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Cloned Meat, Voluntary Food Labeling, and Organic Oreos

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Abstract

In December 2006, the Food and Drug Administration (FDA) announced that it had reviewed all the available evidence and was poised to approve meat and milk from cloned animals and their progeny. Such products, said the FDA, are virtually identical to meat or milk from a non-clone. Further, the FDA announced it would almost certainly not require food from clones to be labeled as such. Part I of this article identifies three functions that labels perform, outlines the types of information usually required, and introduces the rule that voluntary label information cannot be misleading. Part II focuses on process information and its implications. The article argues that there is no truly voluntary labeling when consumers care about a feature; if some products are labeled, then unlabeled products bear a de facto label by implication. Partly because of the de facto mandatory labeling principle, process labeling has the potential to mislead consumers. In Part III the article examines some relevant characteristics of consumers and argues that not all consumers can be misled by label information. Consumers who have no preferences or who are very knowledgeable about the labeled feature are not misled by process labeling. Finally, using labeling of genetically modified (GM) ingredients as an example, the article suggests that mandatory labeling of some process information could enhance consumer sovereignty and welfare.

Keywords

FDA, cloned animal meat, food labeling, food identity approach, science based approach, genetically modified food, consumer information, process labeling

Disciplines

Agriculture Law | Consumer Protection Law | Food and Drug Law

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DONNA M. BYRNE*

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I. INTRODUCTION

In December 2006, the Food and Drug Administration (FDA) announced that it had reviewed all the available evidence and was poised to approve meat and milk from cloned animals and their progeny.¹ I remember telling one of my colleagues, a patent law

* Professor of Law, William Mitchell College of Law. A lot of people helped me think about these issues. I am grateful to Peter Hemberger for reading multiple drafts and his great research assistance. Thanks also to Margaret Sova McCabe and Paul Smith, who read earlier drafts and provided useful and encouraging comments. My 2008 Food Law Seminar students heard and commented on a

professor, who should be as comfortable with technology as anyone, about this development, and his response was, "Yuck. *I'm* not eating it!" To which of course I replied, "Humph. You won't know the difference." Meat or milk from a clone or its descendant is virtually identical to meat or milk from a non-clone, said the FDA, as it also announced that it would almost certainly not require food from clones to be labeled.²

Information on food labels must be true and not misleading.³ If food is chemically different from the standard, it must be so labeled,

presentation of an early version, as did participants in the Food, Law & Society session of the 2008 American Society for Law and the Humanities meeting. Finally, if it were not for Mark Schmitz, I would still be floundering; he helped me make this a priority, and even mowed my lawn. I am deeply grateful.

1. Press Release, U.S. Food & Drug Admin., FDA Issues Draft Documents on the Safety of Animal Clones (Dec. 28, 2006) [hereinafter FDA Press Release], available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108819.htm>. The announcement in December of 2006 included a draft of a risk assessment on animal cloning completed by the FDA's Center for Veterinary Medicine. A final version of that draft assessment was released in January of 2008. See CTR. FOR VETERINARY MED., U.S. DEP'T OF HEALTH & HUMAN SERVS., ANIMAL CLONING: A RISK ASSESSMENT 330 (2008) [hereinafter FDA DRAFT RISK ASSESSMENT], available at <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AnimalCloning/UCM124756.pdf>; see also Andrew Martin & Andrew Pollack, *F.D.A. Says Food from Cloned Animals Is Safe*, N.Y. TIMES, Jan. 16, 2008, at A1, available at http://www.nytimes.com/2008/01/16/business/16clone.html?_r=1; *Milk and Meat from Cloned Animals Safe to Eat, FDA Says*, THE ONLINE NEWS HOUR, Dec. 28, 2006, http://www.pbs.org/newshour/updates/science/july-dec06/cloning_12-28.html.

2. FDA Press Release, *supra* note 1; U.S. Food & Drug Admin., Consumer FAQs, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055516.htm> (last visited Oct. 24, 2009) (stating that labeling of cloned meat and dairy would not be required because "there is no science-based reason to use labels to distinguish between milk derived from clones and that from conventional animals"); see also FDA DRAFT RISK ASSESSMENT, *supra* note 1, at 330 ("Analyses of the composition of meat from bovine and swine clones and milk from bovine clones consistently indicate that there are no biologically relevant differences between the composition of food from clones, or their close comparators. In addition, there is no material difference, based on these studies, between the composition of meat and milk from clones and historical reference ranges of the composition of food from conventionally-bred animals.").

3. See 21 U.S.C. § 343(a)(1) (2006). A food is misbranded if "its labeling is false or misleading in any particular." *Id.*

but if it cannot be distinguished from the standard, then it is the same food, and the label would be misleading if it suggested any difference.⁴ This focus on chemical identity is part of the FDA's "science-based" approach to food labeling, and from this perspective, the decision not to require labels on cloned meat and milk makes perfect sense. If laboratory tests cannot tell whether meat came from a cloned or a non-cloned animal, then, under FDA's science-based approach to labeling, there is no difference. But consumers seem to want and expect more from labels than merely the identity and quantity of the food.

When the FDA announced that it considered meat and milk from cloned animals to be indistinguishable from the same products from non-cloned animals⁵ and, accordingly, safe to eat,⁶ it also concluded that there would be no need to label meat or milk that comes from clones.⁷ Consumers, however, want to know whether their meat or

4. See the Lanham (Trademark) Act, 15 U.S.C. §§ 1051–1141n, which also applies to advertising claims. *See generally* 21 U.S.C. § 343(g).

5. ANIMAL CLONING: A DRAFT RISK ASSESSMENT was released December 28, 2006. FDA Press Release, *supra* note 1. The FDA website no longer has the Draft Risk Assessment posted. However, there is an FDA news release announcing the Draft Risk Assessment and extensive coverage of the Draft in popular media. *See id.*

6. FDA Press Release, *supra* note 1 ("The draft risk assessment finds that meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals.").

7. CTR. FOR VETERINARY MED., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY USE OF EDIBLE PRODUCTS FROM ANIMAL CLONES OR THEIR PROGENY FOR HUMAN FOOD OR ANIMAL FEED 2 (2006), *available at* <http://www.fda.gov/cvm/Guidance/guideline179.htm>. In this Draft Guidance, the FDA states, "there is no science based reason to recommend additional safeguards" because the available studies did not show any risks that are unique to meat and milk products derived from clones. *Id.* at 3. A critique of the draft risk analysis on cloned meat could be the subject of another article. The FDA's reasoning is essentially that no risks are known, so there must not be any. *But see* DENISE CARUSO, INTERVENTION: CONFRONTING THE REAL RISKS OF GENETIC ENGINEERING AND LIFE ON A BIOTECH PLANET (2006) (discussing, generally, the risk analysis of new technology). Caruso points out that "risk isn't about what scientists know. It's about what they *don't* know. Risk is about uncertainty." *Id.* at 32.

milk may have come from clones.⁸ Some are ethically opposed to cloning. Some aren't sure the products will be safe. Some just say "yuck." But sixty percent say they want to know.⁹

Consumers often want information about where their food came from or about the processes employed in producing it.¹⁰ The food identity approach to labeling cannot take process into account unless the process affects the identity of the food. When the process does not change the food in any material way, process information on a label might suggest a difference that does not exist.¹¹ The instinctive "yuck" to the thought of cloned meat highlights the tension between consumer preferences, the government's science-based, food-identity approach, and producers' efforts to differentiate their products.

Part I of this article identifies three functions that labels perform, outlines the types of information usually required, and introduces the rule that voluntary label information cannot be misleading. Part II focuses on process information and its implications. I argue that there is no truly voluntary labeling when consumers care about a feature; if some products are labeled, then unlabeled products bear a de facto label by implication. Partly because of the de facto mandatory labeling principle, process labeling has the potential to mislead consumers. In Part III, I examine some relevant characteristics of consumers. I argue that not all consumers can be misled by label information. Consumers who have no preferences or who are very

8. Matthew R. Kain, Comment, *Throw Another Cloned Steak on the Barbie: Examining the FDA's Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef*, 8 N.C. J.L. & TECH. 303, 305–06 (2007). Kain states that 66 percent of American consumers considered cloning animals to be morally wrong, 63 percent of American consumers would likely not buy food from cloned animals even if the FDA considered food derived from cloned animals as safe, and only one-third would currently consider buying meat and milk from cloned animals without any additional information about cloned food. *Id.* at 305–06.

9. See FOOD MKTG. INST., FMI BACKGROUNDER: FOOD FROM CLONED ANIMAL 4 (2007), available at http://www.fmi.org/media/bg/Cloning_backgrounder.pdf (finding 64 percent "uncomfortable" or "very uncomfortable" with cloning).

10. A familiar example of process labeling is the USDA organic seal. The National Organic Program regulations provide rules about how food must be grown or processed. See generally 7 C.F.R. pt. 205 (2009).

11. See, e.g., *infra* notes 88–91 and accompanying text (discussing milk label claims that the milk comes from cows not treated with bovine growth hormone).

knowledgeable about the labeled feature are not misled by process labeling. Finally, using labeling of genetically modified (GM) ingredients as an example, I suggest that mandatory labeling of some process information could enhance consumer sovereignty and welfare.

II. GENERAL RULES AND ROLES FOR FOOD LABELS

A. *Label Functions*

The earliest federal labeling law in this country did not require any specific label information; rather, the Pure Food and Drugs Act of 1906 simply prohibited false or misleading statements on food labels.¹² The purpose of this was to prevent deception and to help consumers make utility- or welfare-maximizing choices.¹³ Presumably consumers act in their own best interests, given a choice, by choosing the option that provides the most satisfaction or utility.¹⁴ A consumer can get the most utility out of limited dollars to spend on food¹⁵ only if the consumer has accurate information about the foods

12. See Pure Food and Drugs Act of 1906, ch. 3915, § 8, 34 Stat. 768, 770 (repealed 1938); see also Frederick H. Degnan, *The Food Label and the Right to Know*, 52 FOOD & DRUG L.J. 49, 50 (1997) (stating the purpose of the misbranding statute was to prevent deception); Peter Barton Hutt, *Regulating the Misbranding of Food*, 43 FOOD TECH. 288 (1989), as reprinted in PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 37 (2d ed. 1991). See generally Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 47–53 (1984). For a recounting of the historical context that gave rise to 1906 Pure Food Act, see James Harvey Young, *The Long Struggle for the 1906 Law*, FDA CONSUMER, June 1981, at 12, cited in Caroline Smith DeWaal, *Food Safety and Security: What Tragedy Teaches Us About Our 100-Year-Old Food Laws*, 40 VAND. J. TRANSNAT'L L. 921, 921 (2007).

13. Degnan, *supra* note 12, at 50.

14. See Matthew A. Smith & Michael S. McPherson, *Nudging for Equality: Values in Libertarian Paternalism*, 61 ADMIN. L. REV. 323, 324 (2009) (containing brief statement of this assumption of behavioral economics).

15. In the recent documentary, KING CORN (ITVS 2007), former Secretary of Agriculture Earl Butz points out that we now spend only about 16 percent of our disposable income on food. In earlier times, it was higher. According to a USDA ERS report, the average household spends something closer to 10 percent of its disposable income on food. NOEL BLISARD & HAYDEN STEWART, U.S. DEP'T OF

under consideration. Accordingly, the goal of label information is to help consumers identify the food products that best match their preferences, thus helping consumers spend wisely. Subsequent legislation requires additional kinds of information, still aimed at preventing deception.¹⁶

To this end, label claims perform three primary functions. The most obvious function is identification. A product's label helps a consumer know what product is inside the wrapper (if there is a wrapper). If a consumer has a preference, knowing the identity of a product obviously enables the consumer to choose the preferred product. In this context, providing information increases welfare and increases liberty by allowing consumers to exercise freedom of choice.¹⁷ Information about food identity is generally neutral or positive; it helps sales because it helps consumers find the foods they want. Contrast the informational role with another—warnings.

Unlike product identification, a warning is not neutral. Rather, it clearly suggests one choice over another.¹⁸ Information about allergens, for example, warns shoppers with food sensitivities or allergies to avoid products that could cause them harm.¹⁹ Similarly, if an ingredient is known to cause cancer, consumers might think twice be-

AGRIC., ECONOMIC INFORMATION BULLETIN 23, FOOD SPENDING BY AMERICAN HOUSEHOLDS, 2003–04, at iv (2007), available at <http://www.ers.usda.gov/publications/eib23/eib23.pdf>.

16. See, e.g., Fair Packaging and Labeling Act, Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified as amended at 15 U.S.C. §§ 1451–1461 (2006)); Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified as amended at 21 U.S.C. §§ 451–472); Filled Milk Act, ch. 262, 42 Stat. 1486 (1923) (codified as amended at 21 U.S.C. §§ 61–64); Federal Meat Inspection Act, ch. 2907, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. §§ 601–695).

17. Cf. Smith & McPherson, *supra* note 14, at 330 (providing a definition of liberty for this purpose: “people should be free to do what they like—and to opt out of undesirable arrangements if they want to do so . . . [P]eople should be ‘free to choose.’” (quoting RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* 5 (2008))).

18. Some warnings help consumers avoid danger by using the product correctly rather than avoiding the product altogether. Safe handling instructions are a good example.

19. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202, 118 Stat. 905, 905–06.

fore choosing to consume it.²⁰ A label that indicates the presence of a known carcinogen provides information that is not neutral.

Some labels that appear neutral on their faces also seem to have a value-laden impact. The labeled presence of peanuts is a warning to people with peanut allergies, but it may also be positive information for people who like peanuts. In some cases, the *absence* of information also acts as a warning, at least for some consumers.²¹

A third possible function of label information is education for public health purposes. The mandatory nutrition panel has this function to some extent.²² It alerts consumers to the importance of nutrition, reminding them that they should care about vitamins and nutrients, and highlighting the important ones.²³ Congress has determined that consumers *should* want this information.²⁴ In this way, required nutritional information educates consumers about what their needs are and helps them identify the products that best meet their needs. Voluntary health claims on labels also perform this educational function. For example, a sample health claim for oat bran reads: “*Soluble fiber from foods such as oat bran, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart*

20. Of course, consumers do consume products known or believed to be detrimental to health. Consider cigarettes, for example. Examples of bad-for-us foods intentionally consumed are harder to find, but consumers do choose food products that cannot be said to enhance health or that have no nutritional value other than calories—cotton candy comes to mind.

21. In this regard, see Guillaume P. Gruère & S.R. Rao, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, 10 *AGBIOFORUM* 51, 55 (2007) (citing Jill E. Hobbs & William A. Kerr, *Consumer Information, Labeling and International Trade in Agri-Food Products*, 31 *FOOD POL'Y* 78 (2006)), for the proposition that mandatory labeling is better than an import ban except when the label acts as a warning, in which case the result is no genetically-modified products.

22. *But see* Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 *WIS. L. REV.* 1161, 1187 (asserting that a purpose of the nutrition label, for example, is to warn consumers about overconsumption of certain nutrients).

23. For more on the nutrition panel, see *infra* notes 28–30 and accompanying text.

24. *See, e.g.*, Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2, 104 Stat. 2353, 2353–57 (codified as amended at 21 U.S.C. §343(q) (2006)). *But see* Degnan, *supra* note 12, at 54 (seeing this as another form of providing limited identification information).

disease.”²⁵ This language tells consumers not only that this product has oat bran, but that this information is significant because reducing heart disease should matter to them. Without the health claim, the presence of oat bran in the ingredients list might not be noticeable, especially to consumers who do not read the ingredients list. One study showed that consumers did not notice the words “genetically modified corn” on a candy bar label, but once it was pointed out to them, it became important, and they modified their behavior.²⁶ If the information had been more prominent, perhaps the result would have been different: the label would have alerted consumers to an issue they should think about.

All three functions thus help prevent deception and help facilitate utility-maximizing choices.

B. *Mandatory Label Information*

The current statute that governs most food labeling issues is the Food, Drug, and Cosmetic Act (FDCA).²⁷ It requires much of the information that we are accustomed to seeing on food labels and specifies formats for those statements. For example, the nutrition panel is familiar to most food consumers.²⁸ While a consumer might not be able to list all of the nutrients listed in the nutrition panel, most probably do have a sense that the panel has to be there, and that it has to include calories, saturated fat, and now trans fat, as well as sodium and other items,²⁹ but the rule has other requirements too.³⁰

25. 21 C.F.R. § 101.81(e)(1) (2009).

26. Charles Noussair et al., *Do Consumers Not Care About Biotech Foods or Do They Just Not Read the Labels?*, 75 ECON. LETTERS 47 (2002).

27. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399a.

28. *See, e.g.*, 21 U.S.C. § 343(q) (requiring specific nutrition information such as the serving size, number of servings per container, the total number of calories, and the amounts of specified nutrients).

29. *See* Alvin Schupp et al., *Consumer Awareness and Use of Nutrition Labels On Packaged Fresh Meats: A Pilot Study*, J. FOOD DISTRIBUTION RES., July 1998, at 24, 28 (reporting a high-rate (as high as 78.5 percent) of usage of the nutrition labels, especially where the nutrient content was not previously known by the consumer).

30. *See* Fed. Sec. Adm’r v. Quaker Oats Co., 318 U.S. 218 (1943); *see also* 21 U.S.C. § 343(e) (requiring “an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count”); OFFICE OF NUTRITION, LABELING,

Less commonly known is the rule requiring that the label tell you what the specific food is—not just its brand name, but a description of the food itself.³¹ Most consumers probably do not realize that many foods have “standards of identity”—definitions for each kind of food—which are actually provided in the regulations.³² For example, “enriched farina” must contain vitamin B1, riboflavin, nicotinic acid, folic acid, and iron.³³ Plain-old “farina” is not enriched at all.³⁴ In a 1943 case, *Federal Security Administrator v. Quaker Oats Co.*,³⁵ the Supreme Court held that farina enriched with only vitamin D is not “farina” (which does not contain vitamin D), and it is also not “enriched farina” because it lacks the other substances required by the federal regulations.³⁶ The Quaker Oats company had marketed farina enriched only with vitamin D.³⁷ The label said “Quaker Farina Wheat Cereal Enriched with Vitamin D.”³⁸ The Court held that the product was misbranded because the label used the terms

AND DIETARY REQUIREMENTS, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE (2008), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>. This food guide is a non-binding guidance for industry that was revised as recently as April of 2008.

31. 21 U.S.C. § 343(g); 21 C.F.R. § 101.105 (2009). *But see* 21 U.S.C. § 341 (excluding “fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons”).

32. *E.g.*, 21 C.F.R. § 101.4(b)(20) (“For purposes of ingredient labeling, the term ‘sugar’ shall refer to sucrose, which is obtained from sugarcane or sugar beets in accordance with the provisions of § 184.1854 of this chapter.”). *See generally id.* pts. 101–181 (including food and “indirect food additives”). The regulations provide definitions for everything from “nonstandardized breaded composite shrimp units,” to milk. *Id.* §§ 131.110, 102.55. Even definitions for “indirect food additives” such as “odorless light petroleum hydrocarbons” may be found. *Id.* § 178.3650.

33. *Id.* § 137.305; *see Quaker Oats*, 318 U.S. at 234–35.

34. 21 C.F.R. § 137.300.

35. 318 U.S. 218. *See generally* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES & MATERIALS 162–80 (3d ed. 2007) (containing casebook chapter on food identity standards including an edited version of the *Quaker Oats* case).

36. *Quaker Oats*, 318 U.S. at 234–35; *see also* 21 C.F.R. § 137.300.

37. *Quaker Oats*, 318 U.S. at 224.

38. *Id.*

“farina” and “enriched,” and the enrichments did not include all of the specified nutrients.³⁹ In other words, it was not “farina” because it *was* enriched, but it was not “enriched farina” because it was not enriched enough.

C. *Voluntary Label Information*

The required information on a label is only part of what we read at the breakfast table. Most labels also bear voluntary information usually provided to enhance marketability. For example, the front of a randomly chosen box of “Mom’s Best Naturals” breakfast cereal claims to have “44 g of whole grain per serving.” The front of the box also lists “no artificial preservatives,” “no artificial colors or flavors,” “no hydrogenated or palm oil,” “no high fructose corn syrup,” and “family-owned for four generations.”⁴⁰

The FDCA imposes a limitation on all voluntary label claims—information on a label must be truthful and not misleading.⁴¹ Under § 343(a), if the label information is either untrue *or* misleading, the food is considered to be “misbranded.”⁴² In other words, the statute prohibits label claims that are misleading, even if the claims are true.⁴³ As early as 1924, the United States Supreme Court endorsed

39. *Id.* at 234.

40. A picture of the cereal box is available at <http://momsbestnaturals.com/all-natural-products/sweetened-wheat-fuls.php>.

41. *See* 21 U.S.C. §§ 321(n), 343(a) (2006).

42. *Id.* § 343(a)(1). Note that “misbranded” means incorrectly labeled—it has nothing to do with “brand” names. *See id.*

43. *See id.*; Julie Caswell, *Should Use of Genetically Modified Organisms Be Labeled?*, 1 *AGBIOFORUM* 22, 23 (1998) (pointing out that when there are no real differences between products, label information could actually be deceptive). When the FDA has specified how a type of claim should read, any label statement of that type must comply. For example, under 21 C.F.R. § 101.13(b), “A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label” unless the claim is made in accordance with applicable regulations. In *Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996), we see the following statement: “For example, a claim about nutritional levels can only be made ‘if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.’” *Id.* at 15 (citing 21 U.S.C. § 343(r)(2)(A)(i)). This case is one in a long line of cases that discuss whether or not restaurants are exempt from these food-labeling regulations

this aspect of the statute: “Deception may result from the use of statements not technically false or which may be literally true [The Pure Food and Drugs Act of 1906]⁴⁴ was enacted to enable purchasers to buy food for what it really is.”⁴⁵

For example, a food such as applesauce cannot be labeled as “low fat” without a qualifier such as “a naturally low fat food.” A consumer who prefers to follow a low fat diet could be misled by a label that says “low fat applesauce,” erroneously thinking that other jars of applesauce that are not labeled “low fat” actually contain a higher fat product. Applesauce, however, is always low fat—that is the nature of applesauce. Although “low fat applesauce” might be a truthful description of the product, it would be misleading for consumers who do not know much about applesauce.

This rule could be termed the “not-misleading rule.” The rule lurks in the background in the case of mandatory labeling; whether label information could be misleading is one of the considerations behind new labeling requirements. It surfaces on a case-by-case basis where voluntary labeling is at issue.

III. THE NOT-MISLEADING RULE AND IMPLICATIONS FOR PROCESS INFORMATION

A. *Process Information*

The not-misleading rule is perhaps most relevant in the context of process information. Sometimes consumers may want, and producers may wish to provide, information about the processes by which a food is produced, even when that information does not say anything about the “scientific” identity of the food.⁴⁶ In some cases,

and, if so, to what extent. *See, e.g.,* N.Y. State Rest. Ass’n v. New York City Bd. of Health, 556 F.3d 114, 120 (2d Cir. 2009).

44. ch. 3915, 34 Stat. 768 (repealed 1938).

45. *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 443 (1924) (citing *United States v. Schider*, 246 U.S. 519, 522 (1918); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914); *United States v. Antikamnia Chem. Co.*, 231 U.S. 654, 665 (1914)).

46. This information is sometimes called a “credence attribute” because consumers cannot tell the difference by taste or appearance. *See* ASTRID DANNENBERG ET

information about process is even required. Process information or “credence attributes” must simply be believed—there is no way for consumers to confirm the truth of a process claim because the resulting food itself is not changed. For example, the U.S. Department of Agriculture (USDA) organic seal, probably the best-known process designation, means that the food was (or its ingredients were) grown or produced in compliance with National Organic Program (NOP) regulations.⁴⁷ The NOP regulations require *specific* production practices:⁴⁸ rules about process—no pesticides or antibiotics,⁴⁹ no comingling with non-“organic” products,⁵⁰ three years of organic crop production,⁵¹ and so on. Compliance with these processes is rewarded with the right to use the green and white USDA Organic symbol on the label even though most organic food is chemically indistinguishable from its non-organic counterpart.⁵²

AL., CTR. FOR EUROPEAN ECON. RESEARCH, DISCUSSION PAPER NO. 08-029, DOES MANDATORY LABELING OF GENETICALLY MODIFIED FOOD GRANT CONSUMERS THE RIGHT TO KNOW? EVIDENCE FROM AN ECONOMIC EXPERIMENT (2008), *available at* <ftp://ftp.zew.de/pub/zew-docs/dp/dp08029.pdf>.

47. U.S. Dep’t of Agriculture, National Organic Program, <http://www.ams.usda.gov/AMSV1.0/NOP> (last visited November 22, 2009).

48. *See generally* 7 C.F.R. pt. 205.

49. *Id.* § 205.206 (providing a crop pest, weed, and disease management standard); *id.* § 205.238(c) (prohibiting certain livestock healthcare practices and certain medications).

50. *Id.* § 205.270 (providing organic handling requirements).

51. *Id.* § 205.202(b) (forbidding the use of prohibited substances from being applied to land for three years).

52. For some foods, organic production does result in measurable differences. *See* Carl K. Winter, *Organic Foods: IFT’s Latest Scientific Status Summary*, FOOD TECH., Oct. 2006, at 44, *available at* <http://members.ift.org/NR/rdonlyres/79831BA3-2224-4787-A9CC-A03E837F6148/0/1006organic.pdf>. This article summarizes the findings of the Institute of Food Technologists’ study “compar[ing] organic and conventional foods with respect to pesticide residues, nutritional components, naturally occurring toxins, and microbiological safety.” *Id.* at

44. The study found that:

[p]esticide residues were 3.2 times more likely to be found in conventional produce than in organic produce according to the [U.S. Department of Agriculture’s Pesticide Data Program] data, 4.8 times more prevalent in the [California Department of Pesticide Regulation] data, 2.9 times greater in the [Consumers Union] study, and 4.1 times more likely in another study using Belgian data.

Other examples include Fair Trade designations,⁵³ the country of origin of the food,⁵⁴ or the fact that the food was grown without de-

Id. at 46 (citing Luc Pussemier et al., *Chemical Safety of Conventionally and Organically Produced Foodstuffs: A Tentative Comparison Under Belgian Conditions*, 17 FOOD CONTROL 14 (2006)). The study continued by stating that “[m]ost comprehensive reviews comparing nutrient levels in organic and conventional foods have been inconclusive, yielding mixed results, with the exception of nitrate levels, which are typically lower in organic foods.” *Id.* at 47 (citing Diane Bourn & John Prescott, *A Comparison of the Nutritional Value, Sensory Qualities, and Food Safety of Organically and Conventionally Produced Foods*, 42 CRITICAL REVIEWS FOOD SCI. & NUTRITION 1 (2002); Katrin Woese et al., *A Comparison of Organically and Conventionally Grown Foods—Results of a Review of the Relevant Literature*, 74 J. SCI. FOOD & AGRIC. 281 (1997); Virginia Worthington, *Nutritional Quality of Organic Versus Conventional Fruits, Vegetables, and Grains*, 7 J. ALTERNATIVE & COMPLEMENTARY MED. 161 (2001)). However, it is noted that “[m]any recent studies . . . have demonstrated that some plant secondary metabolites such as organic acids and polyphenols are produced at greater levels under organic growing conditions.” *Id.* The complete article, Carl K. Winter & Sarah F. Davis, *Organic Foods*, 71 J. FOOD SCI. R117 (2006), is available at <http://members.ift.org/NR/rdonlyres/A5367812-A6CF-46C0-80B9-B1EF39A0BCC4/0/OrganicFood.pdf>. See also Danny K. Asami et al., *Comparison of the Total Phenolic and Ascorbic Acid Content of Freeze-Dried and Air-Dried Marionberry, Strawberry, and Corn Grown Using Conventional, Organic, and Sustainable Agricultural Practices*, 51 J. AGRIC. & FOOD CHEM. 1237, 1237 (2003), available at <http://mitchell.ucdavis.edu/publications/OrgConAEM.pdf> (“Statistically higher levels of [polyphenols] were consistently found in organically and sustainably grown foods as compared to those produced by conventional agricultural practices.”); Woese, *supra*, at 290 (finding higher nitrate levels and pesticide residues in conventionally-grown foods generally but “no major differences” found in nutritional quality between conventional and organic foods); Worthington, *supra*, at 161 (finding that “[o]rganic crops contained significantly more vitamin C, iron, magnesium, and phosphorus and significantly less nitrates than conventional crops”). Interestingly, the Woese study found that “[i]n feed selection experiments it has been shown that animals differentiate between foods from the various agricultural systems and prefer organic produce.” Woese, *supra*, at 290; see also Catharine Paddock, *Organic Food is More Nutritious Say EU Researchers*, MED. NEWS TODAY, Oct. 29, 2007, <http://www.medicalnewstoday.com/articles/86972.php>.

53. Probably the most well known of the fair-trade designations is the TransFair USA Fair Trade Certified label, available at <http://www.transfairusa.org> (last visited Nov. 3, 2009). However, there are other fair-trade certifiers such as FLO-CERT, which certifies and regulates for the Fairtrade Labeling Organization (FLO) International, available at <http://www.flo-cert.net/flo-cert/main.php?lg=en> (last visited Nov. 3, 2009).

stroying any rain forests.⁵⁵ Similarly, the presence or absence of genetically modified organisms (GMOs) in a food product is process information,⁵⁶ as is the fact that chickens were or were not treated with antibiotics.⁵⁷ The federal government does not regulate all

54. See U.S. Dep't of Agriculture, Agricultural Marketing Service, Country of Origin Labeling, <http://www.ams.usda.gov/AMSV1.0/cool> (last visited Sept. 15, 2009). The website provides a brief history of country of origin labeling:

The 2002 and 2008 Farm Bills amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of muscle cut and ground meats including beef, veal, lamb, pork, chicken, and goat meat; wild and farm-raised fish and shellfish; perishable agricultural commodities (fresh and frozen fruits and vegetables); peanut, pecans, and macadamia nuts; and ginseng. On October 5, 2004, the Agricultural Marketing Service (AMS) published an interim final rule (IFR) for fish and shellfish (69 FR 59708) that went into effect on April 5, 2005. Legislation delayed the implementation of mandatory country of origin labeling (COOL) for all covered commodities except fish and shellfish until September 30, 2008. On August 1, 2008, AMS published an interim final rule for all remaining covered commodities (73 FR 45106). On January 15, 2009 AMS published a final rule for all covered commodities combined (74 FR 2658) which became effective on March 16, 2009.

Id.

55. See Rainforest Alliance, Sustainable Agriculture Introduction, <http://www.rainforest-alliance.org/agriculture.cfm?id=main> (last visited Nov. 3, 2009). The website states that "Rainforest Alliance Certified farms have reduced environmental footprints, are good neighbors to human and wild communities and are often integral parts of regional conservation initiatives." *Id.*

56. See Moira Dean et al., *Moral Concerns and Consumer Choice of Fresh and Processed Organic Foods*, 38 J. APPLIED SOC. PSYCHOL. 2088, 2094-95 (2008) (finding *inter alia* concerns about chemicals used in production, the affects of production of that food product on the environment, and having "trust" in the way the product was produced as important for those that bought certified organic foods—an example of a food product exhibiting a process label); Mario F. Teisl et al., *Labeling Genetically Modified Foods: How Do US Consumers Want to See It Done?*, 6 AGBIOFORUM 48 (2003); see also JAMES L. VETTER, FOOD LAWS AND REGULATIONS 11 (1996); Samia N. Rodriguez, *Food Labeling Requirements*, in 1 FUNDAMENTALS OF LAW AND REGULATION 237, 254 (Robert P. Brady et al. eds., 1997).

57. United States Standards for Livestock and Meat Marketing Claims, 67 Fed. Reg. 79,552, 79,554 (Dec. 30, 2002) ("Antibiotic-free" is not approved for use by the USDA. "No antibiotics administered," "no detectable antibiotic residue," and "raised without antibiotics" are acceptable for use.); FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., ANIMAL RAISING CLAIMS IN THE LABELING OF

process labels, but when it does, the regulating agency is likely to be the USDA.⁵⁸ In addition to overseeing the NOP, the USDA is also responsible for country-of-origin labeling rules as well as irradiation and other agricultural production processes and their labels.⁵⁹ In contrast, the FDA's authority stems from the FDCA whose labeling provisions are aimed only at preventing economic deception by providing accurate information about food identity.⁶⁰ For the most part, then, the FDA does not require process information.

Some process information, however, is actually required. For example, meat and fish, and now produce, must be labeled with the country of origin.⁶¹ This information tells us nothing about the food

MEAT AND POULTRY PRODUCTS 15 (2008), available at http://www.fsis.usda.gov/PPT/Claims_Poretta_101408.ppt ("FSIS has decided to initiate a review of its policies for evaluating and approving animal raising claims. To facilitate this review, the Agency published a *Federal Register* notice on October 10, 2008, to solicit public input."); FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., MEAT AND POULTRY LABELING TERMS 3 (2006), available at http://www.fsis.usda.gov/PDF/Meat_and_Poultry_Labeling_Terms.pdf ("The terms '*no antibiotics added*' may be used on labels for meat or poultry products if sufficient documentation is provided by the producer to the Agency demonstrating that the animals were raised without antibiotics."). While the "no antibiotics added" label may be voluntarily used, it may not be used if it is false or misleading. See Press Release, Food Safety & Inspection Serv., U.S. Dep't of Agric., Statement by Under Secretary for Food Safety Dr. Richard Raymond Regarding the Tyson Foods, Inc. Raised Without Antibiotics Label Claim Withdrawal (June 3, 2008), available at http://www.fsis.usda.gov/News_&_Events/NR_060308_01/index.asp (stating that the FSIS, upon finding out that Tyson was regularly administering antibiotics to its chickens, was rescinding labels that claimed that the product was "raised without antibiotics"); see also *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 547 F. Supp. 2d 491 (D. Md. 2008) (claim of false advertising on label about being "raised without antibiotics").

58. See, e.g., 21 U.S.C. § 343 (2006).

59. See *infra* notes 63, 65–68 and accompanying text.

60. 21 U.S.C. § 341; see Dean et al., *supra* note 56, at 2094–95 (finding *inter alia* concerns about chemicals used in production, the affects of production of that food product on the environment, and having "trust" in the way the product was produced as important for those that bought certified organic foods—an example of a food product exhibiting a process label); Teisl et al., *supra* note 56; see also VETTER, *supra* note 56, at 11; Rodriguez, *supra* note 56, in 1 FUNDAMENTALS OF LAW AND REGULATION 237, 254 (Robert P. Brady et al. eds., 1997).

61. U.S. Dep't of Agriculture, Agricultural Marketing Service, *supra* note 54.

itself (such as whether the cow died of mad cow disease),⁶² merely where it came from. Moreover, fish that is farm-raised must also be so-labeled,⁶³ a designation that primarily provides process information, but may provide some food identity information as well.⁶⁴

62. See GEOFFREY S. BECKER, CONG. RESEARCH SERV., COUNTRY-OF-ORIGIN LABELING FOR FOODS 5–6 (2003), available at http://lugar.senate.gov/services/pdf_crs/country_of_origin.pdf.

Proponents of the new program have long argued that U.S. consumers have a right to know the origin of their food, particularly during a period when food imports are increasing. Such information is particularly important to consumers whenever specific health and safety problems arise that may be linked to imported foods, proponents add. They cite as one prominent example concerns about the safety of some foreign beef due to outbreaks of bovine spongiform encephalopathy (BSE, or “mad cow disease”). In May 2003, the discovery of a single cow with BSE in Canada prompted U.S. officials to impose a ban on all Canadian ruminant and ruminant product imports. Complicating matters has been a demand by Japan for verification that all imports of U.S. beef come from animals born, raised, and slaughtered in the United States. These developments have been used by some COOL supporters to argue the need for country labeling.

Id. More recently, many U.S. consumers have been concerned about food from China because of some melamine incidents. See, e.g., Max Thornsberry, *Country-of-Origin Labeling More Important Tool Than Ever for U.S. Consumers*, CATTLEMEN’S NEWSL., July 2007, at 7 (“The need for COOL is once again driven home by the [FDA’s] discovery that the tainted Chinese feed additives were labeled as wheat gluten and rice protein, but actually were ordinary wheat flour illegally mixed with melamine.”); George Reynolds, *Country-of-Origin Labeling Is Anti-Import, Claims Industry Body*, FOOD PRODUCTION DAILY, May 29, 2007, <http://www.foodproductiondaily.com/Supply-Chain/Country-of-origin-labeling-is-anti-import-claims-industry-body> (“Fears have arisen over meat and poultry imports . . . because of outbreaks of avian flu, and more recently the discovery of melamine in feed.”).

63. “The notice of country of origin for wild fish and farm-raised fish shall distinguish between wild fish and farm-raised fish.” 7 U.S.C.A. § 1638a(a)(3)(B) (West Supp. 2009).

64. In the case of farmed salmon, for example, artificial colorant is added to the feed and is present in the final fish product. See Donna Byrne, *Disclosing the Potentially Dangerous Dyes that Make Gray Salmon Pink: The California Supreme Court Holds that Actions to Enforce the State’s Food Labeling Law Are Not Preempted by Federal Law*, FINDLAW, Feb. 18, 2008, http://writ.news.findlaw.com/commentary/20080218_byrne.html.

Irradiation is another process that must be labeled even though the food itself is essentially unaltered. Food can be irradiated to eliminate bacterial contamination.⁶⁵ According to Debra Strauss, when the FDA approved ionizing radiation, it also required labeling “because such processing is a material fact” that must be disclosed to prevent deception.⁶⁶ The FDA found, however, that irradiation actually can change food properties without changing the appearance of the food.⁶⁷ The irradiated food may appear not to have been processed at all, and this would be misleading. If food properties are changed, then labeling the food as “irradiated” does convey something about the food itself, and not merely about the process.

Oddly enough, some processes are permitted even though the result is intentionally misleading. For example, meat and fish are often packaged with carbon monoxide in order to prolong the color of fresh meat.⁶⁸ The purpose of this practice can only be to make the meat more attractive to consumers by helping it stay red longer.⁶⁹ Informed consumers know that the “use-by” date is supposed to be the best indicator of freshness, and they will not buy food after its

65. Kim M. Morehouse, *Food Irradiation: The Treatment of Foods with Ionizing Radiation*, FOOD TESTING & ANALYSIS, June/July 1998, at 9, 32, 35.

66. See Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 184 (2006) (citing Irradiation in the Production, Processing, and Handling of Food, 21 C.F.R. § 179.26 (2003)); see also Degnan, *supra* note 12, at 52–53 (citing Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (Apr. 18, 1986) (codified at 21 C.F.R. pt. 179); 21 C.F.R. § 179.26(c) (1996)).

67. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. at 13,390.

68. *Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply—Part IV—Deception in Labeling: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) (statement of Daniel Engeljohn, Deputy Assistant Administrator, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service), available at <http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-oi-hrg.111307.Engeljohn-Testimony.pdf> (“Carbon monoxide is used to stabilize the color pigment of meat, when it is red and, therefore, most appealing to consumers.”).

69. *Id.*

freshness date has come and gone.⁷⁰ Informed consumers also know that smell is a better indicator of freshness than color.⁷¹ So the practice of color enhancement with carbon monoxide should have no effect on the purchase decisions of informed consumers. Nevertheless, most shoppers evidently interpret bright color as an indication of freshness in meat. The use of carbon monoxide predictably would influence uninformed consumers to buy with less regard to the use-by date or the smell of the product.⁷² In other words, the practice itself seems intended to mislead consumers about the freshness of the product.

Carbon monoxide does not change the meat itself, however, and does not preserve its freshness; it merely keeps the color from changing. If the meat itself were unchanged, then presumably the use of carbon monoxide would not be mandatory label information.

B. Voluntary Labeling Means De Facto Mandatory Labeling

Although most process information is voluntary, process labeling becomes mandatory, in a sense, if the feature in question has positive and negative marketing values. For example, if some foods are labeled as USDA organic, the consumer can assume that unlabeled foods are not “organic.” The USDA organic symbol has positive marketing value, so presumably qualifying products will be labeled. Logically, then unlabeled products must have been produced with

70. *But see* Letter from Chris Waldrop, Consumer Fed’n of Am., et. al. to U.S. Representative 2 (Jan. 18, 2004) (citing *Seeing Red: Spoiled Meat May Look Fresh*, CONSUMER REP., July 2006, available at http://www.consumerreports.org/cro/consumer-protection/consumer-interest/meat-treated-with-carbon-monoxide-spoiled-meat-may-look-fresh-7-06/overview/0607_spoiled-meat_ov.htm (finding that some meat was spoiled before the “use by” date)), available at <http://www.whistleblower.org/doc/Janu18.pdf>.

71. *See* Letter from John D. Dingell, U.S. Representative, et al. to Michael O. Leavitt, U.S. Sec’y of Health & Human Servs. 2 (Mar. 30, 2006) available at http://archives.energycommerce.house.gov/Press_109/109-ltr.Leavitt%2033006%20meat%20safety.pdf.

72. *Id.* Consumers that are aged or otherwise impaired so that they are unable to see the small print on the label or unable to smell for off odors, may be misled by the color of the meat, which is the only indicator left. *Id.* (stating further that studies completed by the meat industry have found that the primary characteristic used by consumers to determine freshness of meat is the color).

“conventional” methods and do not qualify for the organic sticker. Similarly, many consumers would regard “wild” salmon as superior to farm-raised salmon.⁷³ The “wild” label usually has positive valence—it is a positive label when applied to fish, salmon in particular, and wild salmon typically sells for more than farm-raised salmon.⁷⁴ Until recently, labeling of farm-raised salmon was mandatory, but labeling of wild salmon was not.⁷⁵ There is no need to require positive information—producers provide it voluntarily because it differentiates the product and may even provide a price premium. But the presence of positive information on some products may also serve as a warning about unlabeled products. If wild fish is good, then there must be something bad about farm-raised fish. If “no GMOs” is worth mentioning, then GMOs must be bad. If milk from cows not treated with recombinant bovine somatotropin (rBST) is worth boasting about, then rBST must be bad. So in a sense, there is no truly voluntary labeling. Once some producers use a label, other products bear a de facto label in the opposite direction.

A decision to require labeling of a “negative” process characteristic, accordingly, has marketing implications for all products. Perhaps it is appropriate that the FDA’s focus is narrowly on the chemical identity of the food. The result is that most process information is not required. The FDA did not require labeling to show that meat or milk came from a clone or its progeny, or to show that milk came from cows treated with rBST, or to disclose the presence of GMOs. These decisions were probably correct given the FDA’s focus. Process information has the potential to suggest a material difference in the food itself even when there is no such difference.

Because of the de facto mandatory nature of voluntary labeling, however, a second question arises: should process information be prohibited altogether? Of course, in some cases the warning function is intentional. In California, foods containing substances known to be carcinogenic must be labeled as such.⁷⁶ In these intentional

73. See generally Byrne, *supra* note 64.

74. The price premium may go in the opposite direction for other kinds of fish.

75. Under the COOL regulations, fish and shellfish subject to COOL must also be labeled wild and/or farm-raised. 7 C.F.R. § 60.200 (2009).

76. CAL. HEALTH & SAFETY CODE § 25249.6 (West 2006) (“No person in the course of doing business shall knowingly and intentionally expose any individual

warning situations, labeling is either mandatory or at least regulated.⁷⁷ For voluntary information that may serve as a warning, however, producers decide for themselves whether and how to provide the label information. When information is deemed to be negative or seems likely to be understood as a warning, producers understandably prefer not to provide it. Information that provides a warning is clearly negative. If an ingredient is known to cause cancer, for example, consumers might prefer to avoid it. A label that indicates the presence of a known carcinogen, then, provides negative information and functions as a warning. Other warnings, such as allergy information are only warnings to some consumers, but certainly are negative information for those consumers.⁷⁸

When the unlabeled feature is somehow perceived to be inferior, producers would understandably prefer not to bring the feature to the attention of consumers. But the de facto mandatory nature of voluntary labeling means that consumers can identify those products produced with conventional methods, those animal products that might come from clones, and those products that contain GMOs, even if the label does not point out these characteristics. Producers of products with “negative” features have an incentive to encourage the prohibition of even voluntary process labels.

The possibility of actually prohibiting truthful process information has been playing out around the bovine growth hormone issue for some time. In 1993, the FDA approved rBST for use in dairy

to a chemical known . . . to cause cancer.”); *id.* § 25249.11(f) (providing that the warnings can and should be provided on labels by the producer).

77. *See, e.g.*, Food Allergen Labeling and Consumer Protection Act of 2004 § 203(a), 21 U.S.C. § 343(w) (2006) (requiring labeling of eight major allergens).

78. Logically, there could be voluntary negative labels, but these generally do not exist. For example, a label that indicates that the milk is from cows that were treated with recombinant bovine growth hormone (rBGH), or that claims the product contains genetically engineered soy, or that the meat is from a cloned animal, would be voluntary labels, but we do not see such labels. The negative information is not required, and the positive information generally is not prohibited. For example, some products bear a small white box with black print stating that no GMOs were used. The positive information is available for consumers who look for it, but the negative information hides in the background. This is the labeling scenario that intrigues me most.

cows.⁷⁹ rBST is a genetically engineered hormone that promotes increased milk production.⁸⁰ According to the product website, it “continues to prove itself to be an effective management tool that helps dairy producers, both large and small, improve their operations, lower their cost for producing high quality milk[,] and achieve higher profitability.”⁸¹ It mimics a cow’s natural hormones, so it does not harm the cow.⁸² But the increased lactation does tend to

79. Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,946 (Nov. 12, 1993) (codified as amended at 21 C.F.R. §§ 510.600, 522.2112); Press Release, U.S. Food & Drug Admin., FDA Approves New Animal Drug Sometribove (Nov. 5, 1993) Bovine somatotropin is a naturally produced growth hormone (in a cow) that controls milk production. *Recombinant* bovine somatotropin is a genetically engineered hormone—recombinant means that genetic material has been recombined. rBST is injected in cows to increase milk production. rBST is often referred to as rBGH.

80. See Press Release, Monsanto Co., Eli Lilly and Company to Acquire Monsanto’s POSILAC Brand Dairy Product and Related Business (Aug. 20, 2008), available at <http://monsanto.mediaroom.com/index.php?s=43&item=629>.

POSILAC bovine somatotropin is an FDA-approved animal pharmaceutical used by U.S. dairy farmers to increase productivity. Since it was first sold in the United States in 1994, POSILAC has become the country’s leading dairy animal supplement. POSILAC safely increases productivity of dairy cows thereby allowing family farm owners to more easily provide for their family and employees, reinvest in their farms, and conserve resources like land, water and energy. Over the past 14 years, more than a half billion units of POSILAC have been successfully and safely used by tens of thousands of dairy producers on millions of cows to produce wholesome, nutritious, safe and affordable milk and dairy products.

Id.; see also Press Release, Monsanto Co., FDA Approves POSILAC Production at Monsanto’s Augusta Facility (Mar. 20, 2006) [hereinafter Press Release, FDA Approves POSILAC Production] (on file with author), available at <http://monsanto.mediaroom.com/index.php?s=43&item=109&printable> (stating that POSILAC is used to “safely enhance[] milk production,” “improve the efficiency and profitability of [dairy] operations,” and to give dairy farmers “additional economic security by increasing the return on their investment”).

81. Elanco, POSILAC Product Page, <http://www.elanco.us/products/posilac.htm> (last visited Aug. 28, 2009).

82. Press Release, FDA Approves POSILAC Production, *supra* note 80 (stating that POSILAC is used to “safely enhance[] milk production,” “improve the efficiency and profitability of [dairy] operations,” and to give dairy farmers “additional economic security by increasing the return on their investment”).

make cows vulnerable to infections,⁸³ and cows that are treated with rBST are also likely to be treated with more antibiotics.⁸⁴

rBST is added to the cow, not the milk, so in theory, the milk itself is not affected. There are those who claim otherwise,⁸⁵ but the FDA says it cannot tell the difference.⁸⁶ We should assume, for sake

83. See I.R. Dohoo et al., *A Meta-Analysis Review of the Effects of Recombinant Bovine Somatotropin* (pt. 1), 67 CANADIAN J. VETERINARY RES. 241, 247, 249 (2003), available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=280708&blobtype=pdf> (finding that while “the overall effect of rBST was to produce an increase in 3.5% fat-corrected milk of approximately 4.4 kg per day,” it “reduced the body condition of cows”); *id.* (pt. 2) at 252–64, available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=280709&blobtype=pdf> (finding that rBST: increased the risk of clinical mastitis by approximately 25% during the treatment period, increased the risk of a cow failing to conceive by approximately 40%, and increased the risk of a cow developing clinical signs of lameness by 50%). See generally Scientific Comm. on Animal Health and Animal Welfare, *Report on Animal Welfare Aspects of the Use of Bovine Somatotropin* (Mar. 10, 1999), available at http://ec.europa.eu/food/fs/sc/scsah/out21_en.pdf (reporting on, *inter alia*, reproductive problems, leg and foot disorders, and mastitis in dairy cows as a result of being injected with rBST).

84. Increased incidents of mastitis (an infection of the udder) will likely result in higher rates of treatment with antibiotics.

85. U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., REPORT ON THE FOOD AND DRUG ADMINISTRATION’S REVIEW OF THE SAFETY OF RECOMBINANT BOVINE SOMATOTROPIN (2009), <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm> [hereinafter FDA, SAFETY OF rBST] (“It may be calculated, based upon consumption of 1.5 liter of milk per day, by a 10 kg child, with a concentration of approximately 5 micrograms (μg : 10^{-6}) rbST per liter of milk, that children are exposed to 7.5 $\mu\text{g}/\text{kg}/\text{day}$.” (footnote omitted)). The report goes on to say that this is not of concern because “bGH and rbGH are biologically indistinguishable” and levels of rBGH several hundred times stronger than this were needed in order to see an immunological response in rats. *Id.* In spite of being “biologically indistinguishable,” the concern about the presence of rBGH in milk products is evidenced by the consumer demand for rBGH-free products.

86. See Degnan, *supra* note 12, at 58 (citing Animal Drugs, Feeds, and Related Products; Sterile Somatotribove Zinc Suspension, 58 Fed. Reg. 59,946 (Nov. 12, 1993) (codified as amended at 21 C.F.R. §§ 510.600, 522.2112)) (explaining that in approving rBST, the FDA concluded that dairy products from treated herds were indistinguishable from products from untreated herds); see also *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 70 (2d Cir. 1996) (“The United States Food and Drug Administration has determined that there is no significant difference between milk from treated and untreated cows.”); EXPERT PANEL ON HUMAN

of argument, that the milk really is indistinguishable from milk from non-treated cows. Accordingly (and predictably), there is no mandatory labeling requirement.⁸⁷

Nevertheless, some consumers want to know whether their milk comes from treated cows or untreated cows. Consumers want this information for a variety of reasons. For example, some consumers prefer not to consume any foods produced with genetically engineered inputs.⁸⁸ Others may feel that the evidence of safety was not conclusive enough when rBST was approved.⁸⁹ Some may have worried that the hormone itself would appear in their milk.⁹⁰ For whatever reason, when the FDA approved rBST treatment, a market for milk from cows that had not been treated soon came into existence and still exists today.⁹¹

Although the FDA did not require rBST labeling, the State of Vermont promptly passed legislation requiring that retail milk products from treated cows be so-labeled.⁹² The required label informa-

SAFETY OF RBST, HEALTH CANADA, REPORT OF THE ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF CANADA (1999), http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep_rcpsc-rap_crmcc_final-a-eng.php (“When cows receive the recommended doses of rbST, the content of bST (measured as natural plus recombinant somatotropin) in milk does not increase.” (citing Paul P. Groenewegen et al., *Bioactivity of Milk from bST-Treated Cows*, 120 J. NUTRITION 514 (1990))).

87. 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. 6,279, 6,280 (Feb. 10, 1994).

88. Teisl, *supra* note 56, at 49.

89. FDA, SAFETY OF RBST, *supra* note 85 (citing the desire of public interest and consumer groups to have the studies reviewed to see if the findings that suggest that there is no harmful impact of rBGH on milk).

90. *See id.*

91. *See* Tirtha Dhar & Jeremy D. Foltz, *Milk by Any Other Name . . . : Consumer Benefits from Labeled Milk* 18 (Food Sys. Research Group, Working Paper No. 2, 2003), available at http://www.aae.wisc.edu/fsrg/working_papers.htm (finding that “consumers pay significantly more for” milk marketed as rBST-free).

92. VT. STAT. ANN. tit. 6, § 2754 (Supp. 1997) (repealed 1998); *see* Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996) (holding in favor of the dairy manufacturers that challenged the constitutionality of VT. STAT. ANN. tit. 6, § 2754(c) on First Amendment grounds). In 1994 Vermont “enacted a statute requiring that “[i]f rBST has been used in the production of milk or a milk product

tion would have been truthful,⁹³ but proponents of rBST objected to the labeling requirement. The statute was struck down on First Amendment grounds; the court saw the non-treated language as “the functional equivalent of a warning.”⁹⁴

While rBST labeling is not mandatory, some products do bear a label stating that rBST was *not* used. The voluntary labeling of some products creates a negative “label” on other products. Consumers who see some milk cartons labeled as not from treated cows may interpret the absence of such a label as an indication that a dairy product does come from treated cows. Since the use of rBST is seen as negative, this is a marketing challenge for dairies that use rBST as well as for the makers of rBST. Accordingly, the Monsanto Company, a well-known agricultural technology corporation, has tried over the years to bring about a prohibition of the non-treated label language.⁹⁵

In 1994, the FDA published interim guidance on the labeling of milk products from treated or non-treated cows.⁹⁶ While the guidance does not require specific language, it emphasizes the rule that

for retail sale in this state, the retail milk or milk product shall be labeled as such.” *Id.* (alteration in original).

93. A label stating that rBST had been used in the production of the milk is true when rBST has been used in the production of that milk.

94. *Int'l Dairy Foods Ass'n*, 92 F.3d at 73.

95. See Shawn Dell Joyce, *Deciphering Labels*, HILL COUNTRY TIMES (Spring Branch, Tex.), Nov. 11, 2009, available at http://www.hillcountrytimes.com/print_this_story.asp?smenu=140&sdetail=2729 (“Monsanto is suing the Food and Drug Administration to remove the [rBST] label from the marketplace.”).

96. 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. 6,279, 6,280 (Feb. 10, 1994).

[The] FDA believes such misleading implications could best be avoided by the use of accompanying information that puts the statement in a proper context. Proper context could be achieved in a number of different ways. For example, accompanying the statement “from cows not treated with rBST” with the statement that “No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows” would put the claim in proper context. Proper context could also be achieved by conveying the firm’s reasons (other than safety or quality) for choosing not to use milk from cows treated with rBST, as long as the label is truthful and nonmisleading.

Id.

labeling must not be misleading under FDCA § 403(a).⁹⁷ Milk producers who wish to label their products as those derived from non-treated cows are advised under the rule to provide the context for their statements.⁹⁸ Although the FDA suggested language such as: “No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows[,]”⁹⁹ the Interim Guidance explained that this language is not actually required and other contextualizing statements might suffice.¹⁰⁰ The Federal Trade Commission also cited the Interim Guidance when it considered the same issue in a 2007 response to Monsanto.¹⁰¹ As a practical matter, nearly all producers provide some version of the “no significant difference” statement.

C. Process Information and the Not Misleading Rule

Consumers want process information and in some instances have applied enough pressure to win mandatory labeling rules, such as country-of-origin labeling. Even though process information is not required, it has not been prohibited, despite industry efforts. However, process information may collide with the not-misleading rule. Why *do* consumers reject cloning? Do they think the meat will be radioactive? Do they think the milk will be green? Do they really imagine that they will be able to tell the difference? Under the not-misleading rule, a label that reads “Not a Clone” could be misleading unless some of the above sentiments prove to be true. If the clone product proves to be the same, however, then its method of production is irrelevant, and therefore should not be used for product differentiation and price premium.

97. *See id.*; *see also* Federal Food, Drug, and Cosmetic Act § 403(a), 21 U.S.C. § 343(a) (2006).

98. *See id.*

99. *Id.*

100. *Id.*

101. Letter from Mary K. Engle, Assoc. Dir., Div. of Adver. Practices, Fed. Trade Comm'n, to Jodie Z. Bernstein & Dana B. Rosenfeld (Aug. 21, 2007), *available at* <http://www.ftc.gov/os/closings/staff/070821monsanto.pdf> (declining Monsanto's request to institute enforcement action against milk companies with rBST-free labels).

But perhaps when consumers think about food, they think about more than just the chemical “identity” of that food. Even if food products from cloned animals are the same as those from non-clones, some consumers disapprove of the cloning process itself.¹⁰² Similarly, even if all the milk is the same, some consumers disapprove of rBST as a process component and prefer to buy milk from cows that were not treated. The process by which the milk was produced is what matters to them, even if the final product is not changed.¹⁰³

The examples above notwithstanding, most process information is voluntary, and accurate statements about process are allowable even though the food they adorn is not distinguishable from similar food. A well-known example is the USDA Organic label, which is won through specific production practices,¹⁰⁴ and is permissible even though most organic food is chemically indistinguishable from its non-organic counterpart.¹⁰⁵ Similarly, the presence of GMOs in a food product is voluntary label information, as is a label indicating whether chickens were or were not treated with antibiotics.¹⁰⁶ Are process labels such as the USDA Organic symbol and non-GMO statements such as “no antibiotics,” or “no rBST” misleading? Does process information imply that a product itself is superior to its unlabeled counterparts?

One argument against allowing process information on labels is that it presents the potential for fraud because labeling regulations are only as good as the possibility of enforcement.¹⁰⁷ If the finished

102. NANCY FARMER, *THE HOUSE OF THE SCORPION* (2002) is an entertaining and chilling picture of where cloning could go. In this Newberry Award-winning novel, human clones are raised to produce replacement organs for transplantation. *Id.* The main character is the clone being grown for his brain. *Id.*

103. *But see* Margaret Sova McCabe, *Got Controversy? Milk Does*, 13 *DRAKE J. AGRIC. L.* 475, 478–79 (2008) (arguing that consumers prefer milk from untreated cows because of safety concerns due in part to the increased use of antibiotics).

104. 7 C.F.R. pt. 205 (2009).

105. For some foods, organic production does result in measurable differences. *See Winter, supra* note 52, at 48.

106. United States Standards for Livestock and Meat Marketing Claims, 67 *Fed. Reg.* 79,552, 79,554 (Dec. 30, 2002).

107. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, *FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS* (2008), available at <http://www.gao.gov/new.items/d08597.pdf> (“FDA’s

products differ, enforcement of labeling information is quite feasible—all that is needed is some product testing to ensure that the box actually contains what the label maintains that it does.¹⁰⁸ When the

oversight and enforcement efforts have not kept pace with the growing number of food firms. As a result, FDA has little assurance that companies comply with food labeling laws and regulations for, among other things, preventing false or misleading labeling.”). Within the Department of Health and Human Services, the FDA is responsible for enforcing federal food labeling requirements, in accordance with the FDCA. *Id.* at 1. The “FDA oversees industry compliance with the food labeling requirements” through the Center for Food Safety and Applied Nutrition (CFSAN). *Id.* at 2. The FDA’s Office of Regulatory Affairs (ORA) is responsible for performing inspections and enforcement actions. *Id.* The FDA has various ways to respond when food-labeling violations are found. *Id.* The FDA may request a voluntary recall or send a warning letter. *Id.* If the violation is not corrected the FDA may seize the food product or enjoin the violator from continuing to act in a violating manner. *Id.* For imported food, the FDA may issue an import refusal to keep food from entering the U.S. if there is a labeling violation. *Id.* at 2–3; *see also* 21 U.S.C. §§ 332–334 (2006) (discussing enforcement options).

108. *See* FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2010 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 189–216 (2009), *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153559.pdf>. This description of ORA activities provides one with an understanding, both of how much testing is done and how much importance is given to testing for accuracy in food labeling.

The laboratory analytical function of ORA is conducted in 13 laboratories located throughout the country. The ORA laboratory structure consists of five Regional Labs, four District Labs, and four Specialty Labs. Regional Labs are large general purpose laboratories that participate in most major analytical programs. District Labs participate in several analytical programs and have specialties in specific areas. Specialty labs conduct analyses in specific areas of laboratory service including; engineering, biological, and chemical hazards associated with medical devices, electronic products, and radiopharmaceuticals; and, forensic analysis of samples related to criminal activities that fall under FDA jurisdiction; including drug counterfeiting.

Id. at 194. However, the ORA claims that they have “improved lab facility usage overall and efficiency in analytical response to emergencies, outbreak, consumer complaints as well as routine import and domestic sample collections.” *Id.* In a 2005 letter to then-Commissioner Eschenbach, representatives of the Center for Science in the Public Interest voiced their concerns for the low priority that labeling violations are given by the ORA and the FDA. Letter from Michael F. Jacobson et al., Ctr. for Sci. in the Pub. Interest, to Andrew von Eschenbach, Acting Comm’r, U.S. Food & Drug Admin. (Oct. 27, 2005) (citing FOOD & DRUG

finished products cannot be distinguished, however, enforcement is more costly because it requires monitoring the production system.¹⁰⁹ So in the case of process information, there may be an increased possibility of fraudulent label claims.

The focus here, however, is quite different; when one label bears a truthful claim about process, all products are effectively labeled with respect to that process. If a processed-salmon package indicates that the salmon is “wild,” a consumer who is paying attention would reasonably assume that an unmarked package contains farmed salmon. If milk is labeled as derived from untreated cows, then all milk not bearing this label can be assumed to come from treated cows. Because of the de facto mandatory nature of voluntary labeling, consumers may interpret process information as a claim about the identity of both the labeled and unlabeled products.

IV. CHARACTERISTICS OF CONSUMERS

Information requires an audience, which plays an important role in the transfer of knowledge.¹¹⁰ The effect of information depends

ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FIELD MANAGEMENT DIRECTIVE 119: CONSUMER PRODUCTS COMPLAINT SYSTEM (1994), *available at* <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061481.htm>, *available at* http://www.cspinet.org/new/pdf/misleading_labels_letter.pdf (remarking on the lack of ability to enter a complaint for a labeling violation).

109. See Gruère & Rao, *supra* note 21, at 52–53. One of the criticisms leveled against rBST absence labeling is that there is no way to tell from the finished product if the label is truthful or not, which makes untruthful labeling difficult to detect.

110. See generally JAMES M. NEHILEY, THE ROLE OF THE AUDIENCE IN THE COMMUNICATION PROCESS 1 (Fla. Dep't of Agric. Educ. & Comm'n, AEC 317, 1997), *available at* <http://www.okcareertech.org/CIMC/titles/lifeskills-comm/Resources/CommUnit3/FLaudiencerole.pdf> (“Without the audience there is no real need to communicate. Does a tree falling in the desert make a sound? Who cares?”); Geoff Hart, “Prescriptive” Audience Analysis: Moving Beyond the Purely Descriptive, TECHWR-L, Sept. 10, 2007, <http://www.techwr-l.com/prescriptiveanalysis> (citing KAREN A. SCHRIVER, DYNAMICS IN DOCUMENT DESIGN (1997)) (discussing audience considerations in rhetoric); Bonni Graham, Identity Crisis: The Persona as a Tool for Formulating and Evaluating Information Design, Presentation at the 48th Society for Technical Communication Conference

on what the audience brings to the transaction. Individual consumers receive information in different contexts—with prior knowledge or total ignorance, with predetermined opinions or open minds, with indifference or passion—but labeling regulations are one size fits all. This section examines the intersection of consumer preferences and consumer knowledge with respect to process labeling. Not all consumers can be misled, and consideration of consumer characteristics may lead to a better labeling policy.

For example, in the case of carbon monoxide in meat packaging, a label that says “packed with carbon monoxide” may not have any effect on the behavior of informed consumers who already base their purchase decisions on the freshness date, but it may encourage greater diligence in uninformed consumers. The information on the label would have an educational function for these consumers because it would bring forth an issue of concern that was not previously on their radars. On the other hand, the UDA organic seal on a package of Oreos may have no effect on consumers who know that “organic” refers to the agricultural methods employed in growing the grains and sugar that went into the cookies. But some consumers might be lead to believe that organic Oreos are somehow more nutritious than conventional Oreos. The organic symbol would be misleading for these consumers—cookies are bite-sized bundles of refined carbohydrates, whether the sugar and white flour were grown with chemicals or not.

Labeling policies should minimize the extent to which consumers are misled to their detriment while enabling consumer sovereignty. Carbon monoxide packaging notwithstanding, process information in particular seems to collide with the not-misleading rule because individual consumers bring such varied perspectives. Or do they? Do most consumers know or care about growth hormones, genetically engineered crops, how fish are grown, whether a Rabbi supervised a kitchen, or whether a sheep grazed a meadow in central Oregon or on the other side of the world? Perhaps a consideration of consumer characteristics is in order.¹¹¹

(May 13–16, 2001)) (“Editing and writing both require an understanding of our audience . . .”).

111. See McCabe, *supra* note 103, at 478 (calling for consumer studies).

A. Consumer Preference and Consumer Knowledge

1. Consumer Preference: Negative, Positive, Irrelevant

Labeling rules should maximize consumer utility by enabling consumers to get what they want.¹¹² Consumers can be misled to their detriment or tricked into spending too much when they care about the information on the label, and they rely on the label to provide the information. Consumers who are indifferent or are very knowledgeable—and so don't need to rely on the label—cannot be misled. This section will develop these consumer characteristics and explore the application of the not-misleading rule in this context.

The prohibition against misleading consumers is based on the presumption that choices based on lack of information or wrong information diminish utility. This presumption is not always correct. Sometimes people make choices that increase their welfare based on misunderstandings or based on false assumptions. If choices that increase welfare are desirable, then they are the “right” choices. Reasoning based on false information or misapprehension is to be avoided, and thus represents a “wrong” reason. In other words, sometimes people make the right choices for the wrong reasons. Sometimes label information leads consumers to the “right” choices,¹¹³ but not always for the “right” reasons.

Presumably consumers know what they want. When consumers are indifferent, however, labeling may not matter. Does the information on a label really matter at all? And if so, in what way does it matter? Information itself is neutral. A cloned cow is simply a cloned cow. A brown cow is a brown cow. For some consumers, the information is interesting but irrelevant, and for other consumers, it may not even be interesting.

112. See Smith & McPherson, *supra* note 14, at 330 (providing a definition of liberty for this purpose: “People should be free to do what they like—and to opt out of undesirable arrangements if they want to do so. . . . [P]eople should be ‘free to choose.’” (quoting THALER & SUNSTEIN, *supra* note 17, at 5)).

113. Thinking of labels as leading consumers may be paternalistic, but it is a liberty-enhancing paternalism along the lines of the “libertarian paternalism” described in recent writings. See *id.*; Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1159 (2003).

Kosher food provides a useful example. When delivering a presentation on this issue, I show two slides of the same food label. On one slide, the label bears a small symbol called a *heksher* indicating that the product is kosher.¹¹⁴ On the next slide, the *heksher* has been removed from the label. I ask the audience if they see anything on the labels that would make one product more or less attractive than the other. I go back and forth a few times. Those in the audience who happen to be Jewish and keep kosher may notice that the first slide is kosher and the second is not, and as a result, some may express a preference. But most people see no difference at all; the *heksher* provided no information whatsoever. Moreover, many people do not even *see* the *heksher*. And for many who know that this symbol identifies the product as kosher, the presence of the *heksher* probably makes no difference. This information is completely neutral for most consumers. It plays no role in their purchasing behavior.¹¹⁵

When information is irrelevant to consumers, there seems to be only a limited role for regulation. Some state statutes limit the use of the word “kosher” to foods prepared in accordance with orthodox Jewish dietary laws,¹¹⁶ and similar statutes apply to the word *halal* requiring that it only be used to designate foods made in accordance with Islamic dietary standards.¹¹⁷ While these statutes may raise

114. A *heksher* is the trademark of a kosher certification organization. The most widely known is the symbol of the Orthodox Union and appears as a U within a Circle. See Judaism 101, Kashrut: Jewish Dietary Laws, <http://www.jewfaq.org/kashrut.htm> (last visited Oct. 30, 2009).

115. Of course, if the label designation is false, the product is misbranded whether or not anyone reads it or cares. In the case of kosher foods, lawsuits and challenges to labels are likely to be brought by competitors. Another article could address when federal regulation of label claims is warranted.

116. Such statutes have faced court challenges. Most recently, Georgia’s kosher labeling statute has been challenged under the Anti-Establishment Clause of the First Amendment because it requires orthodox supervision for kosher certification. See First Amended Complaint at 9–10, *Lewis v. Irvin*, No. 2009cv1173206 (Ga. Super. Ct. Aug. 7, 2009), available at http://www.aclu.org/pdfs/religion/lewis_v_irvin_complaint.pdf; see also Elijah L. Milne, *Protecting Islam’s Garden from the Wilderness: Halal Fraud Statutes and the First Amendment*, 2 J. FOOD L. & POL’Y 61, 63 n.11 (2006) (providing a list of state statutes).

117. Only a handful of states (California, Illinois, Michigan, Minnesota, New Jersey, and Texas) have adopted statutes that regulate the use of the term *halal* on

First Amendment issues,¹¹⁸ the issue here is the use of label information to convey something about process. The general *kashrut* designation does not make any claims about ingredients or the chemical composition of the food.¹¹⁹ Accordingly, a product such as kosher orange juice would not necessarily be any different from the non-kosher version of that product.¹²⁰

If, however, consumers care about a certain characteristic, then using a label to identify the presence of the characteristic should facilitate the decision to purchase. Caffeine presents another example. Some carbonated beverages contain caffeine, while others do not.¹²¹ The presence of caffeine does not usually carry a strong emotional load one way or another, but consumers have preferences in both directions. People who feel a need for stimulants want products with caffeine, while others prefer caffeine-free products. If soda cans were not labeled, but some soda had caffeine while others did not, then consumers who wanted caffeinated beverages would likely choose another beverage such as coffee or tea. Consumers who can-

food labels. See Milne, *supra* note 116, at 63 n.9, 71–72 (citing CAL. PENAL CODE § 383c (West 2005); 410 ILL. COMP. STAT. 637/5 (2005); MICH. COMP. LAWS § 750.297f (2005); MINN. STAT. §§ 31.658, 31.661 (2005); N.J. STAT. ANN. §§ 56:8-98 (2005); TEX. BUS. & COM. CODE ANN. § 17.881 (Vernon 2005)).

118. First Amended Complaint, *supra* note 116, at 7–10.

119. Many independent certifiers have arisen for both kosher and *halal* foods and state statutes do not explicitly prefer one certifier over the others. In other words, there is no federal or state “kosher” mark. Governmental participation is limited to declaring that if food is marketed as “kosher” then it must be marked in a certain way by a certain kind of person. See Milne, *supra* note 116, at 63 n.9, 71–72 (citing statutes). In addition, Minnesota law explicitly mentions the placement of marks on meat. See MINN. STAT. ANN. § 31.661 (West Supp. 2009).

120. Some *kashrut* symbols do add a small “d,” meaning that the food is dairy, or the word “Pareve” or “Parev,” indicating that the food has no dairy or meat ingredients. See Judaism 101, *supra* note 114. The focus here, however, is on the process information.

121. For example, in a 12 ounce container of 7up, Sprite, or Barq’s Diet Root Beer there are 0 mg. of caffeine. However, the same amount of Mountain Dew has 54 milligrams of caffeine, the same amount of Coke has 35 milligrams, and the same amount of Barq’s Root Beer has 23 milligrams. Mayo Clinic, Caffeine Content for Coffee, Tea, Soda and More, <http://www.mayoclinic.com/health/caffeine/an01211> (last visited Oct. 30, 2009). *But see Caffeine Content in Soda Can Vary, Study Finds*, MSNBC, Sept. 4, 2007, <http://www.msnbc.msn.com/id/20593038>.

not tolerate caffeine, on the other hand, would do well to avoid all soda. Only the consumers who are indifferent to the presence of caffeine would consume soda regardless of labeling. In the case of caffeine labeling on carbonated beverages, the presence of information on labels helps consumers to choose the products they want and assists the carbonated beverages market.¹²² Thus, the labeling of caffeine is mandatory.¹²³

In the case of caffeine, as in the case of *kashrut*, the information itself is neutral; it is the character of the consumer that makes the information meaningful and determines its function.¹²⁴ But for Jewish consumers who care about eating kosher food, the information that a food is kosher is critical, and for some ritually observant Jews, non-kosher food products are not even “food.” Similarly, for consumers with a peanut allergy, products that contain peanuts are like a poison. And for those sensitive to caffeine, caffeinated beverages are like a dangerous drug.

When consumers have no preference for one product feature over another, label information cannot mislead them to their financial detriment. Such consumers will make purchase decisions based on the product features that matter to them—price, the attractiveness of a package, or placement near the checkout registers. Consumers who *do* have a preference, however, might be expected to take label information into account when choosing foods. Consumers who have preferences other than price, such as a preference for caffeine or no caffeine, could be misled.

2. Consumer Knowledge

Consumer preference, however, is only half the equation. Consumer knowledge is the other half. Labels can only be misleading if consumers have a preference *and* rely on label claims to inform their

122. Similar analysis could be made for sugar versus artificial sweetener, the presence or absence of nuts or raisins, and other food characteristics.

123. *See generally* 21 C.F.R. § 101.4 (2009). Caffeine is considered a “generally recognized as safe” substance as long as the product contains no more than .02 percent caffeine. *Id.* § 182.1180.

124. *See* Gruère & Rao, *supra* note 21, at 52 (noting that in all countries with labeling regulations, labeling is mandatory for genetically engineered products that are not substantially equivalent to their conventional counterparts).

buying behavior. Consumers who know about kosher food, and know what certain symbols signify, cannot be misled by the presence or absence of truthful labeling. Similarly, consumers who know absolutely nothing, but also do not care, will not be misled by truthful process labeling.

Recall the low fat applesauce example.¹²⁵ Consumers who are trying to follow a low fat diet may do so by looking for food products labeled “low fat,” or they may choose to learn the fat content of the foods they like in order to make choices in the absence of label information. A label that reads “low fat applesauce” could mislead a consumer who cares about fat content and relies on labels, but does not actually know much about dietary fat. Such a consumer might believe that other applesauce brands are *not* low fat.

A consumer who knows that applesauce is always low fat cannot be misled. And a consumer who does not care about fat content cannot be misled. It is only the consumer who has a preference, wants “low fat,” but is not knowledgeable about that preference who can be misled. Similarly, a consumer who wants to avoid rBST and knows that Tillamook brand cheese comes from cows not treated with rBST may choose to buy Tillamook brand cheese even though it is not labeled to this effect. A consumer who prefers organically produced vegetables and who personally knows a farmer using organic production methods may happily buy produce from the farmer, even in the absence of USDA certification and labeling. So in general, a consumer who is very knowledgeable about a food product feature cannot be misled by a label claim and, as noted above, a consumer who has no preference one way or another also cannot be misled.

Of course, consumers who have clear preferences may be motivated to become knowledgeable because of their preferences. But sometimes consumers *would* have a preference if they knew that they had a choice. Most consumers twenty years ago had no preference for organically produced food; most did not know there was such a thing.¹²⁶ Most would have said, however, that they preferred

125. *See supra* Part II.C.

126. *U.K. Has Third-Largest Food Market*, INDEPENDENT (London), Nov. 6, 2003, available at <http://www.independent.co.uk/news/uk/this-britain/uk-has->

produce grown without pesticides, other things being equal.¹²⁷ Presumably consumers opposed to pesticides would prefer organically grown produce *if they knew that* “organic” meant “no pesticides.”

It is only the consumer who develops a preference in the presence of labeling, or who has a preference but no knowledge, who can be misled by the label.

The FDA’s misbranding statute is supposed to prevent economic harm by protecting consumers from paying for products that they do not really want.¹²⁸ The FDA should not construe the statute in such a way that would cause consumers to make decisions on bad information. When knowledgeable consumers do not have a preference, there is no need for labeling, especially if the presence of information on a label would affect the behavior of non-knowledgeable consumers. Since labels often have an educational function, consumers may develop a preference in the presence of labeling. A potential for misapprehension arises. For example, knowledgeable consumers may know that sugar can be derived from sugar cane or from beets.¹²⁹ Until recently, however, this information probably did not

thirdlargest-organic-food-market-734751.html (“Twenty years ago, those who espoused the cause of organic food were considered a strange, marginal species.”).

127. According to a recent documentary, Americans who have grown up in the past thirty years have probably never tasted grass-fed beef. KING CORN, *supra* note 15. Most beef cattle are corn fed, at least at the end of its lifetime. *Id.* Consumers who do not know anything about the cattle that becomes their hamburgers may not have a preference for grass-fed beef, but they might have a preference if they knew they had a choice. Interestingly, one court used this example of the absurdity of allowing consumer interest to impose labeling requirements: “For instance, with respect to cattle, consumers might reasonably evince an interest in knowing which grains herds were fed” *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996). However, the court continued to say that “[a]bsent . . . some indication that this information bears on a reasonable concern for human health or safety . . . the manufacturers cannot be compelled to disclose it.” *Id.*

128. See 21 U.S.C. § 393(b) (2006). The stated mission of the FDA is to protect public health and safety. *Id.* Economic safety is a part of public health and safety and is illustrated by the context in which the FDCA arose. At the time of the FDCA’s creation there was a concern about people being duped into buying products based on misleading claims. See MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH* 233 (2002).

129. In fact, 56.1% of U.S. sugar comes from sugar beets and the remaining 43.9% comes from sugar cane. See USDA Economic Research Service Briefing Room, Sugar and Sweeteners: Recommended Data, <http://www.ers.usda.gov/>

influence their purchase decisions one way or another;¹³⁰ those who are avoiding refined carbohydrates will eschew products containing sugar derived from either source, and those willing to eat sugar will accept sugar from either source.¹³¹ Uninformed consumers, however, may think that beet sugar or cane sugar is a new ingredient.¹³² The process information, “comes from beets,” might cause an uninformed consumer to develop a preference. If an uninformed consumer thought that the label implied a difference in the sugar because of its source, then such a consumer might be induced to pay more for one type or the other. In other words, truthful label information could mislead some consumers to their economic detriment, which would be contrary to the statutory goal of preventing economic harm.

Neither consumers who do not care about a product feature nor consumers who know a lot about a product feature will be harmed if the feature is labeled. Consider the following chart:

Briefing/Sugar/data.htm (follow link to “Table 16”) (last visited Oct. 30, 2009). Globally 78% of sugar comes from sugar cane. ILOVO SUGAR LTD., ANNUAL REPORT 2008, at 44 (2008), available at http://www.ilovo.co.za/Libraries/2008_Annual_Report/Annual_Report_2008_Part_6.sflb.ashx.

130. The USDA’s Animal and Plant Health Inspection Service approved glyphosate-resistant (Roundup Ready) sugar beets for commercial production in 1998. See Novartis Seeds and Monsanto Co.; Availability of Determination of Nonregulated Status for Sugar Beet Genetically Engineered for Glyphosate Herbicide Tolerance, 64 Fed. Reg. 1,177, 1,177–78 (Jan. 8, 1999); AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Sugar Beet Genetically Engineered for Glufosinate Herbicide Tolerance, 63 Fed. Reg. 25,194, 25,194–95 (May 7, 1998). However, sugar cane has not yet been genetically engineered. Consequently, consumers who are determined to avoid GMOs will now have a reason to make a distinction between sugar from beets and sugar from sugar cane.

131. Andrew Pollack, *Round 2 for Biotech Beets*, N.Y. TIMES, Nov. 27, 2007, at C1, available at <http://www.nytimes.com/2007/11/27/business/27sugar.html> (quoting David Berg, president of American Crystal Sugar, the nation’s largest sugar beet processor, about consumer attitudes toward the new genetically engineered sugar beet: “Basically, we have not run into resistance.”).

132. While typical consumers may not be aware of sugar coming from both sugar beets and sugar cane, they are becoming more aware of sweeteners derived from corn, such as high fructose corn syrup. Kim Severson, *Sugar Is Back on Food Labels, This Time as a Selling Point*, N.Y. TIMES, Mar. 21, 2009, at A1, available at <http://www.nytimes.com/2009/03/21/dining/21sugar.html>.

		Consumer Preference	
		Don't Care	Do Care
Consumer Knowledge:	Informed	Not misled to own detriment	Not misled to own detriment
	Not informed	Not misled to own detriment	<i>Can</i> be misled

The only consumers who can be misled are those who are uninformed or unaware of a product feature *and* who have a preference, or would likely develop a preference in the presence of labeling. Labeling policies aimed at preventing deception should consider the likelihood that labeling will create a preference as well as the possibility that consumer ignorance will lead to detrimental purchasing decisions.

B. Role of Consumer Concern in Labeling Regulation

1. Current Practices

The FDCA mandates labeling when the labeled feature involves facts material to possible consequences of use of the product because of “material” chemical differences in the food—in other words, labeling is mandatory when the label information is needed to identify the food.¹³³ Labeling is usually voluntary when there is no material difference.

In *Alliance for Bio-Integrity v. Shalala*,¹³⁴ a federal district court noted that it was not clear whether “materiality” in the statute refers only to safety or also to consumer interest.¹³⁵ The FDA took the position that the genetic engineering of foods did not result in any material change.¹³⁶ The plaintiffs argued that the FDA should have considered consumer interest, in addition to the special concerns of

133. 21 U.S.C. § 321(n).

134. 116 F. Supp. 2d 166 (D.D.C. 2000).

135. *Id.* at 178.

136. *Id.*

religious groups and those with allergies.¹³⁷ The court noted that the statute was silent on whether “material” includes consumer interest as well as safety.¹³⁸ Consequently, the agency’s interpretation was entitled to deference if it was reasonable.¹³⁹ Ultimately, the court found that the FDA’s interpretation of “material” was a reasonable interpretation and deferred to the agency’s judgment.¹⁴⁰ The court questioned whether the agency would even be authorized to require labeling merely because of consumer interest.¹⁴¹

For producers, of course, labels are marketing tools. If a food product can bear a positive process label, the producer may enjoy a higher profit margin. Producers would rather not provide negative information. Julie Caswell suggests that a rule against labeling indicates a fear of “consumer sovereignty.”¹⁴² However, if the “negative” information is about the use of new technology, providing the information could possibly impede adoption of the technology.¹⁴³

137. *Id.*

138. *Id.*

139. *Id.* 178 (citing *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 864 (1984)).

140. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

141. *Id.* (“In the absence of evidence of a material difference between [milk from cows treated with a synthetic hormone] and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.” (alteration in original) (quoting *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995)).

142. Caswell, *supra* note 43, at 23 (arguing that allowing no label “has the drawback of suggesting that regulators and producers who use the technology are afraid of consumer sovereignty and want to suppress other producers’ ability to differentiate products based on nonuse of the technology”).

143. *Id.* Whether slowing the adoption of technology is a bad thing, of course, may be subject to debate. See CARUSO, *supra* note 7, at 32–33 (presenting an intriguing treatment of risk analysis in adoption of new technology). The interpretation of neutral information as warning or boast could be a result of media coverage of subject. According to a study of news coverage of GMOs, articles about GMOs in 2001 and 2002 generally did not emphasize a positive or negative aspect of agricultural biotechnology, although when they did address risks and benefits, they covered both. Joan Thomson & Laura Dininni, *What the Print Media Tell Us About Agricultural Biotechnology: Will We Remember?*, 20 CHOICES 247, 250 (2005), available at <http://www.choicesmagazine.org/2005-4/GMOs/2005-4-07.htm>. But at peak GMO coverage in 2001, risks were emphasized more often than benefits. *Id.*

But who decides which information is positive and which is negative? The positive or negative value of label information makes sense in the case of religious dietary rules or allergens, but where do other kinds of information get their value? Is “contains caffeine” a positive statement or a warning? Why is “genetically engineered” deemed to be negative? Why is “organic” positive? Why is “cloned” negative?¹⁴⁴

There are costs associated with labeling policies. Aside from any possible effect on market share, the cost of providing label information is not merely the cost of extra ink. To provide information on a label one must have that information; accordingly, a labeling requirement necessarily forces producers to segregate products that differ with respect to the labeled characteristic.¹⁴⁵ For example, a company that makes conventional and “organic” corn flakes must keep them separate in order to use the “organic” label.¹⁴⁶ So one

144. Professor Margaret McCabe, a law professor at Franklin Pierce Law Center, asked students to make arguments both ways. Students in favor of GMOs said they wanted GMOs to be labeled because they wanted to support the intended consequences of some genetically engineered plant properties such as fewer pesticides and no-till farming. Other students wanted GMOs to be labeled because they wanted to avoid the perception that GMOs are not “natural.”

145. See JAMES A. RIDDLE, *A PLAN FOR CO-EXISTENCE: BEST MANAGEMENT PRACTICES FOR PRODUCERS OF GMO AND NON-GMO CROPS* (2004), http://www.wkkf.org/pubs/foodRur/BiotechBMPs03.final_00253_03862.pdf (explaining the extensive lengths that producers must go to keep non-GMO and GMO products segregated); see also DANNENBERG ET AL., *supra* note 46, at 6 (highlighting the increased costs of segregation, labeling, and testing under a mandatory labeling scheme as opposed to a voluntary labeling scheme); A. Bryan Endres, *Coexistence Strategies, the Common Law of Biotechnology and Economic Liability Risks*, 13 *DRAKE J. AGRIC. L.* 115, 127 (2008) (“[S]egregation is not merely an issue of on-farm measures (e.g., seed testing, buffer zones, equipment cleaning, and transportation segregation) [but it also] . . . extends beyond initial processing and requires segregation measures at each stage [of production].”).

146. 7 C.F.R. § 205.272(a) (2009) (“The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.”). *But see* National Organic Program, 65 Fed. Reg. 80,548, 80,556 (Dec. 21, 2000) (“[7 C.F.R. § 205.105] prohibits the use of excluded methods in organic operations. [But t]he presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reason-

question is whether the additional cost is worth it. For consumers who are indifferent, the additional cost of process labeling would result in disutility. If, for example, beet sugar and cane sugar had to be labeled, consumers might develop a preference for one over the other resulting in one sugar source carrying a premium price. But the cost of segregation would be passed to all consumers, even those who do not have a preference and were happy already. Indifferent consumers would be paying more but would not be getting anything for the extra cost.

There is only an extra cost if producers actually do segregate the products. If a consumer preference only goes in one direction then segregation is not needed for the conventional product. In the case of foods made with genetically modified (GM) ingredients, for example, consumers are generally indifferent or they prefer non-GM products. Few, if any, would wish to avoid non-GM products. Most process feature preferences are mono-directional: consumers prefer organic products or are indifferent; they prefer non-irradiated products or are indifferent; they prefer non-rBST products or are indifferent. Are there consumers who actually seek out non-organic produce? In contrast, there are some preferences that go both ways: consumers prefer either caffeine or no caffeine; they prefer non-fat milk or whole milk. If the preference only goes one way, then not all producers need to segregate their products. Thus in the case of GM foods, consumers who are willing to buy GM products are generally also willing to consume non-GM products. Only producers of non-GM foods need to segregate their products, and thus only the non-GM products carry the extra costs.

Another role for label information is to provide consumers with the feeling that they are making choices. Exercising the right to choose can be a benefit or a burden.¹⁴⁷ While all consumers say, "Surprise me," from time to time, they also like to think they are in

able steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.").

147. Alice G. Abreu, *Taxes, Power, and Personal Autonomy*, 33 SAN DIEGO L. REV. 1, 12 (1996).

control of their lives.¹⁴⁸ Debra Strauss cites studies that show that over 90 percent of Americans think genetically engineered foods should be labeled, but a significantly smaller percentage would actually look for that information on the label.¹⁴⁹ In other words, consumers want information not only when it matters for decision making, but just for information's sake. Information helps consumers think they are making better decisions, even when they are ignoring the information in front of them.

If labeling were mandatory, and if the default products contain GM ingredients, a U.S. producer would generally label all products as containing GM soy even though some products also contain non-GM soy.¹⁵⁰ The extra cost would only be borne by the special non-GMO products, which would then be the unlabeled products. Gruère and Rao argue that if all of the products are labeled as containing GMOs, whether or not they do, consumers still have no choice.¹⁵¹ Consumers may not have a choice, but they would have access to information that is currently absent.

Federal statutes and FDA labeling regulations do not account for this kind of label value. Indeed, the statutory requirement that labeling must not be misleading may sometimes run counter to this notion. When truthful label information is prohibited because it might be "misleading," some consumers will feel deprived of their decision-making power.

148. John A. Edwards & Gifford Weary, *Antecedents of Causal Uncertainty and Perceived Control: A Prospective Study*, 12 EUR. J. PERSONALITY 135, 135 (1998) (finding that feelings of lack of control and causal uncertainty related to increased levels of "depressive symptomatology").

149. Strauss, *supra* note 66, at 190 & nn.187–88.

150. Gruère & Rao, *supra* note 21, at 56 (citing Xiangyang Chang, *Labeling Policy in China*, in INT'L FOOD POLICY RESEARCH INST. & RESEARCH & INFO. SYS. FOR DEVELOPING COUNTRIES, ECONOMIC CONSIDERATION OF BIOSAFETY AND BIOTECHNOLOGY REGULATIONS IN INDIA 16 (2007) (stating that mandatory labeling results in almost all soybean oil labeled as GM)).

151. *Id.*

V. CONCLUSIONS—CAN'T MISLEAD ALL CONSUMERS

GMOs make a particularly interesting case study because the labeling requirements differ between Europe and the U.S. A recent study of consumer welfare found that introducing and labeling GM food, on the whole, has been “welfare enhancing” for U.S. consumers.¹⁵² This means that the benefit of lower cost outweighs any preference for non-GM food.¹⁵³ The same study came to the opposite conclusion for European consumers.¹⁵⁴ What explains the difference?

In the European Union, the presence of GMOs in foods must be labeled.¹⁵⁵ In the U.S., however, if the food is “substantially equivalent”—a term with no clear meaning¹⁵⁶—then no labeling is required.¹⁵⁷ Accordingly, there is no mandatory labeling of GMOs, although the absence of GMOs may be shown voluntarily. Economists have studied the characteristics of consumers in both markets, and have theorized about the cultural influences that account for those differences. For example, one study showed that Americans perform better than Europeans on quizzes about the genetic con-

152. Jayson L. Lusk et al., *Consumer Welfare Effects of Introducing and Labeling Genetically Modified Food*, 88 ECON. LETTERS 382, 384 (2005).

153. See Kym Anderson & Lee Ann Jackson, *Why Are US and EU Policies Toward GMOs So Different?*, 6 AGBIOFORUM 95, 98 (2003), available at <http://www.agbioforum.org/v6n3/v6n3a02-jackson.pdf> (finding that U.S. farmers have much more to lose in terms of real income from anti-GMO policies, whereas EU farmers benefit in terms of real income from a protectionist anti-GMO policy).

154. Lusk et al., *supra* note 152, at 384.

155. Council Regulation 1829/2003, art. 13, 2003 O.J. (L 268) 1, 11–12; see Rachele Berglund Bailey, Comment, *A Tale of Two Systems: A Comparison Between U.S. and EU Labeling Policies of Genetically Modified Foods*, 15 SAN JOAQUIN AGRIC. L. REV. 193, 202–10 (2006) (comparing U.S. and E.U. regulations).

156. Strauss, *supra* note 66, at 174. Strauss also claims that European opposition to GMOs was a reaction to lack of choice, rather than an aversion to the goods themselves. *Id.* at 181.

157. *Id.* at 183–84 (citing Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992)).

cepts,¹⁵⁸ but that they are less aware of the existence of GMOs in the food supply.¹⁵⁹

Response to GM foods has been far more negative in Europe and parts of Asia.¹⁶⁰ Europeans in general are more opposed to GM foods than are Americans. As a result, GM foods were initially banned in Europe and are only slowly gaining a toehold. Since the presence of GM ingredients must be labeled, however, most foods do not include GM ingredients. Moreover, the labeling requirement creates trade challenges for U.S. producers.

While it is not completely clear why attitudes towards GM foods are so different in the U.S. and Europe,¹⁶¹ two theories stand out with respect to the discussion of consumer knowledge and preferences. One is that Americans have a tendency to place a lot of trust in both government agencies and scientists.¹⁶² So when the FDA publicizes its “science-based” findings, many Americans find the agency’s statements highly reliable. The information available may be just enough to keep Americans from asking for more specific information and, consequently, to prevent them from developing a preference. Perhaps American consumers would develop preferences if they were given more information, but as it stands, American consumers do not have enough information to even contemplate looking for more.

It may be possible that American consumers are simply not exposed to enough information. One study found that the European press had covered GM issues more extensively than the American

158. See W. Carl Hebden et al., *Consumer Responses to GM Foods: Why Are Americans So Different?*, 20 CHOICES 243, 243 (2005), available at <http://www.choicesmagazine.org/2005-4/GMOs/2005-4-06.htm>.

159. *Id.* “[L]ess than half of Americans realize that foods containing GM ingredients are sold in supermarkets and less than one in three believe that they have personally consumed GM foods. Those who know GM foods are sold in supermarkets are also confused as to which products are on the shelf.” *Id.*; see also William K. Hallman & W. Carl Hebden, *American Opinions of GM Food: Awareness, Knowledge, and Implications for Education*, 20 CHOICES 239, 239 (2005), available at <http://www.choicesmagazine.org/2005-4/GMOs/2005-4-05.htm>.

160. Hebden et al., *supra* note 158, at 243.

161. *Id.* at 244–45.

162. *Id.*

media.¹⁶³ Another study showed that a lot of media coverage about GM foods does not go into risks and benefits.¹⁶⁴ Accordingly, it is not surprising that most American consumers are poorly informed on this topic and that they have no preference regarding GMOs.

William Hallman and Helen Aquino suggest that labeling policies in Europe and the U.S., at least theoretically, do accommodate consumer preferences by minimizing costs while allowing the majority of consumers to make the choices they prefer.¹⁶⁵ In Europe, where the majority of consumers presumably do not want GMOs, unmarked packages cannot contain GMOs. Any additional cost of labeling is borne by foods that do contain GMOs.

In the U.S., the majority of consumers presumably do not care about the presence of GMOs in food products, and unlabeled products may contain GMOs. Any additional labeling cost is borne by those who wish to avoid GMOs. Implicit in this policy choice is the notion that consumers should not care about GMOs, which the FDA, using its science-based approach, has determined to be safe. Although the voluntary labeling approach does allow consumers with clear preferences to avoid products containing GMOs, it is only at additional expense.

Overall, European consumers, who receive their information from nonprofit organizations, are opposed to GMOs;¹⁶⁶ the negative information must appear on the label. The European requirement that negative information should appear on labels has affected the choices available to Europeans. Most European producers do not use GMOs, and therefore they do not have to provide label information.¹⁶⁷ The default label in Europe indicates that there are no GMOs in the product, *and consumers know this fact, or believe it*. This ar-

163. Thomson & Dininni, *supra* note 143, at 247.

164. *Id.* at 250.

165. William K. Hallman & Helen L. Aquino, *Consumers' Desire for GM Labels: Is the Devil in the Details?*, 20 CHOICES 217, 218 (2005), available at http://www.foodpolicyinstitute.org/docs/pubs/consumers_desire_for_GM_labels.pdf.

166. *An Overview of European Consumer Polls on Attitudes Toward GMOs*, GMO COMPASS, Apr. 16, 2009, http://www.gmo-compass.org/eng/news/stories/415.an_overview_european_consumer_polls_attitudes_gmos.html.

167. See Jeremy Smith, *European Shelves Mostly GMO-Free*, REUTERS, Feb. 3, 2005, available at <http://www.organicconsumers.org/ge/gmofree20705.cfm>.

guably shows that mandatory labeling does not increase consumer choice, but instead tips the market towards the majority consumer preference.¹⁶⁸ In the U.S., GMOs are not labeled, so the default label—the unmarked package—means the product might contain GMOs, *but consumers are unaware of this possibility*. Most processed foods do contain GMOs, so Americans are not presented with much choice either. And while most American consumers do not have strong preferences, as it turns out, it is because they have never thought about the issue. Most soy in the U.S. is Roundup Ready soy—genetically engineered to be glyphosate tolerant.¹⁶⁹ However, most consumers probably do not know this fact.¹⁷⁰

Interestingly enough, American consumers may change their minds when they are provided with adequate information. Although U.S. consumers generally have few preferences, this is not true of all U.S. consumers. One study found that consumers who are relatively well informed about genetic engineering do not want GMOs and are willing to pay a premium to avoid them.¹⁷¹ Well-informed consum-

168. See Wallace E. Huffman et al., *The Effects of Prior Beliefs and Learning on Consumers' Acceptance of Genetically Modified Foods*, 63 J. ECON. BEHAV. & ORG. 193, 199–201 (2007); Jayson L. Lusk et al., *Alternative Calibration and Auction Institutions for Predicting Consumer Willingness to Pay for Nongenetically Modified Corn Chips*, 26 J. AGRIC. & RESOURCE ECON. 40, 53 (2001).

169. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *GENETICALLY MODIFIED CROPS IN THE UNITED STATES* 3–4 (2004), http://www.pewtrusts.org/uploaded-Files/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Genetically_Modified_Crops_Factsheet0804.pdf. According to the Pew Initiative, in 2004, 85 % of the soy grown in the United States was genetically engineered, as was 45% of the corn, and 76% of the cotton. *Id.* Moreover, because genetically engineered corn and soybeans are often commingled with conventional crops, the percentage of processed soy or corn products containing some genetically engineered component, is probably even higher, and those processed foods that contain soy or corn products, generally contain some genetically engineered crops.

170. See Hebden et al., *supra* note 158, at 243 (“It is . . . unlikely that many Americans are aware that there is a worldwide controversy surrounding the foods they eat every day[,]” and “less than one in three believe that they have personally consumed GM foods.”).

171. DANNENBERG ET AL., *supra* note 46, at 16 (finding that consumers were willing to pay 47–59 percent more for the same product that was not genetically engineered); see also Edna Einsiedel, *Consumers and GM Food Labels: Providing Information or Sowing Confusion?*, 3 AGBIOFORUM 231, 232 (2000) (“[A] summary of consumer attitudes to GM food labeling showed that anywhere from 57%

ers look for GMO information on labels and consider it to be process information, albeit for a process they wish to avoid.¹⁷² Less knowledgeable consumers, however, do not look for information about GMOs¹⁷³ and are more likely to regard GMO labeling as a warning with implications about the quality or safety of the product.¹⁷⁴ It is precisely this interpretation of the label that makes the label misleading, potentially making the food misbranded.¹⁷⁵

Ironically, both groups of consumers end up behaving the same way, but for different reasons. Consumers who are most aware of genetic engineering tend to disapprove of the process and would regard a GMO label as negative information and would avoid the product.¹⁷⁶ Consumers who do not know about genetic engineering would regard a GMO label as a warning and would also avoid the product. Both groups would avoid the product;¹⁷⁷ the label would lead the uninformed and easily misled consumer to behave like a knowledgeable consumer.

Interestingly, in studies, consumers who would perceive “contains GM” as a warning also said that they would be more likely to

of consumers in the US to 82% of German consumers said they would be ‘less likely to buy GM-labeled products.’” (citing Peter W.B. Phillips & Heather Foster, *Labeling for GM Foods: Theory and Practice* (NSERC/SSHRC Chair Program, Working Paper 3, 2000)).

172. See DANNENBERG ET AL., *supra* note 46, at 14.

173. A recent FDA call for comments claims that in 2002, 19 percent of all consumers surveyed said they “never” look at the food label when buying a product for the first time. Agency Information Collection Activities: Proposed Collection; Comment Request; Internet Survey on Barriers to Food Label Use, 74 Fed. Reg. 42,676, 42,677 (Aug. 24, 2009); *see also* Hallman & Aquino, *supra* note 165, at 219 (finding that when asked what additional label information they wanted, 78 percent of consumers said none).

174. Caswell, *supra* note 43, at 23 (finding that problems may arise when process labels are interpreted as indicators of product safety in cases where regulators believe it is not an indicator of safety); *see also* Hallman & Aquino, *supra* note 165, at 220 (finding that less aware consumers say they would want more information about biotechnology before buying GM-labeled products).

175. 21 U.S.C. §§ 321(n), 343(a) (2006). Labeling that misleads the consumer into thinking that there is a material difference in the product where no material difference exists, is a misleading label. What responsibility does the labeler have to educate the consumer so that the label does not mislead?

176. Hallman & Aquino, *supra* note 165, at 220.

177. *Id.*

buy GM products if they had adequate assurances of safety from trusted sources such as the FDA.¹⁷⁸ In a sense, these consumers may now be making the “right” choice for them, but for the “wrong” reason. They choose GM foods because it never occurred to them that the foods *are* GM foods. If the consumers knew that the foods were GM and had enough information about the process, they might still choose to buy the GM products, fully aware of what they were buying. In doing this, they would be exercising consumer sovereignty by choosing to consume GM foods. But what if these same consumers, given the information they say they would want, would choose to avoid GM products? What if most consumers would choose to avoid GM products if they knew more about genetic engineering? If that is the case, then most consumers are currently being misled by the *absence* of labeling on most products.

Is there not an argument to be made that consumers only truly have preferences when they have information? What is a preference if not a choice? If the presence of label information causes consumers to behave as if they were knowledgeable, then the label has the effect of improving economic efficiency. When consumers prefer a product out of ignorance when they would disapprove it with knowledge, producers enjoy a marketing position that is assumption-based, not science-based.¹⁷⁹

In my opinion, this evidence merits further study: American consumers who are the *most* aware of GMOs prefer to avoid them. American consumers who know nothing about GMOs do not care and are motivated by price. When presented with information on a label, assuming they notice it, and they do not always notice it,¹⁸⁰ the unknowing consumers tend to perceive the label information as a

178. *Id.*

179. Angela Tregear, *Proximity and Typicity: A Typology of Local Food Identities in the Marketplace*, ANTHROPOLOGY FOOD, Mar. 2007, <http://aof.revues.org/index438.html>. “[B]ecause of the economic values inherent in high reputation distant specialty food brands, other manufacturing firms outside the *distant specialty* production area are often tempted to ‘steal’ a portion of the economic rent through copying, counterfeiting and usurpation of the name or brand.” *Id.*

180. Hallman & Aquino, *supra* note 165, at 219 (finding that less aware consumers say they would want more information about biotechnology before buying GM-labeled products).

warning. The label does two things—it tells them there is an issue of concern, serving an educational function, and it *warns* them about this product. The *unknowing* and *misled* consumer behaves just like a knowledgeable consumer because of the warning function the label serves. In other words, when the label functions as a warning and there is no real issue of safety, consumers may make the “right” choice, the choice that reflects a knowledgeable consumer’s preferences and would reflect *this* consumer’s preferences if enabled to develop a preference. The choice would be the utility maximizing choice, but it would be made for the “wrong” reason—a fear of a non-existent safety issue.

Mandatory labeling for negative information would help guide consumers to products they really prefer in instances where they would care if they had adequate information. Voluntary labeling presumably provides information for consumers who really care about the issue. With respect to those consumers, voluntary labeling is de facto mandatory labeling because the absence of a label becomes meaningful. But voluntary labeling does not provide enough educational value for consumers who know nothing. Voluntary labeling may mean that the educational function of a label is lost due to fear that information will be misinterpreted as a warning. Consumers lose as a result of a lack of knowledge, and therefore a lack of choice.

The USDA Organic label, for example, means something about process, but means nothing about the end product. Is it misleading? Does anyone really think that organic Oreos are a healthy choice or that they are different from conventional Oreos? Probably. There are likely consumers who buy organic junk food because they think it is better for them. They are doing the right thing for the wrong reason. Why is buying organic the “right” thing? Most consumers presented with facts about organic production—that it is created without pesticides, that it is more sustainable and more environmentally friendly—would choose organically produced foods when other things, such as cost, are equal. If consumers buy a product they would prefer if they had all of the information, they are making the “right” choice; the choice that lines up with their preferences. But if they buy the organic cookies for some other reason, such as an erroneous belief that “organic” means nutritious, they are acting for the

wrong reason. When acting for the wrong reason gives the consumer the “right” product, the consumer suffers no economic detriment.

