mass transportation, the increasing specialization of farming, the drastic decline of self sufficient farms, expansion into new markets, and the rise of educational opportunities that allows the dissemination of knowledge about science and technology.<sup>37</sup> According to two historians of the agriculture:

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<sup>33</sup>Wilkins, *supra* note 2, at 18

<sup>34</sup>Wilkins, *The neglected intangible asset: The influence of the trade mark on the rise of the modern corporation*, BUSINESS HISTORY, January 1992, at 72.

<sup>35</sup>L.Mass. 1785, reprinted in 31 FOOD DRUG COSM L.J. 246 (1976).

<sup>36</sup>L. Va. 1786, c.53, 12 Hening 336.

<sup>37</sup>WOOD, DONNA J., STRATEGIC USES OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA 122 (1986)

The commercialization of agriculture was in evidence well before 1850, as in the case of cotton. But it was only after that date that transportation facilities, farm machinery, and a money economy were well enough developed to make the change dramatic... farmers gave up growing their own wheat and carrying to the local grist mill to be ground into flour, preferring instead to buy their flour at the local store. They stopped churning their own butter and making their own cheese. Even dairy farmers sometimes purchased oleomargarine. And in some cases they even gave up growing fruits and vegetables for themselves, claiming that it was cheaper to buy canned or frozen foods in the nearby shopping center.

Thanks to the advent of the steamship and the railroad, transportation became much more rapid, and combined with refrigeration to allow food to be sold to consumers in markets very distant from the source of production.<sup>38</sup>The invention of the pressure kettle allowed canned food to be sealed and stored in reliably sanitary conditions.<sup>39</sup>Canning allowed preserved food to be sold nationwide, and such food quickly became an inexpensive and reliable staple for many consumers. The advent of small packaging allowed baked crackers to be sealed and easily shipped and distributed.<sup>40</sup>Previously in the late 19<sup>th</sup> century, the modern corporation came into being. All these changes meant the death of the personal relationship between the food producer and food consumer. Instead, producers sold mass goods made in large quantities to consumers in distant places who they did not personally.

One food production is dominated by mass production and distribution, the balance of power shifts against the consumer. When the consumer no longer has a personal relationship with the producer or at least

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<sup>38</sup>Wilkins, *supra* note 2, at 26.

<sup>39</sup>WOOD, *supra* note 37, at 125.

<sup>40</sup>HAYES, SAMUEL P. THE RESPONSE TO INDUSTRIALISM, 1885-1914 (1957).

the peddler of the food products, then the consumer can no longer rely on trust as a guide to making good purchases. When a product is canned, bottled, or simply pre-packaged, the consumer has no way of monitoring its quality at purchase.<sup>41</sup>The only way a consumer might ever know of a product's poor quality is if they become ill from using it. Worse yet, the manufacturer can engage in sophisticated adulteration techniques that go completely undetected by the consumer, and can in fact only be detected by an inspector. Producers figured out ways to subtly alter the chemical composition of pre-packaged foods so that quality of production without the consumer perceiving any drop in the quality of the product. Even if an occasional customer might be able to detect low quality, the company knows that on average, more customers will continue buying the products than will be alienated by perceived quality concerns.

In the language of economics, asymmetry of information exists between the food consumer and the food marketer.<sup>42</sup>Food manufacturers and retailers are as a matter of course better informed about the nature of the products they sell than are the consumers of those products. Unfortunately, the asymmetry of information provides food producers and sellers with the incentive to minimize the quality of their products. The producers, the more knowledgeable group are in position to encourage consumer misperception about their product.<sup>43</sup>In classic economics language, a market for lemons develops. In a market with two food products, one safe and nutritious and one not, the seller can tell which is the better product, but the buyer cannot. Because of the buyer cannot distinguish, the better product can only be sold at the same price as the inferior product. The producer will only supply the inferior product, and the superior product will be forced off the market.<sup>44</sup>Commentators at the time noted that manufacturers and distributors who might otherwise

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<sup>41</sup>Henson, Spencer, and Bruce Trail. *The demand for food safety: Market imperfections and the role of government*. FOOD POLICY, April 1993, at 158.

<sup>42</sup>*Id.*

<sup>43</sup>*Id.*

<sup>44</sup>*Id.*

have provided pure goods may have been forced by pressure from unscrupulous competitors to engage in rampant adulteration and misbranding.<sup>45</sup> The pervasive nature of the problem in the early twentieth century is evident in the humorous testimony of an executive of a food distribution company. Speaking before the House Committee on Interstate and Foreign Commerce to oppose passage of the 1906 Pure Food and Drug Act, he stated “make us leave preservatives and coloring matter out of our food and call our products by the right name and you will bankrupt every food industry in the country.”<sup>46</sup>

## **The Repersonalization of the Producer/consumer Relationship Through Labeling**

However, industrialization did not mark the end of consumers knowing their producers; now customers knew who they were buying from based on the label the good came in, the trade mark. A standardized product tells the consumer what he has tasted before and whether he has liked or disliked it. “Trade marks assure an anticipated standard.”<sup>47</sup> For that reason, branded products are almost always sell better than generic products, which consumers lack trust in due to concerns about their liability. Brand names allow choices between predictable, standardized products giving consumers the ability to maximize preferences. A known brand name provides the consumer with some assurance that they won’t get sick from the product, since they have gotten sick when they previously consumed it.<sup>48</sup> Producers realized the power of branding

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<sup>45</sup>Wiley, H.W., *Test of Foods, Beverages, and Toilet Accessories, Good and Otherwise*, 1914, in PORTER, D. AND R. EARL, EDS., FOOD LABELING: TOWARD NATIONAL UNIFORMITY 41(1992).

<sup>46</sup>*Id.* at 41.

<sup>47</sup>Wilkins, *supra* note 2, at 25.

<sup>48</sup>*Id.*

long before the industrial revolution. A Bavarian court's Brewing Purity Law of 1516 was enthusiastically adopted by German brewer, who understood that branding was a tool that could enhance their beer's marketability. Many companies that pioneered new technologies of food production quickly began selling branded products.<sup>49</sup> Gail Borden, who pioneered condensing and canning of milk attached a trade name to his product as soon as his first factory began production in 1861.<sup>50</sup> Underwood, a maker of devilled ham, registered its trade mark in 1870 under the first federal Trade Mark Act. Libby, McNeil, & Libby extensively marketed its canned beef in the Eastern US using a specially designed tin and extensive advertising of its trademark.<sup>51</sup> In the 1880s, as the mass production of food accelerated and competition became more fierce as producers tried to increase market share in more distant markets, breakfast food makers, meat packers, brewers, distillers, and sugar refineries all began branding their products and aggressively advertising the brand names. Trademarks gave the companies opportunities to maintain volume production and lower unit costs.

Brands have other benefits for consumers. Lower per unit production costs from volume production indirectly lead to lower food prices for consumers. Modern distribution of branded packaged food products lowers consumer search costs because the brands signals the consumer to buy the same product they've bought before. The only time that a modern food consumer does not rely on brand names is in the course of selecting from items at a local restaurant or shop. In that case, the consumer is in much the same position as a pre-modern consumer, reliant on his personal relationship of trust with restaurant owner or shopkeeper.

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<sup>49</sup> *Id.* at 26.

<sup>50</sup> MORGAN, H. *SYMBOLS OF AMERICA*, (1986).

<sup>51</sup> Wilkins, *supra* note 2, at 27.

## **The Inadequacies of the Trademark as the Sole Means of Quality Control**

Although branding provides significant benefits to food consumers, it is not a complete assurance of producer reliability. It takes time for a company to build an effective brand that can assure consumers. In the meantime, before any particular brand has won a high level of loyalty, producers seeking to maximize short term profit can cheat consumers by providing a substandard product. A brand can sell the perception of quality even though the product is actually low in quality. A brand previously relied upon by consumers as a indication of high quality can decide in the face of falling profitability to commit brand suicide and maximize short term profits by producing cheaper lower quality goods and selling them at the same price as the higher quality goods that consumers had come to expect.

### **Need for Regulation of Adulteration but not Misbranding**

The thorough recognition of adulteration coincided with the development of modern chemistry, which made detection far easier. By 1700, a number of treatises on chemistry had been published, and many of them referred to the detection of food adulteration. The progression of chemistry in the seventeenth and eighteenth centuries permitted the wide detection of adulteration. Throughout the 18th century, the research and published literature on the problem of food adulteration expanded, culminating in the work of German-born chemist Frederick Accum, who published *A Treatise on Adulteration of Food and Culinary Poisons* was

published in 1820.<sup>52</sup>The treatise was an instant success, catching the worldwide attention of newspapers and the general public.<sup>53</sup>The success of Accum gave rise to whole generation of food adulteration treatises. If not for the prevalence of laissez faire economics philosophy at the time, food regulations might well have passed through British Parliament in the 1820s. The work of Dr. Arthur Hassall finally brought food adulteration research into the modern era, with his massive investigations of food adulteration. He revolutionized the study of food adulteration by introducing the microscope to detect numerous previously undetectable forms of adulteration.<sup>54</sup>In the face of the evidence he compiled, Parliament passed a statute in 1860 prohibiting the adulteration of food and drink.<sup>55</sup>Several other European countries established food adulteration statutes around this time. But because these acts were before the complete industrialization of food production and the nearly ubiquitous use of food labels, the statutes did not address labeling issues.<sup>56</sup>A notable exception was in Belgium. In 1856, Belgian parliament added to earlier regulations governing harmful substances in food by requiring that producers indicate to the consumer when any substance, whether or not it was harmful, has been added to the food.<sup>57</sup>A new criminal code adopted in 1867, in a general manner, sanctioned any fraud regarding the identity, nature, origin, or quantity of food or beverage products.<sup>58</sup>

## **US Food Law:Tackling Adulteration *and* Misbranding**

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<sup>52</sup>F. ACCUM, A TREATISE ON ADULTERATION OF FOOD AND CULINARY POISONS (1820).

<sup>53</sup>Schuette, *Death in the Pot*, 35 TRANSACTIONS OF THE WISCONSIN ACADEMY OF SCIENCES, ARTS, AND LETTERS 283 (1943); Browne, *The Life and Chemical Services of Fredrick Accum*, 2 J. CHEM. EDUC. 829, 1140-1144

<sup>54</sup>Curran, *British Food and Drug Law—A History*, 6 FOOD DRUG COSM. L.J. 247, (1951); Beeston, *A Brief History of Food and Drug Legislation in Great Britain*, 8 FOOD DRUG COSM. L.J. 495 (1953); Jephcott, *To the Prejudice of the Purchaser*, 15 FOOD DRUG COSM. L.J. 359 (1960).

<sup>55</sup>23 & 24  
Vict., c. 84 (1860).

<sup>56</sup>LISTER, CHARLES, THE REGULATION OF FOOD PRODUCTS BY THE EUROPEAN COMMUNITY 41 (1992).

<sup>57</sup>Everaert, P. *Belgium in* CAMPBELL AND LANG, EDs., INTERNATIONAL FOOD AND BEVERAGE LAW, at 61, (1996).

<sup>58</sup>*Id.* at 61.

In 1846, Dr. Lewis C. Beck, a professor of chemistry at Rutgers and Albany Medical College, published the first work about food and drug adulteration in the U.S. But the real impetus for public awareness of adulteration as a public health dilemma came from a report issued in 1850 by mathematician and statistician Lemuel Shattuck. The report documented a marked decline in the average life expectancy of citizens of major American urban centers, and indicted food adulteration as a major public health problem.<sup>59</sup> As a result of these concerns, many U.S. states adopted anti-adulteration statutes in the second half of the nineteenth century.

Unfortunately state regulations were woefully inadequate because states lacked enforcement resources and could not regulate food was transported across state lines. State laws were a confusing patchwork of regulations in area where the need for uniformity was obvious. Even as early as 1879, E.R. Squibb, the head of forerunner of Bristol Myers Squibb, speaking before the Medical Society of State of New York, stated “it is self-evident that a law to be most effective in preventing adulteration of food and medicine should be general or national in order to secure universality and uniformity of action.”<sup>60</sup> Federal legislation was proposed the very same month that Squibb made his comments, but thanks to concerns about federal regulation intruding into matters of local and state concern, such legislation did not pass until 27 years later.<sup>61</sup> One factor that may have ultimately persuaded Congress to pass anti-misbranding legislation was the negative effect of misbranding on perfectly honest food companies. Many food companies became outspoken proponents of national legislation, including H.J. Heinz, who appointed his son to head their company’s lobbying efforts, and Federick Pabst, the head of the a major beer brewing company. A biographer of Heinz states that Heinz: knew that unscrupulous processors... were hurting all other manufactureres in the industry by creating suspicion of the quality and purity of all products on the market. He his industry would not grow to major

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<sup>59</sup>See generally, SHATTUCK, L. REPORT OF THE SANITARY COMMISSION OF MASSACHUSETTS, 1850.

<sup>60</sup>Squibb E.R. *The Collected Papers of Edward ROBINSON SQUIBB*, M.D., 1819-1900., IN PORTER, D. AND R. EARL, EDS., FOOD LABELING: TOWARD NATIONAL UNIFORMITY 39 (1992).

<sup>61</sup>*Id.* at 39.

estate until it has earned public confidence. The way to earn that confidence was to work in partnership with a federal regulatory agency. Regulation would make the industry respected and trusted – an achievement beyond any price.”

Associations of small producers of food products marketed based on geographic origin also wanted to protect their products from competition by mislabeling. These producers made such unique products as Pennsylvania beer, New York cream cheese, Wisconsin cheddar, Kentucky bourbon, Tennessee sourmash, Michigan cherries, Maryland oysters, Washington salmon, Georgia peaches and California olives.<sup>62</sup> Producers of regional specialties were losing money and consumer good will thanks to entrepreneurs willing to seize on the products’ regional identities and sell fraudulent items with no connection to region. Vincent Carosso, a historian of the wine industry in California, described the industry’s interest in seeing federal legislation passed.

As California became better known as a wine-producing area... and the demand for its wines grew, Eastern traders stopped calling California wine men counterfeiters. Instead, Eastern merchants in this period bottled anything that looked and smelled like wine under a California label, a practice that considerably damaged California’s out-of-state trade as well as the general reputation of California wines. The many prizes, medals, and honorable citations California wine received at Eastern exhibits and fairs did not dispel the idea that the state produced mainly worthless imitations. The fight to gain a national pure-food law indicates the length of the battle to prevent adulterations and impress upon the Eastern market the real character of the California product.<sup>63</sup> A summary of congressional testimony in 1900 and 1901 concluded that “manufacturers would apparently be willing to label their goods properly if their competitors were required to do the same thing.” In 1906, Senator Porter J. McCumber stated:

Every honest manufacturer in the United States is pleading for this bill, because he says that if he manu-

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<sup>62</sup>WOOD, *supra* note 37, at 146.

<sup>63</sup>CAROSSO, VINCENT. P, THE CALIFORNIA WINE INDUSTRY: A STUDY OF THE FORMATIVE YEARS 171 (1951).

factures his goods in accordance with pure food laws in the several states or territories, it is impossible for him to compete justly an fairly with the bogus articles that are put in competition with those manufactured by him.<sup>64</sup>

Another new argument was that without uniformity in food labeling regulations, food manufacturers could not maximize efficiencies from mass production and marketing because of the costs of complying with several different labeling regimes. Echoing Squibb's earlier calls for uniformity and universality through a federal approach to food and drug regulations, many food industry lobbyists complained about the compliance costs of conforming to a patchwork of state regulations. Business leaders testified before Congress:

The chief objection, especially from the standpoint of the manufacturer, to leaving the matter in the hands of state governments is the lack of uniformity of state laws, which makes necessary different kinds of labels according to the state to which the goods are to be shipped. It is also urged that the state laws are insufficient from the lack of appropriations necessary to enforce them, and through the lack of sufficient knowledge and efficiency on the part of the officials charged with their enforcement.<sup>65</sup>

Moreover, reputable manufacturers in a given state has no protection from the competition offered by adulterated or misbranded goods produced out of state. Individually, a state could not regulate commerce in unbroken food packages traveling between states.<sup>66</sup>

### **The Pure Food and Drug Act of 1906: the First Federal Anti-Misbranding Statute**

The need for national legislation finally culminated in the passage of the Pure Food and Drug Act of 1906, the first federal effort to prevent misbranding of food products. The acts only regulation of labeling was the prohibition of false or misleading statements on food labels.<sup>67</sup> However, the act did not require any specific information, such as the name of the food, the ingredients, quantity, or the name and address of

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<sup>64</sup>Congressional Record, Senate. 1216 Jan. 18, 1906.

<sup>65</sup>Senate Document No. 141, 1900, cited in WOOD, *supra* note 37, at 144.

<sup>66</sup>WOOD, *supra* note 37, at 148.

<sup>67</sup>Hutt, P. *Regulating the Misbranding of Food*, 43 FOOD TECHNOLOGY 288, September 1989, in HUTT, P. AND MERRILL, R. FOOD AND DRUG LAW: CASES AND MATERIALS, 2d. Ed., 1991, at 37.

the manufacturer and distributor. Even though the FDA has already informally implemented over 200 standards of identity for food even before the act was passed, the act failed to formalize FDA authority to set food standards. Nonetheless, the act did provide FDA with authority on certain matters through by setting standards, procedures, and criminal and civil enforcement powers.<sup>68</sup> The FDA made full use of its limited authority to curb most fraudulent and outrageous claims on food labels. Case law flushed out the details of what constituted misbranding.<sup>69</sup> Judicial definitions of misbranding did not focus on the chemical, scientific, or technical accuracy of the food label.<sup>70</sup> Instead, courts understood significance of the label to person of ordinary intelligence, familiar with the product, and conversant in the English language.<sup>71</sup> The label could not misstate the nature or identity of the article.<sup>72</sup> The label could not create the false or misleading impression that the food contained ingredients that were in fact absent.<sup>73</sup> Where for a long period of time a product had an important ingredient noticed on the label and the new label failed to prominently disclose that a substitution had occurred, the product was considered misbranded.<sup>74</sup> Courts rigorously protected geographical terms intimately associated with particular products.<sup>75</sup> However, if the geographic terms had become so generic as to indicate type, classes, or styles rather than places of origin or manufacture, then the

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<sup>68</sup>Mackie, John, and Kimberly Corcoran, *United States in CAMPBELL AND LANG*, supra note 54, at 368 (1996).

<sup>69</sup>*Legislation: The Consumer's Protection Under the Federal Pure Food and Drugs Act*, 32 COLUM. L. REV. 720, 723-24 (1932)

<sup>70</sup>*U.S. v. Scanlon*, 180 F. 485 (N.D. Ohio 1908), *U.S. v. Seventy-Five Boxes of Alleged Pepper*, 198 F. 934 (D.N.J. 1912), *U.S. v. One Hundred and Fifty Cases of Fruit Pudding*, 211 F. 360 (D. Mass 1914)(cornstarch, though botanically a fruit cannot be labeled as fruit-flavored)

<sup>71</sup>*Id.* at 724, citing *US v. Seventy-Five Boxes of Alleged Pepper*, at 935; *US v. One Car Load of Corno Horse & Mule Feed*, 188 F. 453, 462 (M.D. Ala. 1911).

<sup>72</sup>*Id.* at 724, citing *US v. Ninety-Five Barrels of Vinegar*, 265 U.S. 438, 44 Sup. Ct. 529 (1924); *US v. Five Case of Champagne*, 205 F. 817 (S.D.N.Y. 1913); *F.B. Washburn v. U.S.*, 224 F. 395 (1st Cir. 1915); *Libby, McNeill & Libby v. U.S.*, 210 F. 148 (4th Cir. 1913).

<sup>73</sup>*Newton Tea & Spice Co. v. U.S.*, 288 F. 475, 479 (6th Cir. 1923).

<sup>74</sup>*Royal Baking Powder Co. V. F.T.C.*, 4 F.T.C 1 (1921), aff'd 281 F. 744 (2d Cir. 1922).

<sup>75</sup>*U.S. v. One Hundred Cases of Tepee Apples*, 179 F. 985 (W.D. Mo. 1908); *U.S. v. Two Hundred and Sixty-seven Boxes of Macaroni*, 225 F. 79 (W.D. Pa 1915) (mfg. in U.S. printed in small letters where all wording in Italian and name of Italian city used).

courts relaxed their scrutiny.<sup>76</sup>Courts also required the product to satisfy its package's representation as to strength, quality, grade, or purity.<sup>77</sup>There were two narrow statutory exemptions to the basic rule. Mixtures or compounds known as articles of food and sold under their own distinctive names where the distinctive name is accompanied with a statement of the place of manufacture.<sup>78</sup> Compounds, imitations, or blends are not misbranded if plainly tagged or labeled compound, imitation, or blend.

Offering greater specificity than the Pure Food and Drug Act, the Beef Inspection Act, also passed in 1906.<sup>79</sup>Perhaps, as a result of the public outcry from Upton Sinclair's *The Jungle*, a scathing look at the meat packing industry, the act placed more stringent labeling requirements on beef than the Pure Food and Drug Act placed on all other food labels. Beef labels had to list the name of the manufacturer, as a means to facilitate consumer complaints. Boastful adjectives such as best or superfine had to be proven by the manufacturer, or else removed. After having their products tested and approved by the Department of Agriculture, beef producers could use an official USDA seal of approval on their products.

Once, fraud and gross misrepresentation were curbed, it became apparent that more detailed labeling regulations to prevent more subtle forms of misrepresentation. The Gould Amendment of 1913 added the first American federal affirmative labeling requirement, a statement of quantity of the package contents.<sup>80</sup>A similar requirement was later added for meat packaging in 1921.

### **The Food Drug and Cosmetics Act of 1938: Modern Affirmative Labeling**

Reflecting the need for greater regulatory specificity and clarification of the Fades authority, the Federal

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<sup>76</sup>*U.S. v. Thomson & Taylor Spice Co.*, 198 F. 565 (N.D. Ill. 1912).

<sup>77</sup>*W.B. Wood Mfg. Co. v. U.S.*, 286 F. 84 (7th Cir. 1923); *U.S. v. Two Hundred Cases of Canned Salmon*, 289 F. 157 (S.D. Tex. 1923).

<sup>78</sup>*Id.* at 723, citing Regs 18.

<sup>79</sup>Pub. L. No. 59-242, 34 Stat. 1260 (1907); CAMBRIDGE ENCYCLOPEDIA OF FOOD, *supra* note 7, at 1622.

<sup>80</sup>Hutt, P. *Regulating the Misbranding of Food*, 43 FOOD TECHNOLOGY 288, September 1989, in HUTT AND MERRILL, *supra* note 64, at 37.

Food, Drug and Cosmetic Act was passed in 1938. The acts requirements became the standard for food labeling regulation, and even most current food labeling statutes have done little to exceed the regulatory scope of the 1938 Act. Under Section 403(a) “A food shall be deemed to be misbranded if its labeling is false of misleading in any particular.” This language is intended to be comprehensive in character. It is designed to apply to all misrepresentations of whatever kind, whether of origin, identity, quality, effect, or other description or property; whether made as averments of fact or statements of opinion; whether conveyed directly, or by implication.<sup>81</sup> Provision 403(b) and (c) recited the existing law prohibiting the sale of one food under the name of another.<sup>82</sup> 403(d) defines a food as misbranded if its container is so made, formed, or filled as to mislead the purchaser.<sup>83</sup> 403(e)(1), which requires that the label bear the name and place of business of the manufacturer, packer, seller, or distributor, was included as result of industry lobbying efforts to prevent the sale of commodities under labels which remain silent with respect to the sponsorship of the product or which utilize merely fictitious names.<sup>84</sup> 403(f) required informative statements on the label to be prominently displayed and easily readable by the consumer.<sup>85</sup> 403(g) defined a food as misbranded if purports to be a food for which a food standard exists, and it fails to conform to the definition and standard prescribed under the regulation.<sup>86</sup> Standards of identity and definition of particular foods were to be promulgated according to section 401. Even before the 1938 Act, the FDA has informally promulgated 200 standards of identity for food. Over the next thirty years, the FDA would use the authority provided by 401 and 403(g) to establish

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<sup>81</sup>DUNN, CHARLES, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 244 (1938).

<sup>82</sup>*Id.*

<sup>83</sup>*Id.*

<sup>84</sup>*Id.* at 244.

<sup>85</sup>*Id.* at 245.

<sup>86</sup>*Id.*

standards of identity for half of all food consumed in the US.<sup>87</sup> Paragraph (h) applies to foods that fall below the standard of quality and fill of the container.<sup>88</sup> Such food must be labeled as below standard, or else be considered misbranded. Fruits and vegetables were exempted from standards of quality. Paragraph (i) applies to foods that are not governed by any standard of identity. The article is to bear its common or usual name, and the common or usual name of each ingredient. The legislative history stated that:

The requirement is necessary to discourage the practice of coining fanciful, high-sounding names for products composed largely of cheap ingredients, which could not be extensively marketed at the exorbitant prices charged except by cloaking its identity under such a name. Such products are sold in competition with standard food composed of standard ingredients. On the other hand, proprietary food composed of valuable ingredients will gain public confidence and goodwill from disclosure. It should be noted that this provision does not compel the disclosure of formulas... Not only is this paragraph in the interest of fair dealing between manufacturer and consumer, but it has a distinct public-health significance. A surprisingly large proportion of our people are made – some violently so – by common ingredients of food most people consume with impunity.<sup>89</sup> Ironically, the legislative history states that regulations need to be established to exempt food from the naming of ingredients where having a label declaring such information would be impractical, such as in the case of assorted confections or baked products.<sup>90</sup> This is ironic what was then the foremost labeling law exempted baked goods, considered that baked good were precisely the most commonly labeled item in prior years.

Section 403(j) allows the FDA to make detailed regulations concerning special dietary use foods, including

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<sup>87</sup>*Id.* at 246

<sup>88</sup>*Id.* at 247.

<sup>89</sup>*Id.* at 248-49.

<sup>90</sup>DUNN, CHARLES, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD, (1938)

infant foods, invalid foods, slenderizing foods, and other dietary products intended for special nutritional requirements.<sup>91</sup> According to the legislative history, the FDA is authorized to require statements concerning vitamin, mineral, and other properties needed for intelligent use by the consumer.” The science of nutrition is rapidly extending the field of its usefulness. In order to keep abreast of these developments, it is necessary that regulation making power be given. Such was thought particularly necessary in the case of baby foods. In 1941, the FDA used its 403(j) authority to pass regulations on vitamin-mineral supplements, fortified food products, special dietary foods such as infant food, hypo-allergenic food, and weight control food.<sup>92</sup> Finally, Section 403(k) requires labels to indicate the presence of food additives including artificial colors and flavors, and chemical preservatives.<sup>93</sup> Probably due to the revolutionary sweeping scope the act, little overall change in labeling regulations occurred in the three decades following the passage of the Food, Drug, and Cosmetics Act. The Oleomargarine Act of 1950 required clear labels on margarine distinguishing them from butter.<sup>94</sup> The Poultry Act of 1957 authorized the labeling of poultry.<sup>95</sup> The Fair Packaging and Labeling Act of 1966 set up a system for federal preemption of state labeling regulations.

### **The Cutting Edge of Current Labeling Regulation: Nutrition Information**

Beginning in the 1960s, increasing scientific evidence on the effects of nutrition on long term health made apparent the importance of nutrition education as an essential aspect of public health policy. There was considerable evidence regarding the hazards of cholesterol and a fat-rich diet. Long-recognized general health benefits of consuming fruits, vegetables, and complex carbohydrates were bolstered by growing indications of more specific benefits. The new findings were reported in the various government publications previously

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<sup>91</sup>*Id.* at 248.

<sup>92</sup>HUTT AND MERRILL, *supra* note 64, at 39.

<sup>93</sup>*Id.* at 248.

<sup>94</sup>Pub. L. No. 81-459, 64 Stat. 20 (1950).

<sup>95</sup>Pub. L. No. 85-172, 71 Stat. 441 (1957).

mentioned, and the media rapidly spread the word among the public.<sup>96</sup>In 1969, the White House Conference on Food, Nutrition, and Health issued a report recommending that the FDA develop a system for identifying nutritional information about each food.<sup>97</sup> The report also recommended that manufactures be encouraged to provide truthful nutritional content to enable consumers to follow recommended daily intakes of particular nutrients. The report mentioned the need to survey consumers to determine their information needs and their ability to use labeling, as well as the need for an educational campaign to raise consumer awareness on how to use nutrition information in making food consumption decisions.

Partially in response to the report, in 1973, the FDA promulgated regulations on nutrition labeling.<sup>98</sup> Although the regulations made nutrition labeling voluntary on most foods, they set out a standard form for such labels. Labeling was mandatory on foods that added nutrients or made nutritional claims. These provisions were a significant leap in regulatory policy concerning food labels. The USDA, known for being more sensitive to food manufacturer interests than the FDA, waited until 1989 to issue similar guidelines concerning nutritional labels on beef and poultry products.

In 1978 and 1979, the FDA, the USDA Food Safety and Quality Service, and the Federal Trade Commission held public meetings on numerous labeling issues and published a note in the Federal Register regarding a range of issues, including ingredient labeling, nutrition labeling, label format, open dating, disease prevention claims, and standards of identity.<sup>99</sup> However, thanks largely to a still limited scientific consensus on the issue coupled with political forces favoring less regulation, the report did result in any change in regulations.

At the same time that the government failed to respond to increasing scientific evidence on nutrition and long term health effects, the marketplace was responding. By the mid-1980s, food manufactures routinely

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<sup>96</sup>Shank, Fred R., THE NUTRITION LABELING AND EDUCATION ACT OF 1990, FOOD AND DRUG L. J. 247, 248 (1992).

<sup>97</sup>White House Conference on Food, Nutrition and Health., Final Report, (1970).

<sup>98</sup>Food and Drug Administration, Regulations for the Enforcement of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act; Nutrition Labeling. January 19, 1973. Fed. Reg. 38:2125-2132.

<sup>99</sup>US Dept. of Health, Education, and Welfare; US Dept. of Agriculture; and Federal Trade Commission, Advance Notice of Rulemaking, December 21, 1979, Fed. Reg. 44:75990-76020

used nutrient content and disease prevention claims in the marketing of their products. By 1989, 40 percent of the new food products introduced in the first half of the year were labeled with general and specific health claims.<sup>100</sup> Previously, FDA policy was to classify any food product making health claims as an unapproved drug. This policy was a relic of long-standing needs to combat fraud in the peddling of remedies. But the mounting evidence of the connection between diet and effects on long term chronic disease made the FDA consider revision of this policy. In the absence of FDA enforcement while the FDA was in limbo weighing the policy options, state Attorneys General carried on enforcement of the FDA traditional policy, viewing foods making health claims as unapproved drugs.

The fruits of the policy debate were the introduction of legislation in Congress to mandate nutrition labeling on food products, the Nutrition Labeling and Education Act, the new gold standard of food labeling regulation. As a result, US food labeling rules are the most comprehensive in the world. All food products other than raw fish, fruits, and vegetables and food served in cafeteria and restaurants are subject, the stringent food labeling regulations regime. The food label must state calories, fat calories, cholesterol, sodium, protein, carbohydrates, Vitamin A, Vitamin C, calcium, and iron. These mandatory label requirements extend beyond anything required in any other country. Additionally, other vitamins and minerals must be listed if they are added as a supplement, or the packaging or advertising makes a claim about them.<sup>101</sup> For certain types of foods, additional information is mandatory. In foods made with enriched flour, for instance, the label must list thiamin, riboflavin, and niacin levels.<sup>102</sup> Extensive requirements were added to prevent consumer confusion. Type face is carefully specified.<sup>103</sup> Serving size is not only required, but must be a size

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<sup>100</sup>Stephen H. McNamara, *FDA's Rules on Health Claims for Foods—Including the Most Recent Proposed Regulations, Issued Under the Nutrition Labeling and Education Act (NLEA)*, in BUC, NANCY L. & GEOFFREY M. LEVITT EDS., *THE NEW FOOD LABEL: UNDERSTANDING THE CHANGES IN LABELING REQUIREMENTS UNDER THE NUTRITION LABELING AND EDUCATION ACT OF 1990* 62 (1992).

<sup>101</sup>27 C.F.R. 101.9

<sup>102</sup>27 C.F.R. 101.9

<sup>103</sup>27 C.F.R. 101.9(d)

that would be reflective of the quantity that a consumer would actually eat in one sitting.<sup>104</sup> Serving size must be displayed in both common household measurements, such as cups, teaspoons, and tablespoons, as well as in metric units.<sup>105</sup> A product can also be considered mislabeled if it includes extraneous information. “No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label.”<sup>106</sup> Additionally, the label may not indicate that a food has special dietary properties if those properties have no significant value. Likewise, a label may not state that a balanced diet will not supply adequate nutrition, because that statement would imply that a diet including the product being marketed would supply adequate nutrition.

A very innovative feature of the NLEA is congressional emphasis on educating the public about the means to intelligently choose foods and interpret the information that appears on food labels.<sup>107</sup> The FDA also believes that consumers should be made aware of the potential health benefits of foods and that food labels should be clear and informative. Any health claims on the label can stress that a specific nutrient is only part of an overall healthy diet. By placing a health claim in the context of a total diet, the agency is alleviating the danger of consumer reliance on a particular food for therapeutic effects. This educational component of the NLEA is the result of congressional, industry, and agency concerns that consumers lack enough information to make sound dietary choices.

There is a certain brilliance to the NLEA in giving food manufacturers and, to an even greater extent, supermarkets, a new role as consumer educators. In response to the NLEA, the National Food Processors Association, one of the largest and most influential food trade organizations, began a collaborative effort within the industry to develop a food label education guide to help consumers understand new nutrition la-

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<sup>104</sup>27 C.F.R. 101.12(b)

<sup>105</sup>27 C.F.R. 101.9(d)(3) and 109(b)(7).

<sup>106</sup>27 C.F.R. 101.9(c).

<sup>107</sup>Michaels, Mara A., *Comment: FDA Regulation of Health Claims under the Nutrition Labeling and Education Act of 1990: A Proposal for a Less Restrictive Scientific Standard*, 44 EMORY L.J. 319, 323 (1995)

being. Supermarkets educated their own employees, so that industry workers who dealt most directly with consumers could help the consumers make responsible choices given all the information at their disposal thanks to the new labels. Other supermarket operators prepared to recruit dieticians from local hospitals to lead educational tours through stores. Some in the industry see this new educational role as a logical outgrowth of existing consumer-oriented activities, others are concerned that this new educational role will turn the people we have working in our bakeries into doctors, with consumers expecting supermarket employees to make a critical health decision for them. In the environment created by the NLEA, food merchants understood the need to educate their employees and their customers in order to survive in a market inundated with nutrition information.

Prior to NLEA, most food manufacturers viewed food labels as primarily a marketing tool intended to attract and keep consumers. Says one food marketer, only secondarily does it provide basic nutritional information in the words of one industry leader.<sup>108</sup> When faced with the regulations, most food companies maintained that the strict new labeling requirements would get in the way of... saying how wonderful a product is.<sup>109</sup> They believed that so much information will be required that there will be little room for brand names or brand symbols and packages will take on a generic appearance.<sup>110</sup> On the other hand, producers of nutritious and high quality products saw the additional disclosure required by NLEA as free advertising for their products.

#### **Nutrition Labeling Requirement and the Economic Power of Information.**

Returning to our discussion of asymmetries of information, another marketplace hazard faced by consumers is that food producers and sellers, to increase demand for their own product, may overemphasize the nutritional drawbacks of their competitor's products. For example, a maker of low sugar foods might seek to increase sales by overemphasizing the negatives effects of sugar consumption. As result, producer might be

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<sup>108</sup> *The Impact of the Nutrition Labeling Act of 1990 on the Food Industry*, 47 ADMIN L. REV. 606, 618 (1995)

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

able to raise demand for their own products without producing any real benefit to the nutrition level of food consumers.<sup>111</sup> All the food maker has succeeded in doing is oversupplying a nutrition enhanced product beyond the actual societal needs to enhance nutrition.

Government intervention such as the NLEA corrects imperfections in the market for nutrition, and allows the redirection of the flow of information to achieve the socially optimal level of nutrition.<sup>112</sup> Labeling is an information remedy that improves the level of consumer information, consequently minimizing the asymmetry of information, and, in so doing, markedly increases the consumer's bargaining power.<sup>113</sup> This is not to say that consumers will necessarily make wise use of the information that a label provides them. A consumer with strong preferences can simply ignore the information they have been given. And psychological studies have in fact shown that people tend to accept information that agrees with what they already believe, but people tend to discard information that conflicts with what they believe. Nonetheless, nutrition education has a role to play to coincide with food labeling to give consumers maximum bargaining for their relations with food producers and retailers. The NLEA nutrition education efforts truly set it apart from all other food labeling laws.<sup>114</sup> The NLEA is particularly revolutionary in light of the nature of food labeling regulations in the rest of the world. Most food labeling regulation elsewhere has more in common with the Food, Drug and Cosmetics Act of 1938, than the NLEA; this is the case even in other major industrialized countries where one might have instead expected a more hands on approach.

### **European Labeling Regulation in the Twentieth Century: Haphazard and Vague**

Although European countries were far ahead of the US in establishing national food adulteration laws, Eu-

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<sup>111</sup>Henson, *supra* note 41, at 158.

<sup>112</sup>*Id.* at 160.

<sup>113</sup>*Id.* at 161.

<sup>114</sup>For detailed view on the food label as an agent for the improvement of public health, see Merrill, *Food Labels: Couriers of Public Health*, 1 WORLD FOOD REG. REV. 18-21 (1991).

European countries lagged behind the US in developing comprehensive food labeling laws during much of the twentieth century.<sup>115</sup> European food regulation policy was driven by concerns about the economic well being of farmers, national employment levels, and military security. In this environment, nutrition was not even viewed as a legitimate policy priority; instead, with the exception of the period immediately when Europeans needed to organize agricultural production to overcome food shortages, nutrition was primarily dismissed as an issue of concern only to developing countries. This misconception was addressed in 1974 at the World Food Conference, which discussed that need for all countries to have nutrition policies regardless of their level of economic advancement.<sup>116</sup> As a result, a few European countries, including the UK, France, West Germany, and Norway began to consider the importance of nutrition in regulatory policy. However, even after nutrition policy programs were set up, and the need for information and public education were seen as key to elements of nutrition policy, national regulations still failed to mandate labeling on all processed foods.

A major impediment to comprehensive food labeling requirements has been the push to establish a common market. As a result, the food labeling standards in the European Union have often been in lowest common denominator paradigm so that the food can easily be sold anywhere within the EU, rather than what is the most helpful policy for consumers. Any labeling regulations on top of what the EU regulations are not allowed unless the EU makes a special exception.<sup>117</sup> For example, the European Court held that France could not prohibit any reference in the labeling of artificial sweeteners to sugar.<sup>118</sup> The weakness in EU regulations is most obvious in the very basic level of information that is required on any label. EU regulations show the basic policy impulse of attempting to prevent misinformation.<sup>119</sup> Food labeling must not mislead

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<sup>115</sup>CAMBRIDGE WORLD ENCYCLOPEDIA OF FOOD, *supra* note 7, at 1621.

<sup>116</sup>*Id.*

<sup>117</sup>Council Directive 79/112/EEC (OJ 1979 L33/1), article 7(3).

<sup>118</sup>See Case 241/89 *SARPP Sarl v. Chambre Syndicale des Raffineurs et Conditionneurs de Sucre de France* (1990).

<sup>119</sup>LISTER, *supra* note 56, at 53; Council Directive 79/112/EEC (OJ 1979 L33/1), art 5(1).

the consumer as to the characteristics of the foodstuffs, including composition, durability, and method of production. The label must not attribute properties or effects to the food that the food does not have, nor should the label suggest that food possesses special characteristic when the so-called special characteristics are found in all foods. Labels must state the product name<sup>120</sup>, the ingredients<sup>121</sup>, the net quantity<sup>122</sup>, the date of minimum durability<sup>123</sup>, any special storage conditions or conditions of use<sup>124</sup>, the name and address of the manufacturer or packager<sup>125</sup>, particulars of the place of origin in cases where the consumer might be misled as to true origin<sup>126</sup>, and instructions for use in cases where it would be impossible to make appropriate use of the food stuff.<sup>127</sup> However, EU nutrition labeling regulations are a decade behind US regulations. They merely require that a label indicate energy (i.e. calories), protein, carbohydrates, and fat.<sup>128</sup> If the manufacturer wants to list more contents, it can follow the optional big 8 requirements, including the four aforementioned, as well as sugars, saturated fatty acids, roughage, and sodium, or go even further and list six more items (starches, added value alcohols, mono-unsaturated fatty acids, poly-unsaturated fatty acids, cholesterol, and vitamins and minerals. The manufacturer is only required to comply with the big 8 rule if it makes an affirmative nutritional claim on the label.<sup>129</sup> EU members are forbidden from adopting more

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<sup>120</sup>Council Directive 79/112/EEC (OJ 1979 L33/1), article 3(1)(1) 5.

<sup>121</sup>Article 3(2), 6.

<sup>122</sup>Article 8.

<sup>123</sup>Article 9.

<sup>124</sup>Article 10.

<sup>125</sup>Article 3(1)(6).

<sup>126</sup>Article 3(1)(7).

<sup>127</sup>*Id.*

<sup>128</sup>Article 4(1).

<sup>129</sup>LISTER, *supra* note 56, at 76.

detailed nutrition labeling regulations.<sup>130</sup>

### **Austria**

Austrian labeling regulations require the designation of type of food and its consistency, the address or the producer or packager, the food's place of origin, the net amount, the price, the preservability of product, the "consumer before..." date, the storage temperature, the ingredients, instructions for use, and the alcohol content. If the label emphasizes a particular characteristic of the food, such as low fat content, then the label must quantify the claim. Additional labeling regulations apply to sugar and cocoa packages. Packaging may not be confusing or constitute a danger to health. The label may not give the impression that the food cures disease, nor may the label make reference to medical recommendations, or use illustrations concerning organs of the human body.

### **Belgium**

Belgium's food regulations trace back to the era of French rule, with the French Decrees of August 16-28, 1790 and July 19-22, 1791 regarding the control of food hygiene.<sup>131</sup> The first food law passed by the Belgian originated law on food began with the Law of 17 March 1856, prohibiting food tampering. The 1867 Criminal Code contained provision sanctioning fraud regarding the nature, origin, and identity of food products. New laws on food were passed in 1890 and 1964, but neither of these involved labeling requirements.<sup>132</sup> Belgian food labels must list the name of the food, the ingredients, the date, the storage conditions, the name and address of the producer or packager, instructions for use, place of origin (if failure to disclose might mislead consumer as to the food's origin), net quantity, and the alcohol volume if more than 1.2%.

Food labels must be labeled in the language of the region of Belgium being marketed to, i.e. French, Dutch, or German. Minimum durability must be displayed in French or Dutch.

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<sup>130</sup>*Id.*

<sup>131</sup>INTERNATIONAL FOOD AND BEVERAGE LAW, *supra* note 54, at 61-62.

<sup>132</sup>*Id.* at 62.

## European Union

A directive is a requirement by the Council of the EC that all member states shall adopt national measures to meet its objectives. It is a statement of Community objective which must be given effect in every member state by national legislation or, where permitted, by

administrative or voluntary means. A time limit for implementation by member states is normally laid down in the directive and failure to implement a directive in full in due time is actionable by the EC Commission.<sup>133</sup> Any EC regulation is directly binding on all

member states. The regulation must be given effect through imposition of penalties on those regulators who violate it.

Article 30 of the Treaty of Rome, and the Cassis de Dijon judgment of

the European Court of Justice in 1979 established the principle that

any product lawfully marketed in one member state must be admitted to the

market of other member states, unless it is excluded on public health

ground pursuant to Article 36 of the Treaty.<sup>134</sup> EC members are free to legislate nationally only on matters which are not currently the subject of EC law. Even then, proposals for legislation have to be submitted to the Commission before enactment.<sup>135</sup>

The weakness in EU regulations is most obvious in the very basic level of information that is required on any label. EU regulations show the basic policy impulse of attempting to prevent misinformation.<sup>136</sup> Food labeling must not mislead the consumer as to the characteristics of the foodstuffs, including composition, durability, and method of production. The label must not attribute properties or effects to the food that the

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<sup>133</sup>PAINTER, A.A., BUTTERWORTHS FOOD LAW, 1992.

<sup>134</sup>*Id.* at 5.

<sup>135</sup>*Id.* at 6.

<sup>136</sup>Council Directive 79/112/EEC (OJ 1979 L33/1).

food does not have, nor should the label suggest that food possesses special characteristic when the so-called special characteristics are found in all foods. Article 3 of the main Directive governing labeling requires that the label state the product name, the ingredients, the net quantity, the date of minimum durability, any special storage conditions or conditions of use, the name and address of the manufacturer or packager, particulars of the place of origin in cases where the consumer might be misled as to true origin, and instructions for use in cases where it would be impossible to make appropriate use of the food stuff.<sup>137</sup> However, EU nutrition labeling regulations are a decade behind US regulations. They merely require that a label indicate energy (i.e. calories), protein, carbohydrates, and fat. If the manufacturer wants to list more contents, it can follow the optional big 8 requirements, including the four aforementioned, as well as sugars, saturated fatty acids, roughage, and sodium, or go even further and list six more items (starches, added value alcohols, mono-unsaturated fatty acids, poly-unsaturated fatty acids, cholesterol, and vitamins and minerals.<sup>138</sup> The manufacturer is only required to comply with the directive, if it make an affirmative nutritional claim on the label.

### **Germany**

The primary purpose of German food law is to protect the health of the consumer.<sup>139</sup> Protection of the consumer has been an ancillary goal.<sup>140</sup> Food labeling law is governed by Section 17 of the “Draft law on the reform and revisions of the legislation concerning the marketing of food and beverages, tobacco products, cosmetic agents, and other articles of daily use” (LMBG), passed by the Bundestag in 1973.<sup>141</sup> Pre-packaged foods must be labeled with a marketing designation, then name and address of the producer, packager, or seller,

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<sup>137</sup>O’ROURKE, EUROPEAN FOOD LAW 28 (1998).

<sup>138</sup>Council Directive 90/496/EEC (OJ 1990 L276/40).

<sup>139</sup>*Id.* at 143.

<sup>140</sup>*Id.* at 144.

<sup>141</sup>*Id.*

a list of ingredients, and the “best before...” date. If a beverage exceed 1.2 percent alcohol content by volume, then the alcohol content must also be displayed. The required information must be displayed in the German language.

The Batch Labeling Ordinance (LKV) also requires that all marketed food and beverages indicate their batch number, which is assigned by the manufacturer or packager.<sup>142</sup> Optional nutrition labeling information can be displayed pursuant to Ordinance on Information Concerning the Nutrient Value of Foods and Beverages.<sup>143</sup> A product making claims about nutrition must quantify those claims.

### **Hungary**

All packaged foods with greater than 10 centimeters of surface area must display the food’s name, the producer’s name and address (or in the case of imported food, the importer’s name and address), a lot identification code, and a list of all ingredients. Food names of protected indications of provenance and geographical marking as well as certified names of food with special properties are given regulatory protection.<sup>144</sup> The quantity of ingredients is only required to be listed if the food label makes special mention of the food containing particular ingredients.

Foods packaged in an atmosphere with a composition other than that of air in order to extend their shelf life shall be provided, in connection with their name, with the labeling packaged in a protective gas. On the label of foods treated with ionizing radiation and within the same field of vision as the name of the product, the expression treated with ionizing radiation shall be indicated in a distinctly visible manner. Food whose ingredients treated with ionizing radiation do not exceed 5% of the product ready for consumption need not be labeled with the expression treated with ionizing radiation. On foods provided with nutritional recommendations, in addition to the data prescribed for the type of food in question, the designation of the

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<sup>142</sup>*Id.* at 162.

<sup>143</sup>NährwertkennzeichnungsVO of 25 August 1988, BGBl, 1988 I.

<sup>144</sup>Hungarian Rules of Law in Force, Volume VII, Issue 14, (Verzal) July 15, 1996.

nutritional value under the provisions of HFC shall be indicated.

Any label, advertisement or note claiming or implying that the food in question possesses extraordinary nutritional properties different from the average must quantify those claims. Food produced and marketed in this country may be provided with labeling in a foreign language, but text of the Hungarian shall be placed in the main field of vision, and the type-size of the relevant parts thereof shall not be smaller than that of the text in the foreign language.

### **United Kingdom**

Most UK food law results from the implementation of EC Directives and Regulations. In 1990, EC directives were implemented through the Food Safety Act of 1990. A food may not be sold in a manner which falsely describes the food or is likely to mislead as to nature or substance or quality of the food. Food Safety Act 1990, s. 15(1). Like the rest of the EC, UK labeling regulations are controlled by the labeling directive (Council Directive 79/112/EC), which was implemented in the UK as Food Labeling Regulations of 1984.<sup>145</sup> The labeling requirements include the name of the food, a list of ingredients, an indication of durability, any special storage conditions or conditions of use, the name or business name of the manufacturer.

EC members are free to legislate nationally only on matters which are not currently the subject of EC law. Even then, proposals for legislation have to be submitted to the Commission before enactment. In 1990, after a thorough review of food labeling regulations by Food Advisory Committee, a number of labeling regulations were recommended, but these were not implemented due to lack of EC support.

### **Food Labeling Regulation Around the World**

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<sup>145</sup>PAINTER, *supra* note 119, at 47.

In the rest of the world, food labeling regulations are, like in Europe, less extensive than in the U.S.

### **Australia**

Labeling regulation is based on the Food Act of 1981, passed to insure national uniformity in Australian food and drug law.<sup>146</sup> The act was modeled after food acts in the United Kingdom, Ireland, New Zealand, and Canada. Sections 9 and 10 prohibit deceptive labeling. Sec. 14 requires every packaged food item to be labeled with the name of the food and the name and business address of the manufacturer, the vendor or packer, and, in the case of imported food products, the importer.<sup>147</sup> Sec. 15 allows regulations requiring the label to list a statement of ingredients, the place of manufacture, the country of origin, and a date marking with respect to the shelf life of the food.<sup>148</sup> If the label claims that the food item contains a particular ingredient, then the label must list the proportion by weight of that ingredient contained in the food.<sup>149</sup>

### **Bangladesh**

The initial foray into food labeling regulations was The Pure Food Ordinance of 1959, whose primary purpose was to curb food adulteration in what was then East Pakistan.<sup>150</sup> Section 7 covers the prohibition of false labels: 1) No person shall, directly or indirectly and whether by himself or by any other person acting on his behalf, with any article of food sold by him, give to the purchaser a label, whether attached to or printed on the container in which such article is sold or not, which falsely describes that article or is otherwise calculated to mislead as to its nature, substance or quality. 2) In any prosecution under this section, it shall not be a defense to allege that the person who gave such a label had no knowledge and could not with reasonable diligence have ascertained its character.

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<sup>146</sup>GERKENS, MAURICE W., and RANDALL J. GERKENS, FOOD LAW IN AUSTRALIA 1 (1985).

<sup>147</sup>*Id.* at 189.

<sup>148</sup>Sec. 15(a)-(d), *in* GERKENS, *supra* note 122, at 190.

<sup>149</sup>*Id.* at 191, citing sec. 15(5).

<sup>150</sup>Masud, A. R., THE PURE FOOD LAWS 1 (1995).

The Cantonments Pure Food Rules of 1967 set out the mode of labeling of pre-packaged food in s. 13. These rules include affirmative label requirements. All pre-packaged foods must contain a label which indicates 1)the name of the food, 2) the address of the manufacturer or seller, 3) a listing of ingredients, 4)the quantity or weight or the food. Labels are prohibited from making claims about the vitamin or mineral content of the food content of the food, unless the vitamin or mineral is on an approved list of vitamins and minerals (Vitamins A, carotene, b1, B2, nicotinic acid, C, D, D2, and D3, and minerals calcium, iodine, iron, and phosphorous).<sup>151</sup>If the package is too small to specify all information, then some information can be left off the label. Fruit and vegetables (unless canned), milk, eggs, fish (unless canned), and any catered meals are exemption form the basic labeling requirements of s.13-15.<sup>152</sup>However, milk is subject to its own special requirements of s.17.<sup>153</sup>The label must display in Urdu, Bengali, or English the type of animal from which the milk is derived. Every tin of skimmed milk must indicate that in large bold letters that the milk is not fit for consumption by babies.<sup>154</sup>

## **China**

On April 25, 1991 decree 208 announced new standards governing all food labels. The basic principle of Chinese food law labeling law is the prohibition of incorrect, confusing, or deceptive description of the packaged products.<sup>155</sup>Wording, pictures, and other designs that mislead the consumer about the nature of the food product are prohibited. Wording, symbols, and designs must be grammatical, easy to understand, correct, and scientific. Each food label must list the proper name of the product's properties, a table of ingredients,

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<sup>151</sup>*Id.* at 344-45 (citing s. 15).

<sup>152</sup>*Id.* at 345-46 (citing s. 16).

<sup>153</sup>*Id.* at 346-47.

<sup>154</sup>*Id.* at 347.

<sup>155</sup>CHRIS HUNTER, MANAGING ED., ENCYCLOPEDIA OF CHINESE LAW 213 (1993).

net contents, and volume, the manufacturer's name, address, and phone number, the batch number, production date, storage instructions, expiration date, method of use, quality grade, product standard code, and the trademark (Article 4). The label's contents may not be obscured by an external layer of packaging. The label must use standard Chinese characters. Complex forms of simple characters, non-standard simplifications, and incorrectly written characters are prohibited. The use of a foreign language or pinyin romanization of Chinese and foreign is permissible, as long it corresponds to everything written in Chinese characters. Units of measure must only be those authorized by the state.

## India

The object of the Prevention of Food and Adulteration Act of 1954 was to prevent the adulteration and misbranding of food.<sup>156</sup>The label was required to indicate the name or description of the food, the name and business address of the manufacturer or importer, the net weight of the food, and a batch number or code number in Hindi or English, and the month and year in which the product is manufactured or packed.<sup>157</sup>If preservatives, coloring agents, antioxidants, or vitamins have been added to the food, the label must say so.<sup>158</sup>Small packages of biscuits, bread, confectionery, and sweets and carbonated water containers are exempt from the weight and batch number listing requirements.<sup>159</sup>Milk and soft drink bottles, packages containing less than 20 grams, and packages containing bread or uncanned fruits, vegetables, ice cream, butter, cheese, fish, meat, or any other like commodity are exempt from the month and year requirement. Food claiming to be enriched with nutrients such as minerals, protein, or vitamins shall give the quantities of the added nutrients on the label. All

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<sup>156</sup>AGARWAL, R.D., R.B. SETH'S THE PREVENTION OF FOOD ADULTERATION ACT: WITH CENTRAL AND STATE RULES, 10th Ed., 6 (1983).

<sup>157</sup>*Id.* at 799-800.

<sup>158</sup>*Id.* at 799 (citing Prevention of Food Adulteration Rules, 1979, under GSR 55 (E) dated 31-1-79).

<sup>159</sup>*Id.* at 800.

information required by the labeling rules must be written in English, or in Hindi in Devanagari script, though nothing in the rules prevents the use of additional languages. Labels may not contain any statements, claims, designs, fancy names, or abbreviations which are misleading as to the food in the package, the quantity, the nutritive value, or its place of origin. However, existing fancy labels such as Ginger Beer, Gold Spot, and Cream Cracker were exempt from this regulation.<sup>160</sup> Imitation food cannot be marked as pure.<sup>161</sup> Coffee and chicory mixtures must be labeled with a table showing the percentage of coffee and the percentage of chicory. Condensed and dried milk labels must indicate their equivalent in liter of liquid milk.<sup>162</sup> Condensed milk labels must also say NOT TO BE USED BY INFANT BELOW SIX MONTHS. Fluid milk bottles must be marked with a letter to clearly indicate what animal the milk came from. Buffalo milk bottles must be marked with a B. Cow milk bottles must be marked with a C. Goat milk bottles must be marked with a G. Standardized milk bottles must be marked with an S. Toned milk bottles must be marked with a T. Double toned milk bottles must be marked with a DT. Skimmed milk bottle must be marked with K. Pasteurized milk bottles must be marked with a P which appears before the letter indicating the origin of the milk. Every ice cream dealer must display the name and address of the manufacturer of the ice cream. Every label for an article of food containing an addition, admixture, or deficiency must describe the food as containing such.<sup>163</sup> But salt in butter and margarine and vitamins in food are not deemed admixtures. The word pure cannot be used on any food containing

Japan

In Japan, economic policies are planned and implemented to focus on a particular product, and consumer

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<sup>160</sup> *Id.* at 802

<sup>161</sup> *Id.* at 804.

<sup>162</sup> *Id.* at 804-05.

<sup>163</sup> *Id.* at 810.

protection laws also tend to be implemented using a product by product approach. This is dual-edged sword, resulting in both the fragmentation of consumer protection laws and, at the same time, the extremely effective implementation of consumer protection measures.<sup>164</sup> Japanese administrative law contains a jurisdictional split between food adulteration regulation and food labeling regulation. Hazard prevention in food products is regulated by the Sanitary Food Act of 1947 (Shokuhin Eisei Ho, Law No.233) administered by the Health and Welfare Ministry (Kosei-sho), the Agricultural Chemicals Act of 1948 (Noyaku Torishimari Ho, Law No.82) administered by the Ministry of Agriculture, Forestry, and Fisheries (Nosui-sho), the Insuring Safety and Improving Quality of Agricultural Feeds Act of 1953 (Shiryo no Anzensei no Kakuho oyobi Hinshitsu no Kaizen ni Kansuru Horitsu, Law No.35), and the Waterworks Act of 1957 (Suido Ho, Law No.177) administered by the Health and Welfare Ministry.<sup>165</sup> On the other hand, standardization and labeling of food products is governed by the two acts, the Standardization and Proper Representation of Quality for Agriculture and Forestry Products Act (Norin Busshi no kikakuka Oyobi Hinshitsu Hyoji no Tekiseika ni Kansuru Horitsu, Law No.175, 1950), and the Better Nutrition Act (Eiyo Kaizen Ho, Law No.248, 1952). The first act is governed by the Ministry of Agriculture, Forestry, and Fisheries. The Minister of Agriculture, Forestry, and Fisheries establishes certain standards regulating the quality and representations of quality and determines whether those standards are met at the national, prefectural, and local levels. A special JAS mark (Japan Agricultural Standards) may be affixed to products which meets the minister's standards. Submission of JAS appraisal is mostly voluntary. But the Minister may set mandatory standards for representations about the quality of products that are considered of special importance. The Minister can publicly disclose non-compliance with such standards. The second act is administered by the Health and Welfare

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<sup>164</sup>Doing Business in Japan s.8.03[2] (Mathew Bender) (2000).

<sup>165</sup>*Id.* at s. 8.05[a][i].

Ministry<sup>166</sup> Japan is considered more restrictive than most countries in its adoption of industrial and agricultural standards, and many are seen as barriers to trade.

To reflect consumer opinion, the government adds consumer representatives to all investigative committees related to consumer affairs. The government monitors matters of interest to consumers by conducting questionnaires on consumer opinions. The Standardization and Proper Representation of Quality for Agriculture and Forestry Products Act provides for hearing of consumer proposals and complaints.

Japan also has a significant consumer education infrastructure. Consumer problems are discussed in schools and citizens' groups, including women's groups. The Japan Consumer Information Center and local consumers train workers on how to handle consumer complaints. The Japan Consumer Information Center other government ministries and agencies, and local governments attempt to provide useful information consumers by advertising in radio, television, and newspapers. These organizations also conduct tests of how consumer complaints are handled, and publish the results of these tests.<sup>167</sup> Nigeria

Nigerian food and drug law originated in the Food and Drugs Act of 1974, Decree No.35.<sup>168</sup>The law prohibits false and misleading labeling (sec. 5), including packaging likely to lead the food in question to be mistaken for a different food, and allows the Commissioner the power to promulgate regulations with respect to the labeling and packaging of any food (sec. 16(c)(i)). National Agency for Food and Drug Administration and Control (NAFDAC) is charged with regulating labeling.<sup>169</sup>The agency has published Pre-packaged Food Labeling Regulations in 1995, and Bottled Water Labeling Regulations in 1996.

Labeling of any product must indicate name of product and constituents of or ingredients in product as well as manufacturer of product, expiration date, and trademark. Labeling or must not misrepresent nature,

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<sup>166</sup>*Id.* at s. 8.05[1][c].

<sup>167</sup>*Id.* at s.8.06[3].

<sup>168</sup>Nigeria Law Digest *in* Martindale-Hubbell International Law Digest (2001).

<sup>169</sup>NAFDAC Decree No. 15 of 1993.

qualities or origin of product or be otherwise misleading. Information regarding ionization or other special treatment of prepackaged food must be provided; for food products, details of any nutritional claim must be stated on labeling.

### **Pakistan**

Food labeling regulation began with The Pure Food Ordinance of 1960, whose primary purpose was to curb food adulteration and profiteering.<sup>170</sup>Section 7 states simply: “No person shall keep or store for sale, or sell or offer to sell any prepackaged food unless he has complied with the rules made in this behalf.” The relevant rules are sec. 13 and 14 of the Pure Food Rules of 1965. All pre-packaged foods must contain a label which indicates 1)the name of the food, 2) the address of the manufacturer or seller, 3) a listing of ingredients, 4)the quantity or weight or the food.<sup>171</sup>Labels are prohibited from making claims about the vitamin or mineral content of the food content of the food, unless the vitamin or mineral is on an approved list of vitamins and minerals (Vitamins A, carotene, b1, B2, nicotinic acid, C, D, D2, and D3, and minerals calcium, iodine, iron, and phosphorous).<sup>172</sup>If the package is too small to specify all information, then some information can be left off the label. Fruit and vegetables (unless canned), milk, eggs, fish (unless canned), and any catered meals are exemption from the basic labeling requirements of s.13-15.<sup>173</sup>However, reflecting the importance of milk in the diets of young children, milk is subject to its own special requirements of s.18.<sup>174</sup>The label must display in Urdu or English the type of animal from which the milk is derived. Every tin of skimmed milk must indicate that in

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<sup>170</sup>KHAN, A. K., THE PURE FOOD LAWS: WITH LATEST CASE LAW 1 (1992).

<sup>171</sup>*Id.* at 57.

<sup>172</sup>*Id.* at 58-59 (citing s. 15).

<sup>173</sup>*Id.* at 60, (citing s. 16).

<sup>174</sup>*Id.* At 60.

large bold letters inside a dark box that the milk is not fit for consumption by babies.<sup>175</sup> Rule 20-A, added in 1971, is a special provision governing the labeling of tea, another staple of the Pakistani diet.<sup>176</sup> It requires every tea container to list the Pakistan standard number, the name and type of material, the name of the garden or shippers, the batch or code number, net weight in kilograms or pounds. Additionally, each tea package must be marked with a PSI certificate mark.<sup>177</sup>

## **Peru**

Peru is one of the few countries where a consumer's right to information is a principle of Constitutional law. Article 72 of the Peruvian Constitution states that:

The government shall protect the interests of consumers and users. Toward this end, the government guarantees the right of information about goods and services entering the market. The government shall safeguard the health and safety of the population.<sup>178</sup> The Consumer Protection Law regulates the obligation of manufacturers. The law is administered by the National Institute for the Defense of Competition and Protection of Intellectual Property (Instituto Nacional de defensa de la Competencia y de la Propiedad Intelectual, INDECOPI), an entity under the Ministry of Industry, Tourism, Integration, and International trade Negotiations.<sup>179</sup>

Specific regulations were revised in 1990s to streamline the information so as to avoid providing excess information that confuses rather than helps the consumer. Like all product labels, food labels must truthfully provide sufficient, appropriate and easily accessible information regarding the product. Required information on food labels includes a listing of ingredients. All food labeling advertising, and packaging of products

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<sup>175</sup> *Id.* at 60-62.

<sup>176</sup> *Id.* at 63.

<sup>177</sup> *Id.* at 63.

<sup>178</sup> BEATRIZ BOZA, ED., *DOING BUSINESS IN PERU: THE NEW LEGAL FRAMEWORK*, 2d. Ed., 293 (1994).

<sup>179</sup> *Id.* at 293.

manufactured in and intended for consumption in Peru must be in Spanish. Information in Spanish must be added to the labels of imported products.<sup>180</sup> Penalties for violations include fines, confiscation and auctioning of merchandise, temporary shutdown of the business for up to 60 days, and permanent shutdown.<sup>181</sup>

### **Russian Federation**

Article 18 of the Federal Law No. 29-FZ of January 2, 2000 on the Quality and Safety of Food Products requires that food labels display in the Russian language the food's nutritive value (caloric value, content of proteins, fats, carbohydrates, vitamins, and macro and micro elements), the date of manufacture, and the date of packing.<sup>182</sup> Additionally labels on children's food, dietary foods and biological active additives must indicate the food's purpose and conditions of application. Labels on precooked dishes must describe the methods and conditions involved in the manufacture of the dishes.

Products subject to storage regulations must be labeled with an indicator of conditions for storage.<sup>183</sup> **Chal-**

### **lenges of the Future**

#### **Genetically Modified Foods: the latest labeling regulation controversy**

New technology is a frequent source of dilemma in regulatory policy making, and thus it is no surprise that advances in biotechnology have created dilemmas in the food labeling arena. Manipulation of genetics through selective breeding has been critical to agricultural production for thousands of years. However, selective breeding is limited in that it requires lots of time to produce good results because it takes many generations to produce a new organism with desirable characteristics from an agricultural standpoint. Genetic engineering

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<sup>180</sup>*Id.* at 293-94.

<sup>181</sup>*Id.* at 295.

<sup>182</sup>Economic Law of Russia, (Garant) (2001)

<sup>183</sup>Decision Government of the Russian Federation No. 883 of November 22, 2000, Chapter IV, Article 18. General Requirements to Ensuring the Quality and Safety of Food Products: Requirements to Ensuring the Quality and Safety of Food Products in Their Prepackaging, Packing and Marking.

eliminates the limitations of selective breeding. Recombinant DNA techniques can isolate a single gene in an organism and transplant that gene to another organism.<sup>184</sup> *Genetic engineering allows plant breeders greater precision in breeding for desirable*

a result, the gene pool available to a plant breeder seeking to modify the traits in any particular plant is vastly broadened. Potatoes can be modified by inserting the genes of soil bacterium that produce natural insecticides. Corn can be modified to produce a toxin that makes the corn resistant to corn borers. Cheese can be produced using a genetically modified enzyme called chymosin. On the whole, genetically engineered crops may produce higher yields while requiring fewer pesticides and fertilizers, thus making farming more efficient, while at the same time reducing the negative environmental effects of pesticides and fertilizers.<sup>186</sup> Given the many advantages of genetic modification, it is not surprising that at present between twenty-five and forty-five percent of the major crops cultivated in the U.S. are genetically modified.<sup>187</sup> Food labeling policy with regard to genetically modified foods involves a balancing of a consumer's right to know relevant information on their food label versus the need to avoid tainting a perfectly safe product by revealing irrelevant information. Proponents of genetically modified food labeling argue that consumers have a right to know the health risks and in some cases the environmental risk of genetically modified products.<sup>188</sup> Labeling is also seen by opponents of genetically modified production as a means to influence production practice, perhaps by discouraging agricultural producers from using GMO by exploiting their fear of losing customers due to consumer backlash.

On the other hand, labeling opponents view labeling as a means to unfairly stigmatize and discourage the

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<sup>184</sup>Winn, Lara Beth, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks Used by FDA and Food Producer*, 54 FOOD & DRUG L.J. 667 (1999).

<sup>185</sup>*Id.*

<sup>186</sup>*Id.* at 668

<sup>187</sup>*Id.* at 670; Pollack, Andrew, *Biotechnology Treaty Stalls as U.S. and Developing Nations Quarrel*, N.Y. TIMES, Feb. 23, 1999, at A9

<sup>188</sup>Appleton, Arthur E., *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENV'T'L L. J. 566, 567-68 (2000).

development of a extremely promising new technology.<sup>189</sup>Manufacturers are particularly fearful in this regard. They note that in the United Kingdom, sales of a particular brand of tomato paste fell sharply when it was revealed that the paste made from genetically modified tomatoes. Labeling opponents also see labeling as an expensive burden in the production process. It would be particularly costly to separate genetically modified and non-genetically modified products in the production process, especially in the case of fungible products such as corn and soy.

Given this dilemma, different countries have taken quite different approaches to GMO labeling. Switzerland is an interesting case study in the labeling regulation of genetically modified organisms. Switzerland has population very concerned about the environmental effects of technology, but at the same time, the nation has an economy dependent on major food, pharmaceutical and biotech companies, who would benefit from lax regulations of GMOs.<sup>190</sup> Like many consumers all over Europe, Swiss consumers have largely rejected food products containing GMOs.<sup>191</sup>Many major European supermarkets have bowed to consumer pressure by refusing to carry genetically modified food. <sup>192</sup>Consumers fear that consumption of GMO food products will lead to risks to their own health as well as risks to entire ecosystems. Consumers also have ethical concerns, such the worry that GMOs will create a bifurcation of agriculture between rich farmers who can afford the high new varieties and poor farmers who cannot. <sup>193</sup> Switzerland began in the early 1990s to address GM food and genetic engineering issues. In 1992, the Swiss people voted on and passed a referendum in 1992, which resulted in the adoption of a constitutional amendment which required the federal government to consider not only the safety of humans, animals, and the environment, as well as the dignity of creation when

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<sup>189</sup>*Id.* at 569.

<sup>190</sup>*Id.* at 586.

<sup>191</sup>*Id.* at 586-588.

<sup>192</sup>*Id.* at 587.

<sup>193</sup>*Id.* at 587-88.

regulating genetic engineering and GMOs.<sup>194</sup> In 1995, Switzerland adopted regulations requiring a GM food to be approved before it was introduced into the market and that GM food be labeled. In June 1998, the Swiss population rejected by a two-to-one vote a constitutional amendment prohibiting all transgenic animals, all releases of transgenic crops into the environment, and the patenting of certain biotechnological inventions, indicating that there is a broad acceptance of genetic engineering for pharmaceutical, medical, and scientific purposes in Switzerland. This makes sense given the dependence of the Swiss economy on the pharmaceutical industry.

In spite of the vote, most Swiss citizens continue to reject the use of genetic engineering in food production. Because labeling allows provides the consumer with the information to make their choice about whether to GMO products, labeling is a key part of Swiss GMO policy. Prior to June 1999, regulations required all food products containing GMOs to be labeled. However, products may be contaminated unintentionally with GMOs during their growth, production, transportation, and processing, making it impossible to guarantee that even traditionally grown food products that are totally segregated from GMO products are 100% GMO free. Reflecting that concern, since June 1999, regulations have required a food product must be labeled produced with GMOs if any of its ingredients contain more than 1% of GMOs. The consensus is that to fall below this one percent threshold, traditionally grown products must be harvested, transported, and processed separately from those that have been genetically modified.

On the other hand, a food product may be labeled produced without genetic engineering if three criteria are met: no GMOs were used during the production and processing of the food or its ingredients; none of its ingredients contain more than one percent GMOs; and a similar GM food product or ingredient which may be used for the production of this product has been approved for the Swiss market.<sup>195</sup> Due to belief that it is not possible to guarantee that a product is 100% free of GMO contamination, labels proclaiming that a

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<sup>194</sup>*Id.* at 590-91.

<sup>195</sup>Lebensmittelverordnung (LMV), arts. 22b(8) (SR 817.02, March 1, 1995).

food product is GMO free are not permitted under Swiss regulations.<sup>196</sup>

The EU and other countries throughout the world, e.g. South Korea, have also adopted regimes allowing regimes for labeling GMOs. By contrast, the U.S.F.D.A. has decided not to require any special labeling food containing GMOs.<sup>197</sup>The FDA feels that foods containing GMOs but labeled as such are not misleadingly labeled, because a label is only misleading to the extent that it omits material information. Material information is information which the consumer thinks is important and the omission of which may mislead the consumer.<sup>198</sup> The FDA has stated that consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food.<sup>199</sup>The FDA feels that GMOs are only a further advance in the use of selective plant breeding, and apparently not enough.<sup>200</sup> Many commentators have taken exception to the FDA approach, arguing that it has failed to considers sufficiently access consumer's demand for information on GMO foods.<sup>201</sup>

Ultimately, FDA policy may reflect that consumers in the US are not as concerned about GMOs in food as citizens in the rest of the world. Labeling as a regulatory adjustment to the process of industrialization of food. It is not surprising that Europe, which has been much less accepting of the industrialization of food, and is today much less accepting of the further introduction of technology into food, is as well slower to adopt American standards of food labeling. In Europe, tradition seems to play a larger role in the way in which

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<sup>196</sup> *Id.* At 598.

<sup>197</sup> Winn, *supra* note 184, at 669.

<sup>198</sup> *Id.*

<sup>199</sup> 57 Fed. Reg. at 22,991.

<sup>200</sup> *Id.* at 671.

<sup>201</sup> *Id.* at 670

people select the food they eat.<sup>202</sup> Thus, in Europe people are more willing to eat cheeses made from raw milk, even though scientific evidence suggests that such food may be unsafe.<sup>203</sup> European consumers have also been much less accepting of the introduction of biotechnology into the food production process. By contrast, American consumers are much more likely to go along with scientifically verifiable safety levels, and as such are less willing to consume unpasteurized dairy products. American consumers have also been unconcerned about any harmful effects arising from food involving biotechnology, and the US had traditionally been permissive in adopting new technologies of food production.<sup>204</sup> Given this different cultural orientation, it would appear that American consumer may be more receptive to detailed nutrition labeling as a guidepost for them when shopping.

### **The Localism v. Uniformity Dilemma**

Throughout history, whatever labeling regulations on the books have been largely local in nature. To take advantage of extent that the impact of labeling regulations extended beyond the local sphere. Today, although labeling regulation regime in most jurisdictions require the same general information, one can detect local flavors in each jurisdiction's requirements Austria has special labeling regulations governing cocoa and sugar, not surprising given that nations rich tradition of pastry and chocolate making. Hawaii has special regulations for what constitutes poi (a past made from taro root tubers) and oriental noodles; poi is a traditional food of native Hawaiians, and noodles are an important element of the diet of Hawaii's heavily Asian-descent population. Policy makers might see these regulations as essential to prevent adulteration because the FDA, a national regulatory agency with limited resources, might be unlikely to regulate a product such as poi that is unlikely to be consumed anywhere else in the US outside of Hawaii. Minnesota

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<sup>202</sup>Echols, Marsha, *Food Safety Regulation in the European Union and the United State: Different Cultures, Different Laws*, 4 COLUM J. EUR. L. 525, 526 (1998)

<sup>203</sup>*Id.* at 528.

<sup>204</sup>*Id.* at 542.

and Wisconsin have regulations concerning wild rice.<sup>205</sup> New York and Vermont have regulations concerning grading and identity of maple syrup.<sup>206</sup> Some regulations seem clearly designed for no other purpose than to protect the economic interests of a local regions' food producers. Such seems clearly the case in New Mexico where regulations limit pinon nut labeling so that only pinon nuts from two species of pinon trees native to New Mexico can be labeled as pinon nuts.<sup>207</sup>

In a world involving the increasing internationalization of agricultural production, the importance of labeling regulations beyond the borders of that country is an area of increasing concern. In particular, labeling regulations can be viewed as an impediment to global trade. At the same time there is a need to honor local cultural preferences that are reflected in specific local food labeling regulations; some cultures want to be fully aware of new technologies in foods such as GMOs while other cultures may view new production technologies as irrelevant to food consumption choices. Local food regulations also reflect differing national policies with regard to food and nutrition. Simply adopting the lowest common denominator of labeling regulation may enhance trade but do little to serve the interests of a nation and its consumers if no attention is paid to the concerns that prompt differing local labeling regulation.

### **The Choice Paradigm: Labeling as the Instrument Allowing Choice**

In a world where food crosses borders to an extent never before seen, consumers still have strong preferences about the foods they eat. The GMO debate demonstrates that fact all too well. Knowledge of foods gained through clear labeling facilitates exercise of these preferences. Similarly, as nations seek to implement nutrition policies, they will ultimately leave most decisions up to the consumers. Norway is the only country in the world to institute an agricultural policy that plans production levels based on the nutritional needs

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<sup>205</sup>Minn. Stat. s.30.49 and Wis. Stat. 97.57.

<sup>206</sup>N.Y.Agric.&Mkts. Laws.203 and s. 204; Vt. Stat. Ann. Title 6, s.481, s.492, s.493).

<sup>207</sup>N.M. Stat. Ann. s.25-101 to 3.

of the population.<sup>208</sup> Almost everywhere else in the world, consumer demand sets production levels. Given that reality, education of the consumer is the key to getting consumers to consume a nutritious diet. And labeling is major mode of communication of socially beneficial consumer information.

## Conclusion

Having traced the history of food labeling laws, we can see that labeling regulation has come a long way from the branding of bread during the reign of King John in the thirteenth century. The food label has gone from a mere enforcement devise to a marketing tool to an instrument for fulfillment of nutrition policy. Labeling regulation has transformed from simple rules to avoid fraud and mispresentation to complex affirmative requirements to help the consumer understand the labeled food in the context of their overall diet. If the next 100 years involve as much development in food labeling regulations as the past 100 years, then it will be an interesting future indeed.

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<sup>208</sup>Kipple, *supra* note 7, at 1622.