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Andrew J. Nicholas

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# As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods

Andrew J. Nicholas\*

## I. Introduction

The United States Department of Agriculture (“USDA”) recently announced its decision to issue a national seal and to apply national standards to all organic food produced in the United States, assuring consumers that food labeled “organic” is really organic.<sup>1</sup> As of October 21, 2002, all organically grown food in the United States will carry the federal government’s National Organic Seal.<sup>2</sup> Unfortunately, the federal government has failed to provide consumers with the same assurances for genetically modified food. Although genetically modified food is more common than organic food, no national standard system of labeling exists.

Parts II and III of this article will provide a brief description of the organic food and genetically modified food industries. Part IV will analyze current federal regulations controlling both food types,

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\* J.D. candidate, May 2004, Loyola University Chicago School of Law; M.A., Public Administration, 2001, Marywood University; B.A., 1980, American University. The author would like to dedicate this article in memory of his parents, Albert and Louise Nicholas, who believed in their son no matter what. The author would also like to recognize his stepmother, Sandra Beynon Nicholas, for encouraging him to pursue his dreams. And finally, the author would be remiss if he did not thank his loving wife and biggest fan, Penny Lindgren-Nicholas.

<sup>1</sup> See Press Release, U.S. Dep’t of Agric., Veneman Marks Implementation of USDA National Organic Standards (Oct. 21, 2002) (statement of Agriculture Secretary Ann M. Veneman announcing implementation of the USDA’s national organic standards for agricultural products providing consistent labeling on products from coast to coast) (on file with author), <http://www.usda.gov/news/releases/2002/10/0453.htm>.

<sup>2</sup> See *id.*

as well as the regulation of milk produced using Bovine Growth Hormone ("BGH"). Part V will discuss the case law that has developed around the use of BGH. Finally, Part VI will analyze those cases and examine developing legal trends and potential inconsistencies among the courts. Further, this article will highlight the double standard in the American food industry: one standard for organic food growers, requiring them to follow strict guidelines and use a nationally recognized label, and another standard for the biotech industry, which treats genetically modified food the same as conventional food and does not require labeling.

## II. Organic Food

The organic food industry began as a grass roots movement in the 1960s. Since then, it has blossomed into an \$11 billion-a-year business.<sup>3</sup> From 1998 to 2000 alone, organic food sales increased a staggering 29%.<sup>4</sup> The most cited reason for purchasing organic foods is the perceived health benefits.<sup>5</sup>

Consumers also buy organic foods out of concern for the environment.<sup>6</sup> Organic farmers conserve soil and water and do not use pesticides, antibiotics, or growth hormones.<sup>7</sup> In place of synthetic fertilizers, organic farmers use crop rotations, legumes to provide nitrogen to the soil, and livestock manures. These practices tend to conserve or increase organic matter into the soil.<sup>8</sup> They combine established farming methods with modern science to produce sustainable farming systems that rejuvenate and preserve damaged land and produce healthy food with little or no chemical residue.<sup>9</sup> Organic farms use methods such as crop rotation, mechanical cultivation, biological pest control, and organic wastes instead of

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<sup>3</sup> Geoffrey Cowley, *Certified Organic*, NEWSWEEK, Sept. 30, 2002, at 50, available at <http://www.organicconsumers.org/Organic/newsweek092302.cfm>.

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

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

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

<sup>7</sup> AGRICULTURAL MARKETING SERVICE, THE NAT'L ORGANIC PROGRAM: ORGANIC FOOD STANDARDS AND LABELS: THE FACTS, at <http://www.ams.usda.gov/nop/Consumers/brochure.html> (last visited May 15, 2003).

<sup>8</sup> James Stephen Carpenter, *Farm Chemicals, Soil Erosion, and Sustainable Agriculture*, 13 STAN. ENVTL. L. J. 190, 222-23 (1994).

<sup>9</sup> Catherine Sudholz, *Organic Farming: A Growing Trend*, WEEKLY TIMES, Sept. 13, 2000, at 87.

artificial chemicals such as herbicides, pesticides, and fertilizers.<sup>10</sup> For example, weeds are controlled through cultivation, livestock grazing management, rotations, or hand weeding.<sup>11</sup> These farming techniques are designed to improve the quality of the soil, maintain productivity and break disease cycles.

Finally, many consumers think organic foods taste better.<sup>12</sup> Top chefs around the country agree, and some insist on serving foods made from organic ingredients.<sup>13</sup> According to one chef, “when people taste asparagus or string beans grown in richly composted soil, they can’t get over the depth and vibrancy of the flavor.”<sup>14</sup>

But, the benefits of organic foods come with a cost. Organic foods are more expensive than conventional foods.<sup>15</sup> Organic farmers incur additional costs from their labor-intensive weeding practices, more expensive natural fertilizers, and greater crop loss. Moreover, retailers take advantage of the popularity of organic foods and charge a premium.<sup>16</sup> Because they pay extra, it is important that when consumers are buying organic they are getting organic. There are three principal ways consumers can make sure they are getting what they pay for. First, organic foods should be certified.<sup>17</sup> Second, they should be authenticated.<sup>18</sup> Third, and most important for consumers, they should be labeled.<sup>19</sup>

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<sup>10</sup> *Id.*

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

<sup>12</sup> Cowely, *supra* note 3.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* (quoting Executive Chef Peter Hoffman, owner of New York’s Restaurant Savoy and chairman of the Chef’s Collaborative).

<sup>15</sup> EARTHBOUND FARMS ORGANIC, FREQUENTLY ASKED QUESTIONS, at <http://www.ebfarm.com/faq.html> (last visited May 15, 2003).

<sup>16</sup> *Id.*

<sup>17</sup> See Organic Foods Production Act of 1990 § 2107, 7 U.S.C. § 6506(a)(1)(A) (2002).

<sup>18</sup> See ORGANIC CONSUMERS ASS’N, HOW ORGANIC FOOD IS AUTHENTICATED, at [www.organicconsumers.org/organic/edenfood090902.cfm](http://www.organicconsumers.org/organic/edenfood090902.cfm) (last visited May 15, 2003).

<sup>19</sup> See Press Release, U.S. Dep’t of Agric., *supra* note 1.

### III. Genetically Modified Foods

Many foods available at the local grocery store are produced using modern technology. Today, modern biotechnology allows scientists to select genetic material from one organism and insert it into another, thereby creating genetically modified organisms (“GMOs”).<sup>20</sup> Generally, there are three different categories of GMOs.<sup>21</sup> In the first category are crops that have been genetically modified to be insect resistant or herbicide tolerant,<sup>22</sup> for example, tomatoes, potatoes, squash, corn, and soybeans.<sup>23</sup> In the second category are crops whose characteristics have been materially altered.<sup>24</sup> For example, genetically modified canola oil is used as a replacement for cocoa butter. In the third category are GMOs that are used to produce products that are traditionally produced by other means. Bacteria, for example, have been modified to produce the enzyme used in the production of cheese.<sup>25</sup>

GMOs have some benefits, including the production of more nutritious and more flavorful food from disease and drought-resistant plants that require fewer natural resources.<sup>26</sup> GMOs can also increase the food supply, give foods a longer shelf life, and create faster-growing plants and animals.<sup>27</sup> But GMOs also have some drawbacks. For example, there is a risk that modified plants or animals might produce unexpected and harmful genetic changes.<sup>28</sup> Also, it is possible that GMOs could interbreed with natural organisms and displace them, leading to extinction of the original organism.<sup>29</sup> Finally, genetically modified plants might become less resistant to

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<sup>20</sup> J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L. J. 105, 106 (2000).

<sup>21</sup> *Id.* at 107.

<sup>22</sup> *Id.*

<sup>23</sup> YAHOO! INC., GENETICALLY ENGINEERED FOODS, at [http://health.yahoo.com/health/encyclopedia/002432/\\_0.html](http://health.yahoo.com/health/encyclopedia/002432/_0.html) (last visited May 15, 2003).

<sup>24</sup> Beales, *supra* note 20, at 107.

<sup>25</sup> *Id.*

<sup>26</sup> YAHOO! INC., *supra* note 23.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

some pests and more susceptible to others.<sup>30</sup>

The dairy industry provides an instructive example of some of the advantages and disadvantages of genetically modified organisms. Researchers have found a way to increase the milk production of cows beyond their natural capacity by giving them a drug named Posilac.<sup>31</sup> Posilac is commonly known as recombinant bovine somatotrophin (“rBST”), or bovine growth hormone (“BGH”).<sup>32</sup> BGH is a synthetically created version of a hormone that occurs naturally in cows to regulate milk production.<sup>33</sup> It was the first genetically modified product approved for use in livestock food production.<sup>34</sup> Cows injected with BGH show a 10–15% increase in milk production.<sup>35</sup> That increase, coupled with relatively stable consumer demand, saves natural resources because fewer cows are needed on the farm.<sup>36</sup>

Unfortunately, there may be health risks to cows and humans associated with the use of BGH. The greatest risk to cows is an increase in the incidence of mastitis, an inflammation of the udders usually caused by infection.<sup>37</sup> According to some studies, the health risks to humans are also considerable. Milk produced using BGH has higher levels of Insulin Growth Factor-One (“IGF-1”) than non-BGH milk, and IGF-1 has been linked to several forms of cancer.<sup>38</sup> The FDA approved Posilac despite studies by the Council of Scientific Affairs, a part of the American Medical Association, that found research on the drug to be insufficient.<sup>39</sup> Studies have since suggested

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<sup>30</sup> *Id.*

<sup>31</sup> Terence J. Centner & Kyle W. Lathrop, *Labeling rBST-Derived Milk Products: State Responses to Federal Law*, 45 KAN. L. REV. 511, 511–12 (1997).

<sup>32</sup> Kirsten S. Beaudoin, *On Tonight’s Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 243 (1999).

<sup>33</sup> Centner & Lathrop, *supra* note 31, at 511.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 513.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 514.

<sup>38</sup> Beaudoin, *supra* note 32, at 247–48.

<sup>39</sup> Jennifer R. Thornley, *Got “Hormone-Free” Milk?: Your State May Have Enough Interest to Let You Know*, 76 IND. L. J. 785, 793 (2001).

an increased risk of colon cancer<sup>40</sup> and breast and gastrointestinal cancers from milk produced using BGH.<sup>41</sup>

In addition, higher levels of antibiotics are given to cows with mastitis, and those antibiotics are passed along to humans when they drink milk.<sup>42</sup> Long-term exposure to even small levels of antibiotics can cause humans to develop a resistance.<sup>43</sup> The Centers for Disease Control (“CDC”) has, in the past, issued warnings of a “major public health crisis” when certain disease-causing bacteria failed to respond to treatment with antibiotics.<sup>44</sup> The CDC has also found a link between the injection of antibiotics into animals and increased human resistance to antibiotics.<sup>45</sup> Nevertheless, the federal government does not require the labeling of milk produced using BGH.<sup>46</sup>

#### IV. Regulation

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (“FDCA”) to protect the public health.<sup>47</sup> Although it establishes fundamental objectives, the FDCA does not mandate any specific regulations.<sup>48</sup> It does, however, require the FDA to consider four factors before approving a drug: (1) the likelihood that the drug or a substance the drug causes to be formed in food will be consumed, (2) the cumulative effect that the drug will likely have on humans or other animals, (3) safety factors that experts consider

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<sup>40</sup> Thornley, *supra* note 39, at 793 n.79.

<sup>41</sup> *Id.* at 793 n.80 (noting a finding by the public health committee commissioned by the European Commission that showed an increase in “highly potent variants” of IGF-1 and concluding that this increase posed serious risks of breast and prostate cancer).

<sup>42</sup> Emily Marden, *Recombinant Bovine Growth Hormone and the Courts: In Search of Justice*, 46 DRAKE L. REV. 617, 623–24 (1998).

<sup>43</sup> Thornley, *supra* note 39, at 793.

<sup>44</sup> *Id.* at 793–94 (citing David Abouafia, *Pushing RBST: How The Law And The Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 603, 605 (1998)).

<sup>45</sup> *Id.* at 794.

<sup>46</sup> Centner & Lathrop, *supra* note 31, at 517.

<sup>47</sup> Federal Food, Drug, and Cosmetic Act, ch. 675 § 1, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301–399 (2002)).

<sup>48</sup> Michele J. Brace, *Regulation of Genetically Engineered Foods Under the Federal, Food, Drug, and Cosmetic Act*, 33 AM. U. L. REV. 899, 902 (1984).

appropriate for extrapolating from animal experimentation data, and (4) whether it is likely that the conditions of use proposed or suggested in the labeling will be followed.<sup>49</sup> The FDCA further prohibits any adulterated foods from being put into interstate commerce.<sup>50</sup> In general, a food is “adulterated” if it “bears or contains any poisonous or deleterious substance which may render it injurious to health,”<sup>51</sup> or if the food is missing “any valuable constituent” normally found in that food.<sup>52</sup>

The FDA’s oversight authority extends to all foods, organically produced as well genetically modified.<sup>53</sup> For oversight purposes, however, the FDA treats organic foods and genetically modified foods the same.<sup>54</sup> Current federal regulations fail to distinguish between the two foods based on the method of production, and instead regulate based on the particular food itself.<sup>55</sup>

### A. Regulation of Organic Foods

On November 28, 1990, Congress passed the Organic Food Production Act (“OFPA”), establishing national standards for organic food in the United States.<sup>56</sup> The OFPA has three purposes: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in organically produced products.<sup>57</sup> Although the OFPA allows producers who meet

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<sup>49</sup> See *Stauber v. Shalala*, 895 F. Supp. 1178, 1191 (W.D. Wis. 1995) (citing 21 U.S.C. § 360b(d)(2) and 21 C.F.R. § 514.111(a)(4)).

<sup>50</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(b), (g) (2002). The FDCA defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” *Id.* § 321(f).

<sup>51</sup> *Id.* § 342(a)(1).

<sup>52</sup> *Id.* § 342(b)(1).

<sup>53</sup> Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant bST*, 22 COLUM. J. ENVTL. L. 227, 252 (1997).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> Organic Foods Production Act of 1990, Pub. L. No. 101-624, 104 Stat. 3935 (codified as amended at 7 U.S.C. §§ 6501–6523 (2002)).

<sup>57</sup> See Organic Foods Production Act of 1990, 7 U.S.C. § 6501(1)–(3).



the standards to use a seal of approval on their organic food labels,<sup>58</sup> the seal did not become a reality for twelve years.<sup>59</sup>

The OFPA also created a panel of experts known as the National Organic Standards Board (“NSOB”) to advise the USDA on organic foods.<sup>60</sup> The NSOB is made up of members with diverse backgrounds in areas such as organic farming, organic retailing, environmental protection and resource conservation, consumer interest, biotechnology, and organic certification.<sup>61</sup> The OFPA also directed the USDA to establish a “National List” of substances approved for use in organic production.<sup>62</sup> In order to be labeled “certified organic,” foods must comply with the National List.<sup>63</sup>

The USDA is responsible for implementing the OFPA, but it has traditionally promoted the latest technologies developed by agribusiness and biotech companies, which creates an inherent conflict of interest.<sup>64</sup> This conflict explains, in part, why so many of the NSOB’s policy proposals have been rejected.<sup>65</sup> It also explains why, under USDA control, NSOB proposals for “organic” standards have included the use of genetic engineering, nuclear irradiation, pesticides, toxic sewage sludge fertilizers, and other practices incompatible with organic farming.<sup>66</sup>

The OFPA was a great start for the organic food industry, but it fell short. Although it established guidelines for growing, certifying, handling, and marketing organic foods, it did not provide a definition for organic food. Nor did it provide a labeling system for organic foods. A workable definition and a national labeling system did not come until the USDA’s national organic seal was issued twelve years after the OFPA.<sup>67</sup>

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<sup>58</sup> See 7 U.S.C. § 6505(a)(2).

<sup>59</sup> Press Release, U.S. Dep’t of Agric., *supra* note 1.

<sup>60</sup> See 7 U.S.C. § 6518.

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

<sup>62</sup> See 7 U.S.C. § 6517(c)(1)–(c)(2).

<sup>63</sup> 7 U.S.C. § 6517(a).

<sup>64</sup> Beaudoin, *supra* note 32, at 268–69.

<sup>65</sup> *Id.* at 269.

<sup>66</sup> *Id.*

<sup>67</sup> Elizabeth Becker, *Organic Gets an Additive: A U.S.D.A. Seal to Certify It*, N.Y. TIMES, Oct. 21, 2002, at A10.

## 1. Certification

The OFPA governs organic certification; one of its purposes is to establish national standards for the marketing of organic agricultural products.<sup>68</sup> The Secretary of Agriculture implements the certification program through certifying agents.<sup>69</sup> A certifying agent is the chief executive officer of a state or any person accredited by the Secretary as a certifying agent for the purpose of certifying organic farms.<sup>70</sup>

Farmers who gross over \$5000 annually in sales must be certified in order to sell or label their products as organic.<sup>71</sup> Section 6505 of the OFPA sets the guidelines for certification of producers of organic livestock and food and fiber crops, as well as handlers of organic products.<sup>72</sup> A handler is any operation that receives, processes, packages, or stores agricultural products.<sup>73</sup> For example, a processing company that buys organic tomatoes and makes canned organic spaghetti sauce must be certified in order to advertise their product as “organic.”

Farmers who gross less than \$5000 annually are exempt from certification, but they must sign a declaration stating that they are in compliance with the certification process.<sup>74</sup> They cannot use the term “certified organic” when marketing their products, and can sell their products only through direct sales (for example, farm stands or farmers’ markets).<sup>75</sup>

A farmer or handler seeking certification must submit an “Organic Plan” to a USDA-accredited certification program.<sup>76</sup> The plan must detail all current growing or handling methods and any materials that will be used during production.<sup>77</sup> It must also include

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<sup>68</sup> See Organic Foods Production Act of 1990, 7 U.S.C. § 6501 (2002).

<sup>69</sup> *Id.* § 6503(d).

<sup>70</sup> *Id.* § 6502(3).

<sup>71</sup> *Id.* § 6505(d).

<sup>72</sup> See *id.* § 6505.

<sup>73</sup> *Id.* § 6502(8), (9).

<sup>74</sup> ORGANIC CERTIFICATION, RESOURCES & LINKS, at <http://www.organic.org/7/guide/certification.html> (last visited May 15, 2003).

<sup>75</sup> *Id.*

<sup>76</sup> See 7 U.S.C. § 6513(a).

<sup>77</sup> See *id.*

future intentions and improvements to all areas of production.<sup>78</sup> Even growers of organic wild crops, such as fiddlehead ferns, must develop a plan showing that harvesting practices will not be destructive to the environment or to future crops.<sup>79</sup> The plan must include a three-year history of the management of the farmland showing that no prohibited substances have been applied.<sup>80</sup>

## 2. Authentication

After a farm or handling operation receives organic certification, certifying agents perform periodic on-site inspections.<sup>81</sup> Inspections of commercial farms provide authentication through what is known as an “audit trail.”<sup>82</sup> An audit trail is a series of documents that allows food to be traced back to its source.<sup>83</sup> The audit trail starts at the farm, with detailed field maps showing farm layout, boundaries, hedgerows, and buffer zones.<sup>84</sup> Producers who operate a certified organic farm or handling operation must maintain records going back a minimum of five years.<sup>85</sup> Records of seeds and crop samples are especially important to ensure that no chemically treated or genetically engineered seeds are used.<sup>86</sup> An organic farm’s audit trail also includes storage records, water tests, inspection reports, sales records, and a lot numbering system.<sup>87</sup>

Each organic food is assigned a lot number that follows it all the way to the distributor or grocer.<sup>88</sup> Lot numbers are used through every stage of the growing, storage, transportation, handling, processing, and distribution process, which allows the product to be

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<sup>78</sup> See 7 U.S.C. § 6513(a).

<sup>79</sup> See *id.* § 6513(f).

<sup>80</sup> *Id.* § 6513(f)(2).

<sup>81</sup> *Id.* § 6506(a)(5).

<sup>82</sup> ORGANIC CONSUMERS ASS’N, *supra* note 18.

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

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

<sup>85</sup> 7 U.S.C. § 6511(d).

<sup>86</sup> ORGANIC CONSUMERS ASS’N, *supra* note 18.

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

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

traced from the field to the grocers' shelves and back again.<sup>89</sup> After organic food and livestock is certified and authenticated, the next step before going to market is to affix the USDA's national organic seal.

### 3. Labeling

As of October 21, 2002, all foods labeled organic were required to meet to the USDA's standards.<sup>90</sup> Called "Organic Monday," the day was hailed by organic farmers, environmental groups, consumers, and chefs as a huge day for the organic food industry.<sup>91</sup> These groups lobbied for national standards for twelve years, and it finally paid off.<sup>92</sup>

Previously, the definition of "organic" varied from one state to the next, leaving consumers confused.<sup>93</sup> Today, all products meeting the new national organic standard are required to follow the new USDA organic labeling guidelines.<sup>94</sup> Existing certification and authentication requirements have not changed, and farms and handlers of organic food are still bound by the OFPA.<sup>95</sup> Two things have changed, however. First, the federal government has promulgated a clear definition of organic food.<sup>96</sup> Section 6502 of the OFPA did not define organic food; it simply stated that "'organically produced' means an agricultural product that is produced and handled in accordance with this title."<sup>97</sup> Second, food that meets the definition is labeled with the new national organic seal.<sup>98</sup> Previously, foods were labeled either "organic" or "all natural" or some variation thereof.

Today, labeling requirements are based on the percentage of

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<sup>89</sup> *Id.*

<sup>90</sup> Press Release, U.S. Dep't of Agric., *supra* note 1.

<sup>91</sup> Becker, *supra* note 67 (coining the term "Organic Monday" in her article announcing the debut of the USDA Organic Seal).

<sup>92</sup> *Id.*

<sup>93</sup> Cowley, *supra* note 3.

<sup>94</sup> Press Release, U.S. Dep't of Agric., *supra* note 1.

<sup>95</sup> Telephone Interview with Neil O'Manski, Congressional Department, United States Department of Agriculture (Apr. 29, 2003).

<sup>96</sup> See National Organic Program, 7 C.F.R. §§ 205.300–309 (2002).

<sup>97</sup> Organic Foods Production Act of 1990, 7 U.S.C. § 6502(14) (2002).

<sup>98</sup> 7 C.F.R. § 205.311.

organic ingredients in a product.<sup>99</sup> To be eligible for the new label, foods must fall into one of four categories: (1) 100 % organic, (2) organic, (3) organic ingredients, or (4) some organic ingredients.<sup>100</sup>

Foods in the "100% organic" category contain only organically produced ingredients, excluding water and salt, and cannot be processed with non-organic additives.<sup>101</sup> Products that are 95–99% organic bear the label "organic." Many products are labeled "organic" instead of "100% organic" because some ingredients, by their nature, cannot be organic, such as salt and baking powder.<sup>102</sup> Products that are only 70–94% organic carry the label "organic ingredients" and cannot carry the "organic" label.<sup>103</sup> Nevertheless, such products may be labeled "made with organic ingredients," and the label may list up to three organic ingredients.<sup>104</sup> Foods with "some organic ingredients" are less than 70% organic and cannot carry the new seal.<sup>105</sup> The word "organic" cannot be displayed anywhere on the front of the packaging, although organic ingredients can be identified on the list of ingredients.<sup>106</sup>

The OFPA enforces the accuracy of the labels.<sup>107</sup> Anyone who mislabels a product as organic faces a fine of up to \$10,000.<sup>108</sup> The Secretary of Agriculture, the applicable governing State official, and certifying agents are also responsible for residue testing to assist in enforcement.<sup>109</sup> These standards allow consumers to buy organic products with confidence.

## B. Regulation of Genetically Modified Foods

Although the organic food industry is governed by a set of national standards, the biotech industry is not. And, although 25 to

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<sup>99</sup> AGRICULTURAL MARKETING SERVICE, *supra* note 7.

<sup>100</sup> *Id.*

<sup>101</sup> National Organic Program, 7 C.F.R. § 205.301 (2002).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> See Organic Foods Production Act of 1990, 7 U.S.C. § 6519 (2002).

<sup>108</sup> *Id.*

<sup>109</sup> See 7 U.S.C. § 6511(a).

45% of the major crops grown in the United States are genetically modified, the Federal Government has deemed it unnecessary to establish national labeling standards.<sup>110</sup> Instead, genetically modified foods are governed by existing regulatory standards under the FDCA.<sup>111</sup> Unfortunately, when Congress passed the FDCA, it could not have foreseen the vast changes in genetically modified food.

In 1958, Congress amended the FDCA by passing the Food Additives Amendment, authorizing the FDA to seize adulterated foods before they enter the market.<sup>112</sup> The amendment further required manufacturers to obtain pre-market approval before using food additives.<sup>113</sup> Under the FDCA, a food additive is presumed unsafe unless a qualified person determines it to be generally recognized as safe.<sup>114</sup> Once a product is approved for a specific use, any manufacturer can use it without pre-market approval.<sup>115</sup>

The FDCA grants authority for food labeling to the FDA.<sup>116</sup> Although the FDA does not require special labeling for genetically modified foods, it has advised that labeling requirements that apply to foods in general also apply to genetically modified foods.<sup>117</sup> Therefore, genetically modified foods are presently regulated under the existing framework of the FDCA.<sup>118</sup> The requirements for labeling under the FDCA are very broad; they merely require that labeling bear the common or usual name of the food.<sup>119</sup> The FDCA also prohibits foods that are misbranded; a food is misbranded if its

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<sup>110</sup> See Alicia T. Simpson, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Food?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 226–27 (2001).

<sup>111</sup> See Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L ENVTL. L. REV. 779, 799 (2000).

<sup>112</sup> Brace, *supra* note 48, at 906.

<sup>113</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(b) (2002).

<sup>114</sup> See 21 U.S.C. 348(a); see also Brace, *supra* note 48, at 908.

<sup>115</sup> Brace, *supra* note 48, at 909 (citing Edward L. Korwek, *FDA Regulation of Biotechnology as a New Method of Manufacture*, 37 FOOD DRUG COSM. L. J. 289 (1982) (discussing regulation of biotechnology process under the Act)).

<sup>116</sup> See 21 U.S.C. § 343 (2002) (regulating “misbranded food”).

<sup>117</sup> See Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (1992).

<sup>118</sup> *Id.*

<sup>119</sup> See 21 U.S.C. § 343(i)(1).

labeling is false or misleading.<sup>120</sup>

### C. Regulation of Bovine Growth Hormone

BGH is produced in laboratories using recombinant technologies and is injected into the bloodstream of a cow to increase milk production.<sup>121</sup> Although milk produced using BGH is not genetically modified, the FDA treats milk produced using BGH and genetically modified foods the same.<sup>122</sup> The Monsanto Company manufactures the BGH drug, Posilac.<sup>123</sup> Monsanto was required to apply for approval with the FDA.<sup>124</sup> It filed its application with the FDA in 1987 and supplemented it with studies documenting its safety.<sup>125</sup> The FDA approved Posilac for use in November of 1993.<sup>126</sup>

The FDA approved BGH despite considerable criticism and safety concerns from scientists, economists, farmers, and environmental groups.<sup>127</sup> In addition, the FDA received thousands of letters from consumers asking it to deny approval or to require labeling of milk products derived from cows treated with BGH.<sup>128</sup> The FDA decided that it was unnecessary to label these products and instead required that Posilac be labeled upon shipment to farmers.<sup>129</sup> In addition, the FDA concluded that there was no appreciable difference between milk products from BGH-treated cows and milk from untreated cows, and issued an interim guidance on voluntary

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<sup>120</sup> See 21 U.S.C. § 343(a).

<sup>121</sup> Simpson, *supra* note 110, at 227; see also *id.* at 226 n.1 (explaining that the term "recombinant DNA technologies" refers to the techniques such as hybridization, chemical or radiation-induced mutagenesis, cell culture, embryo rescue, and protoplast used by scientists to transfer discrete pieces of genetic material from one kind of plant, animal, or microorganism into another, sometimes quite different, animal, plant, or microorganism).

<sup>122</sup> *Id.* at 233 n.12.

<sup>123</sup> Centner & Lathrop, *supra* note 31, at 515.

<sup>124</sup> Elie Gendloff, Stauber v. Shalala: *Are Environmental Challenges to Biotechnology Too Difficult?* 4 WIS. ENVTL. L. J. 41, 51 (1997).

<sup>125</sup> Stauber v. Shalala, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995).

<sup>126</sup> *Id.*

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

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 1186.

labeling of milk from untreated cows.<sup>130</sup> The FDA concluded that producers could not label such milk “rBST free,” because rBST occurs naturally in milk, but allowed them to label it “from cows not treated with rBST.”<sup>131</sup>

## V. Litigating Bovine Growth Hormone

### A. *Stauber v. Shalala*

In *Stauber v. Shalala*, a group of American consumers of commercially produced milk challenged two FDA decisions: (1) its approval of Posilac, and (2) its decision not to require labeling of milk products derived from cows treated with BGH.<sup>132</sup> The court imposed an onerous standard of review: if the FDA considered all relevant factors and the court could discern a rational basis for the agency’s decision, the court would uphold the decision.<sup>133</sup> It refused to conduct a *de novo* review of the agency’s decision and its factual underpinnings.<sup>134</sup> Rather, the court held that it was limited to reviewing only evidence considered by the FDA.<sup>135</sup>

The plaintiffs argued that the FDA’s decision to approve Posilac was arbitrary and capricious for three reasons.<sup>136</sup> First, they argued that the Posilac label does not adequately address the health risks to cows.<sup>137</sup> The side effects could only be managed properly if

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<sup>133</sup> *Id.* at 1186; *see also* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that have not been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994). Although the FDA published its Interim Guidance of labeling standards for the States to follow, ambiguities remained on what was allowable. The guidelines provided that labeling may be made voluntary and that all labels contain the following statement: “No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.” Although the guidelines did not require labeling, it was unclear whether they permitted mandatory labeling laws—leaving it up to the states to adopt their own laws.

<sup>131</sup> *Stauber*, 895 F. Supp. at 1186 (quoting 59 Fed. Reg. 6279–80 (1994)).

<sup>132</sup> *See id.* at 1190–93.

<sup>133</sup> *See id.* at 1189.

<sup>134</sup> *See id.* at 1189–90.

<sup>135</sup> *See id.* at 1190.

<sup>136</sup> *Id.* at 1182.

<sup>137</sup> *Stauber*, 895 F. Supp. at 1191.



the farmers were able to adopt herd management techniques and programs as recommended by the Posilac label.<sup>138</sup> But, the plaintiffs contended, the Posilac label would be confusing to farmers and therefore ineffective.<sup>139</sup>

Second, the plaintiffs argued that the FDA did not adequately consider the risk of higher levels of antibiotic drug residues in milk consumed by humans.<sup>140</sup> Higher levels of antibiotics create a resistance to certain bacteria, particularly human digestive bacteria.<sup>141</sup> In addition, the plaintiffs argued that the regulatory scheme for testing drugs used to treat infected dairy animals is inadequate.<sup>142</sup>

Third, the plaintiffs argued that the FDA did not adequately consider the risks associated with an increased level of Insulin Growth Factor-One ("IGF-1") in milk from cows treated with Posilac.<sup>143</sup> IGF-1 is a protein hormone with the same biochemical composition in humans and cows and is linked to several forms of cancer.<sup>144</sup> There is also some evidence that the form of IGF-1 found in the milk of cows treated with BGH is especially potent.<sup>145</sup>

Although the *Stauber* court agreed that the plaintiffs had valid concerns about the use of Posilac, it concluded that the FDA's decision to approve the drug was not arbitrary and capricious.<sup>146</sup> First, the court held that the FDA adequately assessed the health risks to cows and that its conclusion that Posilac posed a lower risk of mastitis than other causes, such as seasonal changes, was not irrational.<sup>147</sup> Although mastitis can be a serious problem, the court reasoned, it is not new to dairy farmers, and they are familiar with its diagnosis and treatment.<sup>148</sup> Second, the court held that the record supported the FDA's decision to rely on the current regulatory scheme to prevent an increase in the levels of antibiotics consumed

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<sup>138</sup> *Stauber*, 895 F. Supp. at 1191.

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

<sup>140</sup> *Id.* at 1192.

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

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

<sup>143</sup> *Id.* at 1192.

<sup>144</sup> *Stauber*, 895 F. Supp. at 1185; *see also* Thornley, *supra* note 39, at 793.

<sup>145</sup> Beaudoin, *supra* note 32, at 248.

<sup>146</sup> *See Stauber*, 895 F. Supp. at 1191-92.

<sup>147</sup> *See id.*

<sup>148</sup> *See id.*

by humans.<sup>149</sup> The court was persuaded by the FDA's determination that, because the increased risk of mastitis from Posilac was not great, the rise in the use of antibiotics to treat mastitis would not be great either, especially because milk was already being tested for the drugs most commonly used to treat mastitis.<sup>150</sup> Third, the court upheld the FDA's determination that increased levels of IGF-1 was not a significant human health concern.<sup>151</sup> The FDA based its determination on a two-week rat study conducted by Monsanto, which resulted in no adverse affects, and on other evidence indicating that levels of IGF-1 increased only slightly in cows treated with BGH.<sup>152</sup> Although no long-term studies had been done, the court held that the plaintiffs presented no admissible evidence that would show the two-week rat study was inadequate.<sup>153</sup> Without any admissible evidence to refute the FDA's conclusions, the court held that its decision was not arbitrary and capricious.<sup>154</sup>

The plaintiffs in *Stauber* next argued that the FDA's decision not to require labeling of food products derived from cows treated with Posilac was arbitrary and capricious under 21 U.S.C. § 343(a)(1), which prohibits "false or misleading" labeling, and 21 U.S.C. § 321(n), which defines "misbranding."<sup>155</sup> If a product is alleged to be misbranded, the FDA must determine whether the label fails to reveal any material fact.<sup>156</sup> Material facts are facts that are representative of the product or facts that indicate consequences as a result of use of the product.<sup>157</sup>

First, the plaintiffs argued that milk derived from cows treated with Posilac is materially different from ordinary milk because human sense organs can tell the difference.<sup>158</sup> Therefore, the plaintiffs contended, if the milk is not labeled, it is misleading under

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<sup>149</sup> *See id.* at 1192.

<sup>150</sup> *See id.*

<sup>151</sup> *See id.* at 1192.

<sup>152</sup> *See Stauber*, 895 F. Supp. at 1192.

<sup>153</sup> *See id.*

<sup>154</sup> *See id.*

<sup>155</sup> *Id.* at 1192-93.

<sup>156</sup> *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n) (2002).

<sup>157</sup> *See id.*

<sup>158</sup> *Stauber*, 895 F. Supp. at 1193.

§ 343(a)(1) and misbranded under § 321(n).<sup>159</sup> Second, the plaintiffs argued that consumer demand for labeling of milk products from cows treated with BGH is strong and that this “high demand” is a material fact.<sup>160</sup> The FDA does not ordinarily consider consumer demand when making labeling decisions.<sup>161</sup> Instead, it considers only whether there are material differences between what the product is and what it purports to be.<sup>162</sup>

The court concluded that, because the plaintiffs did not present any evidence showing perceptible differences between regular milk and milk from cows treated with BGH, or demonstrate any harmful effects from that milk to consumers, they failed to show that the FDA’s decision not to require labeling of milk products derived from cows treated with Posilac was arbitrary and capricious.<sup>163</sup>

## B. Monsanto Fights Back

After *Stauber*, and armed with the FDA’s voluntary labeling policy,<sup>164</sup> two dairy marketing firms began to label their milk as produced from “untreated cows.”<sup>165</sup> The Monsanto Company sought an injunction against the firms, Swiss Valley Farms, Inc., and Pure Milk & Ice Cream Company.<sup>166</sup> Monsanto claimed that the labels gave consumers the impression that the defendants’ milk was safer or of higher quality than ordinary milk.<sup>167</sup> These cases never went to trial, and the settlement agreements are not available to the public; it is unclear whether the defendants were permitted to continue using their labels.<sup>168</sup>

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<sup>159</sup> *Stauber*, 895 F. Supp. at 1193.

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

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

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

<sup>163</sup> *See id.*

<sup>164</sup> *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that have not been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994).

<sup>165</sup> *Monsanto Sues Two Dairies with Hormone-Bashing Labels on Milk*, *Biotechnology Newswatch*, Mar. 7, 1994, available at 1994 WL 2260191.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *See* Wesley J. Smith, ‘Scorched Earth’ Litigation Corrupts Judicial

Nevertheless, Monsanto sent a clear message to the dairy industry: label your milk and you are likely to face the wrath of Monsanto's legal team. Monsanto has invested heavily in biotechnology; it spent \$300 million developing Posilac.<sup>169</sup> The lawsuits against Swiss Valley Farms and Pure Milk & Ice Cream Company illustrate how far Monsanto was willing to go to stop dairy marketers from informing consumers about Posilac. Monsanto's lawsuits forced the defendants to spend thousands of dollars in legal fees defending their right to tell consumers that they did not use milk from cows injected with BGH.<sup>170</sup>

### C. *International Dairy Foods Ass'n v. Amestoy*

The confusion created by the lack of federal labeling laws has resulted in other litigation as well. In *International Dairy Foods Ass'n v. Amestoy*, dairy manufacturers challenged the constitutionality of a 1994 Vermont law requiring them to identify products from cows treated with BGH.<sup>171</sup> The plaintiffs argued that the law violated their First Amendment right not to speak and sought enjoin its enforcement.<sup>172</sup>

Vermont did not cite health or safety reasons for passing the labeling law.<sup>173</sup> Instead it defended the law, primarily, on the consumer's right to know.<sup>174</sup> In reviewing the district court's decision to grant the injunction, the Second Circuit considered two factors: whether the law caused irreparable harm and the plaintiffs' likelihood of success on the merits.<sup>175</sup>

The court noted that the loss of First Amendment freedoms historically constitutes irreparable harm.<sup>176</sup> The Vermont law required the plaintiffs to make a statement whenever they offered their products for sale.<sup>177</sup> The court held that, although purposeful

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*Process*, DAYTON DAILY NEWS, Jan. 9, 1997, available at 1997 WL 3923277.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

<sup>172</sup> *Id.* at 70.

<sup>173</sup> *Id.* at 73.

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

<sup>175</sup> *See id.* at 74.

<sup>176</sup> *See id.* at 71.

<sup>177</sup> *Amestoy*, 92 F.3d at 71.

suppression of speech is usually the issue in First Amendment cases, Vermont's labeling law infringed on the plaintiff's constitutional right *not* to speak.<sup>178</sup> The court concluded that, because the statute limited First Amendment freedoms, it constituted an irreparable harm.<sup>179</sup>

In determining the plaintiff's likelihood of success on the merits, the court considered four factors: (1) whether the expression concerned lawful activity and was not misleading, (2) whether the government's interest was substantial, (3) whether the labeling law directly served the asserted interest, and (4) whether the labeling law was no more extensive than necessary.<sup>180</sup> The court held that Vermont failed to establish the second prong of the test.<sup>181</sup> By justifying the law on consumer demand, Vermont failed to demonstrate a substantial government interest that would justify compromising protected constitutional rights.<sup>182</sup>

Writing for the dissent, Judge Leval criticized the majority for failing to recognize the legitimate concerns of consumers and their desire for labels to help them make informed choices.<sup>183</sup> He also criticized the majority's First Amendment analysis.<sup>184</sup> Judge Leval concluded that the plaintiff's concern about being forced to say something it did not believe was without merit, considering that the signs placed near their dairy products recognized the FDA's findings of no harm.<sup>185</sup>

#### D. *Ben & Jerry's Homemade, Inc. v. Lumpkin*

The controversy surrounding BGH is also illustrated in *Ben &*

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<sup>178</sup> See *Amestoy*, 92 F.3d at 71 (citing *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) ("We begin with the proposition that the right of freedom of thought protected by the First Amendment against state action includes both the right to speak freely and the right to refrain from speaking at all.")).

<sup>179</sup> See *id.* at 72.

<sup>180</sup> See *id.* (citing *Central Hudson v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980)).

<sup>181</sup> See *id.* at 73.

<sup>182</sup> *Id.*

<sup>183</sup> See *Amestoy*, 92 F.3d at 76 (Leval, J., dissenting).

<sup>184</sup> See *id.* at 74 (Leval, J., dissenting).

<sup>185</sup> See *id.* at 79–80 (Leval, J., dissenting).

*Jerry's Homemade, Inc. v. Lumpkin*.<sup>186</sup> In 1996, Ben & Jerry's and a number of other dairy manufacturers sued officials of the State of Illinois and the City of Chicago for effectively barring them from labeling their products as BGH-free in violation of their First Amendment right to commercial free speech.<sup>187</sup> The plaintiffs wanted to inform consumers that their products did not contain BGH.<sup>188</sup> The defendants never reached the substantive issues in the complaint, arguing instead a lack of authority over plaintiff's products and a lack of enforcement power of certain laws relating to milk and milk products.<sup>189</sup> The United States District Court for the Northern District of Illinois disagreed, but nevertheless denied the defendant's motion to dismiss.<sup>190</sup> The case never went to trial; instead the parties reached a settlement that allowed Ben & Jerry's to use labels such as "we oppose BGH," and "[the] family farmers who supply our milk pledge not to treat their cows," provided that they also note that the FDA did not find any difference between treated and untreated milk.<sup>191</sup> This is essentially the result the people of Vermont were seeking in *Amestoy*.

## VI. Analysis

The mandatory labeling laws for organic food come at a time when consumer interest is at an all-time high. The USDA National Organic Labeling Standard is great news for consumers. It creates a uniform definition of "organic." It establishes a certification system to ensure that organic products meet USDA standards. And it creates a USDA "Organic Seal" that allows consumers to identify products that meet those standards. In sum, the new standards allow consumers to buy organic products with confidence.

Nevertheless, there are still many food products on the shelf with unknown ingredients. Organic foods provide less than two percent of the nation's food supply and cover less than one percent of its agricultural land.<sup>192</sup> Genetically modified foods, in contrast, cover

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<sup>186</sup> *Ben & Jerry's Homemade, Inc. v. Lumpkin*, 1996 WL 495554 (N.D. Ill. 1996).

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* at \*1.

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

<sup>190</sup> *See id.* at \*2.

<sup>191</sup> Marden, *supra* note 42, at 629.

<sup>192</sup> Cowley, *supra* note 3.

over 80 million acres of farmland.<sup>193</sup> And, most supermarket food items now “test positive” for the presence of genetically modified ingredients.<sup>194</sup> Yet, the federal government does not require the producers of these products to provide consumers with the information they need to make informed decisions about the foods they eat.

Consumers are worried about a variety of risks associated with genetically modified foods and they want sufficient testing methods and adequate labeling. The case law discussed in this article illustrates the problems in the dairy industry surrounding the use of BGH and how the courts are dealing with consumer concern about the product. For example, in Wisconsin, the *Stauber* court heard arguments concerning damage to dairy farmers, consumers, producers, and others caused by FDA’s approval of Posilac. In Vermont, the *Amestoy* court heard challenges to the State’s mandatory labeling laws. Both courts, however, refused to deal with the hard issues.

Consumer demand did not persuade the *Stauber* Court not to defer to the FDA’s approval of Posilac. Despite valid consumer concerns, without evidence of differences between BGH-treated dairy products and non-treated products, the court was unwilling to fault the FDA’s approval of Posilac or its decision not to require labeling. Consumer demand was not enough for the *Amestoy* court either, which dismissed Vermont’s mandatory labeling law as an effort to satisfy “consumer curiosity.” The courts simply do not recognize consumer demand as a legitimate concern. Instead, they defer to the biotechnology industry.

Judge Leval’s dissent in *Amestoy* is the only voice of reason on the record that firmly recognizes consumer concern. Judge Leval recognized the legitimate concerns of many consumers who would like to avoid milk products from cows treated with BGH. Leval noted that the majority’s ruling deprived Vermont of the right to protect its consumers by requiring truthful disclosure on a subject of legitimate concern. His dissent discussed concerns about nature, economics, safety, and even corporate intentions. These are difficult issues that the courts are hesitant to deal with, but there are legitimate consumer interests surrounding the BGH issue, and the courts must find a way

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<sup>193</sup> RONNIE CUMMINS, ORGANIC CONSUMERS ASS’N, HAZARDS OF GENETICALLY ENGINEERED FOODS AND CROPS, WHY WE NEED A GLOBAL MORATORIUM, at <http://www.organicconsumers.org/ge/whymoratorium.cfm> (last visited May 15, 2003) (arguing a list of harmful side effects).

<sup>194</sup> *Id.*

to address those interests.

The Federal Government has helped fuel confusion surrounding the labeling of genetically modified foods. By adhering to a “no-labeling” standard, Congress has refused to address the hard issues. After its recent passage of mandatory labeling law for organic food, however, perhaps Congress will reconsider requiring labeling of genetically modified foods as well. Consumers deserve the opportunity to make informed choices about these foods as well as organic food. Why should they be given that option only with foods that are free from chemical additives? The reverse would make more sense: labeling genetically modified food instead of organic food.

As BGH demonstrates, modern biotechnology is extremely accurate in copying naturally occurring hormones. Unfortunately, the Federal Government’s current review standards are based on whether a final product differs from the original. These standards are outdated. The FDA’s inability to find material differences between products should not keep consumers from making informed purchases merely because Monsanto and other companies are able to invent sophisticated drugs like Posilac. Although the purpose of the FDCA is to protect the public health, the FDA has so far been unwilling or unable to provide consumers with the information they deserve. The USDA has stepped up to the plate with regard to organic food labeling. It is now time for the FDA to do the same for genetically modified foods.

## **VII. Conclusion**

The USDA’s national standards and organic seal is a great step forward for consumers. Future policies should respond to consumer demand and help Americans make informed decisions when shopping for food—both organic and genetically modified. To accomplish that goal, the government will have to develop standards and labeling requirements for genetically modified foods.



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