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FATTENING FOOD: SHOULD PURVEYORS OF FAST FOOD BE REQUIRED TO WARN? A CALL FOR A NEW TORT

Charles E. Cantu[*]

INTRODUCTION

Being overweight,[1] continues to be an important issue for many Americans.[2] The latest diet fad is likely to include at least one title

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1. MEDLINE PLUS MEDICAL ENCYCLOPEDIA, *How to Determine Your BMI, available at* http://www.nlm.nih.gov/medlineplus/ency/article/007196.htm:
Your body mass index (BMI) estimates whether you are at a healthy weight. Your BMI estimates how much you should weigh, based on your height. Here are the steps to calculate BMI:

* Multiply your weight in pounds by 703.
* Divide that answer by your height in inches.
* Divide that answer by your height in inches again.

For example, a woman who weighs 270 pounds and is 68 inches tall has a BMI of 41.0.

The webpage for this article also provides a chart explaining the BMI ranges: below 18.5 is underweight, 18.5 - 24.9 is healthy, 25.0 - 29.9 is overweight, 30.0 - 39.9 is obese, and over 40 is morbidly obese. *Id.*

2. *See* Connie L Bish et al., *Diet and Physical Activity Behaviors among Americans Trying to Lose Weight: 2000 Behavioral Risk Factor Surveillance System*, 13 OBESITY RES. 596 (2005) (reporting that forty-six percent of women and that thirty-three percent of men in America are trying to lose weight); *see also* Paul Krugman, *Girth of a Nation*, N.Y. TIMES, July 4, 2005, A13 (stating that number of obese American adults has doubled to more than thirty percent and that research shows high health cost). Krugman focuses on the attempts of Center for Consumer Freedom, a group financed by food providers such as Coca-Cola, Wendy's, and Tyson Foods tried to change the public impression of obesity issues in part through a Fourth of July

on the current bestseller list,[3] and newspapers carry daily articles on the most recent study regarding risks related to obesity.[4] Heeding these concerns, the federal government has added its own impetus by requiring the packaged food industry to list, not only nutritional information, but also calories.[5] Perhaps the most influential voice in this arena has been the medical profession.[6] They have determined

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media campaign to convince Americans that worrying about obesity is American. *Id.*

3. A look at the New York Times Bestseller list on July 9, 2005 reveals the following books which are related to obesity and weightloss: MIREILLE GUILIANO, FRENCH WOMEN DON'T GET FAT (2004); ARTHUR AGATSTON, THE SOUTH BEACH DIET A WEIGHT-LOSS PLAN DESIGNED BY A MIAMI CARDIOLOGIST (2005); JORDAN RUBIN, THE MAKER'S DIET (2004); PAMELA PEEKE, BODY FOR LIFE FOR WOMEN (2005). N.Y. Times, July 9, 2005.

4. *See* Fred Barbash, *It's a Weighty Problem, But A Crisis? C'mon*, THE WASHINGTON POST, Aug. 31, 2003, at B1 ("I'm alarmed by the hysteria in the mass media, reflected in words such as 'crisis' and 'epidemic.' There's been an epidemic of alarmist stories about obesity and its costs in the past year (about 2,000 according to my Internet search)"); Neil Buckley et al., *WHO Warns Against Media Obsession With Obesity*, FINANCIAL TIMES, June 24, 2003, at International Economy 14 (reporting the World Health Organization view that the media is too focused on obesity).

5. Nutrition Labeling and Education Act of 19990 (NLEA), Pub. L. No. 101-535, 104 Stat.2353 (1990) (codified in various sections of 21 U.S.C.). The requirement for nutritional information and calories is at 21 U.S.C. § 343(q)(1) (2000):

> Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—
> (A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or
> (ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,
> (B) the number of servings or other units of measure per container,
> (C) the total number of calories—
> (i) derived from any source, and
> (ii) derived from the total fat,
> in each serving size or other unit of measure of the food,
> (D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,
> (E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices. *Id.*

6. The involvement of the medical community in obesity is clear from the volumes of recent articles on the subject in medical journals, including a peer reviewed

that obesity,[7] is more than a health risk; it shortens one's life span.[8] To summarize, obesity kills. It is a leading cause of death in the United States.[9] There is no doubt eating fattening food, especially of the fast food variety, has a rippling effect.[10] Larger girths are not the only consequence; cardiovascular disease, diabetes, high choles-

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medical journal published twelve times a year and devoted to medical studies related to obesity. *See generally* OBESITY RES. published by The North American Association for the Study of Obesity, *available at* http://www.obesityresearch.org; *see also* United States Dept. of Health and Human Servs. (DHHS), *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* 1-3 (2001), *available at* http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf. [hereinafter DHHS Obesity Call to Action].

7. MEDLINE PLUS MEDICAL ENCYCLOPEDIA, *Obesity*, *available at* http://www.nlm.nih.gov/medlineplus/ency/article/003101.htm. "Obesity is also defined as a BMI over 30 kg/m2 . . . . An adult male is considered obese when his weight is 20% or more over the maximum desirable for his height; a woman is considered obese at 25% or more than this maximum weight. Anyone more than 100 pounds overweight is considered morbidly obese." *Id.*

8. Jay S. Olshansky et al., *A Potential Decline in Life Expectancy in the United States in the 21st Century*, 352 NEW ENG. J. MED. 1138, 1138-46 (2005) (predicting a shortening in the life expectancy of Americans and attributing at least in part to the rise in obesity).

9. *Compare* Katherine M. Flegal et al., *Excess Deaths Associated With Underweight, Overweight, and Obesity*, 293 J. AM. MED. ASS'N 1861 (2005) (revising the Center for Disease Control's (CDC) mortality rate attributable to obesity for the year 2000 from over 400,000 to 111,909 deaths in that year), *and* David H. Mark, *Deaths Attributable to Obesity*, 293 J. AM. MED. ASS'N 1918, 1918-19 (explaining that a small change in the determination of how much of a risk factor obesity is towards specific conditions, such as cardiovascular disease, creates a large variation in the overall measurement of obesity on mortality rates), *with* Christine Gorman, *Is It O.K. to Be Pudgy?*, TIME, May 9, 2005, at (noting that CDC and Flegal believe that despite the revised mortality rate, the numbers are likely to change again and that what is certain is obesity is on the rise and the negative health effects of carrying extra weight are undeniable).

10. *See* Martha L. Daviglus et al., *Relation of Body Mass Index in Young Adulthood and Middle Age to Medicare Expenditures in Older Age*, 292 J. AM. MED. ASS'N 2743, 2748 (2004) (studying the relationship between a high BMI at a younger age to medical spending at the age of sixty-five and finding that obesity in young adulthood and middle age has long-term adverse consequences for health care costs in older age); Klea D. Bertakis & Rahman Azari, *Obesity and the Use of Health Care Services*, 13 OBESITY RESEARCH 372, 378 (2005) (warning that as the epidemic of obesity grows there will be an escalating growth in the use of health services).
Olshansky, *supra* note 8, at 1143. "Presently, annual health care costs attributable to obesity are conservatively estimated at $70 billion to $100 billion." *Id.* Olshansky suggests that "[t]he [United States] population may be inadvertently saving Social Security by becoming more obese." *Id.*

terol, sleep apnea, and other health problems are also results of obesity.[11]

Individuals alleging injury and seeking recourse have made an attempt to place fault upon purveyors of fast food.[12] To date, American jurisprudence has not helped.[13] The courts have suggested that, from a products liability perspective, fast food is not defective[14] and writers have concurred.[15] An analogy has been made

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11. The website for the Harvard School of Public Health concludes based on their research that how much a person weighs will influence their chances of: "dying early; having, or dying from, a heart attack, stroke, or other type of cardiovascular disease; developing diabetes; developing cancer of the colon, kidney, breast, or endometrium; having arthritis; developing gallstones; being infertile; developing asthma as an adult; snoring or suffering from sleep apnea; or developing cataracts." *See* Harvard School of Public Health, *Healthy Weight,* Dec. 13, 2004, *available at* http://www.hsph.harvard.edu/nutritionsource/healthy_weight.html); *see also* Olshansky, *supra* note 8, at 1143 (finding that obesity will cause a decline in the life expectancy of Americans),

> With rapid increases in the prevalence of diabetes, and a decrease in mean age at the onset of diabetes, the cost of treating diabetes-related complications, such as heart disease, stroke, limb amputation, renal failure, and blindness, will increase substantially. A similar escalation of health care costs from other complications associated with obesity (e.g., cardiovascular disease, hypertension, asthma, cancer, and gastrointestinal problems) is inevitable. *Id.*

12. *See* Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 519 (S.D.N.Y. 2003) (dismissing claims against McDonald's because of a failure to make a sufficient causal connection between defendants food and the negative health effects suffered by the plaintiffs); *rev'd and remanded by* 396 F.3d 508, 512 (2nd Cir. 2005) (finding that the case was improperly dismissed because the claims were sufficient to survive a motion to dismiss subject to notice pleading under FED. R. CIV. P. 8(a), and that further discovery is appropriate).

13. *See* Pelman, 237 F. Supp. 2d at 542-43 (deciding to dismiss the complaint entirely).

14. *See id.* at 531-32. (reasoning that "the Complaint must allege either that the attributes of McDonald's products are so extraordinarily unhealthy that they are outside the reasonable contemplation of the consuming public or that the products are so extraordinarily unhealthy as to be dangerous in their intended use.") To support its conclusion, the court stated

> Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to some diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by 'unreasonably dangerous'. . . . The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fuel oil, is unreasonably dangerous. Good tobacco

between fattening food and smoking.[16] Its addictive nature aside, an occasional cigarette does not harm, nor can it be considered as being in a defective state.[17] It does exactly what it is suppose to do.[18]

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is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous. *Id.* at 531 (RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965)).

15. *See generally* Charles E. Cantu, *Fattening Foods: Under Products Liability Litigation is the Big Mac Defective?*, 1 J. FOOD L. & POL'Y 165 (explaining why fast food should not be considered a defective product under products liability theory); *cf.* Richard C. Ausness, *Tell Me What You Eat, and I Will Tell You Whom to Sue: Big Problems Ahead for "Big Food"?*, 39 GA. L. REV. 839, 851-55 (2005) (arguing that under multiple analyses fast food can not be a defective product).

16. *See* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 587 (2001) (Thomas, J. concurring) (making the comparison between tobacco and fast food based on their similar marketing techniques, and the type and degree of harm that appears to be inflicted on health and wellbeing of Americans is also similar); *see also* John A. Cohan, *Obesity, Public Policy, and Tort Claims Against Fast-Food Companies*, 12 WIDENER L. REV. 103, 110-11 (2003).

> There are many similarities between the new fast-food cases and the tobacco cases that are relevant in assessing the merits of imposing liability on fast-food manufacturers and retailers. These similarities, discussed below, include the claim that both are devoid of nutritive value, are harmful or dangerous to their consumers, and are associated with high medical costs. Fast-food restaurants and tobacco companies also use targeted advertising campaigns that appeal to certain groups and often target the young. Furthermore, although tobacco use and eating fast food are generally considered voluntary activities, tobacco manufacturers have been held liable for the harmful effects of their products, and the government also has the ability to regulate and tax the sale of tobacco. *Id.*

See also John F. Zefutie, Jr., *From Butts to Big Macs–Can the Big Tobacco Litigation and Nation-Wide Settlement with States' Attorneys General Serve As a Model for Attacking the Fast Food Industry*, 34 SETON HALL L. REV. 1383 (2004) (making a detailed comparison between strategies for suits against fast-food companies based on the precedent of successful tobacco claims and suggests that plaintiffs attorneys face serious obstacles).

17. *See* Thomas C. Galligan, Jr., *Product Liability–Cigarettes and* Cipollone*: What's Left? What's Gone?*, 53 LA. L. REV. 713, 727-29 (1993) (explaining that although cigarettes have tar and nicotine, which are dangerous substances, these substances are intentionally included thus the product is not considered defective, "The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer. . . . Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful." RESTATEMENT (SECOND) OF TORTS §402a cmt. i (1965)).

18. Robert F. Cochran, Jr., *From Cigarettes to Alcohol: The Next Step in Hedonic Product Liability?*, 27 PEPP. L. REV. 701, 702-03 (2000) (explaining that cigarettes are a hedonic product and that their primary purpose is to provide pleasure).

Although once there is excessive use over an extended period of time, serious injury is the result.[19] The medical profession has established a link to lung cancer, emphysema, heart disease, high blood pressure and other illnesses.[20] After much publicity and unassailable testing, the industry has been required to place appropriate warnings on their products.[21]

The same analogy can be made with alcohol.[22] In general, one drink will not harm someone.[23] In fact, some tests would indicate that an occasional cocktail or glass of wine is good.[24] Relaxation, lower cholesterol, and other benefits have been medically documented.[25] Excessive consumption, however, can cause dire consequences.[26] Driving while under the influence of alcohol can cause serious mishaps,[27] Alcoholism,[28] injury to the fetus,[29] and irreparable

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19. *See* DHHS, *The Health Consequences of Smoking: A Report of the Surgeon General* 3 (2004), *available at* http://www.cdc.gov/tobacco/sgr/sgr_2004/chapters.htm ("[R]eports have concluded that smoking is the single greatest cause of avoidable morbidity and mortality in the United States.") [hereinafter HDDS Consequenses of Smoking].

20. *See id.* at 4-8. (listing many diseases for which a medical link has been found for cancer including but in no way limited to those listed in the text).

21. Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C §§ 1331-1341 (2000).

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive [f]ederal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby–
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes. . . . *Id.* §1331.

22. *See generally* Cochran, *supra* note 18 (analyzing the similarities between alcohol and tobacco products in terms of the liability they may create for the companies that sell them).

23. *See* National Institute on Alcohol Abuse and Alcoholism (NIAA), Alcohol Alert, Apr. 1992, *available at* http://pubs.niaaa.nih.gov/publications/aa16.htm [hereinafter NIAA] (examining the potentially positive and negative effects of moderate drinking, explaining that variation in what people consider moderate drinking is what really causes the risk).

24. *See id.* (looking at the evidence of psychological and cardiovascular benefits of moderate drinking).

25. *See id.*

26. *See id.* (suggesting that the greatest risk of moderate drinking is the possibility of a "[s]hift to heavier drinking. . . . Once a person progresses from moderate to heavier drinking, the risks of social problems (for example, drinking and driving, violence, trauma) and medical problems (for example, liver disease, pancreatitis, brain damage, reproductive failure, cancer) increase greatly.") (ciations omitted).

27. Robert F. Cochran, Jr., *"Good Whiskey," Drunk Driving, and Innocent Bystanders: The Responsibility of Manufacturers of Alcohol and Other Dangerous Hedonic Prod-*

harm to the liver,[30] are also foreseeable consequences of alcohol abuse. Due to these foreseeable problems, appropriate warnings have been required.[31]

Clearly, an occasional outing to a fast food establishment, like an occasional cigarette or an occasional alcoholic drink, may not be harmful, but extended use has been found to produce deleterious results.[32] Because there is a precedent to warn the public of hazards regarding cigarettes and alcohol,[33] and because the consuming public, as a result of the media coverage mentioned above, has become increasingly attentive to food choices,[34] it follows that citizens should

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ucts for Bystander Injury, 45 S.C. L. REV. 269, 271 (1994) (focusing on the harm to innocent bystanders but looking at the problem of drunk driving more generally also).

28. *See* NIAA, *supra* note 23 (explaining that the risk of alcoholism is the most important risk associated with moderate drinking).

29. *See* Cochran, *supra* note 27, at 301-02, n.143 (discussing the dangers of fetal alcohol syndrome).

30. *See* NIAA, *supra* note 23 (citing the risk of liver failure as a risk of greater alcohol consumption).

31. Alcoholic Beverage Labeling Act, 27 U.S.C. § 215 (a) (2005), (requiring that Surgeon General warning labels be placed on all alcoholic beverages)

> [I]t shall be unlawful for any person to manufacture, import, or bottle for sale or distribution in the United States any alcoholic beverage unless the container of such beverage bears the following statement:
> "GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems." *Id.*

32. *See* Sandra B. Eskin & Sharon Hermanson, *Nutrition Labeling at Fast-Food and Other Chain Restaurants*, AARP PUBLIC POLICY INSTITUTE, Issue Brief Number 71, at 2-3, *available at* http://assets.aarp.org/rgcenter/consume/ib71-nutrition.pdf (explaining the impact of eating out more often on the obesity epidemic and that "[f]ast-food meals, in particular, often involve higher calorie consumption" and are less healthy); *see also* DHHS Obesity Call to Action, *supra* note 6 at 19, 24 (explaining that part of the Surgeon General's plan to combat obesity is to analyze the marketing tactics of fast food companies and counteract the "excess calories. . .generated by the fast food industry"); SUPER SIZE ME (Roadside Attractions/Samuel Goldwyn Films 2004) In response to the dismissal of the *Pelman* case, filmmaker Morgan Spurlock decided to eat only McDonald's food for a month, which resulted in weight gain of nearly 25 pounds and liver damage such that his doctors suggested that he quit the experiment after three weeks. *Id.*; *see also* Super Size Me Homepage *at* http://www.supersizeme.com (last visited Feb. 19, 2006).

33. *See generally* FCLAA, 15 U.S.C §§ 1331-1341 (2004); Alcoholic Beverage Labeling Act, 27 U.S.C. § 215 (2005).

34. Press Release, Harvard School of Public Heath, Despite Conflicting Studies about Obesity, Most Americans Think the Problem Remains Serious (July 14, 2005), *available at* http://www.hsph.harvard.edu/press/releases/press07142005.html (find-

now enjoy the protection of warnings on food labels also.[35] The public is entitled to know the caloric content of their hamburger, pizza, fried chicken, or other fast food take out,[36] so remainder of this article will present reasons why the public should know about caloric information and other suggestions as to how this warning should be conveyed.

ACTIONABLE NEGLIGENCE

As a rule, liability in the area of food has been based upon actionable negligence,[37] implied warranties,[38] and/or products liability.[39] As previously indicated, our courts have decreed that fattening

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ing in a new opinion poll that three quarters of Americans rate obesity as an extremely or very serious public health problem, also finding that thirty-two percent of Americans report that they keep track of calories and forty-six percent keep track of fat content of the food in their diet).

35. A. Falba & Susan H. Busch, *Survival Expectations of the Obese: Is Excess Mortality Reflected in Perceptions?* 13 OBESITY RES. 754 (2005) (concluding that persons in the study underestimate the mortality risk of obesity and that more public awareness campaigns should be pursued).

36. Public Health Advocacy Institute, *Obesity and Law*, *available at* http://www.phaionline.org/projects_obesity_law.php (calling for the uses of litigation and legislation as a means to curb the obesity epidemic).

37. *See* Kyle v. Swift & Co., 229 F.2d 887, 889 (4th Cir. 1956) (finding sufficient evidence to try both the manufacturer and retailer of food stuff for negligence); Escola v. Coca Cola Bottling Co., 150 P.2d 436, 439 (Cal. 1944) (discussing possible situations in which the defendant manufacturer may be found negligent); Mushatt v. Page Milk Co., 262 So. 2d 520, 523 (La. Ct. App. 1972) (shifting the burden of proof from the plaintiff to the defendant to prove non-negligence once a prima facie case was made); Gramex Corp. v. Green Supply, Inc., 89 S.W.3d 432, 438-39 (Mo. 2002) (en banc) (tracing the history of the determination of liability back to negligence).

38. *See* Martel v. Duffy-Mott Corp., 166 N.W.2d 541, 545 (Mich. Ct. App. 1968) (allowing recovery for unwholesome applesauce on the basis of breach of implied warranty of merchantability); Metty v. Shurfine Cent. Corp., 736 S.W.2d 527, 530 (Mo. Ct. App. 1987) (per curiam) (reiterating the court's policy that food for immediate consumption is impliedly warranted to be wholesome and fit for consumption); Welch v. Schiebelhuth, 169 N.Y.S.2d 309, 314 (N.Y. Sup. Ct. 1957) (interpreting the implied warranty of quality and wholesomeness of food offered for sale as imposing a legal obligation upon the wrong-doer); Ayala v. Bartolome, 940 S.W.2d 727, 729 (Tex. App. 1997)(finding that a retailer who sells unwholesome food is liable under an implied warranty imposed by law as a matter of public policy).

39. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 7 (1998).

> One engaged in the business of selling or otherwise distributing food products who sells or distributes a food product that is defective under § 2, § 3, or § 4 is subject to liability for harm to persons or property caused by the defect. Under § 2(a), a harm-causing ingredient of the food product

fast food is not considered to be in a defective state under products liability law.[40] Because our discussion does not include warranties established either by the common law[41] or the Uniform Commercial Code (UCC),[42] negligence must be pursued.

Actionable negligence came into being around 1825.[43] It was the result of the Industrial Revolution in general,[44] and the widespread use of locomotives in particular.[45] They were known to run over and kill wandering livestock,[46] as well as heads of state,[47] and as

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constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient. *Id.*

See also McCroy ex rel. McCroy v. Coastal Mart, Inc., 207 F. Supp. 2d 1265, 1270 (D. Kan. 2002) (noting that Kansas products liability law merges legal theories of negligence, breach of implied warranty, and strict liability into a 'products liability' claim); Jackson v. Thomas, 21 P.3d 1007, 1009 (Kan. Ct. App. 2001) (recognizing that the Kansas Products Liability Act includes action based on negligence, breach of warranty, or strict liability); Creach v. Sara Lee Corp., 502 S.E.2d 923, 923-24 (S.C. Ct. App. 1998) (allowing an injured plaintiff to recover under negligence, breach of warranty, or strict liability theories); Cobb v. Dallas Fort Worth Med. Ctr.–Grand Prairie, 48 S.W.3d 820, 826 (Tex. App. 2001) (claiming a plaintiff may bring causes of action involving a product in negligence, strict liability, or breach of warranty); *cf.* Hitachi Const. Mach. Co. v. Amax Coal Co., 737 N.E.2d 460, 465 (Ind. Ct. App. 2000) (recognizing that an action based on the Indiana Products Liability Act may sound in negligence or strict liability, while the Uniform Commercial Code governs actions based on a breach of warranty).

40. For a discussion of fast food under products liability law, see Cantu, *supra* note 15, at 165. *See also Pelman*, 237 F. Supp. 2d at 543 (dismissing plaintiffs' claim against McDonald's because of their failure to make a sufficient causal connection between defendants food and the negative health effects suffered by the plaintiffs).

41. For a discussion of common law warranty for foodstuffs, *see* David G. Owen, *Manufacturing Defects*, 53 S.C. L. REV. 851, 891-92 (2002).

42. For a discussion of warranty for foodstuffs under the UCC, see Franklin E. Crawford, *Fit for Its Ordinary Purpose? Tobacco, Fast Food, and the Implied Warranty of Merchantability*, 63 OHIO ST. L.J. 1165, 1217-1223 (2002) (discussing the UCC implied warranty of merchantability in fast food cases).

43. *See* LAWRENCE M. FRIEDMAN, A HISTORY OF AMERICAN LAW 261-62 (2d ed. 1984) (making the point that negligence is mentioned, but treated quite casually as early as the 1820's) (citing NATHAN DANE, A GENERAL ABRIDGEMENT AND DIGEST OF AMERICAN LAW, VOL. III 31, 35 (1824)); *see also* Robert L. Rabin, *The Historical Development of the Fault Principle: A Reinterpretation*, 15 GA. L. REV. 925, 926 (1981) (saying that by 1870, most scholars agree that the "negligence era" had begun).

44. *See* FRIEDMAN, *supra* note 43, at 300, 303 (stating that "[t]he explosion of tort law, and negligence in particular, has to be attributed to the industrial revolution").

45. *See id.* at 300 (explaining that the locomotive generated more tort law than any other product in the nineteenth century).

46. *See* Bethje v. Houston and Cent. Tex. Ry. Co., 26 Tex. 604 (1863) (requiring proof of negligence for the plaintiff to recover from the railroad for injury to plaintiff's cattle); Ft. Worth and R.G. Ry. Co. v. Swan, 78 S.W. 920, 922 (Tex. 1904) (finding the railroad liable for injury to the plaintiff's mule based on statute)

a result, Anglo-American jurisprudence met the challenge by establishing a new cause of action.[48] The elements are well known: duty,[49] the breach of that duty,[50] injury,[51] and proximate cause.[52]

One of its enduring characteristics is that actionable negligence has always had the ability to undergo a metamorphosis.[53] As society

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> Each and every railroad company shall be liable to the owner for the value of all stock killed or injured by the locomotives and cars of such railroad company in running over their respective railways, which may be recovered by suit before any court having competent jurisdiction of the amount. If the railroad company fence in their road, they shall only then be liable in cases of injury resulting from want of ordinary care. *Id.* at 921 (quoting 2 Batts' Civ. St. art. 4528).

47. Ben Webster, *What is Britain's greatest invention? You decide,* THE TIMES (LONDON), Nov. 16, 2004, at T2, 6. "The Rocket caused the first railway passenger fatality–hitting William Huskisson, the President of the Board of Trade, during the opening ceremony for the Liverpool and Manchester Railway in 1830." *Id.*

48. Rabin, *supra* note 43, at 926 (saying that, by 1870, most scholars agreed that the "negligence era" had begun).

49. *See* W. PAGE KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS § 30 (5th ed. 1984) (giving a background explanation of negligence, the elements of the cause of action, and defining "duty" as "[a] duty, or obligation, recognized by the law, requiring the person to conform to a certain standard of conduct, for the protection of others against unreasonable risks").

50. *See id.* (explaining that the "breach of duty" is "[a] failure on the person's part to conform to the standard required").

51. *See id.* (explaining "injury" as "[a]ctual loss or damage resulting to the interests of another").

52. *See id.* (explaining that "proximate cause" is "[a] reasonably close causal connection between the conduct and the resulting injury . . . which includes the notion of cause in fact").

53. There are certainly many examples of changes in actionable negligence that have allowed claims that once seemed untenable to become acceptable in the courts. One example of a change in tort law is the change in negligence law from the "privity requirement" to the *MacPherson* rule. MacPherson v. Buick Motor Co., 111 N.E. 1050 (N.Y. 1916). Negligence claims used to depend on contractual privity before a duty would be imposed on the negligent actor; the *MacPherson* rule simply requires duty based foreseeability–the harm that could result from a defendant's action. *Compare* MacPherson 111 N.E. 1050 (holding the foreseeability rule) *with* Winterbottom v. Wright (1842), 152 Eng. Rep. 402, 405 (Ex. Div.) (requiring privity of contract to find liability on a negligence action). *See also,* Melanie Warner, *U.S. Food Industry Dodging Big, Fat Lawsuits,* THE INT'L HERALD TRIB., July 8, 2005, at 21.

> John Banzhaf, a George Washington University Law School professor and an outspoken supporter of tobacco litigation, acknowledged that public opinion was not currently in favor of obesity litigation. But he added that the situation for tobacco was similar [fifteen] years ago when people began suing cigarette companies for making smokers sick. "People laughed and said, 'You won't even get one of these cases to a jury,' Banzhaf recalled. 'Today it's, ho hum, there's another verdict.'

evolved, the law changed to meet new needs.[54] Many examples can be found of causes of action that were accepted in response to a change in technology, science, or in societal awareness: the law with regard to the negligent infliction of emotional distress,[55] the recognition of wrongful birth,[56] and wrongful life,[57] and other actions such

54. *See generally* DAVID G. OWEN ET AL., MADDEN & OWEN ON PRODUCTS LIABILITY § 2:2 (3d ed. 2000) ("[t]he citadel of privity has crumbled, and today the ordinary tests of duty, negligence and liability are applied widely . . . . This trend was responsive to ever-growing pressure for protection of the consumer coupled with a realization that liability would not unduly inhibit the enterprise of manufacturers . . . .") (quoting Fleming James, *Products Liability*, 34 TEX. L. REV. 44, 44 (1955)).

55. Initially the law in regard to negligent infliction of emotional distress required that a plaintiff show some kind of physical harm to recover for mental injuries. *See* RESTATEMENT (SECOND) OF TORTS § 456 (1965) (allowing recovery for fright, shock, or mental disturbance premised on an initial physical impact). *See also* KEETON ET AL., *supra* note 49, §54 (explaining that courts limited recovery of emotional distress to cases in which there was an impact because of suspicion that mental anguish could be exaggerated, temporary, or feigned). As the medical profession became better able to identify the effects and causes of mental disturbances the courts allowed recovery based on the foreseeability of the emotional distress. *See* Dillon v. Legg, 441 P.2d 912, 919-21 (Cal. 1968) (holding that the standard for liability should be based on foreseeability).

> In determining, in such a case, whether defendant should reasonably foresee the injury to plaintiff, or, in other terminology, whether defendant owes plaintiff a duty of due care, the courts will take into account such factors as the following: (1) Whether plaintiff was located near the scene of the accident as contrasted with one who was a distance away from it. (2) Whether the shock resulted from a direct emotional impact upon plaintiff from the sensory and contemporaneous observance of the accident, as contrasted with learning of the accident from others after its occurrence. (3) Whether plaintiff and the victim were closely related, as contrasted with an absence of any relationship or the presence of only a distant relationship. *Id.*

56. *See* Berman v. Allan, 404 A.2d 8, 14 (N.J. 1979) (allowing recovery only for the emotional distress caused by the "wrongful birth" of a child). Wrongful birth developed as a cause of action as a duty on a defendant doctor to reasonably inform the patients of possible birth defects that could result from having certain medical conditions during the pregnancy. *Id.* A wrongful birth action alleges that a patient would have ended the pregnancy if they had been properly informed or properly tested to allow them to be informed of possible birth defects. *Id. Berman* rejected the claim for wrongful life on behalf of the child because it is impossible to measure the value of the child's life against no life at all. *Id.* at 13. The court also refused to allow parents to recover for all medical, and educational expenses of the child. *Id.* at 14. *See also* Schroeder v. Perkel, 432 A.2d 834, 841-42 (N.J. 1981) (extending the rights of the parents to recover on wrongful birth to medical expenses for those extraordinary expenses that were incidental to the condition which was not detected by the defendant).

57. *See* Procanik v. Cillo, 478 A.2d 755 (N.J. 1984) (allowing recovery to the child, under wrongful life for actual medical expenses for the child). The court

as the loss of chance of recovery,[58] are just a few examples. The two common threads of continuity running through each cause of action is that not one was recognized by early common law and many have a direct link to expert testimony provided by the medical profession.[59] Once doctors were able to establish the existence of a preventable injury, the legal profession was forced to acknowledge the claim and provide an appropriate remedy.[60] At times the process was slow and tedious;[61] at others, our system of jurisprudence was more receptive.[62]

Additionally, the cause of action should be distinguished from conduct that is deemed to be negligent. There is a distinct difference. Negligence is usually defined as doing what a reasonable, prudent person would not do, or not doing what a reasonable, prudent person would do.[63] In each instance, the compared action must be of the same or like circumstance.[64] As a result, it is clear that negligent behavior can be either active or passive.[65] The standard may

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recognized that there were large medical expenses to care for the child which were caused by the defendant's failure to properly warn mother that her medical condition at pregnancy created a significant risk the child would be born with medical defects. *Id.* at 764. The court allowed recovery under wrongful life only for actual medical expenses for the child, that were allowed primarily because the statute of limitations on a wrongful birth action had expired. *Id.*

58. *See* Herskovits v. Group Health Coop. of Puget Sound, 664 P.2d 474, (Wash. 1983) (holding that the fourteen percent reduction in the plaintiff's loss of chance of recovery was sufficient to allow the jury to determine whether the defendant's negligent care was a proximate cause of plaintiff's death).

59. *See supra* notes 54-57. Negligent infliction of emotional distress, wrongful birth, wrongful life, and loss of chance of recovery each required advances in medicine to be able to impose the duty warn or to find causation. *See id.*

60. *See id.*

61. *See* KEETON ET AL., *supra* note 49, §54 (charting the development of negligent infliction of emotional distress over time, in which the requirements for recovery become less demanding as medical assessment of mental conditions become more reliable).

62. Actions under wrongful birth, which were only possible as a cause of action after *Roe v. Wade*, 410 U.S. 113 (1973), have now turned into many causes of action such as wrongful conception and wrongful pregnancy. *See* KEETON ET AL., *supra* note 49, §55.

63. *See* Rhoads v. Serv. Mach. Co., 329 F. Supp. 367, 373 (E.D. Ark. 1971). "[N]egligence is the doing of something that a person of ordinary prudence would not have done in the same or similar circumstances or a failure to do something that a person of ordinary prudence would have done in the same or similar circumstances." *Id.*

64. *See id.* (requiring that there be "same or similar circumstances").

65. *See, e.g.*, Robert A. Prentice & Jonathan J. Koehler, *A Normality Bias in Legal Decision Making*, 88 CORNELL L. REV. 583, 621-22 (2003) (discussing the difference between active and passive negligence in the context of medical malpractice).

be stated as a formula: PL (G) > B = N.[66] This is usually interpreted to mean that if the probability of loss (PL) times the gravity of such injury (G) is greater than (>) the burden of reducing or eliminating such risk (B), then the individual in question is deemed negligent (N).[67] Conversely, if the burden is greater, the defendant is not negligent: PL (G) < B ≠ N.[68] This formula is going to be applied to the issue of whether or not the defendant has breached a duty as a rule.[69] The first question which must be decided in our discussion,

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66. *See* United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) (setting the most complete, or at least best known, explanation of Judge Learned Hand's Risk Utility analysis); *see also* OWEN ET AL., *supra* note 54, § 2:5 (explaining the importance of the Learned Hand Risk Utility Test as it applies to products liability).

67. *See, e.g.*, Brown v. Link Belt Div. of FMC Corp., 666 F.2d 110, 115 (5th Cir. 1982) (stating the balancing test is mandated when determining whether a product is unreasonably dangerous); *see also* Charles E. Cantu, *A Continuing Whimsical Search for the True Meaning of the Term "Product" in Products Liability Litigation*, 35 ST. MARY'S L.J. 341, 372 (2004) (discussing the application of the Learned Hand Risk Utility test to products liability cases).

68. *Carroll Towing Co.*, 159 F.2d at 173 (applying the risk utility test to determine liability).

69. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (1998) (adopting the interpretation in the reporters note that "[w]hile the strict liability standard of § 2(a) is the superior standard for assessing liability for harm caused by manufacturing defects, the 'risk-utility' balancing of costs and benefits embraced by §§ 2(b) and 2(c) is the proper method of defining defects in design, instructions, and warnings"). The Restatement itself defines categories of product defects as follows:

> § 2. Categories of Product Defect
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> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:
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> (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
>
> (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
>
> (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe. *Id.*

See also Fibreboard Corp. v. Fenton, 845 P.2d 1168, 1173 (Colo. 1993) (applying the risk benefit analysis also in a case of negligent design); Ruiz-Guzman v. Amvac Chem. Corp., 7 P.3d 795, 807 (Wash. 2000) (finding that balancing of risks and benefits can be used for marketing and negligent design cases).

therefore, is whether sellers of fast food owe a duty to the plaintiff in the first place.

DUTY

Historically, duty existed only when there was privity between the parties.[70] Requiring a contractual relationship was an attempt to limit the liability of commercial entities.[71] At the time, protecting emerging enterprise was considered more important than protecting the needs of individuals.[72] As society evolved, however, the law changed, and during the early part of the Twentieth Century, the requirement of privity for the most part was eliminated.[73] Apparently, the Industrial Revolution had run its course, and there was no longer a need to protect a fledgling economy.[74] Today, as a rule, duty is imposed whenever an individual is faced with a foreseeable risk of harm that is weighed against and exceeds the magnitude of the burden of guarding against such harm.[75]

Before calling for acceptance of a new tort, all factors that play in the imposition of this new obligation must be considered. To impose a duty there must first be a foreseeable harm.[76] As mentioned, extended consumption of fast food over a period of time will

70. Winterbottom, 152 Eng. Rep. at 404-05. (holding that a plaintiff injured by the negligence and poor coach repair of the defendant could not recover because there was no duty in the absence of privity). The Plaintiff in *Winterbottom* worked for the Postmaster, yet he could not recover based on the negligent defendants repair because the Postmaster, and not the Plaintiff employee, was in privity with the defendant. *Id.*

71. *Id.* (rationalizing the need for privity in negligence actions because without such a limitation there would be unlimited liability on defendants who negligently harm persons).

72. *See also* Rabin, *supra* note 43, at 936-37 (explaining that the Winterbottom v. Wright privity requirement limited liability for nearly one hundred years as a means of insulating manufacturers from liability).

73. *See MacPherson*, 111 N.E. at 1053 (holding, in this American case in which the Plaintiff purchased a vehicle from an auto dealer and was injured due to a broken spoke in a wheel and sued the car manufacturer instead of the dealer from whom he purchased the vehicle, that liability should exist if the danger of the product to any plaintiff was foreseeable to the defendant); *see also* OWEN ET AL., *supra* note 54, § 2:2 (describing the *MacPherson* case as having started the modern era of products liability).

74. *See* OWEN ET AL., *supra* note 54.

75. *Id.* § 2:1 (indicating that now the duty of manufacturers is defined in "terms of foreseeable risks to foreseeable victims" and the requirement that reasonable care must be used to prevent the potential harm to such victims).

76. *See MacPherson*, 111 N.E. at 1053 (holding that duty is dependent on whether a harm to the plaintiff was foreseeable to the defendant).

certainly add unwanted weight with all of the related harmful consequences.[77] The medical profession has established a direct link to resulting illnesses,[78] and the public, as a result of extended media coverage,[79] has become increasingly aware of the dangers of obesity. So knowledgeable, in fact, that the foreseeability of harm is clearly established. It could be said that this foreseeable risk is what has made the consuming public conscious of their food choices, and the existence of choice is the underlying argument for the consumer's right to be informed.[80] One also could argue that the poor are most

77. *See* Sandra B. Eskin & Sharon Hermanson, *supra* note 32, at 2-3 (explaining the impact of eating out more often on the obesity epidemic and that "[f]ast-food meals, in particular, often involve higher calorie consumption" and are also less healthy); *see also* DHHS Obesity Call to Action (stating that part of the Surgeon General's plan to combat obesity is to analyze the marketing tactics of fast food companies and counter act the encouragement of "excess calories.. .generated by the fast food industry"); *see also* SUPER SIZE ME, *supra* note 32 (exposing how unhealthy fast food can be, in a documentary film made in response to the dismissal of the *Pelman* case).

78. *See, e.g.,* DHHS Obesity Call to Action, *supra* note 6, at 9 (listing many diseases attributable to overweight and obesity)

> Obesity is [a]ssociated with an [i]ncreased [r]isk of: premature death; type 2 diabetes; heart disease; stroke; hypertension; gallbladder disease; osteoarthritis (degeneration of cartilage and bone in joints); sleep apnea; asthma; breathing problems; cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast cancer); high blood cholesterol; complications of pregnancy; menstrual irregularities; hirsutism (presence of excess body and facial hair); stress incontinence (urine leakage caused by weak pelvic-floor muscles); increased surgical risk; and psychological disorders such as depression; psychological difficulties due to social stigmatization. *Id.*

79. *See* Barbash, *supra* note 4, (stating in an editorial that, "I'm alarmed by the hysteria in the mass media, reflected in words such as 'crisis' and 'epidemic.' There's been an epidemic of alarmist stories about obesity and its costs in the past year (about 2,000 according to my Internet search)"); Buckley et al., *supra* note 4. Popular media has also paid attention to obesity as is clear from the success of Super Size Me, a documentary movie about the health effects of eating McDonald's food for a month. SUPER SIZE ME (Roadside Attractions/Samuel Goldwyn Films 2004). *See also* Maria Elena Fernandez, *Television; A Few More Ideas to Digest; Moving the Momentum of His 'Super Size Me' Success to the Small Screen, Documentary Filmmaker Morgan Spurlock Again Strikes Out Against Complacency and Convention*, L.A. TIMES, June 12, 2005, at E27 (discussing the success of Super Size Me as the basis for a new television show by the same director).

80. *See* David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth, 1996* U. ILL. L. REV. 743, 762 (1996) (asserting that warnings are important to optimization of public safety because by informing consumers of the dangers inherent in certain products consumers can make the informed choice not to purchase less safe products); *see also* Sandra B. Eskin & Sharon Hermanson, *supra* note

vulnerable.[81] Those whose diet, as well as the lack of opportunity for exercise, have been placed in the highest risk of harm.[82] However, regardless of one's socio-economic status, all consumers, whether on a diet or simply concerned with caloric intake, should be aware of the risks created by excessive consumption of fattening fast food.[83]

WARNINGS

Once the foreseeability of risk has been established,[84] the second element of duty must be addressed: the magnitude of the burden of guarding against such harm.[85] As a general rule, a warning will always appear to be less of a burden than the foreseeable risk involved,[86] and as a result, the element of duty would appear to always arise.[87] The difficulty, however, is that if too much information

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32, at 3 (stating that the use of labels has been shown by research to be associated with more healthy diets).

81. Jane E. Brody, *As America Gets Bigger, The World Does Too*, N.Y. TIMES, Apr. 19, 2005, at F5 (explaining that there is a close correlation between poverty and obesity world; obesity rates rise faster among those who are poorest because as the poor populations are more frequently urban they have access to foods with high concentrations of fat and have lifestyles in which they do not expend much energy).

82. *See* DHHS Obesity Call to Action, *supra* note 6, at 13-14 (correlating socio-economic status with the rate of obesity in men, women, and children in the United States).

83. *See supra* note 79.

84. *See, e.g.*, OWEN ET AL., *supra* note 54, § 9:1 ("[T]he inquiry in a duty to warn case is much more limited, focusing principally on the foreseeability of the risk and the adequacy and effectiveness of any warning" (citing Liriano v. Hobart Corp., 700 N.E.2d 303. 306 (N.Y.1998)).

85. The burden of providing a label with calorie information and a color coded symbol to alert the consumer when a food he or she eats is high in fat or calories would not create a large burden on the manufacturers and retailers off food stuff. *See* OWEN ET AL., *supra* note 54, § 9:1 ("[An adequate warning] by its size, location and intensity of language or symbol, must be calculated to impress upon a reasonably prudent user the nature and extent of the hazard involved.").

86. James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 271-72 (1990) ("[I]n both defective-design and failure-to-warn cases, cost-benefit balancing is inevitably required to determine product defectiveness.").

87. *See* Charles E. Cantu, *Distinguishing the Concept of Strict Liability for Ultra-Hazardous Activities from Strict Products Liability Under Section 402A of the Restatement (Second) of Torts: Two Parallel Lines of Reasoning That Should Never Meet*, 35 AKRON L. REV. 31, 51-53 (2001) (suggesting that risk utility will almost always require a duty to warn of foreseeable dangers) (citing Moran v. Faberge, Inc., 332 A.2d 11, 15 (Md. 1995) (observing that the failure to warn "will almost always weigh in favor of an obligation to warn of latent dangers"); Vicki Lawrence MacDougall, *Products Liability Law in the Nineties: Will Federal or State Law Control?*, 49 CONSUMER FIN. L.Q. REP.

is given, the net result is what is referred to as warnings pollution.[88] If the consumer is inundated and overwhelmed with too much information, he or she will in all likelihood ignore it.[89] The solution is a compromise; convey only that which is deemed adequate to warn the consumer.[90] Whether couched in terms of the "reasonable person" or the "reasonable consumer," there may be some difficulty in attaining this standard.[91] Pity the poor seller. What is an adequate or inadequate warning will be a question of fact for the jury.[92] In almost all cases the seller will not know whether they have complied

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327, 335-36 (1995) (criticizing the risk-benefit analysis because the test focuses on how much an additional warning would cost only to indicate that, because the cost is low, the test generally would result in a defective product).

88. *See* Owen, supra note 80, at 766 (noting that "[i]n this context, it is safety itself that may suffer when product risks are exaggerated and when important safety information is drowned in a sea of trivia. This is the problem of information overload, sometimes called 'warnings pollution,' that results from promoting maximum in lieu of optimal safety and danger information.").

89. *See* Aetna Cas. & Sur. Co. v. Ralph Wilson Plastics Co., 509 N.W.2d 520, 523 (Mich. Ct. App. 1993) ("[E]xcessive warnings on product labels may be counterproductive, causing 'sensory overload' that literally drowns crucial information in a sea of mind-numbing detail"); *see also* Mark Geistfeld, *Inadequate Product Warnings and Causation*, 30 U. MICH. J.L. REFORM 309, 322-27 (1997) (recognizing that people will not stop reading warnings if they feel they do not appropriately disclose all nonmaterial hazards because it is only the material ones that consumers care about).

90. *See* Owen, *supra* note 80, at 765 (explaining that there is both a procedural and substantive reasonableness component to be considered in evaluating warnings).

> [The procedural] component requires that the information be conveyed in a form and manner that is reasonably calculated to reach and catch the attention of persons who need it. Thus, written warnings and instructions must be presented in an appropriate size, color, and style of type, and sometimes should be preceded by a heading; pictures, bells, or buzzers will be necessary for certain types of products. . . . *Id.*

91. *See* Henderson & Twerski, *supra* note 86, at 266 (suggesting that "Failure to warn when a reasonable person would have warned exposes defendants to tort liability").

92. *Compare* Laaperi v. Sears, Roebuck & Co. 787 F.2d 726, 731-32 (1st Cir. 1986)

> The common law duty to warn of inherent dangers of products necessitates a warning comprehensible to the average user and conveying a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person. Whether a particular warning measures up to this standard is almost always an issue to be resolved by a jury,

with George Arthur Davis, Note, *The Requisite Specificity of Alcoholic Beverage Warning Labels: A Decision Best Left for Congressional to Determine*, 18 HOFSTRA L. REV. 943, 978-80 (1990) (arguing that there are problems associated with allowing juries to hear the issue on adequate warning).

with this standard until after a trial.[93] There are, however, some guidelines available.[94] Prior cases have given us the necessary parameters.[95] In order to be deemed sufficient, the warning must reach the consumer, catch their attention, and ultimately, penetrate their mind.[96] In other words, it is the duty of a food seller to ensure that the appropriate information is delivered to the ultimate plaintiff, they must absorb it, and most importantly, they must pay attention to it.

The food industry has used a variety of methods to catch the attention of their target groups in the past, and marketing schemes have been varied and quite innovative.[97] Research is a large part of introducing a product into the stream of commerce, and sellers are

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93. *See Laaperi*, 787 F.2d at 729 ("It is not necessary that the product be negligently designed or manufactured; the failure to warn of hazards associated with foreseeable uses of a product is itself negligence, and if that negligence proximately results in a plaintiff's injuries, the plaintiff may recover."); Brownlee v. Louisville Varnish Co., 641 F.2d 397, 400 (5th Cir. 1981); Stapleton v. Kawasaki Heavy Industries, Ltd., 608 F.2d 571, 573 (5th Cir.1979); Dougherty v. Hooker Chem. Corp., 540 F.2d 174, 179 (3d Cir. 1976); LeBouef v. Goodyear Tire & Rubber Co., 451 F.Supp. 253, 257 (W.D. La. 1978); Berry v. Coleman Sys. Co., 23 596 P.2d 1365, 1369 (Wash. Ct. App. 1979).

94. *See* Bituminous Cas. Corp. v. Black & Decker Mfg., 518 S.W. 2d 868, 872-73 (Tex. App. 1974).

> The question of adequacy of warning in such a situation has been dealt with extensively by courts in Texas as well as in other jurisdictions. In Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 85 (4th Cir. 1962) the court appropriately summarized the essential factors of a legally adequate warning by setting forth two essential characteristics: (1) it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use; (2) the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person. As stated in Walton v. Sherwin-Williams Co., 191 F.2d 277, 286 (8th Cir . 1951) the question of whether or not a given warning is legally sufficient depends upon the language used and the impression that such language is calculated to make upon the mind of the average user of the product. *Id.* (citations omitted).

95. *See id.*

96. *See id.*

97. *See* Marion Nestle & Michael F. Jacobson, *Halting the Obesity Epidemic: A Public Health Policy Approach*, 115 PUB. HEALTH REP. 12, 18 (2000), *available at* www.cspinet.org/reports/obesity.pdf; (stating that the food industry spends about $11 billion annually on advertising and another $22 billion or so on trade shows, supermarket 'slotting fees', incentives, and other consumer promotions); *see also* SUPER SIZE ME, *supra* note 32 (showing a scene filmed in an elementary school in which children more readily recognize Ronald McDonald more than any other figure, except for Santa Clause).

well aware of the importance of good marketing techniques.[98] In the present situation, however, it would seem that an easy and efficient scheme to achieve adequate warning would be to follow a color code system.[99] For example, green if the caloric count as well as the required nutritional values are within a safety zone; yellow if they are relatively moderate to medium; and red for an excessive amount of fat, high calories or unnecessary substances.

Information of this sort is already in use in some restaurants,[100] and has been required for prepackaged foods ranging from candy, chips, canned goods, cereals, nuts, and other foods.[101] Studies show that consumers who read labels are likely to have healthier diets.[102] Under a tagging system our goal could be met. The ultimate consumer would be informed, because in all likelihood they would notice the colored tag, and hopefully, they would choose accordingly.[103]

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98. *See* ERIC SCHLOSSER, FAST FOOD NATION 40-49 (Houghton Mifflin Company 2001) (discussing marketing techniques, especially those directed at children and how this sort of marketing has been part of the development and growth of the fast food industry). Schlosser focuses on McDonald's use of television ads, recognizable characters, and "Playland" playgrounds, which were designed by former Disney set designers to attract children. "The restaurant chain evoked a series of pleasing images in a youngster's mind: bright colors, a playground, a toy, a clown, a drink with a straw, [and] little pieces of food wrapped up like a present." *Id.* at 42.

99. *See generally* J. Stanley McQuade, *Products Liability–Emerging Consensus and Persisting Problems: An Analytical Review Presenting Some Options*, 25 CAMPBELL L. REV. 1, 51 (2002) (suggesting color codes should be used to warn consumers in situations when "some degree of user inadvertence or even carelessness is to be anticipated, how much should this be considered and incorporated into the warnings, e.g. with especially lurid symbols or color codes to catch the user's attention").

100. *See* Lisa Smith & Bryan A Liang, *Childhood Obesity: A Public Health Problem Requiring a Policy Solution*, 9 J. Med. & L. 37, 49-50 (2005) (discussing the need for restaurants to give nutritional information and listing examples of restaurants that already do); *see also* Rebecca S. Fribush, Comment, *Putting Calorie and Fat Counts on the Table: Should Mandatory Disclosure Laws Apply to Restaurant Foods?*, 73 GEO. WASH. L. REV. 377, 384-85 (2005) (analyzing legislative attempts to require labeling in restaurant and also giving examples of companies that have provided nutritional info to clientele).

101. *See* NLEA, 21 U.S.C § 343 (q) (Supp. 2005). (requiring prepackaged foods to provide nutritional labels).

102. *See* Sandra B. Eskin & Sharon Hermanson, *supra* note 32, at 3 (making the point that the use of labels has been shown to be associated with more healthy diets) (citing Matthew W. Kreuter et al., *Do Nutrition Label Readers Eat Healthier Diet? Behavioral Correlates of Adults' Use of Food Labels*, 13 AM. J. OF PREVENTIVE MED. 277 (1997) and Marian Neuhouser et al., *Use of Food Nutrition Labels is Associated with Lower Fat Intake,* 99 J. AM. DIETETIC ASS'N 45 at 45, 50, 53 (1999)).

103. *See* Owen, *supra* note 80, at 762.

> Warnings and instructions thus provide consumers with informational "software" that helps them better understand the true utility[,] cost [, and]

As previously stated, duty is imposed when an individual is faced with a foreseeable risk of harm that exceeds the magnitude of the burden of guarding against it.[104] Some of the most important perspectives of this burden would consist of cost, the utility and/or marketability of the product, and whether such technique is within the state of the art of our technology.[105] Obviously, in this instance, the elements of our burden are minimal.[106] It would be difficult to imagine how much cost would be involved in attaching a colored tag to fast food. Whether hamburgers, pizzas, fried chicken, or other take out, they all have one common characteristic: they are packaged. Adding a colored tag would be a negligible factor. Providing caloric and nutritional information might not impair the utility/marketability of the product.[107] In fact, it could be argued that an

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safety mix that constitutes each product. Providing safety information to consumers promotes two ideals: (1) individual autonomy, by helping consumers make informed choices in the selection and use of products that each consumer decides contain the mix of utility[,] cost [, and] safety that best advances his or her personal goals; and (2) (optimal) safety, by providing consumers with information they may use to reduce (optimally) the risks inherent in the products they choose to purchase. *Id.*

104. *See Group Calls for Soft Drink Warnings*, N.Y. TIMES, July 14, 2005, at C9 (reporting that the Center for Science in the Public Interest has recommended that the FDA should require health warnings similar to those on cigarettes and alcohol to warn of the harmful effects of highly sweetened soda).

105. *See* Smith & Liang, *supra* note 100, at 50 (discussing the need for restaurants to give nutritional information and listing examples of restaurants that already do); *see also* Fribush, *supra* note 100, at 385 (analyzing legislative attempts to require labeling in restaurant and also giving examples of companies that have provided nutritional info to clientele).

106. Margo G. Wootan, Center for Science in the Public Interest, *Anyone's Guess; The Need for Nutrition Labeling at Fast-Food and Other Chain Restaurants* 17 (2003), *available at* www.cspinet.org/restaurantreport.pdf (explaining that many commercial laboratories will provide nutritional analysis). The cost to measure calories alone varies from $55-$95 per meal, and the cost to analyze calories, saturated fat, trans fat and sodium has a cost of about $220 per menu item. *Id.* Wootan argues that nutritional analysis is not prohibitively expensive and because restaurants routinely change menus, when they change items or cost, it would not be difficult to add nutritional information when making one of those changes. *Id.* The overall cost to a restaurant to provide nutritional information and warn consumers would not be prohibitively expensive. *See id.*

107. *See* Caleb E. Mason, *Doctrinal Considerations For Fast-Food Obesity Suits*, 40 TORT TRIAL & INS. PRAC. L. J. 75, 103 (2004) ("If juries begin awarding damages to obese fast-food consumers there will be market consequences, but fast food will only vanish from the marketplace if the price increases necessitated by tort payouts are sufficiently high to suppress demand enough to negate the profitability of selling fast food.") (citing WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF TORT LAW 192 (1987)).

informed public actually might be encouraged to purchase it over competing products. Finally, a color tag is well within the state of our technological development and they would be effective. Even common adhesive tags are found everywhere, and used extensively by children, adolescents, adults and the elderly whether to post a reminder, catch one's attention to a page in a book, or some other purpose.[108] In addition, their very color would convey the necessary information, and are easily noticeable.[109] In essence, tags comply with our objective, and present a burden that is far less than the foreseeable risk of harm we are attempting to prevent.

CALLING FOR A NEW TORT

In summary, it could be stated that excessive consumption of fattening fast food presents a foreseeable risk of harm.[110] The medical profession, as it has done in cases involving alcohol[111] and cigarettes,[112] has established this undeniable fact.[113] The burden of warning of this risk is minimal when compared to the degree of harm threatened. It would follow that a duty to warn is clearly established,[114] and if the other elements of actionable negligence—breach,

108. A visit to a local office supply store, or even grocery store, will show the wide variety of colors in which 3M Post-it® Notes or similar products are available. *See also* http://www.3m.com/us/office/postit/25years/index.jhtml. Also the software imitation of colored notes on computer desktops, such as Stickies 2.1 ©1994-2002, Apple Computer, Inc., shows a fairly clear pattern of use of colored notes to catch the attention of many American consumers.

109. *See* Owen, *supra* note 80, at 765 (suggesting the use of color as one means of capturing the consumer's attention to ensure adequate delivery of the warning).

110. The American awareness of dieting and weight loss as a result of media coverage suggest that the dangers of obesity should reasonably be known. *See* Connie L. Bish et al., *Diet and Physical Activity Behaviors Among Americans Trying to Lose Weight: 2000 Behavioral Risk Factor Surveillance System*, 13 OBESITY RES. 596 (2005) (reporting that forty-six percent of women and that thirty-three percent of men in America are trying to lose weight); *see also* Krugman, *supra* note 2 (criticizing the attempt of Center for Consumer Freedom, a group financed by food providers such as Coca-Cola, that has put forth a 4th of July campaign to convince Americans the worrying about obesity is un-American, and also stating that number of obese American adults has doubled to thirty percent and that research shows high health cost).

111. Alcoholic Beverage Labeling Act, 27 U.S.C. § 215 (Supp. 2005).

112. CLAA, 15 U.S.C §§ 1331-1341 (Supp. 2005).

113. *See, e.g.*, DHHS Obesity Call to Action, *supra* note 6, at 1-3 (the surgeon general as the representative of the medical community in the executive branch of the federal government has made it a priority to deal with issue of obesity in this country).

114. *See supra* notes 83-109.

proximate cause, and injury—are present, a cause of action has been established,[115] but only if American jurisprudence, in the absence of legislation, is willing to accept this new tort. It would seem that the time to do so is now.

CONCLUSION

Choice is ultimately the responsibility of the consumer. The buyer, however, should be informed. Food products should readily and easily allow consumers to differentiate between foods that are a healthy choice in a regular diet and food that is likely to cause harm if eaten frequently. An occasional outing to a fast food establishment does not harm. But, as in the case of smoking and/or drinking alcohol, medical data shows that excessive consumption over an extended period of time will result in physical harm. The obligation to warn, in the case of cigarettes and alcoholic beverages is well established. Now, purveyors of fattening fast food must follow suit. The duty to do so is clear.

115. *See* KEETON,ET AL., *supra* note 49, § 30 (giving a background explanation of negligence and the elements of the cause of action).

PROTECTING ISLAM'S GARDEN FROM THE WILDERNESS: HALAL FRAUD STATUTES AND THE FIRST AMENDMENT

Elijah L. Milne[*]

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I. INTRODUCTION

Like all religions, Islam needs protection from governmental encroachment. As early as 1644, Roger Williams, the founder of Rhode Island, recognized that state involvement in religious matters defiles religion.[1] "When they have opened a gap in the hedge or wall of separation between the garden of [religion] and the wilderness of the world," wrote Williams, "God hath ever broke down the wall itself, removed the candlestick, and made His garden a wilderness . . . ."[2] Although Williams was mostly concerned about the government's impact on Christianity, his oft-quoted metaphor applies equally to the government's influence on Islam. This Article will discuss one facet of that influence–state regulation of the halal food industry.

Halal food, as opposed to *haram* food,[3] is food that is "ritually fit for use" because it has been "sanctioned by Islamic law."[4] The Qur'an[5] forbids Muslims from eating anything except food defined as being *halal*.[6] The problem exists in that "Muslims are not yet in agreement with one another" as to the definition of *halal*.[7] Because

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1. *See* Stephen L. Carter, *Reflections on the Separation of Church and State*, 44 ARIZ. L. REV. 293, 296 (2002) ("Williams coined the metaphor of the garden and the wilderness to describe the relationship between [church and state] . . . . [S]eparating the wilderness from the garden, was a high hedge wall, constructed to protect . . . the garden . . . . The hedge wall existed to keep the wilderness out, not to keep . . . the garden hemmed in.").

2. Roger Williams, *Cotton's Letter Examined* (1644), *reprinted in* 1 COMPLETE WRITINGS OF ROGER WILLIAMS 313, 319 (1963).

3. *See infra* note 65 & accompanying text.

4. *See* MOHAMMAD MAZHAR HUSSAINI, ISLAMIC DIETARY CONCEPTS AND PRACTICES 25-26 (1993); MERRIAM-WEBSTER UNABRIDGED, *available at* http://unabridged.merriam-webster.com (last visited May 18, 2006). The Prophet Muhammad has been recorded as saying: "The halal is that which Allah has made lawful in His Book and the haram is that which He has forbidden, and that concerning which He is silent, He has permitted as a favor to you." *See* HUSSAINI, *supra* note 4, at 22 (internal quotation marks omitted).

5. The Qur'an is the holy book of Islam and constitutes the word of Allah (God) as revealed to the Prophet Muhammad. *See* MSN Encarta, *at* http://Encarta.msn.com/encyclopedia_761557364/Qur%E2%80%99an.html (last visited May 18, 2006).

6. *See* THE HOLY QUR'AN 5:90-91 (Abdullah Yusuf Ali trans., 1987).

7. AHMAD H. SAKR, UNDERSTANDING HALAL FOODS: FALLACIES AND FACTS 3 (1996); *see also* Mariam Jukaku, *A Growing, Confusing Market for Halal Food*, WASH. POST, Mar. 18, 2006, at B09, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/03/17/AR2006031701632.html?referrer=emailarticle

of America's great ethnic and national diversity, disagreement over the meaning of *halal* is especially acute in the United States.[8] Despite the widespread disagreement among and within Islamic "schools of thought" over halal food, various individual states in the United States have attempted to define, by legislative edict, this inherently religious term.[9] The stated purpose behind such legislative definitions of *halal* is to prevent the fraudulent representation of food as being halal. The constitutionality of these government-enacted definitions of *halal* is uncertain.

In order to help dissipate this uncertainty, this Article will analyze the constitutionality of halal fraud statutes under the Establishment and Free Exercise Clauses of the First Amendment to the United States Constitution.[10] Because the advent of halal fraud statutes is relatively recent, analysis of the constitutionality of halal fraud laws will be conducted by comparing them with the more antiquated kosher fraud regulations,[11] which have been enacted in

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(recognizing that "different interpretations of what Muslims consider halal, or religiously sanctioned, has led to confusion, misunderstanding, and even fraud").

8. *Id.* at 4 (stating that division among Muslims over meaning of *halal* has resulted in "a chaos and a confusion").

9. *See, e.g.*, CAL. PENAL CODE § 383c (West 2005); 410 ILL. COMP. STAT. 637/5 (2005) ("Halal Food Act"); 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).

10. Consideration of the constitutionality of halal fraud regulations under the Equal Protection Clause of the Fourteenth Amendment is beyond the scope of this paper. *But see* Benjamin Pi-wei Liu, Comment, *A Prisoner's Right to Religious Diet Beyond the Free Exercise Clause*, 51 UCLA L. REV. 1151, 1176 (2004) (stating that equal protection claim exists where "state circumscribes a religious practice in the context of one religion but not another"); Rain Levy Minns, Note, *Food Fights: Redefining the Current Boundaries of the Government's Positive Obligation to Provide Halal*, 17 J.L. & POL. 713, 737-38 (2001) (same).

11. *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-941 (2005); ARK. CODE ANN. § 20-57-401 (2005); CAL. PENAL CODE § 383b (West 2005); CONN. GEN. STAT. § 53-317 (2005); GA. CODE ANN. § 26-2-330 (2005); 410 ILL. COMP. STAT. 645/1 (2005); KY. REV. STAT. ANN. § 367.850 (West 2005); LA. REV. STAT. ANN. § 608.2 (2005); MD. CODE ANN., COM. LAW § 14-901 (West 2005); MASS. GEN. LAWS ch. 94, § 156 (2005); MICH. COMP. LAWS § 750.297e (2005); MINN. STAT. §§ 31.651, 31.661 (2005); MO. REV. STAT. § 196.165 (2005); N.J. STAT. ANN. § 2C:21-7.2 (West 2005); N.Y. AGRIC. & MKTS. LAW § 201-c (McKinney 2005); OHIO REV. CODE ANN. § 1329.29 (West 2005); PA. CONS. STAT. ANN. § 4107.1 (West 2005); R.I. GEN. LAWS §§ 21-16-1 to 21-16-4 (2005); TEX. BUS. & COM. CODE ANN. § 17.821 (Vernon 2005); VA. CODE ANN. § 18.2-236 (2005); WASH. REV. CODE § 69.90.010 (2005); WIS. STAT. § 97.56 (2005). Tennessee and the District of Columbia once had kosher fraud laws. *See* D.C. CODE § 22-5204 to 22-5206 (repealed 2001); TENN. CODE ANN. § 53-6-101, *repealed by* 1983 Tenn. Pub. Acts, ch. 373, § 1.

many states.[12] This analysis will lead to the conclusion that halal fraud statutes are violative of both the Establishment and Free Exercise Clauses, but that valid means of protecting consumers of halal food from fraud can be instated constitutionally.

In order to set the stage for this analysis, Section II of this Article will provide background information about Jewish and Islamic dietary laws. Subsequently, Section III will give a brief synopsis of First Amendment jurisprudence and will discuss the constitutionality of halal fraud statutes. As noted, this discussion will conclude that halal statutes are unconstitutional as presently constructed. In order to remedy these constitutional defects with halal statutes, Section IV will offer suggestions that legislatures throughout the country should consider.

II. BACKGROUND

To conduct any analysis of the constitutionality of statutes regulating the halal food industry, it is first necessary to develop a rudimentary understanding of Islamic dietary laws. Only after developing such an understanding can one adequately appreciate the inherent religiosity of the term *halal*. However, because halal fraud statutes in the United States are so new, it is unclear how courts will decide constitutional challenges brought under the First Amendment's Religion Clauses.[13] Nevertheless, in light of the similarities between halal and kosher fraud regulations, courts determining the constitutionality of halal regulations will probably resort to the many judicial opinions and scholarly comments regarding kosher regulations for guidance.[14] This is because, unlike halal regulations, kosher regulations have been tried and tested in this country for nearly a century.[15] Thus, in addition to developing an understanding of Is-

12. Shayna M. Sigman, *Kosher Without Law: The Role of Nonlegal Sanctions in Overcoming Fraud within the Kosher Food Industry*, 31 FLA. ST. U. L. REV. 509, 590-91 (2004) (suggesting that examining "kosher fraud can serve as a model for other food industries").

13. *See id.* at 542, 591 (noting that halal certification "is in its infancy" and "lags far behind kosher supervision").

14. *See, e.g.*, Mohamed H. Marei, A Rising Star? Halal Consumer Protection Laws 16-20 (2001) (unpublished comment, *at* http://leda.law.harvard.edu/leda/data/375/Marei.pdf (last visited May 18, 2006)) (observing that "[t]he kosher legal regime provides the closest analog to what a halal fraud statute might look like").

15. The first kosher statute was passed in 1915. HAROLD P. GASTWIRT, FRAUD, CORRUPTION, AND HOLINESS: THE CONTROVERSY OVER THE SUPERVISION OF JEWISH DIETARY PRACTICE IN NEW YORK CITY 1881-1940, at 13 (1974).

lamic dietary laws, it is also necessary to first develop a basic understanding of the Jewish dietary laws that give meaning to kosher fraud regulations.

A. Jewish Dietary Laws

1. Keeping Kosher

The Jewish dietary laws are called *kashrut*.[16] Food which satisfies the strict requirements of kashrut is referred to as *kosher*.[17] For observant Jews, kashrut controls food preparation, cooking, and consumption.[18] Besides Jews, kosher-certified food is also popular among American Muslims, Seventh-day Adventists, vegetarians, people who suffer from allergies or food intolerances, and other health-conscious consumers.[19] Among the different branches of Judaism, the meaning of kashrut is not uniform.[20] For example, controversy exists as to whether certain types of cheeses, wines, gelatin, birds, and fish (e.g., sturgeon and swordfish) are kosher.[21] Gener-

16. MERRIAM-WEBSTER UNABRIDGED, *supra* note 4 (variations include *kashruth* and *kashrus*). For an exposition of the underlying reasons for the Jewish dietary laws, see 1 ISIDOR GRUNFELD, THE JEWISH DIETARY LAWS (1972).

17. MERRIAM-WEBSTER UNABRIDGED, *supra* note 4 (defining *kosher* as meaning "ritually fit" or "proper").

18. TRUDY GARFUNKEL, KOSHER FOR EVERYBODY: THE COMPLETE GUIDE TO UNDERSTANDING, SHOPPING, COOKING, AND EATING THE KOSHER WAY 7 (2004).

19. *Id.* at 1-2.

20. *See* LISË STERN, HOW TO KEEP KOSHER: A COMPREHENSIVE GUIDE TO UNDERSTANDING JEWISH DIETARY LAWS 2 (2004) ("Ask a dozen Jews why they keep kosher, and you'll probably get two dozen answers. Ask them *how* they keep kosher, and you'll get another dozen responses."); *see also* Mark A. Berman, *Kosher Fraud Statutes and the Establishment Clause: Are They Kosher?*, 26 COLUM. J.L. & SOC. PROBS. 1, 9-10, 62 (1992) ("the strain between all" branches of Judaism "has increased in recent years"); Catherine Beth Sullivan, *Are Kosher Food Laws Constitutionally Kosher?*, 21 B.C. ENVTL. AFF. L. REV. 201, 212 (1993) (noting "[t]here is a wide divergence of opinion as to the meaning of 'kosher'"); Aharon R. Junkins, Note, *The Establishment Clause's Effect on Kosher Food Laws: Will the Jewish Meal Soon Become Harder to Swallow in Georgia?*, 38 GA. L. REV. 1067, 1072 (2004) (noting the "[d]istinct interpretive rifts" within Judaism). *But see* Stephen F. Rosenthal, *Food for Thought: Kosher Fraud Laws and the Religion Clauses of the First Amendment*, 65 GEO. WASH. L. REV. 951, 963-64, 980-81 (1997) (arguing that differences of opinion among branches of Judaism are insignificant); Karen Ruth Lavy Lindsay, Comment, *Can Kosher Fraud Statutes Pass the Lemon Test?: The Constitutionality of Current and Proposed Statutes*, 23 U. DAYTON L. REV. 337, 342 (1998) (same). The major branches of Judaism include Orthodox, Conservative, Reform, and Reconstructionist. *See* GARFUNKEL, *supra* note 18, at 2.

21. *See* STERN, *supra* note 20, at 24-26, 61-63.

ally, Orthodox Jews often maintain stricter criteria for observing kashrut than do Conservative, Reform, or Reconstructionist Jews.[22]

Regardless of their differences, most Jews recognize that the laws of kashrut address three basic types of food: (1) inherently kosher food, such as fruits and vegetables; (2) biblically prohibited food, such as pork and shellfish; and (3) food that becomes kosher once processed, such as meat prepared by a ritual slaughterer (known as a *shohet*).[23] Beyond merely identifying food as being kosher, the laws of kashrut are also concerned about the manner in which food is stored, cooked, served, and eaten.[24] By adhering to the rules of kashrut and keeping kosher, observant Jews are more fully able to protect their health, to follow the commands of the Torah, to affirm their faith, to manifest outwardly their religious devotion and cultural identity, and to strengthen their relationship with God.[25]

2. Regulating the Kosher Food Industry

Because the kosher food market is a multibillion-dollar industry in America and because kosher food is often more expensive than non-kosher food,[26] manufacturers historically have easily succumbed to the temptation of fraudulently labeling food as being kosher without satisfying the strict, and often costly, laws of kashrut.[27] In order to protect innocent buyers of kosher products from fraud, hundreds of private, self-regulating kosher certification and supervision organizations have been established.[28] Additionally, at least

22. *See* GARFUNKEL, *supra* note 18, at 2; *see also* STERN, *supra* note 20, at 3, 7-10.

23. GASTWIRT, *supra* note 15, at 14; MERRIAM-WEBSTER UNABRIDGED, *supra* note 4; *see also* STERN, *supra* note 20, at 49.

24. *See* GASTWIRT, *supra* note 15, at 14-15.

25. *See* GARFUNKEL, *supra* note 18, at 8; STERN, *supra* note 20, at 10-14; *see also* Benjamin N. Gutman, Note, *Ethical Eating: Applying the Kosher Food Regulatory Regime to Organic Food*, 108 YALE L.J. 2351, 2363 (1999) (noting that "eating only kosher food is seen as a way of elevating oneself spiritually").

26. This non-kosher food is referred to as *terefah*. MERRIAM-WEBSTER UNABRIDGED, *supra* note 4 (providing variants including *terefa*, *trefah*, or *trefa*).

27. *See* GASTWIRT, *supra* note 15, at 1-13; *see also* GARFUNKEL, *supra* note 18, 1-2 (stating that "the U.S. market for kosher food is approximately $7.5 billion annually"); Joe Yonan, *You Don't Have to Be Jewish*, BOSTON GLOBE, Sept. 28, 2005, *available at* http://www.boston.com/ae/food/articles/2005/09/28/you_dont_have_to_be_jewish.

28. *See* GARFUNKEL, *supra* note 18, at 25 (noting that there are "[m]ore than four hundred organizations and individuals in the United States and Canada" that issue kosher certifications). The most prominent certifying organizations in the United States include the Union of Orthodox Jewish Congregations, the Organized Kash-

twenty-two states have enacted some form of kosher food consumer protection statutes.[29] While a few of these statutes define *kosher* as meaning "prepared under the *traditional* Hebrew rules"[30] or in "accordance with Jewish *religious* dietary requirements,"[31] most statutes employ more controversial language that generally defines *kosher* as "prepared in accordance with *orthodox* Jewish religious standards."[32]

After the first statute regulating the kosher industry was enacted, claims that its definition of *kosher* was unconstitutionally ambiguous immediately surfaced.[33] In 1924, a case challenging a kosher fraud statute under the Due Process and Commerce Clauses was argued before the United States Supreme Court.[34] Because the First Amendment had not yet been held to apply to the States, the Court upheld the statute without considering the Religion Clauses.[35] Since 1925, the United States Supreme Court has not heard any cases challenging a kosher fraud statute.[36] If the Court ever considers such a statute based upon First Amendment grounds, the following

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rus Laboratories, Kosher Supervision Services, and STAR-K Kosher Certification. *See id.* at 25-27.

29. *See supra* note 11 & accompanying text.

30. ARIZ. REV. STAT. ANN. § 36-941(1) (emphasis added).

31. 305 ILL. COMP. STAT. 5/5-5.5a(a) (2005) (emphasis added).

32. MASS. GEN. LAWS ch. 94, § 156(a)(1) (emphasis added); *see also* N.J. STAT. ANN. § 2C:21-7.2(d) (defining *kosher* as being prepared in conformity with "the Orthodox Jewish religion").

33. *See, e.g.*, The People of the State of New York v. Atlas, 170 N.Y.S. 834 (App. Div. 1918); People v. Goldberger, 163 N.Y.S. 663, 665-66 (Ct. Spec. Sess. 1916) (holding statute to be neither ambiguous nor invasive of "religious freedom or personal rights").

34. *See* Hygrade Provision Co. v. Sherman, 266 U.S. 497 (1925). The United States Supreme Court did not incorporate the Free Exercise Clause until 1940. *Cantwell v. Connecticut*, 310 U.S. 296, 303-04 (1940). Subsequently, in 1947, the Court similarly incorporated the Establishment Clause in *Everson v. Bd of Educ. of Ewing TP*, 330 U.S. 1, 15-18 (1947).

35. *Hygrade*, 266 U.S. at 503.

36. However, state courts have heard cases challenging these statutes. *See, e.g.*, Erlich v. Mun. Ct., 55 Cal. 2d 553 (1961) (upholding statute under due-process attack); Sossin Sys., Inc. v. City of Miami Beach, 262 So. 2d 28 (Fla. Dist. Ct. App. 1972) (holding city ordinance did not violate Religion Clauses); United Kosher Butchers Ass'n v. Associated Synagogues of Greater Boston, Inc., 211 N.E.2d 332, 334-35 (Mass. 1965) (refusing to decide case where issue is "so exclusively one of religious practice and conscience"); Prime Kosher Foods, Inc. v. Administrators, Bureau of Employment Servs., 519 N.E.2d 868 (Ohio 1987); State v. Glassman, 441 N.Y.S.2d 346 (1981) (Sullivan County Ct. 1981) (dismissing complaint); People v. Johnson Kosher Meat Prods., Inc., 248 N.Y.S. 2d 429 (N.Y. City Civ. Ct. 1964) (upholding criminal conviction). So also have some federal district courts. *See, e.g.*, Nat'l Foods, Inc. v. Rubin, 727 F. Supp. 104 (S.D.N.Y. 1989) (stating that "[t]he constitutionality of [kosher] laws has long been recognized").

cases invalidating kosher regulations under the Establishment Clause may be indicative of the outcome: *Ran Dav's County Kosher, Inc. v. New Jersey*,[37] *Barghout v. Bureau of Kosher Meat & Food Control*,[38] and *Commack Self-Service Kosher Meats, Inc. v. Weiss*.[39]

In *Ran-Dav's County*, the New Jersey Supreme Court invalidated a state statute that defined *kosher* as "prepared . . . in strict compliance with the laws . . . of the Orthodox Jewish religion."[40] The court held the statute violated the Establishment Clause because it carried "government too far into the religious domain."[41] Given that "there are differences of opinion concerning the application and interpretation of the laws of kashrut," the statute was said to improperly impose "substantive religious standards" on merchants.[42] Because the word *kosher* means "ritually fit," the court rejected the notion that *kosher* had lost its fundamental religious meaning.[43] In addition, the fact that the statute "call[ed] on religious personnel to enforce and certify religious compliance" was also troubling.[44] In particular, the fact that the statute's chief enforcer was an orthodox rabbi, as were most members of the kosher advisory committee, gave credence to the court's belief that the statute had "a principally religious meaning."[45] Indeed, this "close identification" of government with religion suggested that the statute was unconstitutional because it "authorize[d] civil enforcement of . . . religious standards with the assistance of clergy."[46] For these reasons the statute was struck down under the Establishment Clause.

Subsequent to *Ran Dav's County*, the Fourth Circuit in *Barghout* invalidated a Baltimore municipal ordinance, which required that all food labeled as being kosher comply "with the orthodox Hebrew religious rules and requirements."[47] In *Barghout*, a business that had been fined for not satisfying the ordinance's definition of *kosher*

37. 608 A.2d 1353 (N.J. 1992).
38. 66 F.3d 1337 (4th Cir. 1995).
39. 294 F.3d 415 (2d Cir. 2002).
40. *Ran Dav's County*, 608 A.2d at 1355.
41. *Id.*; *see also infra* Section III.A.1.c.
42. *Ran Dav's County*, 608 A.2d at 1356, 1360, 1362. Additionally, the court stated in dicta that the New Jersey statute could possibly be in violation of the "denominational preference" test that was described in *Larson v. Valente*, 456 U.S. 228, 246 (1982). *See Ran Dav's County*, 608 A.2d at 1358-59.
43. *Ran Dav's County*, 608 A.2d at 1360, 1363-64.
44. *Ran Dav's County*, 608 A.2d at 1365.
45. *Id.* at 1357, 1361 (suggesting the advisory committee consisted of nine orthodox rabbis and one conservative rabbi).
46. *Id.* at 1355, 1364-65.
47. *Barghout*, 66 F.3d at 1338, 1340 (internal quotation marks omitted).

brought suit seeking declaration that the ordinance violated the Establishment Clause.[48] After considering the matter, the Fourth Circuit held that the ordinance fostered an "excessive entanglement of religious and secular authority," and that the ordinance had an impermissible effect of advancing tenets of Orthodox Judaism.[49] The court also pointed out that the ordinance created a six-person enforcement bureau, three of the members of which were required to be orthodox rabbis selected by two orthodox associations.[50] For the *Barghout* court, such a composition unconstitutionally delegated governmental authority to religious organizations.[51] These facts, along with others, were enough for the court to conclude that the ordinance was facially unconstitutional.[52]

Similarly, in *Commack*, the Second Circuit held that the State of New York's kosher fraud statutes violated the Establishment Clause and were unconstitutional on their face.[53] Because New York's statutes defined *kosher* by explicitly referring to "orthodox Hebrew religious requirements," the court said the statutes "excessively entangle government and religion."[54] According to the court, the statutes "take sides in a religious matter, effectively discriminating in favor of the Orthodox Hebrew view of dietary requirements."[55] The *Commack* court also stated that the statutes "require the State to take an official position on religious doctrine" and "create an impermissible fusion of governmental and religious functions by delegating civic authority to individuals apparently chosen according to religious criteria."[56] Citing *Ran Dav's County* and *Barghout*, the Second Circuit in *Commack* struck down New York's kosher statutes for basically the same reasons as the laws in *Ran Dav's County* and *Barghout* were invalidated.[57]

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48. *Id.* at 1339.

49. *Id.* at 1344-46.

50. *Id.* at 1339, 1342.

51. *Id.* at 1342.

52. *Barghout*, 66 F.3d at 1342. The *Barghout* concurrence noted that the ordinance promoted a denominational preference of Orthodoxy over other branches of Judaism. *See id.* (Luttig, J., concurring in the judgment); *id.* at 1350 (Wilkins, J., concurring).

53. *Commack*, 294 F.3d at 432.

54. *Id.* at 423, 425.

55. *Id.* at 425.

56. *Id.*

57. The *Commack* court also held that New York's statutes were not narrowly tailored to serve their stated purposes inasmuch as "their avowed purpose" was already "covered by the existing general fraud laws." *Id.* at 431.

B. Islamic Dietary Laws

1. Halal Food

Although there are certain similarities between Islamic and Jewish dietary laws, many differences exist.[58] Islamic dietary laws were originally given by Allah[59] to the Prophet Muhammad in the Qur'an.[60] Through the life, teachings, and traditions of the Prophet, as recorded in the *hadith*,[61] faithful Muslims are more fully able to understand and interpret this dietary code.[62] With the exception of those explicitly prohibited by the Qur'an or the hadith, all other dietary items are permitted for human consumption under Islamic traditions.[63] Food that is permitted is referred to as *halal*, while food that is prohibited is *haram*.[64]

Just as there is disagreement within Judaism over the meaning of the word *kosher*, controversy exists within Islam over what constitutes *halal*.[65] For example, currently a lack of consensus exists among Muslims concerning the use of some dairy and cereal-based products, meat,[66] fish (e.g., catfish), and seafood (e.g., mollusks and crustaceans).[67] Disagreement also exists as to when the name of Allah should be invoked over meat and poultry.[68]

Despite the differences of opinion among the different Muslim schools of thought regarding what constitutes halal, generally the

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58. *See* MIAN N. RIAZ & MUHAMMAD M. CHAUDRY, HALAL FOOD PRODUCTION 164 (2004). For a list of some of the differences between kosher and halal, see HUSSAINI, *supra* note 4, at 41-44.

59. Allah is interpted as meaning *God*. *See* MERRIAM-WEBSTER ONLINE, *at* http://www.merriam-webster.com/dictionary/Allah (last visited May 18, 2006).

60. *See* RIAZ & CHAUDRY, *supra* note 59, at 5.

61. *See* MERRIAM-WEBSTER ONLINE, *supra* note 60 (defining *hadith* as "a narrative record of the sayings or customs of Muhammad and his companions").

62. *See* RIAZ & CHAUDRY, *supra* note 59, at 5.

63. *Id.*

64. *See supra* note 3 & accompanying text; *see also* Fatima Asmal, Scholars, Experts Plan Universal Halal Foods Standards (Sept. 13, 2005), *available at* http://www.islamonline.net/English/News/2005-09/13/article08.shtml (noting that there are "differences and variations" among Muslims as to halal regulation).

65. *See supra* notes 7-8 & accompanying text; *see also* Marei, *supra* note 14, at 5 (stating that "although Muslim scholars agree on a [sic] most issues, Islamic jurisprudence has left a considerable amount of room for differing interpretations of rules and laws") (citing MUSTAFA AZAMI, STUDIES IN EARLY HADITH LITERATURE 217 (1992)).

66. SAKR, *supra* note 7, at 4.

67. *See* RIAZ & CHAUDRY, *supra* note 59, at 2-3, 14, 164.

68. *Id.* at 19, 148-49; *see also* Marei, *supra* note 14, at 25.

following categories of food are considered impermissible: blood, pork, intoxicants, carnivorous animals, birds of prey, amphibians, snakes, the meat of dead animals, and food immolated unto idols.[69] Additionally, meat and poultry items are not halal unless the name of Allah has been verbally pronounced upon them at the time of slaughter.[70] This invocation (referred to as *tasmiyyah*) of the name of Allah at the time of slaughter must be performed by a sane and faithful[71] Muslim who is of proper age.[72] Although it is generally considered adequate to say *Bismillah* ("in the name of Allah") only once at the time of slaughter, the slaughterer should repeat the name of Allah three times for larger animals.[73] The person overseeing these processes should also be Muslim.[74] Failure to follow any of these procedures renders the meat or poultry *haram* (not halal)[75] because "[p]roper Islamic slaughter," for Muslims, "is an act of worship to Allah."[76]

2. Regulating the Halal Food Industry

As the Muslim population in America continues to grow, the demand for halal food in the United States has also significantly increased.[77] In order to protect consumers from fraud, Muslims, like Jews, have organized various private, self-regulating certification agencies to oversee the production and sale of halal products.[78] Nevertheless, as with kosher food, some states—California, Illinois,

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69. *See* RIAZ & CHAUDRY, *supra* note 59, at 9; *see also* MAULANA MUHAMMAD ALI, THE RELIGION OF ISLAM 706-09 (1983); *see also* HUSSAINI, *supra* note 4, at 65-66.

70. RIAZ & CHAUDRY, *supra* note 59, at 9, 11; *see also* ALI, *supra* note 69, at 708-09.

71. "The meat of an animal killed by an idolater, a nonbeliever, or someone who has apostatized from Islam is not acceptable." RIAZ & CHAUDRY, *supra* note 59, at 18.

72. *Id.* at 12-13, 17-19, 164.

73. *Id.* at 62; *see also* ALI, *supra* note 69, at 709-10.

74. RIAZ & CHAUDRY, *supra* note 59, at 63.

75. It is also recommended that the Muslim slaughterer be facing Mecca at the time of slaughter. *Id.* at 67.

76. HUSSAINI, *supra* note 4, at 30.

77. "As of 1992, [the] number [of Muslims in North America is] estimated at 6 to 8 million . . . . According to one estimate, the buying power for food of Muslim consumers in North America was worth $12 billion in 1999. It is estimated that amount of spending by Muslims on food will exceed $15 billion in 2003 . . . ." RIAZ & CHAUDRY, *supra* note 59, at 30 (citations omitted).

78. *See* RIAZ & CHAUDRY, *supra* note 59, at 172-73 (identifying, *inter alia*, the following organizations: International Institute of Islamic Thought, Islamic Food and Nutrition Council of America, Islamic Food Authority Inc., Islamic Services of America, and Institute of Halal Food Control); *see also* SAKR, *supra* note 7, at 86.

Michigan, Minnesota, New Jersey, and Texas–have also deemed it necessary to enact statutes regulating the labeling of food as being halal.[79] Generally, these laws often define the term *halal* as meaning "prepared under and maintained in strict compliance with the laws and customs of the Islamic religion"[80] or "in accordance with Islamic religious requirements."[81] Although many lawsuits have been brought by Muslim inmates seeking halal food as part of the free exercise of their religion while in prison,[82] no cases have been reported as challenging the constitutionality of any halal fraud statute.

III. ANALYSIS AND DISCUSSION

The First Amendment to the United States Constitution provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof."[83] These words from the Constitution are collectively referred to as the Religion Clauses and individually as the Establishment and Free Exercise Clauses.[84] Throughout the history of the Court, various tests have been formulated to determine the constitutionality of a law when challenged under the Religion Clauses. The following sections of this Article will explain some of the most recent tests which the Supreme Court has enunciated for applying the Establishment and Free Exercise Clauses, respectively. In tandem with this explanation of current Supreme Court jurisprudence, the constitutionality of halal fraud statutes will be analyzed and discredited.

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79. *See* statutes cited *supra* note 9. The United Nations ("U.N.") has also established international standards and guidelines for labeling food as *halal.* Joint FAO/WHO Food Standards Programme, Codex Alimentarius Comm'n, *Codex Alimentarius: Food Labelling-Complete Texts,* at 43-46 (2001), *available at* ftp://ftp.fao.org/docrep/fao/0-05/y2770E/y2770E00.pdf. According to the U.N., "Halal Food means food permitted under the Islamic Law." *Id.* § 2.1. Thus, the slaughter of "lawful" animals should be performed "by a Muslim," and accompanied by pronunciation of *Bismillah* "immediately before the slaughter of each animal." *Id.* §§ 3.2.1, 3.2.4.

80. 815 ILL. COMP. STAT. 505/2LL(a) (2005).

81. MICH. COMP. LAWS § 750.297f(1).

82. *See, e.g.*, Williams v. Morton, 343 F.3d 212 (3d Cir. 2003); Johnson v. Simmons, 338 F. Supp. 2d 1241 (D. Kan. 2004); Majid v. Wilhelm, 110 F. Supp. 2d 251 (S.D.N.Y. 2000); Abdullah v. Fard, 974 F. Supp. 1112 (N.D. Ohio 1997); *see also* Liu, *supra* note 10; Minns, *supra* note 10, at 716 (arguing that depriving Muslim prisoners of halal food violates both the First Amendment and the Equal Protection Clause).

83. U.S. CONST. amend. I.

84. *See generally* 16A AM. JUR. 2D *Constitutional Law* §§ 417, 424 (2005).

A. Establishment Clause

The Supreme Court's interpretation and application of the Establishment Clause over the years has been anything but consistent.[85] Nevertheless, despite the many vagaries apparent in the Court's opinions regarding the Establishment Clause, some methods of constitutional analysis have been utilized more often than others. Among the more common methods are the *Lemon* test[86] and the denominational preference test.[87]

1. *Lemon* Test

The *Lemon* test, named after the test the Supreme Court outlined in *Lemon v. Kurtzman*,[88] has perhaps been the single most influential method of Establishment Clause analysis. According to the three-prong *Lemon* test, a law or governmental activity is unconstitutional unless: (1) it has a "secular purpose;" (2) its "principal or primary effect" neither advances nor inhibits religion; *and* (3) it does not foster an "excessive entanglement" with religion.[89] If a law or governmental activity fails to satisfy *any* of these three prongs, the law or activity is considered as violating the Establishment Clause. The following discussion of the respective prongs of the *Lemon* test concludes that halal fraud statutes may fail each of *Lemon*'s three prongs.

a. Secular Purpose

The "secular purpose" prong of the three-part *Lemon* test is often the easiest to satisfy.[90] State action is only invalid under this first

85. In light of the Court's inconsistencies in the Establishment Clause realm, it is often unclear how the Court will decide any given issue and what test the Court will apply in making its decision. Even when the Court applies a traditional test, such as *Lemon*, the manner in which the test is applied is at times somewhat counterintuitive. Thus, a certain degree of vagueness currently exists as to the constitutionality of any specific type of law (e.g., halal fraud statutes).

86. *See supra* Section III.A.1.

87. *See supra* Section III.A.2. *But cf.* Berman, *supra* note 20, at 28 (arguing that "kosher fraud statutes violate the Establishment Clause no matter which analytic framework one applies").

88. 403 U.S. 602 (1971).

89. *See id.* at 612-13 (citing Board of Educ. v. Allen, 392 U.S. 236, 243 (1968); Walz v. Tax Comm'n, 397 U.S. 664, 674 (1970)) (emphasis added).

90. *See* Commack Self-Serv. Kosher Meats, Inc. v. Weiss, 294 F.3d 415, 431 (2d Cir. 2002).

prong when there is "no question that the statute or activity was motivated wholly by religious considerations."[91] Thus, so long as a secular purpose for a law or activity can be articulated, the first prong of the *Lemon* test is usually satisfied.[92] This is due to the fact that the Supreme Court is reluctant "to attribute unconstitutional motives to the States, particularly when a plausible secular purpose for the State's program may be discerned from the face of the statute."[93] Nevertheless, despite the presence of a secular purpose, a law or governmental activity may still be unconstitutional if the "valid secular objectives can be readily accomplished by other means."[94]

Halal fraud statutes clearly have a secular purpose—the prevention of consumer fraud. This fact, however, is insufficient to justify the promulgation of halal statutes because the valid secular purpose of preventing consumer fraud can "be readily accomplished by other means."[95] Another mean available is private certification agencies. As noted earlier, hundreds of private, self-regulating kosher certification and supervision organizations currently exist, which protect Jews and other consumers from fraud in the kosher food industry.[96] No reason exists why similar types of organizations are insufficient to protect purchasers of halal foods; indeed, many such organizations already exist.[97] Also, instead of providing a statutory definition of the word *halal*, legislatures could command that any product labeled as *halal* must also contain information explaining the bases of that claim.[98] Alternatively, states could abolish halal statutes entirely and instead merely prosecute false representations of halal via the states' general consumer protection laws.[99] Thus,

91. Lynch v. Donnelly, 465 U.S. 668, 680 (1984). *But see* McCreary County v. ACLU, 125 S. Ct. 2722, 2735 (2005) ("[A]lthough a legislature's stated reasons will generally get deference, the secular purpose required has to be genuine, not a sham, and not merely secondary to a religious objective.").

92. *See, e.g.*, Zelman v. Simmons-Harris, 536 U.S. 639, 648-49 (2002).

93. Mueller v. Allen, 463 U.S. 388, 394-95 (1983).

94. Larkin v. Grendel's Den, Inc., 459 U.S. 116, 123-24 (1982).

95. *Id.*; *cf.* Berman, *supra* note 20, at 45 (arguing that "the end that the State seeks to attain" by promulgating kosher statutes can also "be accomplished using secular means").

96. *See supra* note 28 & accompanying text.

97. *See supra* note 78 & accompanying text.

98. *See infra* Section IV; *cf.* Berman, *supra* note 20, at 71-72 (suggesting model statute that does not define *kosher*).

99. *See infra* note 158; *cf.* Kent Greenawalt, *Religious Law and Civil Law: Using Secular Law to Assure Observance of Practices with Religious Significance*, 71 S. CAL. L. REV. 781, 790 (1998) (recognizing that "[a] conceivable constitutional worry exists if a statute specifically forbids fraud about supposed approvals of products as kosher, rather than leaving such fraud to be covered by general provisions").

although halal fraud statutes clearly have a valid secular purpose, less-intrusive means are available in order for states to affect their stated purpose.[100] For this reason, courts such as those in *Ran Dav's County*, *Barghout*, and *Commack* may find most of the present enactments of halal fraud statutes to be unconstitutional under the first prong of the *Lemon* test.

b. Primary Effects

Even if a statute or activity has a secular purpose, such statute or activity is still unconstitutional under the second prong of the *Lemon* test if it has the primary or principal effect of either advancing or inhibiting religion.[101] Indeed, it is often said that the government must "be a neutral in its relations with groups of religious believers and nonbelievers."[102] In more recent years, a majority of the Supreme Court has reformulated the second prong of the *Lemon* test as precluding the "endorsement or disapproval" of religion.[103] Regardless of the manner in which this prong is stated, however, the Establishment Clause "does not always bar a state from regulating conduct simply because it 'harmonizes with religious canons.'"[104]

Unfortunately, halal fraud statutes do more than merely harmonize with religious canons; instead, they expressly make Islamic canons the law of the land. By statutorily defining *halal* as meaning "compliance with the laws . . . of the Islamic religion,"[105] halal fraud statutes in effect incorporate the laws of Islam into the statutory code. As one commentator observed, "if a state were to . . . make

100. *But cf.* Gerald F. Masoudi, Comment, *Kosher Food Regulation and the Religion Clauses of the First Amendment*, 60 U. CHI. L. REV. 667, 680 (1993) (concluding that "[a]s long as kosher food laws are motivated by . . . a secular objective, they will pass the [first] of the *Lemon* prongs").

101. *See Lemon*, 403 U.S. at 612-13.

102. Everson v. Bd. of Educ., 330 U.S. 1, 16, 18 (1947) (government cannot "pass laws which aid one religion, aid all religions, or prefer one religion over another"); *see also* Wallace v. Jaffree, 472 U.S. 38, 60 (1985) ("government must pursue a course of complete neutrality toward religion"); *Walz*, 397 U.S. at 666-67 (government must exercise "benevolent neutrality toward" religion); Epperson v. Arkansas, 393 U.S. 97, 104 (1968) ("First Amendment mandates governmental neutrality between religion and religion, and between religion and nonreligion").

103. *Lynch*, 465 U.S. at 688 (O'Connor, J., concurring) (enunciating the so-called "endorsement test"); *see also* County of Allegheny v. ACLU, 492 U.S. 573, 592-94 (1989) (formally adopting the "endorsement test").

104. Marsh v. Chambers, 463 U.S. 783, 792 (1983) (quoting McGowan v. Maryland, 366 U.S. 420, 442 (1961) (Frankfurter, J., concurring)).

105. 815 ILL. COMP. STAT. 505/2LL(a) (2005).

some Christian ritual the law of the land, a court would not hesitate to invalidate it."[106] Similarly, courts should not hesitate to invalidate halal fraud statutes because they have the impermissible effect of facially endorsing Islamic law.[107]

The fact that halal fraud statutes have the impermissible effect of endorsing Islamic law is even more poignant once one recalls that the Islamic dietary laws governing the halal-status of food provide that the meat of land animals may only be halal if, at the time of slaughter, the name of Allah is pronounced upon it.[108] Further, unless the person who slaughters the animal is a faithful Muslim, the meat is still not considered halal.[109] Thus, by requiring that food manufacturers strictly comply with Islamic law in preparing halal food, halal fraud statutes in effect require that food manufacturers recite Muslim prayers and hire Muslim employees to the exclusion of all others. Such a position by government is anything but neutral towards religion, and constitutes an express endorsement of *mainstream* Islam.

Regardless of any alleged endorsement of Islam which halal fraud statutes might present, the Supreme Court has recognized that "the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause."[110] Yet, accommodation of religion "[a]t some point . . . may devolve into 'an unlawful fostering of religion.'"[111] For example, while the second prong of the *Lemon* test permits states "to alleviate significant *governmental interference* with the ability of religious organizations to define and carry out their religious missions,"[112] *Lemon* is violated where "the *government itself* has advanced

106. Berman, *supra* note 20, at 43-44.

107. *But cf.* Jared Jacobson, Comment, Commack Self-Service Kosher Meats, Inc. v. Rubin*: Are Kosher Food Consumers No Longer Entitled to Protection from Fraud and Misrepresentation in the Marketplace?*, 75 ST. JOHN'S L. REV. 485, 503 (2001) (opining that "[r]eliance on Jewish dietary laws does not make the primary effect of [a kosher] statute to advance or endorse Judaism").

108. *See supra* Section II.B.1 & accompanying text. Essentially, individuals who are opposed to saying *Bismillah* would be statutorily required to do so despite their personal objections or would otherwise risk losing their jobs. Government would also be involved in verifying that this invocation of the name of Allah is correctly pronounced.

109. *Id.*

110. Corporation of the Presiding Bishopric of The Church of Jesus Christ of Latter-day Saints v. Amos, 483 U.S. 327, 334 (1987) (quoting Hobbie v. Unemployment Appeals Comm'n, 480 U.S. 136 (1987)).

111. *Id.* at 334-35.

112. *Id.* at 335 (emphasis added).

religion through its own activities and influence."[113] While halal fraud statutes may constitute a form of accommodation of religion as they make it easier for Muslims to identify halal products, any burden which American Muslims might experience if such statutes did not exist would not be the result of "significant governmental interference."[114] Because halal fraud statutes do not relieve Muslims of any significant *government-imposed* burden, they do not constitute a constitutionally-permissible accommodation of religion. Further, given that halal fraud statutes have the effect of endorsing and incorporating Islamic law, they should be found invalid under *Lemon*'s second prong.

c. Excessive Entanglement

The third and final prong of the *Lemon* test looks at whether there is "excessive entanglement" between government and religion.[115] The basic principle underlying this prong was enunciated long ago by the Supreme Court in *United States v. Ballard*.[116] In *Ballard* the Court held that because "[m]en may believe what they cannot prove," secular courts are incompetent to determine the truth or falsity of religious beliefs.[117] To engage in such an analysis of religious beliefs would improperly and unconstitutionally entangle government with religion.[118] In a subsequent decision, the Supreme Court reaffirmed its *Ballard* ruling and held the First Amendment prohibits government from "resolving underlying controversies over religious doctrine" or from employing "organs of government for essentially religious purposes."[119] Similarly, just as government may not determine questions of religious doctrine, religious institutions may not possess or exercise any delegation of governmental

113. *Id.* at 337.

114. *See id.* at 335. *But cf.* Kristin Morgan, Note, *The Constitutionality of New Jersey Kosher Food Regulations Under the Establishment Clause*, 62 U. CIN. L. REV. 247, 279 (1993) (recognizing that not regulating kosher fraud could impose upon Jewish community "the substantial burden of policing the industry").

115. *See Lemon*, 403 U.S. at 612-13.

116. 322 U.S. 78 (1944).

117. *Id.* at 86-87.

118. *See* Presbyterian Church v. Mary Elizabeth Blue Hull Mem'l Presbyterian Church, 393 U.S. 440, 447, 449 (1969); *see also Everson*, 330 U.S. at 16 (stating that government cannot "participate in the affairs of any religious organization or groups and vice versa").

119. *Id.* at 449.

power.[120] Such interactions among government and religion are said to constitute "excessive entanglement."

The question of "excessive entanglement" under *Lemon*'s third prong "is inescapably one of degree" since some governmental involvement with religion is unavoidable.[121] Under this prong, "the questions are whether the involvement is *excessive* and whether it is a *continuing* one calling for official and continuing surveillance leading to an impermissible degree of entanglement."[122] Although courts once considered whether a program caused (1) "political divisiveness" or required (2) "administrative cooperation" and (3) "pervasive monitoring" in determining excessive entanglement, the Supreme Court has since held that the first two of these three considerations are "insufficient by themselves to create an 'excessive' entanglement."[123]

The word *halal*, like *kosher*, is an inherently religious term. Indeed, both words mean "ritually fit."[124] For the New Jersey Supreme Court in *Ran-Dav's County Kosher, Inc. v. New Jersey*,[125] this fact alone may have been sufficient to invalidate the kosher fraud statute at issue in that case.[126] Because no uniform interpretation or application of *halal* or *kosher* exists among Muslims and Jews, any state-

120. *See* Board of Educ. of Kiryas Joel v. Grumet, 512 U.S. 687, 690, 697-99 (1994) (plurality opinion) (invalidating New York statute creating school district for enclave of Satmar Hasidim because the statute was "tantamount to an allocation of political power on a religious criterion"); *County of Allegheny*, 492 U.S. at 590-91; *Larkin*, 459 U.S. at 117, 125 (holding Massachusetts statute that allowed churches to veto applications for liquor licenses was unconstitutional because "[t]hat power may . . . be used by churches to promote goals beyond insulating the church from undesirable neighbors"); Spacco v. Bridgewater Sch. Dept., 722 F. Supp. 834, 842 (D. Mass. 1989) (holding lease of church property constituted "excessive entanglement" because it was "the functional equivalent of sharing with the Roman Catholic Church the power to determine aspects of the public school curriculum").

121. *Walz*, 397 U.S. at 674, 676; *see also Lynch*, 465 U.S. at 684 ("[e]ntanglement is a question of kind and degree").

122. *Walz*, 397 U.S. at 675; *see also* Agostini v. Felton, 521 U.S. 203, 233 (1997).

123. *Agostini*, 521 U.S. at 233-34. Application of these three prongs to halal fraud statutes would also probably find them unconstitutional; this application, however, is beyond the scope of the present Article in light of the fact that halal fraud statutes can be invalidated via other means as stated in this Article.

124. *See* MERRIAM-WEBSTER UNABRIDGED, *supra* note 4.

125. 608 A.2d 1353 (N.J. 1992).

126. *See supra* note 43 & accompanying text; *cf.* Jared A. Goldstein, *Is There a "Religious Question" Doctrine? Judicial Authority to Examine Religious Practices and Beliefs*, 54 CATH. U. L. REV. 497, 548 (2005) (arguing that "a court may not determine whether food actually is ritually fit for consumption according to God's laws," but that "a court may constitutionally determine whether Jews believe the food to be kosher").

defined meaning of *halal* or *kosher* may unconstitutionally entangle government with religious doctrine and require government to take sides in an inherently religious debate. As was recognized by the Second Circuit in *Commack Self-Service Kosher Meats, Inc. v. Weiss*,[127] such a statutorily-imposed interpretation of inherently religious terms would "require the State to take an official position on religious doctrine."[128] This government may not do this without running afoul of the Supreme Court's present interpretation of the Establishment Clause.[129]

Given the fact that most Muslims interpret Islamic law as requiring the slaughter of halal meats be supervised by an observant Muslim, enforcement of halal fraud statutes may also constitute excessive entanglement with religion to the extent that they vest political or governmental power in individuals based on religion.[130] In this context, enforcement of halal fraud statutes would require the person inspecting the preparation of halal meats to be Muslim, to the exclusion of non-Muslims.[131] Regardless of the religious affiliation of the person enforcing halal fraud statutes, such statutes would also require that person to enforce "substantive religious standards."[132] For example, because meat is only halal if the name of Allah has been verbally pronounced upon it at the time of slaughter,[133] enforcement of halal fraud statutes would require the state to punish those who fail to invoke Allah's favor. This type of "official and continuing surveillance" of religious beliefs and practices should be held constitutionally impermissible.[134]

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127. 294 F.3d 415 (2d Cir. 2002).

128. *Id.* at 425.

129. *See, e.g.*, *Presbyterian Church*, 393 U.S. at 449; *Ballard*, 322 U.S. at 86-87.

130. *See Kiryas Joel*, 512 U.S. at 690, 697-99; Masoudi, *supra* note 101, at 686 (stating that "[a] law that requires officers with law enforcement power to be religious figures with religious training creates excessive entanglement"); *see also* sources cited *supra* note 74 & accompanying text.

131. *But cf.* Rosenthal, *supra* note 20, at 995 (arguing that kosher fraud statutes do not involve excessive entanglement because kosher inspectors need not have "religious belief" in the origin of the laws of kashrut).

132. *See Ran-Dav's County*, 608 A.2d at 1365. *But cf.* Shelley R. Meacham, Note, *Answering to a Higher Source: Does the Establishment Clause Actually Restrict Kosher Regulations as* Ran Dav's County Kosher *Proclaims?*, 23 SW. U. L. REV. 639, 659 (1994) (arguing that kosher statutes "do not excessively entangle government in religion because they do not impose substantive religious standards") (footnotes omitted).

133. *See* sources cited *supra* notes 73-74 & accompanying text.

134. *See Agostini*, 521 U.S. at 233-34.

2. Denominational Preference Test

In *Larson v. Valente*,[135] the Supreme Court distinguished the three-prong *Lemon* test as only "intended to apply to laws affording a uniform benefit to *all* religions, and not to provisions . . . that discriminate *among* religions."[136] Where a law is found to discriminate among religions, the *Larson* Court held that strict scrutiny applies, thereby requiring that a law be narrowly tailored to a compelling governmental interest.[137] This test, enunciated by the Court in *Larson*, has been referred to as the "denominational preference test." Under the denominational preference test, "one religious denomination cannot be officially preferred over another" without first satisfying strict scrutiny.[138] Thus, "denominational neutrality" is the preferred standard to which laws ought to conform.[139]

As opposed to kosher fraud statutes, which explicitly refer to Orthodox Judaism's interpretations of *kosher* as dispositive, current halal fraud statutes do not facially prefer one Islamic school of thought over another. In this manner, halal fraud statutes appear (at least facially) to be neutral as between competing Islamic schools of thought.[140] The problem with halal fraud statutes under the denominational preference test appears to result from the observation that such statutes may discriminate in favor of mainstream Islam as opposed to other religions or non-religion. By expressly adopting Islamic law as the standard for interpreting and enforcing halal fraud statutes, states may maintain the appearance of preferring Islam over other religions. Although this argument might have some merit in the formalistic sense, the realities of today's religious demographics and politics in a post-September-11th America make such an argument unwarranted. Nevertheless, because the doctrine of "formal neutrality" is gaining increasing prominence in the Supreme Court's opinions,[141] it may be wise for states to erase all refer-

135. 456 U.S. 228 (1982).

136. *Id.* at 252.

137. *See id.* at 248, 251, 255.

138. *Id.* at 244-45.

139. *Id.* at 246; *see also Ballard*, 322 U.S. at 87 (stating that "[t]he First Amendment does not select any one group or any one type of religion for preferred treatment").

140. A strong argument, however, could easily be made that halal fraud statutes have the purpose or effect of discriminating in favor of *mainstream* Muslims, to the detriment of individuals whose interpretations of halal are counter-majoritarian. In so doing, halal fraud statutes have the impermissible effect of taking sides in a religious debate.

141. *See, e.g.*, Locke v. Davey, 540 U.S. 712 (2004); Zelman, 536 U.S. at 696 (Souter, J., dissenting). Although the so-called doctrine of "formal neutrality" is

ences to Islam or to any other specific religion from their halal fraud statutes.[142] Instead, states could simply require that all halal labels indicate the bases, or lack thereof, for their assertion of being halal (such as certification by a named private organization).[143] Failure to make halal fraud statutes more neutral as between Islam and other religions or non-religion may cause such statutes to be held unconstitutional once subjected to strict scrutiny for lack of narrow tailoring.[144]

B. Free Exercise Clause

The Supreme Court first considered a constitutional challenge under the Free Exercise Clause in *Reynolds v. United States*.[145] In *Reynolds*, the Court upheld the constitutionality of the Morrill Anti-Bigamy Act,[146] which made "spiritual marriage[s]" performed by members of The Church of Jesus Christ of Latter-day Saints ("Mormons") a federal crime.[147] "Laws are made for the government of actions," the Court explained in *Reynolds*, "and while they cannot interfere with mere religious belief and opinions, they may with practices."[148] Over a century later, in *Employment Division v. Smith*,[149] the Supreme Court reaffirmed its prior ruling in *Reynolds*, holding that the government can constitutionally prohibit religiously motivated action if the law prohibiting such actions is neutral and of general applicability.[150] A law is not neutral, however, if the law targets religious belief or "prohibits conduct *because* it is undertaken

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generally only used in the funding context, this Article uses it here to point out the importance of laws not facially preferring one religion, or form of religion, to the exclusion of all others.

142. *See supra* Section III.A.1.a.

143. *See infra* Section IV.

144. *Cf.* Berman, *supra* note 20, at 63 (arguing that "State cannot ban individuals' observance of their own personal interpretation of kashrut by legally establishing one denomination's, *or even many denominations'*, preferred interpretation") (emphasis added).

145. 98 U.S. 145 (1878).

146. Ch. 126, 12 Stat. 501 (1862).

147. *See id.*; *see also* Elijah L. Milne, *Blaine Amendments and Polygamy Laws: The Constitutionality of Anti-Polygamy Laws Targeting Religion*, 28 W. NEW ENG. L. REV. 257 (2006).

148. *Reynolds*, 98 U.S. at 166; *see also* Cantwell v. Connecticut, 310 U.S. 296, 304 (1940) ("Conduct remains subject to regulation for the protection of society").

149. 494 U.S. 872 (1990).

150. *Id.* at 880-81.

for religious reasons."[151] Thus, "if the object of a law is to infringe upon or restrict practices *because* of their religious motivation," such law is invalid unless it can satisfy strict scrutiny.[152]

In regards to halal fraud statutes, an argument may be made that they violate the Free Exercise Clause because they may require consumers of halal food to accept religious practices contrary to their own beliefs.[153] This argument may be further buttressed with the complaint that halal fraud statutes are a form of governmental interference with religious belief and exercise.[154] Nevertheless, because halal fraud statutes appear to be laws of general applicability, they are most likely constitutional under *Smith* so long as they are also neutral.[155] As this Article explained earlier, however, halal fraud statutes, like most kosher fraud statutes, are not neutral because they expressly adopt the standards and beliefs of one religion (i.e., mainstream Islam) to the exclusion of all other religions or of non-religion.[156] Further, given the fact that there is no uniform definition of *halal* among and within the various Islamic schools of thought, by enforcing any statutorily-enacted definition of *halal* government thereby punishes Muslims who hold contrary religious beliefs. Thus, to the extent that halal fraud statutes are not neutral, strict scrutiny should apply.

Although government undoubtedly has a strong interest (regardless of whether that interest is "compelling") in protecting consumers of halal food from fraud, halal fraud statutes should fail strict scrutiny because they are not narrowly tailored to that interest. As this Article has pointed out, halal fraud statutes could be rewritten so as not to define the term *halal*.[157] Also, given the fact that any "discernible burden on the free exercise of religion" which halal fraud statutes might lift was not imposed *by* government, halal fraud statutes may not pass constitutional muster as a valid accommodation of religion.[158] For these reasons, halal fraud statutes should be held unconstitutional under the Free Exercise Clause.

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151. Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 532-33 (1993) (emphasis added).

152. *Id.* at 533 (emphasis added).

153. *But cf.* Sullivan, *supra* note 20, at 240-41 (rebutting this argument in the context of kosher food).

154. *But see id.*

155. *Smith*, 494 U.S. at 880-81.

156. *See supra* Sections III.A.1.b. & III.A.2.

157. *See supra* Sections III.A.1.a. & III.A.2.

158. Lee v. Weisman, 505 U.S. 577, 629 (1992) (Souter, J., concurring) (citations omitted); *see supra* Section III.A.1.b.

IV. SUGGESTIONS

Despite the foregoing discussion of the constitutionality of halal fraud statutes, which has suggested that such statutes violate the Religion Clauses of the First Amendment, consumers of halal food need not be left totally unprotected. Indeed, as this Article has stated, halal fraud statutes could be reworded to require halal-labeled products to state the bases of their assertions of being halal (such as certification by named private organizations).[159] In this manner, private individuals and halal certification agencies,[160] instead of government, would be defining the meaning of the inherently religious term *halal*. By so doing, government would empower consumers to make informed decisions as to which products meet their own individual understandings of *halal*. Thus, by avoiding any state-imposed definition of *halal*, government would also eliminate the constitutional infirmities presently existing in most halal fraud statutes today.[161]

By leaving the regulation of halal food to the private sector, government would also promote a more robust halal food market. "After all, the best guarantee of quality and price is a competitive marketplace–knowing that there are other suppliers forcing each producer to supply adequate quality at a competitive price."[162] Apart from constitutional concerns, additional reasons why private regulation of the halal food industry deserve greater attention include the following observations: (1) market participants often consider private regulation to be a form of promoting their products and attracting customers; (2) private regulation requires companies to put their reputations on the line, thereby promoting higher industry standards; (3) unlike government agencies generally, "[t]hird parties are flexible and responsive and can keep up with technological innovations and advancements;" and (4) private regulation imposes

159. *See supra* Sections III.A.1.a. & III.A.2. Otherwise, as this Article also noted earlier, government could merely enforce halal fraud as it does consumer fraud generally. *See supra* Section III.A.a. Consumers who discover that they may have been defrauded could bring causes of action based upon theories of contract or tort. *Cf.* Sigman, *supra* note 12, at 548-50, 570 (also noting "that not only do general consumer protection statutes punish the same behavior that kosher fraud statutes capture, but in many cases, they may offer clearly superior remedies for the violation").

160. *See supra* note 78 & accompanying text.

161. *See supra* Section III.

162. Yesim Yilmaz, Private Regulation: A Real Alternative for Regulatory Reform (1998), *available at* http://www.cato.org/pubs/pas/pa-303.pdf.

less cost on both government and businesses.[163] Thus, at least one viable and constitutional alternative (i.e., private food-certification agencies) to the present statutory scheme for avoiding halal fraud exists and should be seriously considered.[164]

V. CONCLUSION

As mentioned at the beginning of this Article, Islam is like a sacred garden that needs constitutional protection. Rather than seeking protection *by* government, however, Islam—and all religions—should seek protection *from* government. The Religion Clauses of the First Amendment were enacted for this very purpose: "For the First Amendment rests upon the premise that both religion and government can best work to achieve their lofty aims if each is left free from the other within its respective sphere."[165] By allowing government to impose its interpretation of the inherently religious term *halal* upon Muslims via halal fraud statutes, Muslims and all religionists run the risk of having government determine both religious doctrine and heresy for them. Not only does this uninvited intrusion by government into religion's realm likely violate American Muslim's free-exercise rights, but it also violates the Establishment Clause as presently interpreted by the United States Supreme Court. These constitutional conundrums, however, can easily be avoided by leaving the definition of *halal* up to private individuals and organizations to determine, thereby not only ensuring that consumers of halal products are protected from fraud, but also that Islam's garden is not unconstitutionally trampled upon.

163. *Id. But cf.* Sigman, *supra* note 12, at 532 (observing that "once the volume of [kosher] certifiers is too numerous for consumers to recognize who is the creator of a particular certification, the method of signaling through certification becomes meaningless").

164. For an additional suggestion, see *supra* note 158.

165. McCollum v. Bd. of Educ., 333 U.S. 203, 212 (1948).

CAVEAT VENDITOR: PRODUCTS LIABILITY AND GENETICALLY MODIFIED FOODS

COMMENT

*Kristopher A. Isham**

I. INTRODUCTION

Genetically modified organisms (GMOs) have become a lightning rod for conflict between farmers,[1] corporations,[2] shareholders,[3] government agencies,[4] and other concerned groups.[5] Supporters tout GMOs as a solution to the problems of diminishing returns from traditional crop plants and the rising demand for greater

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1. *See generally* Monsanto Canada Inc. v. Schmeiser, [2001] F.C. 256, *aff'd in part, rev'd in part*, [2004] 1 S.C.R. 902.

2. *See id.*

3. *See, e.g.*, Sysco Corp., Securities and Exchange Commission No-Action Letter, [2002 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 78,323 (Sept. 4, 2002) (regarding a shareholder proposal requesting Sysco Corp. to report to its shareholders regarding its policies for food products containing "genetically modified ingredients").

4. *See generally* Testimony of Janet L. Anderson, Director of Biopesticides and Pollution Prevention, Environmental Protection Agency, Before the Comm. on Agriculture, Nutrition, and Forestry of the United States S., Oct. 7, 1999, *available at* http://www.epa.gov/ocirpage/hearings/testimony/106_1999_2000/100699ja.htm [hereinafter Anderson].

5. *See, e.g.*, Organic Consumers Association, *About the OCA: Who We Are and What We're Doing*, *at* http://www.organicconsumers.org/aboutus.htm#Background (last visited Mar. 22, 2006).

quantities of food.[6] Opponents criticize GMOs for potential toxic and allergic reactions in humans, loss of biodiversity, and pesticide and antibiotic resistance in other plants and insects.[7] As the understanding of potential applications of biotechnology broadens, the risks and benefits of such products are being scrutinized more closely.[8]

Biotech companies, such as Monsanto Company[9] and Syngenta AG,[10] invest a significant amount of resources developing GMOs[11] and protect those investments by obtaining patents for the organisms and by licensing seed products to farmers.[12] Monsanto, Syngenta, and other similar companies also license certain farmers to

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6. *See* Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 586 (2000).

7. *See id.* at 587.

8. Earle Nestmann, Todd Copeland & Jason Hlywka, *The Regulatory and Science-Based Safety Evaluation of Genetically Modified Crops - A USA Perspective*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 1, 1 (Keith T. Atherton ed., 2002).

9. Monsanto Co., SEC Form 10-Q, at 6 (Jan. 9, 2006), *available at* http://www.sec.gov/Archives/edgar/data/1110783/000111078306000002/a10q2006final.txt [hereinafter Monsanto 10-Q].

> Monsanto Company, with its subsidiaries, is a leading global provider of agricultural products for farmers. Monsanto produces leading seed brands, including DEKALB, ASGROW, SEMINIS[,] and STONEVILLE, and develops biotechnology traits that assist farmers in controlling insects and weeds. Monsanto provides other seed companies with genetic material and biotechnology traits for their seed brands. The company also manufactures ROUNDUP herbicide and other herbicides. Monsanto's seeds, biotechnology trait products[,] and herbicides provide growers with solutions that improve productivity, reduce the costs of farming, and produce healthier food for consumers and better feed for animals. *Id.*

10. Syngeta AG, SEC Form 20-F, at 9 (Mar. 25, 2004), *available at* http://www.sec.gov/Archives/edgar/data/1123661/000095010304000439/mar1804_20f.htm (stating that Syngenta is a Swiss company created by Novartis AG and AstraZeneca PLC through the spin-off and merger of the Novartis crop protection and seeds businesses and the Zeneca agrochemicals business). Syngenta "is a world-leading agribusiness that is involved in the discovery, development, manufacture and marketing of a range of products designed to improve crop yields and food quality." *Id.* at ii. "It is Syngenta's intention to devote an appropriate, sustained and competitive level of resources to pursuing the opportunities it believes biotechnology can deliver." *Id.* at 14.

11. *See, e.g.*, Monsanto 10-Q, *supra* note 9, at 11 (disclosing that Monsanto had a "carrying amount" of "acquired biotechnology intellectual property" of approximately $652 million).

12. MONSANTO CO., 2005 ANNUAL REPORT 26 (2004), *available at* http://www.monsanto.com/monsanto/content/media/pubs/2005/MON_2005_Annual_Report.pdf (stating that Monsanto licenses seed biotechnology traits to more than 250 seed partners).

grow patented, genetically modified seeds.[13] Despite the attempt to control such traits via licenses, sometimes the pollen from the GMO crop drifts to neighboring lands and commingles with the crops on that land—a process called "genetic drift."[14] Once the crops are harvested, the retailer or wholesaler who purchases them inherits a potential products liability lawsuit for any harmful effects suffered by those who ingest those products.[15]

This comment provides a brief synopsis of the history of genetics and emergence of GMO food markets.[16] Also provided is a map of the various regulatory agencies and their respective roles in the general regulation of GMOs.[17] In particular, this comment addresses the Food and Drug Administration's proposed rule requiring pre-market notification of a manufacturer's intent to market GMO food products[18] and contrasts that proposed rule with the regulation of organic foods.[19] Next, this comment briefly discusses the process of bringing GMO food products to the market[20] and some of the issues raised by GMOs which have been litigated, primarily GMO drift and labeling.[21] The comment also briefly explores the implications of the Food Allergen Labeling and Consumer Protection Act with regard to the litigation regarding GMOs.[22] Then the comment argues that both of the standard tests for liability for defective food products—the foreign-natural and consumer expec-

13. *See* Yolanda Massieu Trigo, *Transgenic Crops for Small Farmers: A Dream or a Nightmare?*, *in* TRANSGENIC CROP PROTECTION CONCEPTS AND STRATEGIES 351, 367 (Opender Koul & G.S. Dhaliwal eds., 2004) (stating that large biotechnology companies are becoming more interested in having access to genetic information in the form of intellectual property rights).

14. Hillary Preston, Note, *Drift of Genetically Engineered Crops: Rethinking Liability Theories*, 81 TEX. L. REV. 1153, 1154 (2003) (describing genetic drift as the inadvertent spreading of GMOs from a farm choosing to use GMOs to farms which have not chosen to use them). Other possible sources of commingling include transportation, storage, and processing facilities. *See* In re StarLink Prod. Liab. Litig. v. Aventis CropScience USA Holding, Inc., 212 F. Supp. 2d 828, 834 (N.D. Ill. 2002) (stating that corn pollen can "drift over considerable distances").

15. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

16. *See infra* Section II.

17. *See infra* Section III.A.1.

18. *See infra* Section III.A.2.

19. *See infra* Section III.B.

20. *See infra* Section IV.

21. *See infra* Sections V.A. & V.B.1.

22. *See infra* Section V.B.2.

tations tests—are inadequate in the context of GMOs.[23] Then the comment discusses general products liability theories (such as manufacturing and design defects) in the context of GMOs and suggests that issues regarding allergies still remain to be decided by the courts.[24] This comment concludes by stating that due to legal uncertainties regarding GMOs, and the implications of the Food Allergen Labeling and Consumer Protection Act,[25] a company desiring to sell GMOs does so at its own risk.[26]

II. THE HISTORY OF A FUTURISTIC SCIENCE

Gregor Johann Mendel is considered to be the father of modern genetics for discoveries he made while breeding peas in his monastery garden over a century and a half ago.[27] "Mendel was the first to understand that characteristics such as height, color, and shape depend on the presence of determining *factors* . . . ."[28] In 1905, these factors were dubbed "genes" by Wilhelm Johannsen.[29] Colloquially, the word gene refers to both the location on a chromosome and the information contained at that location.[30] Genes are the basic language of life, and when combined in certain patterns they form the building design of an organism, its properties and capabilities.[31] This design is comprised of chains of deoxyribonucleic acid (DNA) molecules.[32] The two general kinds of genetic ma-

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23. *See infra* Section VI.

24. *See infra* Section VII.

25. Pub. L. No. 108-282, 118 Stat. 905 (2004) (codified in scattered sections of 21 and 42 U.S.C.).

26. *See infra* Section VIII.

27. *See* PETER PRINGLE, FOOD, INC.: MENDEL TO MONSANTO—THE PROMISES AND PERILS OF THE BIOTECH HARVEST 9 (2003).

28. *Id.* (emphasis in original).

29. Nick Smith, Chairman on the Subcommittee on Basic Research, United States General Accounting Office, *Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology* 11 (Apr. 13, 2000), *available at* http://www.house.gov/science/smithreport_041300.pdf. [hereinafter Smith].

30. Rebecca M. Bratspies, *Biotechnology Environmental, Health, and Safety Regulation*, A.L.I.-A.B.A. CONTINUING LEGAL EDUCATION, Oct. 16-17, 2003, available on Westlaw at SJ033 ALI-ABA at *8.

31. Physicians and Scientists for Responsible Application of Science and Technology (PSRAST), *A First Introduction to Genetic Engineering*, *at* http://www.psrast.org/gefirstintro.htm (last visited Mar. 22, 2006) [hereinafter PSRAST].

32. *Id.*

terial are DNA and ribonucleic acid (RNA) and, between the two, DNA is the "unit of heredity and reproduction."[33]

In 1953, James Watson and Francis Crick described the double-helix shape of DNA, a discovery that led to the deciphering of genetic code which, in turn, led to "rapid advances in the practical applications of genetics."[34] A significant technique was developed in 1972 by Paul Berg and a group of researchers from Stanford University who were able to "cut" DNA from separate sources and splice the different pieces together into a functional molecule.[35] One year later, Stanley Cohen and Herbert Boyer[36] took the process a step further and transferred a spliced, or recombinant,[37] molecule into a bacterium where the molecule functioned with the bacterium's own genes.[38] This discovery became the "first phase of a new industrial era and a new technological field."[39]

Genetic engineering, in the simplest of explanations, is the intermingling of certain portions of the DNA code of one organism with the DNA code of another organism.[40] Desirable traits are selected from one organism and transferred between species, or even between plants and animals.[41] The terms "transgenic,"[42] "genetic engineering,"[43] and "recombinant DNA"[44] are used to describe this process and are used interchangeably throughout this comment.

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33. *See* Bratspies, *supra* note 30, at 4-5.

34. *See* Smith, *supra* note 29, at 11.

35. *Id.* at 12.

36. Boyer co-founded the world's first biotechnology company, Genentech, which used genetically engineered bacteria to produce human therapeutics and diagnostics. *Id.*

37. *See infra* note 44 and accompanying text.

38. *See* Smith, *supra* note 29, at 12.

39. Jesper Norus, *Biotechnology Organizations in Action: Turning Knowledge Into Business*, 20 PROGRESS IN BIOTECHNOLOGY 29 (2002).

40. *See* PSRAST, *supra* note 31.

41. *See* Preston, *supra* note 14, at 1155.

42. THE AMERICAN HERITAGE COLLEGIATE DICTIONARY 1436 (3d ed. 1993). "Carrying genes transferred from another species or breed." *Id.*

43. "Scientific alteration of the structure of genetic material in a living organism, used, for example, to create bacteria that synthesize insulin." *Id.* at 566.

44. "Genetically engineered DNA prepared by transplanting or splicing genes from one species into the cells of a host organism of a different species." *Id.* at 1141.

III. THE REGULATORY STRUCTURE

A. GMOs

For years, biotechnology has been used in different industries to develop more than a thousand products ranging from human insulin to enzymes used in food production.[45] Companies have been applying techniques of genetic engineering to agricultural products for widespread commercial use since the early 1980s.[46] For example, Calgene's Flavr Savr tomato was one of the first GMO, consumer-ready foods to be produced and marketed in the United States.[47] Since then, over fifty other GMO products have been determined to be substantially equivalent[48] to their conventional counterparts, including soybeans, corn, and cotton.[49] Soybeans, corn, and several other crops[50] are commonly modified to generate their own pesticide.[51]

The regulation of GMOs in the United States has been vested primarily in the Department of Agriculture (USDA),[52] the Food and Drug Administration (FDA),[53] the Environmental Protection Agency (EPA),[54] and various subdivisions of those agencies. In 1986, the Coordinated Framework for Regulation of Biotechnology (Coordi-

45. *See* Smith, *supra* note 29, at "Letter of Transmittal."

46. *See* Anderson, *supra* note 4.

47. Donna U. Vogt & Mickey Parish, *Food Biotechnology in the United States: Science, Regulation, and Issues*, CRS Report for Congress, at 4, Jan. 19, 2001, *available at* http://www.cnie.org/NLE/CRSreports/science/st-41.pdf [hereinafter Vogt & Parish].

48. For a brief discussion of substantial equivalence see *infra* notes 74-76 and accompanying text.

49. Linda Bren, *Genetic Engineering: The Future of Foods?*, FDA CONSUMER MAG. (Nov.-Dec. 2003), *available at* http://www.fda.gov/fdac/features/2003/603_food.html.

50. Other transgenic crops that are currently in the market include cotton and canola. *See* Colorado State University, *Transgenic Crops: An Introduction and Resource Guide*, *at* http://cls.casa.colostate.edu/TransgenicCrops/current.html (last visited Mar. 22, 2006). Crops currently being researched for market in the future include tomato, rice, canola, sunflower, grapes, tobacco, coffee and tea. *See id.*

51. Vogt & Parish, *supra* note 47, at 3.

52. Pursuant to 7 U.S.C. §§ 7701-7772 (2000), and 7 U.S.C. §§ 2321-2583 (Supp. 2004). For general information regarding USDA, see http://www.usda.gov/wps/portal/usdahome.

53. Pursuant to 21 U.S.C.S. §§ 301-399 (Supp. 2004). For general information regarding the FDA, see http://www.fda.gov.

54. Pursuant to 7 U.S.C.S. §§ 135-136y (Supp. 2004). For general information regarding the EPA, see http://www.epa.gov.

nated Framework)[55] stated that "[A]t the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology."[56] Furthermore, Coordinated Framework proposed that genetically modified products be regulated according to their characteristics and not by the methods by which they are produced.[57]

1. The "Coordinated" Framework In Action[58]

a. The USDA's Role

Essentially, the USDA's role in the regulation of GMOs is aimed at plants and plant pests.[59] No fewer than eight USDA agencies, including the Animal and Plant Health Inspection Service (APHIS),[60] collaborate to fulfill the USDA's tasks in regulating GMOs.[61] APHIS reviews plants containing, or plants produced using, biological control organisms.[62] This statutory authority extends to GMO crops

55. The Coordinated Framework is a basic network of federal agencies having jurisdiction over the research and products derived from biotechnology. *See generally* 51 Fed. Reg. 23,302 (June 26, 1986). The Coordinated Framework is supposed to evolve with the experiences of the industry and the agencies. *Id.* at 23,302.

56. *Id.* at 23,306.

57. *See* Vogt & Parish, *supra* note 47, at 6. Although there was reference to regulating "processes" in this release, the FDA's approach regarding the regulation of GMOs since has been to only regulate the "product" and not the process. 57 Fed. Reg. 6753, 6753 (Feb. 27, 1992).

58. Critics of Coordinated Framework claim that it is flawed because it was created before the completion of a comprehensive review of potential risks. *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, And Overlaps: Crisis In The Regulation Of Genetically Modified Plants And Animals*, 45 WM. & MARY L. REV. 2167, 2202, 2258 (2004) (suggesting realignment of the regulation of genetically modified products because the risks of GMOs are better understood now than they were when the Framework was created).

59. A plant pest is defined broadly to include a parasitic plant, bacterium, fungus, virus, or other infectious agent. 7 U.S.C. § 7702(14) (2000).

60. APHIS is responsible for protecting United States agricultural health from agricultural pests and diseases. *See* http://www.aphis.usda.gov/about_aphis/ (last visited Mar. 22, 2006).

61. *See* USDA, *Agriculture: Biotechnology, at* http://www.usda.gov/agencies/biotech/role.html (last visited Mar. 23, 2006).

62. 7 U.S.C. § 7712(g) (2000); 7 C.F.R. § 371.3 (2004); *see also* 7 C.F.R. § 340.2 (2005). A biological control organism is colorfully defined as an "enemy, antagonist, or competitor used to control a plant pest or noxious weed." 7 U.S.C. § 7702(2) (2000).

that are designed to be resistant to plant pests or could themselves become pests for other plants.[63]

A plant pest can be either a substance or organism that directly or indirectly causes disease or damage to plants.[64] APHIS maintains a list of organisms considered to be plant pests that are subject to regulation; APHIS also maintains the procedures required to petition to amend the list, to recognize a certain substance as non-regulated, as well as container requirements for the movement of regulated organisms.[65]

b. The EPA's Role

The EPA's authority to regulate chemical and biopesticides is granted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[66] The role of EPA in regulating GMOs is to ensure that substances used as pesticides, such as plant incorporated protectants (PIPs), are safe for the environment. PIPs are pesticidal substances intended to be produced, or produced by, and used in living plants or their products.[67] In general, all pesticides require registration with EPA prior to sale or distribution in the United States.[68]

Nevertheless, a significant exemption from the EPA approval requirement. A PIP is exempted from registration if its genetic material comes from a plant with which it is sexually compatible—including plants where the targeted genetic material has never been derived from a source that is not sexually compatible with the recipient plant.[69] The reason for this exemption is that maintaining a sexually compatible genetic pedigree does not trigger the fears cre-

63. 7 U.S.C. § 7712(g) (2000); *see also* 7 C.F.R. § 340.2 (2005) (referring to organisms that *are* or *contain* plant pests).

64. *See* 7 U.S.C. § 7702(14) (2000); 7 C.F.R. § 340.1 (2005).

65. 7 C.F.R. §§ 340.0-9 (2005). A full exploration of the APHIS regulations is beyond the scope of this comment.

66. 7 U.S.C. §§ 135-136y (2000).

67. 40 C.F.R. § 174.3 (2005). *Bacillus thuringiensis*, or *Bt*, is an example of a PIP. *Bt* is a common soil microbe which is used to create a protein called Cry9C (made famous in the StarLink controversy) which "kills certain destructive pests of corn." Alejandro E. Sagarra & Jean M. Rawson, *StarLink Corn Controversy: Background*, CRS Report for Congress (Jan. 10, 2001), *available at* http://www.ncseonline.org/nle/crsreports/agriculture/ag-101.cfm (last visited Mar. 22, 2006) [hereinafter Sagarra & Rawson]. A list of PIPs, or biopesticide active ingredients, regulated by the EPA can be found at EPA, *Biopesticide Active Ingredient Fact Sheet*, *available at* http://www.epa.gov/pesticides/biopesticides/ingredients/index.htm.

68. 40 C.F.R. § 152.15 (2005).

69. 40 C.F.R. § 174.25(a),(b) (2005).

ated by juxtaposing genetic traits from sexually incompatible organisms.[70] However, any person who produces a PIP that is exempted from reporting and subsequently receives any information about adverse effects on human health or the environment must submit the information to EPA within thirty days of first possessing or learning of the information.[71]

c. The FDA's Role

The majority of the regulatory authority regarding genetically modified foods is vested in FDA to ensure the safety of all food and food components.[72] Sections of the Federal Food, Drug and Cosmetic Act (FDCA) regarding intentional and unintentional adulteration of foods and substances added to foods are especially relevant to GMOs.[73]

The FDA's longstanding approach has been that GMOs can be regulated using the "generally recognized as safe" (GRAS) standard for food additives.[74] In 1992, FDA further clarified that genetically

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70. *See* 66 Fed. Reg. 37,771, 37,783 (July 19, 2001).

> EPA, nonetheless, recognizes that plant breeding in the United States has a good record of providing a safe food supply and that plant breeders employ accepted standards of practice to maintain this record. This good record provides support to the [EPA's] determination that it can exempt plant-incorporated protectants derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, relying only on the post-market reporting of adverse effects. *Id.*

71. 40 C.F.R. § 174.71(a) (2005).

72. *See* Kelly A. Leggio, Comment, *Limitations of the Consumer's Right To Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 910 (2001).

73. FDCA, 21 U.S.C. §§ 342 and 348 (2000).

74. 51 Fed. Reg. 23,309, 23,310 (June 26, 1986). The requirements of what is generally recognized as safe are discussed at length in 21 C.F.R. § 170.30 (2005). The FDA's decision that GMOs are generally recognized as safe has been the subject of extensive debate and criticism. The debate over whether GRAS status is appropriate mirrors the debate over the advocated advantages and disadvantages of GMOs previously discussed. One interesting argument is that GMO developers are speaking from both sides of their mouths by telling FDA that their GMO products are substantially similar to traditional crops and therefore do not require additional regulation, but they then plead with the United States Patent and Trade Office that the GMO is entirely different and needs a new form of treatment (i.e., is patentable). *See* Richard Caplan & Skip Spitzer, *Regulation of Genetically Engineered Crops and Foods in the United States*, at 4 (Mar. 2001), *available at* http://www.panna.org/resources/documents/geRegulation.pdf. However, this argument neither properly addresses the argument made by the companies nor addresses the FDA's longstanding approach to evaluating GMOs based upon their

modified plant products with "new" genes added via genetic engineering are generally recognized as safe because they are "substantially equivalent" to their conventional counterparts.[75] This "substantial equivalence" approach to GMOs is the current regulatory approach in the United States.[76]

FDA reiterated its approach to genetically modified foods in May 2000, but it also proposed a mandatory consultation process so companies that desire to market genetically modified foods would be required to consult with FDA.[77] However, the FDA's proposal was not implemented; furthermore, FDA also determined that because there was insufficient evidence to prove risk of harm to the public from genetically modified foods, mandatory labeling of GMOs was inappropriate.[78]

In 2001, however, FDA determined that GMO breeding required greater scrutiny than that of traditional breeding stating, "[t]he confluence of the increasingly broader use of [recombinant DNA] techniques . . . suggest[s] that FDA needs to be aware of the various foods developed using [recombinant DNA] technology."[79] Most likely, this renewed FDA attention to GMOs was heightened because traces of genetic material from StarLink[80] corn was discov-

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impact rather than on the manner in which they were designed. *See* Douglas A. Kysar, *Preferences For Processes: The Process/Product Distinction And The Regulation Of Consumer Choice* 118 HARV. L. REV. 525, 557 (2004). Thus, the argument made to FDA is that the *impact* of the GMO is essentially the same as its traditional counterpart so as not to require specific additional warnings or labels, while the argument to the United States Patent Office is that the *method* by which the GMO is made is sufficiently different to justify patent protection of that method. *Id.*

75. 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).

76. *See id. See also* Paul R. Mayers et al., *The Concept of Substantial Equivalence, in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 63, 63-64 and n.1 (Keith Atherton ed., 2002) (describing the concept of substantial equivalence as embodying the idea that existing food sources could be used as a basis for comparison when assessing the safety of GMOs and that the United States was a member of an international organization that developed the concept).

77. *See* Leggio, *supra* note 72, at 911.

78. *Id.* Interestingly, FIFRA preempts any claims based on the inadequacy of labeling or failure to warn about products approved by EPA. *StarLink*, 212 F. Supp. 2d at 835-36 (stating "[FIFRA] expressly authorizes states to regulate pesticide use . . . . But it also prohibits states from imposing any labeling requirements beyond those imposed by the EPA.") (citations omitted).

79. Pre-Market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4712 (Jan. 18, 2001).

80. *See* Sagarra & Rawson, *supra* note 67. "StarLink hybrids contain a plant pesticide protein (Cry9C) derived from a common soil microbe [*Bacillus thuringiensis*, or *Bt*], which kills certain destructive pests of corn such as the European corn borer." *Id.*

ered in taco shells sold in grocery stores.[81] The problem was that when EPA originally approved StarLink, it was approved for use as livestock feed or industrial purposes only, and not for human consumption.[82]

2. The FDA's Modest Proposal: Pre-Market Notification

In January 2001, FDA issued a proposal to create a mandatory consultation process so that GMO developers would be required to consult with FDA at least 120 days prior to the commercial distribution of GMOs.[83] The proposed regulations define bioengineered foods as foods derived from plants developed through transformation events.[84] A transformation event is the introduction of genetic material that has been manipulated in vitro into a plant.[85] Although these proposed regulations have not been promulgated in the form of a final rule, similar results are being pursued by other legislative means.[86] For example, a bill presented in the Arkansas Senate in 2005 was particularly concerned about genetically engineered plants containing human DNA.[87] However, on the judicial front, courts have been unreceptive to claims that GMOs should be labeled as such.[88]

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81. *See id.*

82. *Id.*

83. Pre-Market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4712 (Jan. 18, 2001).

84. *Id.* at 4730 (proposed rule 21 C.F.R. § 192.1(a)).

85. *Id.* (proposed rule 21 C.F.R. § 192.1(e)).

86. *See, e.g.*, Genetically Engineered Foods Act, S. 2546 108th Cong. § 421(a) (2004) (calling for the requirement of GMO producers to obtain pre-market approval before introducing any GMO into interstate commerce).

87. S.B. 318, 85th Gen. Assembly, Reg. Sess. (Ark. 2005) (recommending the prohibition of growing, raising, or cultivating certain genetically engineered plants). This bill proposed that the "State Plant Board" be empowered to impose a civil penalty of not less than $25,000 and not more than $100,000. *Id.* § 2-15-203(a)(2). In determining the severity of the civil penalty, the State Plant Board would be asked to consider the gravity and magnitude of the violation, any actual or potential threat to human health or safety, the amount of benefit the violator realized from the violation, and the past history of the violator. *Id.* § 2-15-203(b)(1)-(3). The bill appeared to be a response to an announcement by Ventria Bioscience that it would collaborate with Northwest Missouri State University to use self-pollinating plants, like rice, as "factories to produce therapeutic proteins and peptides." News Release, Ventria Bioscience, Northwest Missouri State University and Ventria Bioscience Announce Collaboration to Create Northwest Missouri Center of Excellence for Plant-Made Pharmaceuticals (Nov. 18, 2004), *available at* http://www.ventria.com/news/11-18-04%20PR.pdf.

88. *See infra* Section V.B. and accompanying notes.

B. A Brief Contract With the Regulation of Organic Foods

In recent years, the organic food market has been growing at a rate five times faster than food sales in general and has now become an $11 billion-a-year business.[89] Consumers cite perceived health benefits as their primary reason for purchasing organic foods, but, ironically, organic foods are not demonstrably better for consumers because organic foods still pose their own risks (e.g., higher potential for foodborne bacteria such as *E. coli*).[90] Organic food farmers generally use methods such as crop rotation, controlling weeds through cultivation, and livestock grazing management to preserve soil quality and, therefore, food quality.[91]

GMOs and organic foods are treated in the same manner for FDA oversight purposes.[92] However, additional requirements must be met in order to market foods as "organic." The Organic Foods Production Act of 1990 (OFPA)[93] requires farmers who gross more than $5,000 annually to be certified in order to sell or label their foods as organic.[94] In 2002, USDA provided that "organically produced" foods are those products which are produced in accordance with OFPA.[95] Furthermore, products that qualify, may be labeled as either "100 percent organic," "organic," or "made with organic [particular ingredient]" as long as they meet the requisite definitions of

89. *See* Andrew J. Nicholas, Comment, *As The Organic Food Industry Gets Its House in Order, The Time Has Come For National Standards For Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 278 (2003).

90. *See, e.g.*, Thompson v. East Pac. Enter., Inc., No. 49924-6-I, 2003 WL 352914 (Wash. App. Div. 1 Feb. 18, 2003) (regarding a plaintiff who suffered a severe allergic reaction after ingesting an almond chicken dish containing trace amounts of peanut oil); *see also* Thomas P. Redick, *Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence*, 44 JURIMETRICS J. 5, 18 (Fall 2003) ("[E]xisting organic corn growing methods may increase carcinogenic mycotoxin risk compared to biotech corn varieties."); Geoffrey Cowley, *Certified Organic; Stamp Of Approval: New Government Rules Will Define* 'Organic,' NEWSWEEK, Sept. 30, 2002, *available at* http://www-schneider.viscom.ohiou.edu/photoshop6/certified_organic.htm.

91. *See* Nicholas, *supra* note 89, at 278-79.

92. *See generally id.* at 283.

93. 7 U.S.C.S. §§ 6501-23 (Supp. 2004).

94. 7 U.S.C. § 6505 (2000).

95. *Id.* § 6502(14).

each category.[96] Use of this label is determined by the percentage of organic ingredients in the product.[97]

In summary, while the federal government has determined that the labeling of foods as containing GMOs is not necessary, it has determined that organic foods should be specifically labeled as such—presumably to protect consumer expectations.[98] The most reasonable explanation of the inconsistency appears to be that labeling GMO foods would unnecessarily demonize the product, potentially harming the GMO food market, while requiring labels for organic foods establishes consumer trust in those products and, therefore, also protects the organic food market.[99]

IV. THE GMO BUSINESS

Biotechnology companies continuously explore potential uses for biotechnology ranging from a single banana chip that acts as an oral vaccine for one-fifteenth of the cost of an injection[100] to medicines engineered to regenerate human tissues.[101] Some companies are also exploring the possibility of using biotechnology to break down groundwater contaminants.[102] For each of the last ten years, the amount of acreage dedicated to the growth of biotech crops[103] has seen double-digit growth rates.[104] In 2003, the global area in-

96. 7 C.F.R. § 205.301 (2005). *See also* 7 C.F.R. §§ 205.303, 205.304, 205.305 (2005).

97. 7 C.F.R. § 205.301 (2005). For a more in depth discussion of these labeling requirements and the requisite proportions see Nicholas, *supra* note 89.

98. *See* 66 Fed. Reg. 37,772, 37,783 (July 19, 2001) (referring to the recognized safety of breeding sexually compatible plants).

99. *See id.*; 57 Fed. Reg. 22,984, 22,295 (May 29, 1992) (declaring that GMOs that are substantially similar to traditional counterparts are generally recognized as safe).

100. FRANÇOISE SIMON & PHILIP KOTLER, BUILDING GLOBAL BIOBRANDS: TAKING BIOTECHNOLOGY TO MARKET 4 (2003).

101. *Id.* at 5 (describing Apligraf, a product by Organogenis, which was the first engineered skin and was approved by FDA for leg ulcers and another tissue engineering company, Gentis, which uses products to build new cartilage).

102. *Id.* (referring to the company Regenesis, whose products can be reviewed *at* http://www.regenesis.com/products).

103. International Service for the Acquisition of Agri-Biotech Applications uses the term "biotech crop" in its research and includes such items as genetically modified maize, soybean, and cotton. *See generally* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2005*, at 3, *available at* http://www.isaaa.org/kc/CBTNews/press_release/briefs34/ESummary/Executive%20Summary%20(English).pdf.

104. *Id.*

creased by fifteen percent to approximately 167 million acres, in 2004, it increased twenty percent to an estimated 200 million acres, and in 2005, it increased about eleven percent to an estimated 222 million acres.[105] These crops were grown by an estimated 8.5 million farmers in twenty-one countries.[106]

Eighty percent of the conflicts surrounding biotechnology are related to the agricultural application of the science, but agricultural biotechnology only accounts for less than fifteen percent of total private biotechnology research and development.[107] The reason for the focused attention has been attributed to environmental liabilities and other vulnerabilities of first generation biotech crops—particularly those using *Bacillus thuringiensis* (*Bt*).[108]

A company must notify EPA before it can perform certain tests to develop a plant that contains genetically modified microbial pesticides,[109] but notification is not required when the testing is conducted in a facility with adequate containment controls.[110] For example, to minimize the risk of genetic drift, EPA imposed a 660 foot buffer zone between StarLink corn and neighboring fields to minimize the effect of genetic drift.[111] Meanwhile, the developer also is encouraged to consult with FDA to determine whether the GMO introduces any new potential allergens.[112]

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105. *Id.*

106. *Id.*

107. Frederick H. Buttel, *Assessing the Environmental Implications of Agricultural Biotechnologies: A Sociological Perspective, in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 47, 51 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998).

108. *Id. Bt* works as a midgut toxin that is effective only when ingested by insects. Hari C. Sharma et al., *The Utility and Management of Transgenic Plants with* Bacillus thuringiensis *Genes for Protection from Pests, in BACILLUS THURINGIENSIS*: A CORNERSTONE OF MODERN AGRICULTURE 53, 55 (Matthew Metz ed., 2003).

> Insect mortality may occur in hours to days, and takes much longer than for synthetic insecticides. In transgenic crops having Bt genes, the plant tissues produce specific Cry proteins in a soluble form that . . . bind to specific receptors on the insect midgut epitheluem, forming pores and leading to loss of the transmembrane potential, cell lysis, leakage of the midgut contents, paralysis, and death of the insect. Insects that develop resistance to Bt most commonly exhibit decreased or altered receptor binding or even proteolytic inactivation. *Id.* (citations omitted).

109. 40 C.F.R. § 172.45 (2005).

110. 40 C.F.R. § 172.45(d)(2) (2005).

111. *StarLink*, 212 F. Supp. 2d at 834.

112. *See generally*, 66 Fed. Reg. 4706 (Jan. 18, 2001) (proposing a mandatory consultation with FDA prior to market release).

Plant breeding programs are conducted by various state agricultural agencies, colleges and universities, USDA, and private companies.[113] Based upon "agronomic" need, a choice is made as to which trait will be introduced to a certain plant.[114] Then, if the trait is among the genetic resources available, the next decision is how to impart it to the crop—either through sexual hybridization, cross-pollination techniques, or recombinant DNA.[115]

V. THE LITIGATION

Despite efforts to test, develop, harvest, and market a GMO under controlled circumstances, there have been instances where GMOs were discovered in the food supply or otherwise growing on neighboring lands.[116] GMO proponents argue that GMO developers are not presented with any new or additional legal liabilities beyond those faced by developers of traditional crops.[117] Despite that argument, there has been scant litigation where plaintiffs claim to have suffered bodily harm as a result of GMOs. As of late 2005, there were no documented cases of illness due to consumption of GMO food products which resulted in litigation.[118] Therefore, the GMO

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113. *See* Smith, *supra* note 29, at 18.

114. *See id.*

115. *Id.*

116. *See generally* SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004) (regarding patent infringement of GMO anti-depressant drug) (Gajarsa, J. concurring) (discussing the possibility of GMO blue corn blowing across the country at 1030-31); *StarLink*, 212 F. Supp. 2d 828 (N.D. Ill. 2002) (involving StarLink corn discovered in human food supply); Campbell v. AG Finder Iowa Neb., Mgmt. Consultants, Inc., 683 N.W.2d 126 (Iowa Ct. App. 2004) (regarding a breach of contract for sale of in nonconformity where purchaser-farmer unknowingly bought GMO seed and could not sell it due to its GMO status). *See also Bentgrass May Spell Trouble*, L.A. TIMES, Sept. 25, 2004, Science File (discussing the EPA's discovery of GMO grass developed for golf courses 13 miles away from the course).

117. *See* Drew Kershen, *Legal Liability Issues in Agricultural Biotechnology*, at 4 (Nov. 2002), *at* http://www.nationalaglawcenter.org/assets/articles/kershen_biotech.pdf (last visited Mar. 23, 2006) (stating that "the United States leaves the issue of legal liability for agricultural biotechnology products . . . to the laws applicable generally to agricultural products . . . primarily the common law of torts"). An interesting argument raised by Kershen in an earlier article is that manufacturers of traditional crops may be held liable for harms caused by the traditional crops when plaintiffs bring an action on a design defect theory and introduce the GMO as proof of a reasonable alternative design to traditional crops. Drew Kershen, *The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 633-37 (2000).

118. *See* David Hegewood, *Remarks on Regulating Genetically Modified Foods in the United States*, 10 RICH. J.L. & TECH. 10, at *12 (2004) (stating that as of late 2004 no such instances have occurred). The author's research has not discovered any new

developer or anyone who desires to sell or market foods that may contain GMOs needs to assess the risks of liability should the product cause harm.[119] To assess those risks, several cases and the Restatement (Third) of Torts provide some insight into the potential liability for claims based upon the various theories of products liability.[120]

A. Escape

In September 2001, a consumer group called the Genetically Engineered Food Alert[121] reported that a variety of corn not approved for human consumption had made its way into the food supply—specifically in certain taco shells.[122] FDA began an investigation after hearing allegations that the taco shells contained StarLink corn.[123] The producer of the taco shells initiated its own investigation and voluntarily recalled millions of taco shells as soon as the presence of the Cry9C gene was independently verified.[124] It was subsequently confirmed that StarLink was present in the taco shells.[125]

Naturally, the presence of proteins unapproved for human consumption invokes concerns of whether the proteins may cause aller-

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developments as of late 2005. However, the possibility may remain. *See Brazil Nut Project Shows Modified Foods Can Inherit Troubles of Genes They Receive*, STAR TRIB., May 2, 2000, at 12A (noting the spread of allergic proteins from a brazil nut into a genetically modified soybean where the GMO soybean product triggered allergic responses to persons known to be allergic to brazil nuts) [hereinafter Brazil Nut Article].

119. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

120. *See infra* Sections V.A., V.B., VI, and VII.

121. For general information regarding the Genetically Engineered Food Alert see http://www.gefoodalert.org/pages/home.cfm.

122. Raymond Formanek, Jr., *Proposed Rules Issued for Bioengineered Foods, at* http://www.fda.gov/fdac/features/2001/201_food.html (last visited Mar. 23, 2006) [hereinafter Formanek].

123. *Id. See also* Sagarra & Rawson, *supra* note 67 ("StarLink hybrids contain a plant pesticide protein (Cry9C) derived from a common soil microbe [*Bt*], which kills certain destructive pests of corn such as the European corn borer."). The problem is that when StarLink was originally approved by the EPA, it was permitted to be used only as livestock feed or industrial purposes and not for human consumption. *See id.*

124. *Id.* Cry9C is used with corn and is intended to provide protection from certain pests. 66 Fed. Reg. 17,706, 17,707 (Apr. 3, 2001).

125. 66 Fed. Reg. at 17,708.

gic reactions or other dangerous effects when they are consumed.[126] Some commentators argue that the new proteins in GMOs can lead to the creation of new food toxins or to antibiotic resistance because marker genes[127] might be transferred to bacteria, and thereby lead to antibiotic-resistant pathogenic bacteria.[128]

However, such a conclusion is hardly well-settled. Some researchers disagree, citing that technical approaches used to test GMOs for potential allergenicity prevent GMO foods from posing any harmful effects beyond what is posed by any other food product.[129] In fact, some researchers claim that there is even a greater likelihood of predicting whether a GMO plant will cause an allergic reaction than its traditional counterpart.[130]

B. Labeling

1. Litigation

The creation of food definitions and standards is justified by the need to protect a consumer's ability to judge the quality of a food product.[131] Conflicts between consumers and GMO developers generally revolve around the tension between assertions of consumers' right to know what ingredients are in the food they consume

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126. *See* Sharma, *supra* note 108 (discussing the effects of *Bt* on insects which ingest it).

127. A marker gene is a gene used to alleviate the process of identifying transformed cells and is itself resistant to antibiotics. *See* Ann E. Blechl, *Applications of Biotechnology for Improving the Healthfulness and Utility of Cerals, in* AGRICULTURAL BIOTECHNOLOGY CHALLENGES AND PROSPECTS 53, 54 (Mahesh K. Bhalgat et al. eds., 2004).

128. *See generally* ROBERT ALI BRAC DE LA PERRIÈRE & FRANCK SEURET, BRAVE NEW SEEDS: THE THREAT OF GM CROPS TO FARMERS 47-49 (2000).

129. Dean D. Metcalfe, *Allergenicity of Foods Produced by Genetic Modification, in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 94, 107 (Keith A. Atherton ed., 2002).

> [B]ecause almost any food may be allergenic in one or a very few individuals . . . it is not reasonable to expect that modified foods will be absolutely and consistently without allergenic potential in everyone. It is reasonable to expect that the technical approaches available . . . will help prevent the marketing of a modified food with significant allergenic potential. *Id.*

130. *See* NIGEL G. HALFORD, GENETICALLY MODIFIED CROPS 67 (2003); *see also* Brazil Nut Article, *supra* note 118 (stating that some researchers claim that science can be used to control unexpected spread of allergic proteins from one organism to another).

131. Federal Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 230-31 (1943); 35A AM. JUR. 2D *Food* § 19 (2001).

and the developer's right to sell food it claims is just as safe without having to label the product in a manner that arguably suggests it is not as safe. These issues were at the heart of the controversy in *Alliance for Bio-Integrity v. Shalala*.[132]

In *Alliance for Bio-Integrity*, a coalition of groups concerned about GMOs sought to challenge the FDA's GMO policy on several grounds.[133] One challenge was to the FDA's presumption that foods developed through recombinant DNA are generally recognized as safe, thereby making it unnecessary to impose mandatory labeling requirements for GMO foods.[134] The plaintiffs argued that FDA should have considered consumer interests when making its determination.[135] The court gave deference to FDA on the presumptive GRAS status of GMOs.[136] The court reasoned:

> The FDA's exclusion of consumer interest from the factors which determine whether a change is "material" constitutes a reasonable interpretation of the statute. Moreover, it is doubtful whether the FDA would even have the power under the FDCA to require labeling in a situation where the sole justification for such a requirement is consumer demand.137

The plaintiffs also argued that the modification of a traditional food equates to a material fact, as defined in FDCA.[138] Again, the court determined that the FDA's policy was rational and entitled to deference over plaintiff's argument.[139]

The plaintiffs' next argument was that the FDA's policy constituted a violation of their right to free exercise of religion by allowing GMOs into the market without labeling them as genetically modified.[140] The court again dismissed this claim, relying upon a prior

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132. 116 F. Supp. 2d 166 (D.D.C. 2000).

133. *Id.* at 170.

134. *See id.*

135. *Id.* at 178.

136. *Id.* at 179 (stating that plaintiffs did not "recognize the determination that a product differs materially . . . is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact.").

137. 116 F. Supp. 2d at 179.

138. *Id.* at 178. *See also* 21 U.S.C. § 321(n) (2000) (stating that foods shall be considered to be misbranded if the label fails to reveal facts "material with respect to consequences which may result from the use of the [product] . . .").

139. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-80.

140. *Id.* at 179-80. This argument raises an interesting hypothetical point. For example, what if a transgenic crop were designed to retain a trait transferred from a pig? Does the presence of the trait mean that the food is not to be consumed by followers of religions that expressly forbid consumption of products derived from pigs? *See* Alan Goldhammer, *The Regulation of Agricultural Biotechnology: An Indus-*

Supreme Court case which held that "neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion."[141] Essentially, after *Alliance for Bio-Integrity*, the FDA's policy on the GRAS status of GMOs remained unscathed.

Another case regarding the labeling of GMOs is the famous *In re StarLink Corn Products Liability Litigation*[142] case where the plaintiffs sought to impose state tort liability upon a manufacturer of GMOs. In *StarLink*, the defendants argued that FIFRA preempted the state law claims brought by the plaintiffs.[143] The plaintiffs' claim for relief was rejected by the court on grounds that FIFRA preempts state pesticide labeling requirements.[144] It is important to note that the claim for failure to warn of known allergens was premised upon the requirements in FIFRA.[145] This is of particular importance in light of the labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 (Allergen Labeling Act).[146]

2. Food Allergen Labeling and Consumer Protection Act

In 2000, it was reported by a scientific study that certain soybeans (genetically modified with proteins from Brazil nuts) generated allergic reactions to blood serum taken from persons who were known to be allergic to Brazil nuts.[147] This discovery is particularly alarming because, as discussed earlier, GMOs are not presently required to be labeled as having been genetically modified.[148] Therefore, persons who are allergic to Brazil nuts would not be aware that

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trial Perspective, 48 FOOD & DRUG L.J. 501, 507 (1993) (stating that "mainstream Orthodox Jewish groups have accepted microbially-produced calf chymosin, an enzyme used in cheesemaking, as being kosher pareve. Thus, the source of the gene . . . does not preclude a genetically engineered food product from being classified as kosher").

141. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-80. (*citing* Employment Div. v. Smith, 494 U.S. 872 (1990)). In fact, the court reasoned that if the government were to take action to further the practice of an individual's religion, the government would be "precariously close to violating the First Amendment's Establishment Clause." *Id.* at 180.

142. 212 F. Supp. 2d 828 (N.D. Ill. 2002).

143. *Id.* at 836.

144. *See id.* at 835.

145. Plaintiffs'/Intervenors' Class Action Complaint ¶ 25, 212 F. Supp. 2d 828 (N.D. Ill. 2002) (No. 1:01CV04928), 2002 WL 32600026.

146. Pub. L. No. 108-282, 118 Stat. 905-911 (Aug. 2, 2004) (codified in various sections of 21 U.S.C. and 42 U.S.C.).

147. Brazil Nut Article, *supra* note 118, at 12A.

148. *See* discussion *supra* Section V.B.1. and accompanying notes.

certain soy products might trigger their allergic reactions. This would appear to bolster the arguments of opponents of GMOs regarding the alleged hazards of potential allergic reactions in humans as one of the primary concerns raised by GMOs.[149] In 2004, Congress declared its intent to protect consumers from unforeseen allergic reactions by passing the Allergen Labeling Act.[150] By doing so, Congress inadvertently may have revived the debate about whether certain GMOs will be required to be labeled. The new labeling requirements for major food allergens became effective for all foods labeled on or after January 1, 2006.[151]

The Allergen Labeling Act includes several congressional findings such as the eight major foods or food groups that account for approximately ninety percent of food allergies,[152] the difficulty parents face in identifying potential allergens in foods,[153] and that "in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen."[154] The Allergen Labeling Act amends FDCA[155] so that a food will be deemed misbranded if it is not a "raw agricultural commodity and it *is*, or it *contains* an ingredient that bears or contains, a major food allergen."[156] This product is considered misbranded unless either (i) the product also states that it "contains" the "name of the food source from which the major food allergen is derived,"[157] or (ii) "the common or usual name of the major food allergen in the list of ingredients . . . is followed in parentheses by the name of the food source from which the major food allergen is derived . . . ."[158]

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149. *See, e.g.*, Repp, *supra* note 6, at 587.

150. Pub. L. No. 108-282, 118 Stat. 905-11 (Aug. 2, 2004) (codified in various sections of 21 U.S.C. and 42 U.S.C.). *See also* Allergen Labeling Act § 202 (2004) (regarding Congressional findings about the nature and extent of food allergens in the United States).

151. Allergen Labeling Act § 203(d)(2004).

152. *Id.* § 202(2)(A) (finding that milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans account for ninety percent of food allergies). These items are all included in the Act's definition of a "major food allergen." *Id.* § 203(c).

153. *Id.* § 202(4).

154. *Id.* § 202(5)(B).

155. 21 U.S.C. §§ 301-99 (2000).

156. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1) (emphasis added).

157. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1)(A)).

158. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(1)(B)).

The Allergen Labeling Act goes further to state that, in the case of certain foods such as a tree nut, the term "name of the food source from which the major food allergen is derived" means the "specific type of nut."[159] The scope of this requirement even reaches to flavorings, colorings, or incidental additives that are or contain a major food allergen[160] and states that they are subject to these labeling requirements regardless of "any other law."[161] An exemption from the labeling requirement may be applied for, but the applicant must "provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health."[162] But even that exemption does not completely escape public notice because all petitions, along with any corresponding responses, will be posted to a public site.[163]

At first glance, it would appear that the debate regarding labeling of GMOs may have been reopened by the new labeling requirements of the Allergen Labeling Act. However, the Allergen Labeling Act also forecloses on one of the stronger arguments in favor of labeling. By requiring the disclosure of information regarding major food allergens, a definition that includes products including or derived from such products,[164] Congress now has denied GMO opponents the opportunity to continue to argue consumer safety from allergic reactions as a reason to require the labeling of GMOs. Stated another way, the concern of consumers suffering unforeseen allergic reactions because of transferred allergic properties now has been addressed directly by Congress regardless of whether the food contains or is derived from genetically modified foods.[165]

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159. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(2)).

160. Allergen Labeling Act § 203(a) (2004) (codified at 21 U.S.C. § 343(w)(4)). Congress also signaled new regulation for spices, flavorings, colorings, or incidental additives that are, or contain, a food allergen, "other than a major food allergen," as determined by regulation, shall be labeled according to such regulation. *See* Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(x)).

161. Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(w)(4)).

162. Allergen Labeling Act § 203 (2004) (codified at 21 U.S.C. § 343(w)(6)(C)).

163. *Id.*

164. Allergen Labeling Act § 203(a) (2004).

165. *See supra* notes 147-64 and accompanying text.

VI. IS THE FOOD PRODUCT DEFECTIVE?

In food products liability cases, it is difficult to determine whether a harm-causing ingredient is actually a product defect.[166] In some jurisdictions, harm caused by substances natural to the food product will not impose liability for the harm, but harm caused by substances that are not natural to the food product will.[167] This is often called the "foreign-natural test."[168]

California was the first state to adopt this test in *Mix v. Ingersoll Candy Co.*[169] In *Ingersoll*, the California Supreme Court held that because it is well-known that chicken pies occasionally contain chicken bones and, because the bone was natural to the kind of meat being served, the bone is not a foreign substance and therefore no liability attaches to harm caused by that bone.[170] The "foreign-natural" test was revised in *Mexicali Rose v. Superior Court*[171] to provide that if the substance is natural to the *preparation* of the food, then the only cause of action for harm it caused is negligence if the seller failed to exercise reasonable care preparing it.[172] If the substance *is* foreign to the food product, then a products liability claim may be brought, and the trier of fact must decide whether the presence of the substance is (1) reasonably expected by the average consumer and (2) whether its presence rendered the food unfit or defective.[173]

The foreign-natural test has been adopted in a handful of jurisdictions, but it remains the distinct minority approach to products liability for harm caused by food.[174] The criticism of the foreign-

166. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 568 (5th ed. 2004).

167. *See infra* notes 169-76 and accompanying text.

168. This test was first adopted in California. HENDERSON & TWERSKI, *supra* note 166, at 570.

169. 59 P.2d 144 (Cal. 1936), *overruled by* Mexicali Rose v. Superior Court, 822 P.2d 1292 (Cal. 1992).

170. *Id.* at 148. "Bones which are natural to the type of meat served cannot legitimately be called a foreign substance, and a consumer who eats meat dishes ought to anticipate and be on his guard against the presence of such bones." *Id.*

171. 822 P.2d 1292 (Cal. 1992).

172. *Id.* at 1302-03.

173. *Id.* at 1303-04.

174. *See, e.g., id.*; Polite v. Carey Hilliards Rest., Inc., 338 S.E.2d 541, 542 (Ga. Ct. App. 1985) (stating that the possibility of finding a one-inch piece of fishbone in a food prepared from fish is a matter of common knowledge of which the consumer should be aware and guard against himself); Brown v. Nebiker, 296 N.W. 366, 369 (Iowa 1941) (affirming lower court's grant of summary judgment because a pork bone was not a foreign substance in a pork chop); *but see* Bryer v. Rath Packing Co., 156 A.2d 442, 446-47 (Md. 1959) (stating that it is common knowledge that there

natural test is that it has no logical basis for the distinction between what is foreign and what is natural.[175] In addition, the test is criticized because it fails to cover instances where a substance (such as a bone) is natural to the kind of food product but nevertheless should not be in the product because of the way the product was marketed (such as boneless).[176]

The uncertainty between natural and foreign substances would remain unresolved in the context of a case brought for harm caused by the presence of a GMO in a food product. The jury would need to hear expert testimony concerning whether the genetic material inserted into the food product is a foreign or natural substance. The trier of fact would be asked to make that determination.[177] A plaintiff would likely argue that the genetic material is unnatural to the food product because it had to be physically inserted and does not naturally occur within the product.[178] A defendant would likely argue that because the genetic material was compatible with that of the food product, it is a natural combination of the two products, and is therefore not a foreign substance.[179]

Most jurisdictions use a test that evaluates whether the consumer would reasonably expect to find the harm-causing substance in the product, regardless of whether it is foreign or natural to the food product.[180] The "consumer expectations" test is also adopted

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are ingredients in chow mein that resemble bones and make it difficult to anticipate or even guard against the presence of bones, so a canner was held liable where it represented its product as boneless).

175. *See* Clime v. Dewey Beach Enter., Inc., 831 F. Supp. 341, 348 (D. Del. 1993) (stating that the problem with the foreign-natural distinction is that it is artificial because even a natural substance such as "a small, but unforgiving, pearl from an oyster can cause as much damage as a 'foreign' piece of metal when a consumer bites down on it.").

176. *See, e.g., Bryer*, 156 A.2d at 446-47; *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (1998) (stating that most courts have found the foreign-natural test inadequate).

177. *See, e.g., Mexicali Rose*, 822 P.2d at 1301-02.

178. *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

179. *See, e.g.*, C. Neal Stewart, Jr. & Sarah K. Wheaton, *Urban Myths and Scientific Facts About the Biosafety of Genetically Modified (GM) Crops, in* PLANTS, GENES, AND CROP BIOTECHNOLOGY 528, 533 (Maarten J. Chrispeels & David E. Sadava eds., 2d ed. 2003) (stating that even though opponents of GMOs stress that they are unnatural, such seemingly unnatural combinations can occur in nature as well, such as crown gall disease in which bacterial DNA is incorporated into plant DNA).

180. *See* Holowaty v. McDonald's Corp., 10 F. Supp. 2d 1078, 1084 (D. Minn. 1998) (stating that a food product is defective under consumer expectations test if the harm-causing characteristic would not be expected by a reasonable consumer); Cain v. Sheraton Perimeter Park S. Hotel, 592 So. 2d 218, 221 (Ala. 1991) (reaf-

by the Restatement (Third) of Torts in the context of food products.[181] This test has a heritage similar to the theory of implied warranty of merchantability.[182]

Under the consumer expectations test, the primary issue is what a consumer is reasonably justified to expect from his or her food; this is generally a question left for the jury to answer.183 A variation on this approach allows the jury to consider the foreign-naturalness of the harm-causing substance among the factors that create reasonable expectations.184

The consumer expectations test for food products will likely remain the same for a GMO food product. That is, the plaintiff will be required to demonstrate that a consumer would not reasonably expect the food to contain the genetically altered substances.[185]

At first glance, the consumer expectations test seems sufficiently applicable to claims for harm caused by genetically modified food products. However, the manner in which the plaintiff will prove those consumer expectations presents a problem because consumers' attitudes about GMOs are closely related to their beliefs

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firming the adoption of a reasonable expectations standard as the proper standard for food products liability cases); Zabner v. Howard Johnson's, Inc., 201 So. 2d 824, 826 (Fla. Dist. Ct. App. 1967) (stating "[t]he test should be what is 'reasonably expected' by the consumer in the food as served, not what might be natural to the ingredients of that food prior to preparation."); Phillips v. Town of West Springfield, 540 N.E.2d 1331, 1333 (Mass. 1989) (determining that reasonable expectations standard is the appropriate test); Gray v. Manitowoc Co., 771 F.2d 866, 870-71 (Miss. 1985) (comparing consumer expectations standard in a defective food case to a case regarding an allegedly defective construction crane).

181. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998). Interestingly, except for a few types of products such as food products, a product is not defectively designed under the Restatement (Third) unless it fails a risk-utility balancing and if the plaintiff cannot present a reasonable alternative design. *Id.* § 2(b).

182. Gates v. Standard Brands Inc., 719 P.2d 130, 134 (Wash. Ct. App. 1986) (stating that the concept of consumer expectations reflects the same warranty heritage found in the theory of implied warranty).

183. Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 109 (quoting Allen v. Delchamps, Inc., 624 So. 2d 1065, 1068 (Ala. 1993)).

184. Jackson v. Nestle-Beich, Inc. 589 N.E.2d 547, 548-49 (Ill. 1992) (holding that naturalness of the ingredient does not bar recovery but is one factor to be considered in determining whether the product is unreasonably dangerous); Goodman v. Wenco Foods, Inc., 423 S.E.2d 444, 451 (N.C. 1992) (holding that it is not a complete bar to recovery if the harm causing substance is natural to the food product); Betehia v. Cape Cod Corp., 103 N.W.2d 64, 67 (Wis. 1960) (stating that merely classifying a substance as foreign or natural may be important in determining negligence of the processor of food, "but it is not determinative of what is unfit or harmful in fact for human consumption.").

185. *See, e.g., Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

about the science.[186] Furthermore, consumer understanding may be an unreliable standard if forty-five percent of United States consumers do not realize that both GMO and non-GMO food products contain genes.[187] In addition, because corn and soybeans, two of the most widely grown GMOs in the United States,[188] are used in processed food, consumers may not realize that up to seventy percent of all products in the country's supermarkets may contain GMOs.[189]

It has been argued that the consumer expectations test is inappropriate when the case involves GMOs because GMOs (1) have a "design" in the same sense as "manufactured" products and (2) because consumers do not have widely shared standards about GMOs.[190] The latter part of this argument is bolstered by the lack of a labeling requirement for GMOs[191] in contrast with regulatory requirements that must be met in order to market foods as organic.[192] Without a label on the GMO product, how is a consumer supposed to determine what his or her expectations are, or in the alternative, what would such expectations be for an unlabeled, potentially-GMO product when it is on the shelf next to a product labeled as organic? In summary, although standards exist for determining whether a party is liable for harm caused by food products, the present standards being utilized are inadequate in the context of GMOs.

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186. Thomas J. Hoban, *International Acceptance of Agricultural Biotechnology, in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 59, 71 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998).

187. *Id.* at 68.

188. *See* James, *supra* note 103.

189. *See* Stewart & Wheaton, *supra* note 179, at 532.

190. Katharine Van Tassel, *Adding Biotech Foods to the Tort System*, WEST MASS. L. TRIB. (Aug. 2003), *reprinted in part in* JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 571-72 (5th ed. 2004).

> [Basing a claim for harm caused by GMO is] without merit when dealing with GM food. First, GM food clearly has a design like any other manufactured product. Second, while consumers may have well-informed, culturally defined and widely shared standards when it comes to some foods, they certainly do not when it comes to GM foods . . . . A recent survey conducted by the University of Richmond revealed that [sixty-two] percent of those surveyed said that they had not eaten any genetically modified foods, and very few of those surveyed were aware that more than sixty percent of the packaged foods sold in [United States] supermarkets contain bio-engineered ingredients. *Id.*

191. *See generally Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 (D.D.C. 2000).

192. OFPA, 7 U.S.C. §§ 6501-23 (Supp. 2004).

VII. OTHER THEORIES OF PRODUCTS LIABILITY IN THE CONTEXT OF FOOD PRODUCTS

A claim for harm caused by a defective product can be brought primarily under theories of (1) manufacturing defect, (2) design defect, or (3) failure to warn defect.[193] Anyone who sells or distributes a food product found to be defective is subject to liability for harm caused by that defect.[194] Although there has been scant litigation on these matters concerning GMOs, a few cases addressing these forms of liability in the context of food products help analyze what would happen in a food products liability lawsuit regarding GMOs.

A. Manufacturing Defect

A manufacturing defect exists when a product departs from its intended design even though all possible care was exercised in its preparation and marketing.[195] The manufacturer or seller will be held strictly liable for harm caused by the manufacturing defect.[196] Thus, in a manufacturing defect case involving GMOs, the claim might arise when a GMO species finds its way into a product specifically branded or labeled as organic (or otherwise non-GMO) and subsequently causes harm. A good example of such an instance is the *StarLink* incident where corn unapproved for human consumption was discovered in the nation's food supply.[197]

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193. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998). For the moment, it has been settled that GMO products will not be required to be specially labeled. *See also Alliance for Bio-Integrity*, 116 F. Supp. 2d 166 (D.D.C. 2000); *infra* notes 195-256 and accompanying text. However, some researchers claim that in certain situations if a company that does choose to warn against harm by labeling the product, it may be inviting more liability on itself because once some kind of warning is provided, it might serve as an admission by the manufacturer that an underlying duty to warn did exist. *See* HENDERSON & TWERSKI, *supra* note 166, at 328-29.

194. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998).

195. *Id.* § 2.

196. *See, e.g.*, Shoshone Coca-Cola Bottling Co. v. Dolinski, 420 P.2d 855, 856 (Nev. 1966) (holding a bottler strictly liable when plaintiff partially consumed the contents of a bottled beverage containing a decomposed mouse).

197. *StarLink*, 212 F. Supp. 2d 828 (N.D. Ill. 2002). The plaintiffs alleged at least four points in the supply chain where the GMO corn could have entered the food supply: the farmers' supplier inventory was mingled when received, pollen drift from neighboring StarLink fields, transport or storage, or in processing. *Id.* at 842-43. However, it is important to note that no facts were found by the court in this case. It was a ruling on defendants' motion to dismiss and therefore the court was reviewing the facts in a light most favorable to the plaintiffs. *Id.* at 835.

In *StarLink*, a class action lawsuit was filed on behalf of consumers who claimed they ingested food unfit for human consumption.[198] This lawsuit resulted in a $9 million settlement against Aventis, the owner of StarLink.[199] Similarly, in *Monsanto Canada, Inc. v. Schmeiser*,[200] GMO canola was discovered in a neighboring non-GMO, canola field.[201] Again, the parties disputed the means by which the GMO canola arrived in the non-GMO field.[202] Monsanto claimed that Schmeiser acquired the GMO seed in violation of Monsanto's rights as a patent holder.[203] Schmeiser claimed that GMO pollen drifted onto his property or that seed was otherwise transferred to his property accidentally.[204]

These two cases clearly demonstrate the possibility of GMOs escaping from the confines of regulatory controls, either through their own promiscuity with other sexually compatible breeds or by other methods (i.e., transportation, storage, packaging, or processing).[205] The general concept of such a claim is that the GMOs commingled with traditional counterparts, entered the food supply, and caused harm; therefore, the person harmed might recover under a theory of manufacturing defect.[206]

B. Design Defect: Risk-Utility v. Consumer Expectations[207]

Under the Restatement (Third) of Torts, a product is defectively designed if the foreseeable risks of harm could have been re-

198. *See generally id.*
199. *See* Kershen, *supra* note 117, at 15 n.65.
200. [2001] F.C. 256, *aff'd in part rev'd in part*, [2004] 1 S.C.R. 902.
201. *Id.* ¶ 8.
202. *See id.* ¶ 11.
203. *Id.* ¶ 1.
204. *See id.* ¶ 11.
205. Processing poses a completely different problem in that GMO and non-GMO products alike are processed together. *See* Neil E. Harl, *Biotechnology Policy: Global Economic and Legal Issues*, 12 WILLAMETTE J. INT'L L. & DISP. RESOL. 1, 9 (2004) (estimating that seventy percent or more of all processed foods contain GMOs).
206. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (1998). "Food product cases . . . sometimes present unique difficulties when it is unclear whether the ingredient that caused the plaintiff's harm is unanticipated adulteration or is an inherent aspect of the product." *Id.*
207. There are many other issues that arise in a design defect case (such as whether certain kinds of GMOs should be adjudged defective as a product category or whether producing GMOs is an abnormally dangerous activity). *See generally* HENDERSON & TWERSKI, *supra* note 166, at 161-313. However, such issues are beyond the scope of this comment.

duced or avoided by using a reasonable alternative design, and failure to utilize that alternative design renders the product unreasonably unsafe.[208] Some factors considered in deciding whether a product is unreasonably unsafe for failure to adopt an alternative reasonable design include the magnitude and probability of foreseeable risks,[209] the likely effects of the alternative design on production costs, and whether the alternative design was technologically and economically feasible.[210] By contrast, some states apply a consumer expectations standard in the context of a design defect case.[211] In states that apply the consumer expectations standard for a defective design claim, the plaintiff would encounter the same obstacles as he or she would under the consumer expectations standard (i.e., defining reasonable expectations of consumers).[212]

In the context of GMOs, a plaintiff is likely to argue that the manufacturer of the GMO failed to adopt a reasonable alternative design and such failure rendered the product unreasonably safe.[213] Then, under the Restatement (Third) approach, the plaintiff must prove that the reasonable alternative design was technologically and economically feasible.[214] The plaintiff's argument at this point might be that the organic version of the product is the reasonable alternative design that was not adopted. In contrast, the defendant will likely marshal the advantages of GMOs and use risk-utility analysis as a shield from liability.[215] Furthermore, a plaintiff would encounter the same obstacles as in a food product liability case if the consumer

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208. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

209. This consideration comes from the *B* > *PL* risk-utility negligence formula coined by Judge Learned Hand in U.S. v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) where B is the burden placed upon the defendant in preventing foreseeable harm, P is the probability of injury to the plaintiff, and L is the degree of damage that will be caused by breaching a duty owed to the injured party. *Id.*

210. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) cmt. f (1998).

211. *See, e.g.*, Delaney v. Deere & Co., 999 P.2d 930, 946 (Kan. 2000) (holding that the ultimate determination is whether the product is unreasonably dangerous beyond a reasonable consumer's expectations); Green v. Smith & Co., 629 N.W.2d 727, 741 (Wis. 2001) (referring to the standard as the consumer contemplation test).

212. *See supra* notes 186-92 and accompanying text.

213. *See, e.g.*, *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 170. Although this case was not brought as a design defect products liability case, the plaintiffs brought the action to protest GMOs because of their "design" as having been produced by recombinant DNA techniques. *Id.*

214. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) cmt. f (1998) (explaining that a plaintiff must prove that the reasonable alternative design is technologically and economically feasible).

215. *See infra* notes 221-236 and accompanying text.

expectations standard were applied (i.e., proving reasonable consumer expectations).[216]

One commentator has proposed that courts evaluate harm caused by the ingestion of GMOs under a "utilitarian risk/utility" theory of liability.[217] Under this proposal, which closely follows the Restatement (Third) approach to design defect liability for non-food products,[218] the case is more focused upon the conduct of the manufacturer as opposed to the reasonable expectations of the injured plaintiff.[219] Furthermore, the plaintiff would prevail if he or she could prove that a reasonable alternative design (made at a reasonable cost) would have reduced the foreseeable risks of harm to the plaintiff.[220]

C. The Benefit v. Risk Analysis of GMOs

1. Benefits

GMOs have been championed in the United States as a potential solution to world famine and malnutrition.[221] It is argued that crop yields can be boosted, crops would remain fresh longer, be more resistant to insects or disease, and can tolerate herbicides to allow farmers to spray weed killers without damaging the crops.[222] Also included among the advocated advantages are that farmers can minimize their use of chemical fertilizers, pesticides, irrigation, and fuel, and therefore convert those savings into additional output.[223] A final benefit is that higher nutritional value can be achieved through bio-engineering crops.[224]

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216. *See supra* notes 186-92 and accompanying text.
217. Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1688-704 (2004).
218. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).
219. Van Tassel, *supra* note 217, at 1693.
220. *See id.*
221. *See* Julian Wong, Note, *Are Biotech Crops and Conventional Crops Like Products? An Analysis Under GATT*, 2003 DUKE L. & TECH. REV. 27, *3 (Oct. 2003).
222. *See id.*
223. *Id.*
224. *Id.*

2. Risks

Much of the criticism of GMOs stems from the lack of certainty experts have regarding long-term health effects.[225] Potential disadvantages include the unregulated escape of GMOs into the food supply thereby exposing humans to new allergens[226] or lead to the development of antibiotic-resistant bacteria in the human body.[227] Furthermore, critics argue that environmental risks develop by permitting unrestricted gene flow (in the form of bio-engineered traits) to fuse with wild relatives through pollination;[228] this can lead to the creation of uncontrollable "superbugs"[229] or "superweeds."[230] Another cause of concern is that large-scale cultivation of GMOs could lead to the loss of crop diversity.[231]

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225. *See* Greenpeace, *Say No to Genetic Engineering*, *at* http://www.greenpeace.org/international/campaigns/genetic-engineering (stating that there is not adequate scientific understanding of the impact of GMOs on the environment and human health) (last visited Mar. 23, 2006).

226. *See* Britt Bailey, *A Societal Role for Assessing Safety*, *in* ENGINEERING THE FARM 113, 120 (Britt Bailey & Marc Lappé eds., 2002) (stating the major hesitation to widespread acceptance of such GMOs as *Bt* crops is the potential allergic reactions that may be caused by them). For greater detail about *Bt* see *supra* note 67.

227. Sheldon Krimsky, *Ethical Issues Involving the Production, Planting, and Distribution of Genetically Modified Crops*, *in* ENGINEERING THE FARM 11, 22 (Britt Bailey & Marc Lappé eds., 2002) (asserting that antibiotic-resistant genes can be transferred to bacteria in the stomachs of humans or animals and can lead to increased populations of antibiotic resistant bacteria).

228. *Id.* at 18 (referring to the process as "genetic pollution").

229. "Superweeds" and "superbugs" are terms used often in academic criticism of GMOs to describe the effect of insects and weeds that develop immunities to the GMO resistance built into the plants and thus become resistant to pesticide and other traditional pest control mechanisms. Wong, *supra* note 221, at *5. *See also* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 59 (2001). The use of such terms is considered imprecise, or even inappropriate, by some experts because an evolving resistance to pest control mechanisms is a natural consequence that occurs even in natural breeding methods (i.e., selecting and breeding only the healthiest and most resilient specimens). *See* Stewart & Wheaton, *supra* note 179, at 531.

230. *See* Stewart & Wheaton, *supra* note 179, at 531. The theory of "superweeds" has even been dramatized in film. The movie *Corn* took the fear a step further by suggesting that pregnant women who ate meat from sheep who consumed the "superweed" were very likely to miscarry. CORN (Revere Pictures 2004) (regarding the use of GMO corn which leads to a genetically mutated weed that when eaten by sheep causes the sheep to become violent).

231. Marc Lappé, *Perspectives on Anti-Biotechnology Convictions*, *in* ENGINEERING THE FARM 135, 152 (Britt Bailey & Marc Lappé eds., 2002) (suggesting that more research should be completed to determine whether loss of biodiversity is sufficiently detrimental to justify more regulatory control of GMOs).

Another dimension of GMO criticism is the deep suspicion expressed by citizens of many European Union member countries and Japan[232] concerning genetically modified foods.[233] This concern is fueled by consumer fears that modification is an unnatural extension of traditional plant breeding, and products produced using such technology should not be presented to the population for consumption until they are proven to be safe.[234]

Regardless of the side of this debate a person empathizes with, the only certainty about GMOs is that the scientific community cannot reach a consensus on the matter.[235] Therefore, a company that desires to participate in the market of genetically modified foods would be well-served by first determining the regulations governing GMOs and evaluating potential legal risks presented by them.[236]

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232. *See* Press Release, No! GMO Campaign, Monsanto Suspends Development of Herbicide Resistant GM Wheat; Japanese Consumer Petition Stops GM Wheat (2004), *available at* http://www.no-gmo.org/new/2004/510e.htm (announcing that Japanese consumer pressure essentially forced Monsanto to abandon developing GM wheat and rice). However, Japanese rice farmers and consumers may become more accepting of GMO rice that alleviates the effects of hay fever allergies. *See* Jiji Press Ltd., *The Day When People Eat Rice to Alleviate Sneezing and Snivels Caused by Pollen-Induced Allergies May Not be Too Far Away* (Feb. 7, 2005).

233. *See generally* Thomas J. Hoban, *International Acceptance of Agricultural Biotechnology*, *in* AGRICULTURAL BIOTECHNOLOGY AND ENVIRONMENTAL QUALITY: GENE ESCAPE AND PEST RESISTANCE 59 (Ralph W.F. Hardy & Jane Baker Segelken eds., 1998). Hoban conducted a study in the United States, Canada, and several other European countries. The survey provided participants with several different statements and asked the participant to answer whether they thought the statement was "True," "False," or that they didn't know. One statement was that "[o]rdinary tomatoes do not contain genes, while genetically modified ones do." *Id.* at 68. Fifty-two percent of Canadian participants and 46% of United States participants responded "False"—the correct answer. *Id.* By comparison, European participants who responded False were as follows: Austria, 34%; France, 32%; Germany, 36%; Ireland, 20%; Italy, 35%; Spain, 28%; United Kingdom, 40%. *Id.*

234. *See, e.g.*, Stewart & Wheaton, *supra* note 179, at 533 (discussing the popular opinion that GMOs are the byproducts of an unnatural science).

235. *See generally* notes 221-234 and accompanying text.

236. *See* Kershen, *supra* note 117, at 1 (stating that those who produce or use agricultural biotechnology need to know about the legal standards to which they will be held accountable); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 (1998) (stating that one who sells or distributes a food product that is defective is subject to liability for harm caused by the defect).

3. GMOS And Liability For Failing To Warn Of Common Allergens

It is estimated that approximately 11,000,000 people in the United States suffer from food allergies.[237] In general, allergies (including allergies to non-food products) are the sixth leading cause of chronic diseases in the United States and cost the health system approximately $18 billion annually.[238] A food allergy is an immunological response to a food which the body mistakes as being harmful.[239] When that happens, the body creates a specific antibody, immunoglobulin E (IgE), to protect the body from that food product in the future.[240] The next time the individual eats that food, the food interacts with the IgE antibody and triggers the release of chemicals like histamines to protect the body from that food.[241] This process results in a series of allergic symptoms that affect the skin, respiratory system, cardiovascular system, or gastrointestinal tract.[242] An allergic reaction to food can happen within a few minutes or until an hour after eating the food.[243]

Ninety percent of all food allergies involve milk, eggs, peanuts, tree nuts (walnuts and cashews), fish, shellfish, soy, and wheat.[244] The most common symptoms of food allergies are skin irritation (rashes, hives, and eczema) and gastrointestinal symptoms (nausea, diarrhea, and vomiting).[245] The respiratory system is also affected sometimes with such symptoms as sneezing, runny nose, and short-

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237. The Food Allergy & Anaphylaxis Network (FAAN), *Answers to Frequently Asked Questions*, *at* http://www.foodallergy.org/questions.html (last visited Mar. 23, 2006) [hereinafter FAAN FAQs]. Food allergies should not be confused with food intolerances. A food intolerance is a reaction to a food product that does not involve the body's immune system. *See id.* For example, a person who is lactose intolerant has a food intolerance which means he or she lacks an enzyme needed to digest milk sugar. *Id.*

238. National Institute of Allergy and Infectious Diseases (NIAID), *Allergy Statistics*, *available at* http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf [NIAID Statistics].

239. FAAN, *Common Food Allergens*, *at* http://www.foodallergy.org/allergens.html (last visited Mar. 23, 2006) [hereinafter FAAN Common Allergens].

240. NIAID, *Food Allergy: An Overview*, at 3 (July 2004), *available at* http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf [hereinafter NIAID Overview].

241. *Id.*

242. *Id.* at 4.

243. *Id.*

244. FAAN Common Allergens, *supra* note 239.

245. International Food Informational Council Foundation, *Understanding Food Allergy*, at 2, *available at* http://www.ific.org/publications/brochures/upload/Understanding-Food-Allergy-Brochure.pdf.

ness of breath.[246] Although rare, some persons may suffer from anaphylaxis, which is a potentially fatal condition when allergic reactions occur in multiple parts of the body at the same time such as itching, hives, swelling of the throat, difficulty breathing, lower blood pressure, and unconsciousness.[247] Tree nuts and peanuts are the primary causes of anaphylaxis.[248]

James A. Henderson, Jr. has described the paradigm products liability cases involving allergic reactions as follows:

> A widely distributed [product] containing an allergen causes the user or consumer to suffer [an] allergic [reaction] . . . . The onset of symptoms is abrupt, with little or no forewarning . . . . The producer cannot remove the allergen from the product without significantly reducing its effectiveness. The product unit that causes injury is harmless to the large majority of users and consumers who are not allergic to it, and thus including the allergen is a reasonable design choice. Typical of a majority of users and consumers, the victim does not and cannot know ahead of time that he will suffer an allergic reaction to the product or any of its ingredients. The producer knows ahead of time that a small percentage of persons will suffer such allergic reactions . . . and warns of this possibility in its marketing. But neither the producer nor users/consumers can identify those specific individuals who will suffer unexpected adverse reactions until those reactions actually occur.[249]

In general, a warning is required when a substantial number of people are allergic to a harm-causing ingredient of the food product.[250] The ingredient that causes the allergic reaction must be something that consumers do not generally know is present in the product or do not know is dangerous.[251] However, the plaintiff must

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246. *Id.*

247. *Id.*

248. *See* NIAID Overview, *supra* note 240, at 6. About 150 Americans die annually from anaphylaxis caused by food. *See* NIAID Statistics, *supra* note 238.

249. James A. Henderson, Jr., *Process Norms in Products Litigation: Liability for Allergic Reactions*, 51 U. PITT. L. REV. 761, 777-78 (1990).

250. *See* Santarelli v. BP Am., 913 F. Supp. 324, 332 (M.D. Penn. 1996) (regarding ingestion of salmon contaminated with ciguatera toxin); Allen v. Delchamps, Inc., 624 So. 2d 1065, 1069 (Ala. 1993) (regarding a consumer alleging injuries from ingestion of celery hearts treated with sodium bisulfite); Livingston v. Marie Callender's Inc., 72 Cal. App. 4th 830, 840 (1999) (holding that a plaintiff who ate a bowl of soup containing monosodium glutamate after having been told the soup did not contain it should be allowed to bring a claim for failure to warn of an ingredient to which a substantial number people are allergic); Brown v. McDonald's Corp., 655 N.E.2d 440, 444 (Ohio Ct. App. 1995) (involving a customer who suffered severe reaction to carrageenan, a seaweed-derived ingredient in hamburger product). *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

251. *See, e.g.*, Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 536 (S.D.N.Y. 2003) (dismissing plaintiff's allegations that cholesterol, fat, salt, and sugar are al-

show "the allergic predisposition is not unique to the plaintiff."[252] Furthermore, a manufacturer generally is not required to provide warnings about allergic reactions that are not reasonably foreseeable at the time of sale.[253]

When genetic material from a common food allergen is transferred into another food product, people who eat the resulting food product may have an allergic reaction.[254] The plaintiff in that case will have a strong argument that the manufacturer should have warned the consumer that the food product contained allergen substances similar to those in Brazil nuts because Brazil nuts are a commonly known allergen and it is reasonably foreseeable that a consumer would have an allergic reaction after consuming the food product.[255] This is the area of the law of food products liability that may be affected most by the requirements of the Allergen Labeling Act.[256]

VIII. CONCLUSION: CAVEAT VENDITOR

Assuming that a biotechnology company can find its way through the labyrinthine regulations of several different federal agencies, it will be faced with another difficult obstacle in the risk analysis of entering the GMO market. First, if the company must defend a food products liability case, the company will encounter great difficulty in overcoming the challenges regarding either the foreign-natural or consumer expectations tests. Furthermore, if the company faces an allergic reaction case, it is not guaranteed protection from failure to warn if it should have been aware that a substantial portion of persons would have an allergic reaction to its prod-

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lergens for lack of evidence and failing to demonstrate that the existence of such ingredients are unknown to the public); Daley v. McNeil Consumer Prod. Co., 164 F. Supp. 2d 367, 373 (S.D.N.Y. 2001). *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

252. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. k (1998).

253. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. k, m (1998).

254. Lori B. Andrews, *Patents, Plants, and People: The Need for a New Ethical Paradigm, in* ENGINEERING THE FARM 67, 77 (Britt Bailey & Marc Lappé eds., 2002) (referring to Pioneer Hi-Bred's project in which proteins from Brazil nuts were transferred to soybeans and persons allergic to nuts suffered allergic reactions when the soy products were consumed). *See also* T.J. Higgins & Maarten J. Chrispeels, *Plants in Human Nutrition and Animal Feed, in* PLANTS, GENES, AND CROP BIOTECHNOLOGY 152, 178 (Maarten J. Chrispeels & David E. Sadava eds., 2d ed. 2003).

255. *See supra* notes 251-54 and accompanying text.

256. *See* discussion *supra* Section V.B.2 and accompanying notes.

uct—particularly in light of the requirements of the Allergen Labeling Act. Therefore, a company desiring to enter the GMO market does so at the risk of uncertainty as to what legal standard it will be held if its GMO product causes harm. Let the merchant beware.

EUROPEAN UNION FOOD LAW UPDATE

*Nicole Coutrelis**

I. PUBLISHED REGULATIONS

A. Food Hygiene

On December 22, 2005, the European Commission published several regulations supplementing and implementing the provisions of the new food hygiene rules adopted in April 2004, which overhauled previous hygiene legislation in the European Union (E.U.)[1] (so called "Hygiene Package"). The new hygiene rules consisted of the following:

- Regulation (EC) No. 2073/2005/EC "on microbiological criteria for foodstuffs;"[2]

- Regulation (EC) No. 2074/2005/EC "laying down implementing measures for certain products under Regulation (EC) No. 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No. 854/2004 of the European Parliament and of the Council and Regulation (EC) No. 882/2004 of the European Parliament and of the Council, derogating from Regulation

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1. Directive 852/2004 of the European Parliament and Council "on the hygiene of foodstuffs," 2004 O.J. (L 139) 1 (EC); Regulation 853/2004/EC of the European Parliament and Council "laying down specific hygiene rules on the hygiene of foodstuffs," 2004 O.J. (L 139) 55; Regulation 854/2004/EC of European Parliament and Council "laying down specific rules for the organization of official controls on products of animal origin intended for human consumption," 2004 O.J. (L 155) 206; and Regulation 882/2004/EC of European Parliament and Council "on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare," 2004 O.J. (L 165) 1 (EC).

2. Commission Regulation 2073/2005, 2005 O.J. (L 338) 1 (EC).

(EC) No. 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004;"[3]

- Regulation (EC) No. 2075/2005/EC "laying down specific rules on official controls for Trichinella in meat;"[4] and

- Regulation (EC) No. 2076/2005/EC "laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004."[5]

These four new hygiene regulations adopted in 2004 will be effective in all the Member States on January 1, 2006, except for some provisions of Regulation 2074/2005/EC (Chapters II and III of Annex V, dealing with harmonized structures of national websites and with the presentation of lists of approved premises), which shall apply beginning January 1, 2007.[6] Despite providing an effective date for some of the rules, Regulation 2076/2005/EC provides a transitional period until December 31, 2009 for some of the new hygiene rules.[7]

At the end of 2005, in order to assist food business operators and Member States with the implementation of the new food hygiene legislation, the Health and Consumer Protection Directorate-General of the Commission published three guidance documents. The first document published was the Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the Hazard Analysis and Critical Control Point (HACCP) principles in certain food businesses.[8] Following the HACCP Guidance document, a second document was provided, the Guidance document on the implementation of certain provisions of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.[9] Finally, the Commission published its final

3. Commission Regulation 2074/2005, 2005 O.J. (L 338) 27 (EC).
4. Commission Regulation 2075/2005, 2005 O.J. (L 338) 60 (EC).
5. Commission Regulation 2076/2005, 2005 O.J. (L 338) 83 (EC).
6. Commission Regulation 2074/2005, art. 10, 2005 O.J. (L 338) 27 (EC).
7. Commission Regulation 2076/2005, art. 1, 2005 O.J. (L 338) 83 (EC).
8. *See* Europa, Guidance Document–Implementation of Procedures Based on the HACCP Principles, and Facilitation of the Implementation of the HACCP Principles in Certain Food Businesses, *available at* http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf
9. *See* Europa, Guidance document on the implementation of certain provisions of Regulation (EC) 852/2004 on the hygiene of foodstuffs, *available at* http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf.

guidance document, the Guidance document on the implementation of certain provisions of Regulation (EC) 853/2004 on the hygiene of food of animal origin.[10]

B. Organic Farming

On August 6, 2005, the Commission published Regulation No. 1294/2005/EC "amending Annex I to Council Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs."[11] This directive provides for an extension of the transitional period during which the use of conventional feedingstuffs may be authorized for the production of animal products derived from organic farming.[12]

On September 28, 2005, the Council published Regulation No. 1567/2005/EC "amending Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs."[13] Pursuant to Regulation 2092/91 (Article 11(6)(a)),[14] a transitional measure allows Member States to grant derogations for imports from third countries of products that have been produced with equivalent rules to those provided in Regulation 2092/91.[15] This transitional measure has been extended until December 31, 2006. The Commission is considering replacing the current national derogations with a new permanent system; yet, this replacement will take some time.

On November 25, 2005, the Commission published Regulation No. 1916/2005/EC "amending Annex II to Council Regulation (EEC) 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs."[16] This amendment contains a list of vitamins, pro-vitamins and chemically well-defined substances having a similar effect which are authorized in organic farming.[17]

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10. *See* Europa, Guidance document–Implementation of Certain Provisions of Regulation (EC) No. 853/2004 on the Hygiene of Food of Animal Origin, *available at* http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf.
11. Commission Regulation 1294/2005, 2005 O.J. (L 205) 16 (EC).
12. Commission Regulation 1294/2005, whereas (3), 2005 O.J. (L 305) 16 (EC).
13. Council Regulation 1567/2005, 2005 O.J. (L 252) 1 (EC).
14. Council Regulation 2092/91, art. 11(6)(a), 1991 O.J. (L 198) 1, 1-15 (EC).
15. Council Regulation 1567/2005, whereas (1), 2005 O.J. (L 252) 1 (EC).
16. Council Regulation 1916/2005, 2005 O.J. (L 307) 10 (EC).
17. Council Regulation 1916/2005, annex, 2005 O.J. (L 307) 11 (EC).

C. *Food Contact Materials*

On November 19, 2005, the European Commission published Directive 2005/79/EC "amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food."[18] Among other things, this directive modifies the list of monomers which may be used in the manufacturing of plastic materials and articles intended to come in contact with food.[19] It also provides for additions to the list of additives which may be used in the manufacture of plastic materials and articles.[20] Directive 2005/79 is to be implemented into national law by Member States by November 19, 2006.[21] Importation into the E.U. and manufacturing of plastic materials and articles not complying with the new requirements will be forbidden after November 19, 2007.[22]

During the second half of 2005, the Commission updated several documents relating to legislation on food contact materials, including a list of E.U. and Member States' measures on food contact materials and a consolidated list of monomers as well as additives appearing in the directives on plastics for food applications.[23]

D. *Food Allergens*

On October 4, 2005, the Commission published Directive 2005/63/EC "correcting Directive 2005/26/EC concerning the list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council."[24] Pursuant to Directive 2005/63/EC, carotenoids which were mistakenly omitted from the list in the annex to Directive 2005/26/EC of substances not considered to be a risk for allergic people were thereby added.[25]

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18. Commission Directive 2005/79, 2005 O.J. (L 302) 35 (EC).
19. Commission Directive 2005/79, whereas (1), 2005 O.J. (L 302) 35 (EC).
20. Commission Directive 2005/79, whereas (2), 2005 O.J. (L 302) 35 (EC).
21. Directive 2005/79, art. 3, 2005 O.J. (L 302) 36 (EC).
22. *Id.*
23. European Commission, Health & Consumer Protection Directorate-General, Food Contact Materials: Substances Listed in E.U. Directives on Plastic in Contact with Food, *available at* http://ec.europa.eu.int/comm/food/food/chemicalsafety/foodcontact/eu_substances_en.pdf
24. Commission Directive 2005/63, 2005 O.J. (L 258) 3 (EC).
25. Commission Directive 2005/63, whereas (3), 2005 O.J. (L 258) 3 (EC).

E. Genetically Modified Organisms (GMOs)

On August 10, 2005, the Commission published Decision 2005/608 "concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line MON 863) genetically modified for resistance to corn rootworm."[26] Pursuant to this decision, Monsanto has been authorized for ten years to place the genetically modified maize MON 863 on the market for import and processing as animal feed; however, the decision does not cover food or cultivation. MON 863 is the second maize to be authorized following the implementation of Directive 2001/18/EC "on the deliberate release of genetically organisms into the environment."[27]

The Commission authorized the placing on the market of the genetically modified oilseed rape known as GT73 for import and processing during a period of ten years on August 31, 2005, following an application submitted by Monsanto.[28] This market placement is the third GMO product to be approved under Directive 2001/18.[29]

On November 3, 2005, the Commission authorized the genetically modified maize 1507 to be placed on the market for use in animal feed.[30] Maize 1507 is the fourth product to be authorized following the effective date for Directive 2001/18/EC.[31]

F. Novel Foods

On July 29, 2005, the Commission also published Decision 2005/580/EC "authori[z]ing the placing on the market of isomaltulose as a novel food or novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council."[32]

In contrast, however, on same day the Commission published Decision 2005/580/EC "refusing the placing on the market of be-

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26. Commission Decision 2005/608, 2005 O.J. (L 207) 17 (EC).

27. Commission Directive 2001/18, 2001 O.J. (L 106) 1 (EC).

28. Press Release, GMOs : Commission Authorizes Import of GM oilseed rape for Use in Animal Feed, (IP/05/1077), Aug. 31, 2005, *available at* http:europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1077&format=HTML&aged=0&language=EN&guiLanguage=en.

29. *Id.*

30. Commision Decision 2005/772/EC, 2005 O.J. (L 291) 42 (EC).

31. Environment for Europeans, *Striking the Right Balance on GMOs*, Jan. 2006, *available at* http://ec.europa.eu/environment/news/efe/22/article_3606_en.htm.

32. Commission Decision 2005/581, 2005 O.J. (L 199) 90 (EC).

taine as a novel food or novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council."[33] Such a decision is based upon the opinion of the European Food Safety Authority (EFSA), according to which the safety of betaine for the intended use has not been established.

G. BSE Legislation

On August 6, 2005, the Commission published Regulation 1292/2005 "amending Annex IV to Regulation (EC) 999/2001 of the European Parliament and of the Council as regards animal nutrition."[34] Regulation 999/2001 is the framework legislation addressing the control and eradication of BSE and transmissible spongiform encephalopathies.[35] Regulation 1292/2005 is to apply from September 1, 2005.[36]

On December 3, 2005, the Commission also published Regulation No. 1974/2005 "amending Annexes X and XI to Regulation (EC) No. 999/2001 of the European Parliament and of the Council as regards national reference laboratories and specified risk material"[37]

H. Pesticides Residues

The Commission published Directive 2005/48 on August 24, 2005, "amending Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC as regards maximum residue levels for certain pesticides in and on cereals and certain products of animal and plant origin."[38]

33. Commission Decision 2005/580, 2005 O.J. (L 199) 89 (EC).
34. Commission Regulation 1292/2005, 2005 O.J. (L 205) 3 (EC).
35. Commission Regulation 999/2001, 2001 O.J. (L 147) 1, art. 1, (EC).
36. Commission Regulation 1292/2005, 2005 O.J. (L 205) 3, art. 2 (EC)
37. Commission Regulation, 1974/2005, 2005 O.J. (L 317) 4 (EC).
38. Commission Directive 2005/48, 2005 O.J. (L 219) 29 (EC).

II. PENDING DRAFT REGULATIONS

A. Organic Farming

On December 21, 2005, the Commission adopted proposals[39] for Council Regulations on organic production and labelling of organic products, amending Regulation (EEC) No. 2092/91[40] on organic production of agricultural products and indications referring thereto in agricultural products and foodstuffs. This proposal was aimed at entirely revising the current rules for production, labeling, control, and import of organic foodstuffs and hence replace Regulation (EEC) No. 2092/91.[41] According to the Commission proposal, the new rules would be effective as of January 1, 2009, except for the provisions on import which are to be effective beginning January 1, 2007.[42] The import provisions have an early implementation date since the current rules for import are due to expire on December 31, 2006 pursuant to Regulation No. 1567/2005/EC amending Regulation No. 2092/91.[43]

B. Labeling: Health Claims

In December 2005, the Council adopted a Common Position on the Proposal for a Regulation on the use of nutrition and health claims made on foods, which was issued by the Commission in July 2003.[44] Among the large number of amendments proposed by the European Parliament, the Council rejected two controversial ones. First, the Council chose to reject the provision regarding the substitution of the authorization procedure for health claims proposed by the Commission by a simple notification procedure. A second provision was rejected involving the deletion of nutrient profiles for

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39. *See* Proposal for a Council Regulation on Organic Production and Labeling of Organic Products, COM(2005) 671 final, *available at* http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0671en01.pdf.

40. Council Regulation 2092/91, 1991 O.J. (L 198) 1, 1-15 (EEC).

41. *See* Proposal for a Council Regulation on Organic Production and Labeling of Organic Products, COM(2005) 671 final at 3, *available at* http://europa.eu.int/eurlex/lex/LexUriServ/site/en/com/2005/com2005_0671en01.pdf.

42. *Id.* at 8.

43. *Id.*

44. *See* Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Food, COM(2003) 424 final, *available at* http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0424en01.pdf.

foods. This new text has been forwarded to the European Parliament for its second reading, which is expected to take place no sooner than May 2006. Members of the Parliament can submit amendments until February 15, 2006.[45]

C. Food Fortification with Vitamins and Minerals

In December 2005, the Council also adopted a Common Position concerning the Proposal for regulation of the addition of vitamins, minerals and other substances to foods, which was issued by the Commission in November 2003.[46] Such a proposal has been sent to the European Parliament for its second reading, which is expected to take place at the same time as the nutrition and health claims proposal in May 2006.

Until recently, this matter has not been harmonized in the E.U. According to the proposed text, supplementation of food for ordinary consumption would be authorized–under certain conditions–all over the E.U.[47] The authorized substances would be identical to those already authorized for food supplements in Directive 2002/46.[48]

D. Food Additives

In October 2005, the European Parliament adopted the Proposal for a Directive with amendments,[49] amending Directive 95/2/EC on food additives other than colours and sweeteners[50] and Directive 94/35/EC on sweeteners for use in foodstuffs,[51] which was issued by the Commission in the light of recent scientific develop-

45. *See* EurActiv, *Nutrition and Health Claims Made on Foods*, May 9, 2006, http://www.euractiv.com/en/health/nutrition-health-claims-foods/article-133154.

46. European Commission, Proposal for a Regulation of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of Certain Other Substances in Foods, COM(2003) 671 final, *available at* http://ec.europa.eu/comm/food/fs/sfp/df/df_ff_reg1_en.pdf.

47. *Id.* at 12-13.

48. *Id.*

49. 2004/0237 (COD), Proposal for a Directive of the European Parliament and of the Council Amending Directive 95/2/EC on Food Additives Other than Colours and Sweeteners and Directive 94/35/EC Sweeteners for Use in Foodstuffs, *available at* http://www.food.gov.uk/multimedia/pdfs/com2004650.pdf.

50. European Parliament and Council Directive 95/2/EC, 1995 O.J. (L 61) 1, 1-40.

51. European Parliament and Council Directive 94/35/EC, 1994 O.J. (L 237) 3, 3-12.

ments in October 2004. Among other matters, the draft directive amends the conditions surrounding the use of nitrates and nitrites in foodstuffs, following a judgment of the European Court of Justice (ECJ) of March 20, 2003.[52] In this judgment, a Danish regulation was upheld, which was stricter than the E.U. directive regarding the use of those additives.[53] The proposal as amended by the Parliament was forwarded to the Council for adoption.

E. Aquaculture Products

On August 23, 2005, the Commission issued a proposal for a Council Directive "on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals."[54] The proposal's objective was to update and to simplify the existing provisions of Directives 91/67/EEC, 93/53/EEC and 95/70/EC.[55]

III. CASE LAW: JUDGMENTS ISSUED

A. Food Supplements

On July 12, 2005, following the submission of request for a preliminary ruling, the European Court of Justice (ECJ)[56] confirmed the validity of the European Parliament and Council Directive 2002/46/EC "on the approximation of the laws of the Member States relating to food supplements."[57] The validity of the legislation implementing the Food Supplements Directive, which partially har-

52. 2004/0237 (COD), Proposal for a Directive of the European Parliament and of the Council Amending Directive 95/2/EC on Food Additives Other than Colours and Sweeteners and Directive 94/35/EC Sweeteners for Use in Foodstuffs, at 2, *available at* http://www.food.gov.uk/multimedia/pdfs/com2004650.pdf.

53. Case C-300, Kingdom of Den. v. Comm'n. of European Communities, 2003 ECJ CELEX LEXIS 66 (March 20, 2003).

54. *See* Proposal for a Council Directive on Animal Health Requirements for Aquaculture Animals and Products Thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals, COM(2005) 362 final, *available at* http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0362en01.pdf.

55. *Id.* at 2.

56. Joined Cases C-154/04, Alliance for Natural Health & Nutri-Link Ltd. v. Sec'y of State Health and C-155/04 Nat'l Ass'n of Health Stores and Health Food Mnr. Ltd. v. Sec'y of State Health, Nat'l Assembly for Wales, 2005 ECJ CELEX LEXIS 327 (July 12, 2005).

57. Council Directive 2002/46, 2002 O.J. (L 183) 51 (EC).

monized the rules in the European Union (E.U.) governing the marketing of food supplements from August 1, 2005, had been challenged in the United Kingdom (UK) by a European association of manufacturers, wholesalers, distributors, retailers, and consumers of food supplements and a small specialist distributor and retailer of food supplements in the United Kingdom.[58] The claimants argued that the new Food Supplements legislation did not improve the conditions for the establishment and functioning of the single market and some provisions were contrary to the principle of the free movements of goods.[59]

The ECJ confirmed the internal market base of such directive, i.e. Article 95 of the EC Treaty.[60] It also upheld the positive lists of vitamins and minerals that may be used in the manufacture of these products. As a result, some substances which are currently authorized for sale in the UK will be forbidden after a transitional period, but the Court ruled that such a consequence was to be accepted in order to have a single market in this sector.[61]

Also, on September 8, 2005, following an action brought by the European Commission against France on the basis of the infringement procedure provided by Article 226 of the EC Treaty, the ECJ declared that by failing to transpose the Food Supplements Directive 2002/46/EC, the French Republic has failed to fulfil its obligations under that directive.[62] The period prescribed for the transposition of the directive into national law expired on July 31, 2003.[63] Indeed, the French process was very slow because France took this opportunity to review its entire legislation on food supplements, not only regarding vitamins and minerals as provided for in the Directive, but also regarding all substances, including herbal supplements.

B. Residues

Pursuant to the judgment rendered on July 12, 2005, the ECJ did not confirm the judgment of the Court of First Instance pursu-

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58. *See Alliance for Natural Health*, 2005 ECJ CELEX LEXIS 327.
59. *Id.*
60. *Id.*
61. *Id.*
62. Case C-57/05, Commission of the European Communities v. French Republic, *available at* http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs
&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-57%2F05&datefs =&datefe=&nomusuel=&domaine=&mots=&resmax=100.
63. *Id.*

ant to which the European Commission has unlawfully failed to act in regard to the establishment of maximum residue limits for veterinary medicinal products[64] pursuant to Council Regulation 2377/90/EEC "laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin."[65]

At stake in this Court decision was the use of a veterinary product containing progesterone marketed by Pfizer and CEVA Santé Animale.[66] In 1993, CEVA had submitted an application to the Commission for the establishment of maximum residue limits for progesterone in cattle and horses.[67] The Commission did not take any action before January 2000 because of divergent scientific data on the risks with progesterone. In July 2001, the Commission adopted a draft regulation amending Regulation 2377/90/EEC classifying progesterone in Annex I of such regulation (i.e. the list of substances for which maximum residue limits are defined).[68]

In November 2000, CEVA and Pfizer brought proceedings before the Court of First Instance arguing that the Commission had failed to take necessary measures for the classification of progesterone in Annex II to Regulation 2377/90 (i.e. the list of substances for which no maximum residue limit is defined), and as a consequence failed to comply with its obligations under Community law.[69] On February 26, 2003, the Court of First Instance ruled that the Commission's inaction between January 2000 and July 2001 amounted to a breach of the principle of sound administration capable of giving rise to liability of the Community.[70]

On appeal, the ECJ overruled the judgment of the Court of First Instance, stating that the Commission must be given sufficient discretion to allow it to determine on a fully informed basis in order to protect public health.[71]

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64. Case C-198/03, Comm'n v. CEVA Santé Animale SA and Pfizer Enterprises Sàrl, 2005 ECJ CELEX LEXIS 737 (July 12, 2005).

65. Council Regulation 2377/90, 1990 O.J. (L 224) 1, 1-8 (EC).

66. *See CEVA Santé Animale SA and Pfizer Enterprises Sàrl*, 2005 ECJ CELEX LEXIS 737.

67. *Id.*

68. *Id.*

69. *Id.*

70. Joined Cases T-344/00 and T-345/00, CEVA Santé animale SA and Pharmacia Enters. SA v. Comm'n, 2003 ECJ CELEX LEXIS 40 (Feb. 26, 2003).

71. Case C-198/03, Comm'n v. CEVA Santé Animale SA and Pfizer Enterprises Sàrl, 2005 ECJ CELEX LEXIS 737 (July 12, 2005).

C. Use of Name "Feta" (Protected Designation of Origin)

On October 25, 2005, the ECJ upheld the name "Feta" for the cheese produced in Greece as a protected designation of origin (PDO),[72] hereby dismissing the actions brought both by Germany and Denmark against the registration of the name "Feta" as a PDO by Commission Regulation 1829/2002/EC "amending the Annex to Regulation (EC) No. 1107/96 with regard to the name 'Feta,'" the word "Feta" was inserted in the list of PDOs.[73]

In order to benefit from a PDO, a name such as "Feta" must refer to an agricultural product or a foodstuff from a defined geographical environment with specific natural and human factors, capable of conferring on that product or foodstuff its specific characteristics.[74] Additionally, the name cannot have become generic if the product is to be classified as a PDO.[75]

Using these guidelines, the ECJ reached the conclusion that the word "Feta" has not become generic.[76] This ruling puts an end to a longstanding dispute, opposing many non-Greek cheese producers, particularly in France, Germany, and Denmark. Finally, Greece has succeeded in obtaining that, within the E.U., the name "Feta" be allowed only to Greek cheese.[77]

D. Hygiene

On November 24, 2005, following the submission of request for a preliminary ruling, the ECJ held that Austria is entitled, on grounds of public health protection, to prohibit the sale of unwrapped chewing gum products from automatic vending machines.[78] Pursuant to Austrian law, it is forbidden to sell sugar confectionery

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72. Joined Cases C-465/02 and C-466/02, Federal Republic of Germany and Kingdom of Den. v. Comm'n, *available at* http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit= Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-466/02&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100.

73. Commission Regulation 1829/2002, art. 1(1), 2002 O.J. (L 277) 10, 14 (EC).

74. Commission Regulation 1829/2002, whereas (35), 2002 O.J. (L 277) 10, 14 (EC).

75. Commission Regulation 1829/2002, whereas (30), 2002 O.J. (L 277) 10, 14 (EC).

76. Commission Regulation 1829/2002, whereas (29), 2002 O.J. (L 277) 10, 14 (EC).

77. Commission Regulation 1829/2002, art. 1(1), 2002 O.J. (L 277) 10, 14 (EC).

78. Case C-366/04, Georg Schwarz v. Bürgermeister der Landeshaupstadt Salzburg, 2005 ECJ CELEX LEXIS 511 (June 28, 2005).

or similar products in vending machines if the products have not been wrapped.[79]

In an action brought in Austria stemming from unwrapped chewing gum in vending machines, Schwarz lodged an appeal arguing that the Austrian legislation was not compatible with Council Directive 93/43/EEC "on the hygiene of foodstuffs"[80] and the free movements of goods (Articles 28 and 30 of EC Treaty).[81] In this case, the ECJ held that the packaging of confectionery products marketed in vending machines has not been harmonized by Directive 93/43.[82] As a result, national measures in this field must, therefore, be assessed in regard to the EC Treaty provisions relating to the free movement of goods.

The ECJ then stated that Austrian provisions at stake constitute a measure having equivalent effect to quantitative restrictions to importations within the meaning of Article 28 EC.[83] Pursuant to consistent case law, which has held national rules which hinders the free movement of goods is not necessarily contrary to Community law if it may be justified by one of the public-interest grounds set out in Article 30 EC or by one of the mandatory requirements laid down by the Court's case-law where the national rules are applicable without distinction, the ECJ reached the conclusion that such a prohibition constitutes an adequate and proportionate measure for the protection of public health.[84]

E. Genetically Modified Organisms (GMOs)

On October 5, 2005, the E.U. Court of First Instance[85] dismissed the actions for an annulment brought by the region of Upper Austria and Austria against the Commission Decision 2003/653/EC of 2 September 2003 "relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty."[86]

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79. *Id.*
80. Council Directive 93/43/EEC, 1993 O.J. (L 175) 1 (EC).
81. *Schwarz*, 2005 ECJ CELEX LEXIS 511.
82. *Id.*
83. *Id.*
84. *Id.*
85. Joined Cases T-366/03 and T-235/04, Land Oberösterreich and Austria v. Comm'n, 2005 ECJ CELEX LEXIS 454.
86. Commission Decision 2003/653/EC, 2003 O.J. (L 230) 34, 34-43 (EC).

In accordance with Article 95(5) of the EC Treaty, Austria proposed a regulation banning the use of genetically modified organisms in the region of Upper Austria, in derogation to the provisions of the European Parliament and of Council Directive 2001/18/EC "on the deliberate release into the environment of genetically modified organisms."[87] The Commission adopted such a decision thereby rejecting the Austrian proposed legislation because the latter had failed to provide new scientific evidence or demonstrate that a specific problem existed in that region.[88] The Court confirmed the Commission decision.[89]

IV. OTHER RELEVANT NEWS

A. Regulations Entered Into Application

On November 25, 2005, the new allergen labeling requirements, introduced by Directive 89/2003/EC[90] amending Directive 2000/13/EC, became effective.

B. Unofficial Documents and Announcements

1. Food Additives

After the release of the results of the study on the artificial sweetener aspartame during the summer of 2005, the Italian scientific Ramazzini Institute published the completed study in November 2005 in the journal, *Environmental Health Perspectives*.[91] Following this controversial study, the EFSA asked the Director of the Institute to provide full research data so that a complete risk assess-

87. Regulation 2001/18/EC, 2001 O.J. (L 106) 1 (EC).

88. *Land Oberösterreich*, 2005 ECJ CELEX LEXIS 454.

89. *Id.*

90. *See* FoodQualitynews.com, Anthony Fletcher, *EU Strengthens Allergen Labeling*, Nov. 30, 2005, *at* http://www.foodqualitynews.com/news/ng.asp?id=64224-eu-directive-label.

91. *See* Morando Soffritti, et al., First Experimental Demonstration of the Multipotential Carcinogenic Effects of Aspartame Administered in the Feed to Sprague-Dawley Rats, 114 ENVIRONMENTAL HEALTH PERSPECTIVES 379 (March 2006), *available at* http://www.ehponline.org/members/2005/8711/8711.pdf.

ment could be administered within three to five months after the reception of the requested information.[92]

Based upon the study carried on rats, the Ramazzini Institute has been claiming that aspartame is a multi-potential carcinogenic agent, even at a daily dose of twenty milligrams/kilograms of body-weight.[93]

2. Feed Additives

On December 16, 2005, the Commission updated the Community Register of Feed Additives in accordance with Article 17 of Regulation (EC) 1831/2003 on additives for use in animal nutrition,[94] which has only informative purposes.

3. Nutrition Policy

On December 8, 2005, the Commission adopted a Green Paper "Promoting healthy diets and physical activity–a European dimension for the prevention of overweight, obesity and chronic diseases"[95] and launched a public consultation on how to reduce obesity levels and the prevalence of associated chronic diseases in the E.U.[96]

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92. *See* Press Release, EFSA, New Research Data on the Sweetener Aspartame to be Considered by EFSA's Scientific Experts (July 14, 2005, http://www.efsa.eu.int/press_room/press_release/1038/pr_aspartame_en1.pdf.

93. *See* Soffritti, *supra* note 91.

94. *See* European Commission, Community Register of Feed Additives Pursuant to Regulation (EC) No 1831/2003, *available at* http://europa.eu.int/comm/food/food/ animalnutrition /feedadditives /comm_register_19122005.pdf.

95. Promoting Healthy Diets and Physical Activity: a European Dimension for the Prevention of Overweight, Obesity and Chronic Diseases (Green Paper), COM (2005) 637 final (Aug. 12, 2005), *available at* http://europa.eu.int/comm/health/ph_determinants/life_style/nutrition/documents/nutrition_gp_en.pdf.

96. *See* European Commission's Health and Consumer Protection DG, *EU Launches Debate on how to Tackle Obesity*, Dec. 2005, http://ec.europa.eu/comm/dgs/health_consumer/consumervoice/cv_122005_en.pdf.

4. BSE in UK

In July 2005, the Commission adopted a reflection paper, the TSE Roadmap,[97] providing an outline of possible modifications to EU measures on BSE in light of the new developments (less cases of BSE reported, ...).[98] In September 2005, the Commission's Food and Veterinary Office published a favorable report regarding the situation in the UK after the ban on the export of live cattle and all cattle products from the UK subsequent to the BSE crisis in 1996.[99] Based upon the report, the possible lifting of the ban on British cattle could be discussed with Member States.

5. Wines

On September 14, 2005, the E.U. and the United States reached a first-phase agreement regarding the protection of E.U. wine designations and access of European wines to the American market.[100] They also agreed to initiate the negotiations of a second-phase agreement ninety days after the entry into force of the first agreement.[101]

97. European Commission, The TSE Roadmap, COM (2005) 322 final (July 15, 2005), *available at* http://ec.europa.eu/comm/food/food/biosafety/bse/roadmap_en.pdf.

98. Press Release, European Commission, Questions and Answers on TSE Roadmap (July 15, 2005), *available at* http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/263&format=HTML&aged=0&language=EN.

99. Press Release, European Commission, BSE: Prospects for lifting current restrictions on the trade of cattle and beef from the UK (Sept. 28, 2005), *available at* http://europa.eu/rapid/pressReleasesAction.do? reference= MEMO/05/342&format=HTML&aged=0&language=EN.

100. European Commission, United States Barriers to Trade and Investment, March 2006, at 26, 70, http://trade-info.cec.eu.int/doclib/docs/2006/march/tradoc_127632.pdf.

101. *Id.* at 70.

UNITED STATES FOOD LAW UPDATE

*Michael Tingey Roberts**

I. INTRODUCTION

This update summarizes significant changes and developments in food law during the second half of 2005. An update of developments in United States food law is published in each issue of the *Journal of Food Law & Policy*. Each update of United States food law follows the same organization: an update of recent case and administrative decisions; federal statutes, regulations, and agency guidelines; and interesting developments and pending legislation. This framework has limits. Not every change in national food law for the second half of 2005 is included; instead, this update is limited to significant changes in national law. New developments in state law, while certainly important and deserving of attention, are beyond the scope of this update.

These updates provide a starting point for scholars, practitioners, food scientists, and policymakers determined to understand the shaping of food law in modern society. Tracing the development of food law through these updates also builds an important historical context for the overall development of food law.

II. RECENT CASE DECISIONS

A. Judicial Challenge to the Enforcement of the Bovine Spongiform Encephalopathy (BSE) Final Rule

In August 2005, the United States Court of Appeals in the Ninth Circuit held that the district court in Montana erred in issuing

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a preliminary injunction prohibiting the implementation of a final rule known as the BSE final rule.[1] Bovine Spongiform Encephalopathy (BSE), commonly known as "mad cow disease," is a "degenerative, fatal disease affecting the nervous system in cattle."[2] Published in January 2005 by the United States Department of Agriculture (USDA) and effective in March 2005, the BSE final rule reversed a USDA ban of imports of cattle and edible bovine products from Canada.[3] This May 2003 ban was in response to the first case of BSE native to North America being diagnosed in a cow in Alberta, Canada.[4] The BSE final rule reversing the ban has been the subject of controversy due to ill-timed BSE episodes before and after publication and this well-publicized lawsuit in Montana that sought to enjoin its enforcement.[5]

1. Background of Case

Six days after USDA published the BSE final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF)[6] filed suit against USDA, seeking to enjoin the rule's implementation.[7] In early March 2005, the federal District Court of Montana granted R-CALF's motion for a preliminary injunction to pre-

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1. Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric., 415 F.3d 1078 (9th Cir. 2005).

2. *See* Geoffrey S. Becker, *Mad Cow Disease: Agricultural Issues for Congress*, CRS Issue Brief for Congress, CRS-1, Mar. 24, 2005, *available at* http://kuhl.house.gov/UploadedFiles/madcow.pdf.

3. Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities, 70 Fed. Reg. 460 (Jan. 4, 2005) (to be codified at 9 C.F.R. pts. 93-96). USDA published the BSE final rule through its branch, the Animal and Plant Health Inspection Service, commonly known as APHIS. *Id.*

4. The ban was effectuated when on May 20, 2003, the Secretary of USDA issued an Emergency Order adding Canada to the list of regions where BSE was known to exist. *See* Change in Disease Status of Canada Because of BSE, 68 Fed. Reg. 31,939 (May 29, 2003) (to be codified at 9 C.F.R. pts. 93-94). Under the USDA regulations, the Emergency Order effectively banned all imports of live ruminants or ruminant meat products from Canada. *See* 9 C.F.R. §§ 93.401, 94.18 (2005).

5. *See generally* Michael T. Roberts, *United States Food Law Update*, 1 J. FOOD L. & POL'Y 517, 530-32 (2005) (outlining the chronology of four mad cows found in the United States and the regulatory response and implications).

6. R-CALF is a non-profit cattle association that represents cattle producers, cattle backgrounders, and independent feedlot owners on matters of international trade and marketing. *Ranchers Cattlemen*, 415 F.3d at 1090 n.12.

7. *Id.* at 1090.

vent the BSE final rule from taking effect.[8] The court found the BSE final rule to be arbitrary and capricious in violation of the Administrative Procedures Act (APA).[9] The court's principle concern was that USDA "ignoring its statutory mandate to protect the health and welfare of the people of the United States, established its goal of reopening the border to the importation of live beef from Canada and thereafter attempted to work backwards to support and justify this *goal.*"[10] USDA then filed an appeal with the Ninth Circuit to reverse the district court decision.[11]

2. Ninth Circuit's Decision

The Ninth Circuit found that the district court failed under APA to defer to the USDA's judgment and expertise.[12] For example, the Ninth Circuit faulted the district court for rejecting the USDA's calculation in assessing the prevalence of BSE in the Canadian herd and in accepting the prevalence rate provided by R-CALF's expert, completely without explanation.[13] The Ninth Circuit attributed the district court's failure of deference to its misreading of the Animal Health Protection Act (AHPA),[14] the statute under which the BSE Final Rule was promulgated.[15] The Ninth Circuit noted that it was this misreading that led the district court to erroneously interpret APHA to require the USDA regulation to remove *all* risk of BSE entering the United States.[16]

The Ninth Circuit did not stop at finding that the district court failed to defer to the expertise of USDA.[17] The Ninth Circuit further found an adequate basis in the administrative record for the USDA's conclusion that the risks for reopening the border were acceptable.[18] The court relied on what it described as "multiple, interlocking safe-

8. Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric., 359 F. Supp. 2d 1058, 1074 (D. Mont. 2005), *rev'd*, 415 F.3d 1078 (9th Cir. 2005).

9. *Id.* at 1069.

10. *Id.* at 1066 (emphasis in original).

11. *See Ranchers Cattlemen*, 415 F.3d at 1092.

12. *Id.* at 1093.

13. *See id.* at 1093-94.

14. 7 U.S.C. §§ 8301-8321 (Supp. 2004).

15. *Ranchers Cattlemen*, 415 F.3d at 1095 (stating that the district court's misinterpretation of the statute resulted in a "fundamentally flawed" analysis of the Final Rule's compliance with APA).

16. *Id.*

17. *See id.* at 1094.

18. *Id.* at 1095-1104.

guards" within the regulatory system that minimize the risk of BSE to livestock and consumers in the United States.[19] These interlocking safeguards include the low incidence of BSE in Canadian cattle, Canada's feed ban and other measures to ensure that this low BSE incidence rate is decreasing, and the USDA's age restriction against imported cattle over thirty months of age.[20] The Ninth Circuit relied on the USDA's scientific evidence that Canadian cattle less than thirty months of age are less likely to be in the advanced stages of BSE.[21] Further safeguards inside the United States referred to by the Ninth Circuit that limit the spread of BSE include (i) the USDA requirement that Canadian cattle be immediately slaughtered or fed and then slaughtered before they reach the age of thirty months, (ii) the feed ban by the United States Food and Drug Administration (FDA) that ensures that the slaughtered animals are not then fed to other cattle, and (iii) the natural, biological defense of humans being less likely to contract the disease so easily.[22] The Ninth Circuit concluded that based on these interlocking safeguards and the administrative record, the USDA's reopening of the border to Canadian ruminants would not pose a serious risk and satisfied the requirements of AHPA.[23]

The Ninth Circuit's decision took the wind from the sails of the district court's decision. The district court issued an order to cancel a scheduled hearing to consider whether or not to issue a permanent injunction on Canadian cattle imports.[24] As of the end of 2005, the district court had not rendered a final decision. In October 2005, the Ninth Circuit denied R-CALF's request for a rehearing.[25] In light of the scope of the Ninth Circuit's decision, it is difficult to conceive of how the district court could make findings to support permanent injunctive relief.

19. *Id.* at 1095.
20. *Id.* at 1095-96.
21. *See id.* at 1096.
22. *Id.*
23. *Id.* at 1104.
24. *See* Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric., 359 F. Supp. 2d 1058, 1074 (D. Mont. 2005), *rev'd*, 415 F.3d 1078 (9th Cir. 2005). Docket.
25. *Ranchers Cattlemen*, 415 F.3d at 1078, Docket.

III. RECENT FEDERAL STATUTES

A. Rider Amending Organic Foods Production Act

In October 2005, Congress approved a rider to the 2006 agriculture appropriations bill that amends the Organic Foods Production Act of 1990 (OFPA).[26] The rider amendment was in response to *Harvey v. Veneman*, a decision made in January 2005 by the United States Court of Appeals in the First Circuit.[27]

1. Background

OFPA establishes national standards governing the marketing of food products that qualify for the "organic" United States Department of Agriculture (USDA) label.[28] To bear the USDA's "organic" seal, a food product must be at least ninety-five percent organic and produced and handled without the use of synthetic substances in accordance with an organic plan agreed to by an accredited certifying agent and by the producer and handler of the food product.[29] Synthetic substances that are exceptions to this general prohibition against such use are to be listed on a National List following notice and comment and are subject to review.[30]

Harvey held that certain provisions in the National Organic Program Final Rule[31] contravened OFPA.[32] Initially, the First Circuit first held that allowing a converting herd to be fed a diet of only eighty percent organic feed for a period of nine months for newly converting herds violated the OFPA provision that required all organic dairy animals to receive organic feed for twelve months prior to sale of milk or milk products.[33] The First Circuit also held that the Final Rule allowing the listing of synthetics for use in the handling of products labeled organic contravened the OFPA provision that prohibits synthetics in processed foods.[34] The First Circuit also

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26. *See* OFPA, 7 U.S.C. §§ 6501-6523 (2000), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005).

27. *See* 396 F.3d 28 (1st Cir. 2005).

28. *See* 7 U.S.C. § 6501.

29. *Id.* § 6504. Food labeled "100% organic" cannot contain non-organic ingredients or processing aids. 7 C.F.R. §§ 205.301(a), 205.33 (2005).

30. 7 U.S.C. §§ 6517(a), (d), (e); 6518(k), (l), (m).

31. 7 C.F.R. pt. 205 (2005).

32. *See* 396 F.3d at 45-46.

33. *Id.* at 44; *see also* 7 U.S.C. § 6509(e)(2); 7 C.F.R. § 205.236(a) (2005).

34. *Harvey*, 396 F.3d at 40; *see also* 7 U.S.C. § 6509(e)(2); 7 C.F.R. § 205.600(b).

remanded for declaratory judgment as to whether the Final Rule establishes a blanket exemption to the National List requirements for non-organic products that are not commercially available.[35] The First Circuit directs that such a blanket exemption would controvert the OFPA requirements for the National List.[36]

2. Rider

The rider to the 2006 agriculture appropriations bill amends OFPA and modifies the outcome in *Harvey*.[37] The rider allows organic dairy animals to be fed "transitional" organic feed during all of the twelve months of the conversion year.[38] This change in essence allows milk to be sold as organic as soon as the land qualifies as organic.[39] The rider does not allow, however, the twenty percent conventional feed as did the final rule reversed by *Harvey*.[40] In addition, the rider reverses the holding in *Harvey* prohibiting synthetic ingredients in handling by amending OFPA to remove restrictions on synthetic ingredients in post-handling, provided that they are listed on the National List.[41] Finally, the rider amends OFPA to permit the USDA Secretary to develop emergency procedures to designate for the National List agricultural products not commercially available in organic form for a maximum one year period.[42] Presumably these emergency procedures would be subject to notice and comment rulemaking under APA.

B. Sanitary Food Transportation Act of 2005

In August 2005, President George W. Bush signed into law the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A

35. *Harvey*, 396 F.3d at 36.

36. *Id.*

37. *See* Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2006, Pub. L. No. 109-97, § 724, 119 Stat. 2120, 2153 (2005).

38. *See* 7 U.S.C. § 6509(e)(2)(B). (Supp. 2005), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005).

39. *See id.* (stating that "crops and forage from land included in the organic system plan of a dairy farm that is in the third year of organic management may be consumed by the dairy animals of the farm" during the twelve month period before the sale of organic milk and milk products).

40. *See id.*

41. *See id.* §§ 6510(a)(1), 6517(c)(B)(iii).

42. *See id.* §6517(d)(6) OFPA, 7 U.S.C. § 6517(d)(6), *amended by* Pub. L. No. 109-97 (Nov. 10, 2005)..

Legacy for Users.[43] This act contains the Sanitary Food Transportation Act of 2005 (SFTA).[44] SFTA streamlines regulatory jurisdiction over the safe transportation of food and requires the establishment of safety transportation procedures to prevent the adulteration of food during transportation.[45]

Effective October 1, 2005, SFTA amends the Federal Food, Drug, and Cosmetic Act (FDCA) to assign the regulatory authority for food transportation to the United States Department of Health and Human Services (DHHS).[46] SFTA provides the Secretary of DHHS access to required food transportation records.[47] SFTA also requires the Secretary of the Department of Transportation (DOT), in consultation with DHHS and USDA, to establish procedures for transportation safety inspections to ensure that food is not adulterated during transportation by rail or motor vehicle.[48] SFTA further requires the Secretary of DOT to train DOT personnel in the appropriate use of the procedures and to notify DHHS or USDA of any instances of potential food contamination or adulteration of a food product identified during transportation safety inspections.[49] To ensure a working relationship between these three agencies under SFTA, the three agencies plan to enter into a memorandum of understanding.[50]

IV. RECENT FEDERAL REGULATIONS

A. The FDA Amendments to Feed Ban Rule

In October 2005, Food and Drug Administration (FDA) published a proposed feed ban rule to amend the agency's regulations to prohibit the use of cattle origin materials in the food or feed of *all* animals.[51] As BSE is transmitted to cattle when cattle eat BSE-infected tissue, the proposed rule is intended to shore up the FDA

43. Pub. L. No. 109-59, 119 Stat. 1144 (2005).
44. SFTA, Pub. L. No. 109-59, § 7201, 119 Stat. 1144, 1911 (2005).
45. *See id.* § 7202.
46. *Id.* §§ 7201, 7202, 7204.
47. *Id.* § 7202.
48. *Id.* § 7203.
49. *Id.*
50. *See* Safeguarding Food From Contamination During Transportation, 70 Fed. Reg. 76,228, 76,228-76,229 (Dec. 23, 2005).
51. Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. 58,570 (Oct. 6, 2005) (to be codified at 21 C.F.R. pt. 589).

regulatory protection by keeping the BSE-causing agent out of the animal food and feed supply.[52]

The proposed FDA feed ban prohibits the use in the food of all animals the following high risk cattle materials: brains and spinal cords from cattle thirty months of age and older, brains and spinal cords from cattle of any age not inspected and passed for human consumption, entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed, tallow that is derived from the materials prohibited by the proposed rule if the tallow contains more than 0.15 percent insoluble impurities, and mechanically separated beef that is derived from materials prohibited by the proposed rule.[53] All of these proposed prohibitions, except for those related to tallow, have already been banned from cattle feed since 1997.[54]

This FDA feed ban proposal is also notable for what it does not do.[55] It does not ban from non-ruminant feed some of the "specified risk materials" that are now banned by USDA from human food, such as distal ileum, tonsils, and other nervous tissue.[56] The proposal also does not ban from ruminant feeds the use of cattle blood and blood products, plate waste, and poultry litter.[57]

Further context for the overall effectiveness of FDA feed regulation is provided by a February 2005 report from the Government Accountability Office (GAO).[58] The GAO report concluded that while FDA had improved its management of the feed ban, program weaknesses continued to limit its effectiveness, placing United States cattle at risk of spreading BSE.[59] These reported program weak-

52. FDA News, *FDA Proposes Additional "Mad Cow" Safeguards*, Oct. 4, 2005, *available at* http://www.fda.gov/bbs/topics/news/2005/new01240.html [hereinafter FDA News]; *see also* Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. at 58,578-58,580.

53. Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. at 58,580-58,581.

54. FDA News, *supra* note 52.

55. *See* Geoffrey S. Becker, *Bovine Spongiform Encephalopathy (Mad Cow Disease): Agricultural Issues for Congress*, Nov. 7, 2005, at 8, *available at* http://www.nationalaglawcenter.org/assets/crs/IB10127.pdf (outlining the criticisms of the FDA feed rule).

56. *See id.*

57. *See* id.

58. *See* GAO, *Mad Cow Disease, FDA's Management of the Feed Ban Has Improved, But Oversight Weaknesses Continue to Limit Program Effectiveness*, GAO-05-101, Feb. 2005, *available at* http://www.gao.gov/new.items/d05101.pdf.

59. *Id.* at 5.

nesses include a variety of inspection, labeling, and communication problems.[60]

B. The FDA Amendments Allowing Use of Certain Cattle-Derived Materials in Human Foods and Cosmetics

In September 2005, FDA published several amendments to a July 2004 interim final rule on the use of materials derived from cattle in human food and cosmetics.[61] The interim final rule prohibits the use of cattle-derived materials that can carry the infectious agent for Bovine Spongiform Encephalopathy (BSE) in human foods, dietary supplements, and cosmetics.[62] After reviewing the comments received on the interim final rule, FDA decided to make some changes and clarifications prior to the expiration of the comment period.[63] The amendments to the interim final rule became effective in October 2005.[64]

The September 2005 amendments to the interim rule consist of three changes. First, the amendments allow use of the small intestine, provided that the cow's digestive tract, called the distal ileum, has been removed.[65] According to the scientific information provided to FDA during the interim rule's comment period, the distal ileum can be consistently and effectively removed from the other sections of the small intestine.[66] Thus, the entire small intestine is no longer designated as a prohibited cattle material.[67]

Second, the amendments clarify that milk and milk products, hides and hide-derived products, and tallow derivatives are not prohibited for use in human food and cosmetics.[68] Third, the amendments approve the use of a particular method for testing for impuri-

60. *Id.* at 16-30.

61. *See* Use of Materials Derived From Cattle in Human Food and Cosmetics, 70 Fed. Reg. 53,063 (Sept. 7, 2005) (to be codified at 21 C.F.R. pts. 189 and 700).

62. Use of Materials Derived From Cattle in Human Food and Cosmetics, 69 Fed. Reg. 42,256 (July 14, 2004) (to be codified at 21 C.F.R. pts. 189 and 700).

63. Press Release, Food & Drug Admin., FDA Amends Interim Final Rule "Use of Materials Derived from Cattle in Human Food and Cosmetics," (Sept. 6, 2005), *available at* http://www.fda.gov/bbs/topics/news/2005/NEW01229.html.

64. Use of Materials Derived From Cattle in Human Food and Cosmetics, 70 Fed. Reg. At 53,063.

65. *Id.* at 53,065.

66. *Id.* at 53,064-65.

67. *See id.* at 53,065.

68. *See id.* at 53,065-66.

ties in tallow that is less costly and requires less specialized equipment than previous methods.[69]

C. The FSIS Amendments Allowing Use of Certain Specified Risk Materials for Human Food

In September 2005, on the same day FDA published its amendments to the FDA July 2004 interim final rule regarding the use of materials derived from cattle in human food and cosmetic, USDA through its branch agency the Food Safety and Inspection Service (FSIS) published a similar notice.[70] The FSIS amendments amended a January 2004 FSIS interim final rule prohibiting the use of specified risk materials for human food and imposing requirements for the disposition of non-ambulatory cattle.[71] The FSIS amendments permit beef intestine, excluding the distal ileum, to be used for human food and includes methods for removing the distal ileum from the small intestine.[72] The FSIS amendments also require foreign countries exporting meat products to the United States to comply with the same requirements in the amended regulation.[73]

D. The FDA Food CGMP Modernization Recommendations

In November 2005, a "Modernization Working Group" published a number of new recommendations for the FDA's Current Good Manufacturing Practice (CGMP) regulations.[74] The working group was formed in 2002 by the FDA's Center for Food Safety and Applied Nutrition (CFSAN) specifically to examine the CGMP regulations and determine whether the regulations were in need of

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69. *See id.* at 53,066 (crediting the creation of the approved method as being devised and used by the American Oil Chemist Society).

70. *See* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 70 Fed. Reg. 53,043 (Sept. 7, 2005) (to be codified at 9 C.F.R. pts. 310 and 318).

71. *Id.*; *see also* Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (Jan. 12, 2004) (to be codified at 9 C.F.R. pts. 309, 310, 311, 318, and 319).

72. Prohibition of the Use of Specified Risk Materials, 70 Fed. Reg. at 53,047.

73. *Id.*

74. Center for Food Safety and Applied Nutrition (CFSAN), *Food CGMP Modernization–A Focus on Food Safety*, Nov. 2, 2005, *available at* http://www.cfsan.fda.gov/~dms/cgmps3.html [hereinafter CFSAN Food CGMP].

modernization.[75] The CGMP regulations were last modified in 1986.[76]

Determining that the CGMP regulations were in need of modernization, the working group noted two important changes within the food industry since 1986—an increased market for ready-to-eat foods and an expansion of scientific understanding of foodborne illnesses, such as *Listeria monocytogenes*, *Escherichia coli* O157:H7, *Campylobacter jejuni*, *Cryptosporidium parvum*, *Cyclospora cayetanensis*, and *Norovirus*.[77]

The modernization recommendations made by the working group are based on two predicates. The first predicate is matching risk-based regulation to food safety outcomes.[78] The other key predicate is preserving for food manufacturers the flexibility to implement required controls to unique situations as they deem advisable.[79]

Building on these predicates and adhering to comments made to FDA in response to a series of public meetings, the working group offered seven specific modernization recommendations.[80] First, require "appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise" in food and personal hygiene, food protection, and employee health.[81] Second, require processors of foods "containing one or more of the eight major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) to have a food allergen control plan."[82] Third, require processors of ready-to-eat foods that support the growth of *Listeria monocytogenes* to devise a written environmental pathogen control program.[83] Fourth, require food processors to develop and maintain written sanitation procedures that define the scope, objectives, management and recordkeeping responsibilities, monitoring, and corrective action associated with the sani-

75. *Id.*; *see also* Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 C.F.R. pt. 110 (2005).

76. *See* CFSAN Food CGMP, *supra* note 74.

77. *Id.*

78. *See id.*

79. *See id.*

80. *See* Food; Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 40,312 (July 2, 2004) (to be codified at 21 C.F.R. pt. 110); Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 29,220, 29,222 (May 21, 2004) (to be codified at 21 C.F.R. pt. 110).

81. *See* CFSAN Food CGMP, *supra* note 74.

82. *See id.*

83. *See id.*

tation procedure.[84] Fifth, obtain further comments about removing the exclusion from CGMP compliance for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities.[85] Sixth, require food processors to maintain critical records to be made available for review and evaluation by FDA investigators.[86] Seventh, obtain further comments about the use by food processors of time-temperature relationships to incorporate into regulations or guidance for proper refrigerated storage or hot holding.[87]

E. Health Claim Activity

A health claim is considered a labeling claim that characterizes the relationship of a substance to a disease or health-related condition.[88] The announcement in 2004 of two new qualified health claims–omega-3 fatty acids and olive oil–signified a new era of the FDA's treatment of health claims.[89] Since then, including the second half of 2005, there has been much activity concerning health claims.

1. Background

Prior to the 1980s, few health claims were made for food products.[90] FDA treated health claims for food as bringing that food within the FDA's definition of a drug ("intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease").[91] When firms began making health claims for foods without requesting the FDA's approval,[92] FDA published in 1987 a proposed rule

84. *See id.*
85. *See id.*
86. *See id.*
87. *See id.*
88. Health Claims: General Requirements, 21 C.F.R. § 101.14(a)(1) (2005).
89. *See generally* Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD L. & POL'Y 187, 206-08 (2005).
90. *See, e.g.*, Clement Dimitri Pappas, *Maintaining a Level Playing Field: The Need for a Uniform Standard to Evaluate Health Claims for Foods and Dietary Supplements*, 57 FOOD & DRUG L.J. 25, 27 (2002) (implying that FDA faced increased pressure in the 1980s as scientific studies began to show a connection between diet and chronic disease).
91. *See* FDCA, 21 U.S.C. § 321(g)(1)(B) (2000).
92. *See, e.g.*, Pappas, *supra* note 90, at 27 (discussing the successful efforts of Kellogg Company to get permission from the Federal Trade Commission and the National Cancer Institute to list the health benefits of consuming bran on its cereal packaging, a move that was against the FDA regulations at the time and helped lead

addressing health claims.[93] In 1990, FDA published a proposed regulation to establish rules for health claims for foods.[94] Shortly after the 1990 proposed rule, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA), authorizing FDA to allow certain health claims to appear in food labeling.[95] Pursuant to NLEA, FDA was to evaluate health claims using a standard of significant scientific agreement, which required that a sufficient body of sound, relevant scientific evidence show consistency across different studies and among different researchers.[96]

In recent years, judicial scrutiny of the FDA regulatory treatment of health claims has pressured the agency to change its policy.[97] In response to the decision by the United States Court of Appeals for the District of Columbia in *Pearson v. Shalala*,[98] FDA adopted a weight-of-the-scientific-evidence standard in evaluating health claims, which is less stringent than the significant-scientific standard.[99]

In response to the holding of United States District Court for the District of Columbia in *Whitaker v. Thompson*,[100] FDA has adopted an even lower standard of approval by tempering the weight-of-evidence standard "by the test of credible evidence."[101] As of September 2003, FDA implemented, on an interim basis, an evidence-based ranking system that assigns a final rank to the evidence

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to the agency's increased willingness to consider the allowance of qualified health claims).

93. *See* Food Labeling; Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28,843 (Aug. 4, 1987).

94. Food Labeling; Health Messages and Label Statements; Reproposed Rule, 55 Fed. Reg. 5176 (Feb. 13, 1990) (codified at 21 C.F.R. § 101 (2005)).

95. Nutrition Labeling and Health Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

96. *See* 21 U.S.C. § 343(r)(3)(B) (Supp. 2005).

97. *See* Roberts & Alsbrook, *supra* note 89, at 202-06.

98. 164 F.3d 650 (D.C. Cir. 1999).

99. *See, e.g.*, Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for HealthClaims on the Labeling of Conventional Human Food and Human Dietary Supplements; Availability, 68 Fed. Reg. 41,387, 41,389-90 (July 11, 2003).

100. 248 F. Supp. 2d 1 (D.D.C. 2002).

101. *See* Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for HealthClaims on the Labeling of Conventional Human Food and Human Dietary Supplements, 68 Fed. Reg. at 41,388-89.

in support of the health claim and accommodates the use of disclaimers and clarifying language.[102]

2. The FDA Decisions on Health Claim Petitions

In the second half of 2005, employing its evidence-based-ranking system, FDA evaluated several qualified health claims. In August 2005, FDA approved a qualified health claim for chromium picolinate and reduced risk of type 2 diabetes.[103] FDA denied, however, a health claim for chromium picolinate and reduced risk of cardiovascular disease when caused by (i) insulin resistance, abnormally elevated blood sugar levels, or type 2 diabetes, (ii) retinopathy when caused by abnormally high blood sugar levels, and (iii) kidney disease when caused by abnormally high blood sugar levels.[104]

In October 2005, FDA approved a qualified health claim for calcium and reduced risk of colon/rectal cancers and recurrent colon polyps[105] and for calcium and reduced risk of essential hypertension, gestational hypertension, and preeclampsia.[106] FDA denied, however, a health claim for calcium and reduced risk of breast and prostate cancers.[107]

In November 2005, FDA approved a qualified health claim for tomatoes or tomato sauce and reduced risk of prostate, gastric, ovarian, and pancreatic cancers.[108] FDA denied, however, a health claim

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102. *See generally* Health Claims: General Requirements, 21 C.F.R. § 101.14 (2005); Petitions for Health Claims, 21 C.F.R. § 101.70 (2005); *see also* Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for HealthClaims on the Labeling of Conventional Human Food and Human Dietary Supplements, 68 Fed. Reg. at 41,389.

103. CFSAN, *Qualified Health Claims: Letter of Enforcement Discretion–Chromium Picolinate and Insulin Resistance*, Aug. 25, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhccr.html.

104. *Id.*

105. CFSAN, *Qualified Health Claims: Letter Regarding Calcium and Colon/Rectal, Breast, and Prostate Cancers and Recurrent Colon Polyps*, Oct. 12, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhcca2.html [hereinafter CFSAN Calcium and Colon/Rectal Letter].

106. CFSAN, *Qualified Health Claims: Letter of Enforcement Discretion–Calcium and Hypertension; Pregnancy-Induced Hypertension; and Preeclampsia*, Oct. 12, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhcca3.html.

107. CFSAN Calcium and Colon/Rectal Letter, *supra* note 105.

108. CFSAN, *Qualified Health Claims: Letter Regarding "Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition)"*, Nov. 8, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhclyco.html; CFSAN, *Qualified Health*

for tomato-based foods other than tomato sauce and prostate and ovarian cancers; for all tomato-based foods and gastric and pancreatic cancers; for tomatoes and ovarian cancer; for tomatoes or tomato-based foods and lung, colorectal, breast, cervical, and endometrial cancers; and for tomatoes and tomato products which contain lycopene and reduced risk of prostate cancer.[109]

In December 2005, in response to a petition by the National Barley Foods Council, FDA published an amendment to the regulation authorizing a health claim on the relationship between oat beta-glucan soluble fiber and reduced risk of coronary heart disease (CHD).[110] The amendment adds barley as an additional eligible source of beta-glucan soluble fiber.[111]

3. The FDA Evaluation of Effectiveness of Qualified Health Claims

In September 2005, FDA released a report on its consumer research of qualified health claims, entitled "Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims."[112] The purpose of the report is to provide FDA with information about consumers' reactions to qualified health claims and to understand the most effective way to present scientifically based, truthful, and non-misleading information to consumers.[113] The report revealed serious questions about the effectiveness of strength of science disclaimers.[114] The report, as well as other related studies, was the subject of a November 2005 public meeting held by FDA to evaluate the effectiveness of qualified health claims.[115] Underscoring

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Claims Letter Regarding Tomatoes and Prostate Cancer (Lycopene Health Claim Coalition), Nov. 8, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhclyco2.html.

109. CFSAN, *Qualified Health Claims: Letter Regarding "Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition)"*, Nov. 8, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhclyco.html; CFSAN, *Qualified Health Claims Letter Regarding Tomatoes and Prostate Cancer (Lycopene Health Claim Coalition)*, Nov. 8, 2005, *available at* http://www.cfsan.fda.gov/~dms/qhclyco2.html.

110. Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease, 70 Fed. Reg. 76,150, 76,150 (Dec. 23, 2005).

111. *Id.*

112. Brenda M. Derby & Alan S. Levy, *Working Paper: Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 2005), *available at* http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf.

113. *See id.* at 6.

114. *See id.* at 34-39.

115. *See* Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments, 70 Fed. Reg. 60,749, 60,751 (Oct. 19, 2005) (to be codified at 21 C.F.R. pt. 101).

the importance of the report and future studies on the effectiveness of science disclaimers on qualified health claims is the position of the *Pearson* and *Whitaker* cases that a complete ban on a health claim, even under certain circumstances, is only appropriate when the government demonstrates with empirical evidence that science disclaimers "would bewilder consumers and fail to correct for deceptiveness."[116]

F. Tomato Color Claim

In July 2005, FDA amended the color additive regulations to provide for the safe use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods.[117] The term "color additive," as defined by the United Stated Food, Drug and Cosmetics Act (FDCA), means any material when added to food that is capable of imparting color, except those that the Secretary of the Department of Health and Human Services (DHHS), by regulation, determines are used "solely for a purpose or purposes other than coloring."[118] Under FDCA, FDA must preapprove color additives, which are subject to an extensive notice-and-comment rulemaking procedure.[119] To be approved, color additives must be shown with reasonable certainty to pose no risk to human health, not deceive consumers, and accomplish an intended effect.[120] Unlike with food additives, FDCA does not exempt generally recognized as safe (GRAS) color additives or prior sanctioned color additives from the requirement for pre-approval.[121]

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116. *Pearson v. Shalala*, 164 F.3d 650, 659-60 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 5 (quoting *Pearson*, 164 F.3d at 658).

117. Listing of Color Additives Exempt From Certification; Tomato Lycopene Extract and Tomato Lycopene Concentrate, 70 Fed. Reg. 43,043 (July 26, 2005) (to be codified at 21 C.F.R. pt. 73).

118. FDCA, 21 U.S.C. § 321(t)(1)(B) (2000).

119. *Id.* § 379e(a)(1)(A).

120. *Id.* § 379e(b).

121. FDCA exempts two groups of substances from the food additive approval process. The first group is substances determined safe for use by FDA or USDA in specified food products prior to the 1958 amendment. These substances are designated as prior-sanction substances. The second group is substances known as GRAS, an acronym for the phrase "Generally Recognized as Safe." A substance is GRAS if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. FDCA, 21 U.S.C. § 321(s) (2000).

G. Food Labeling and Sodium Levels

In September 2005, FDA published a final rule that amends its regulations concerning the maximum sodium levels for foods that bear the implied nutrient content claim "healthy."[122] The final rule retains the current, less restrictive, "first-tier" sodium level requirements for all food categories, including individual foods (480 milligrams (mg)) and meals and main dishes (600 mg).[123] The final rule eliminates the "second-tier," more restrictive, sodium level requirement for all food categories, which had been stayed until January 2006.[124]

The amendment responds to industry and consumer advocate concerns that implementing the second-tier sodium requirements would risk the elimination of existing "healthy" products from the marketplace because the levels were unattainable.[125]

V. RECENT GUIDELINES

A. FDA Issues Final Rule on Maintenance of Records Under Bioterrorism Act

In November 2005, the United Stated Food and Drug Administration (FDA) issued a guidance document that includes answers to inquiries regarding the implementation of the FDA recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness Act, commonly referred to as the Bioterrorism Act.[126] These recordkeeping provisions were published in December 2004 by FDA in a final rule.[127] The rule was passed to help address concerns about the vulnerability of the country's food supply.[128] The recordkeeping

122. Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy," 70 Fed. Reg. 56,828 (Sept. 29, 2005) (to be codified in 21 C.F.R. pt. 101).

123. *Id.*

124. *Id.* at 56,828-29.

125. *Id.* at 56,830.

126. CFSAN, *Questions and Answers Regarding Establishment and Maintenance of Records*, Nov. 10, 2005, *available at* http://www.cfsan.fda.gov/~dms/recguid2.html; *see also* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002) (codified in scattered sections of 42 U.S.C.).

127. Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562 (Dec. 9, 2004) (to be codified at 21 C.F.R. pts. 1 and 11).

128. *Id.* at 71,562.

rule is the fourth rule in a series of regulations issued by FDA under the Bioterrorism Act.[129] The rule applies to all those who manufacture, process, pack, transport, distribute, receive, hold, or import food.[130] Farms, restaurants, foreign persons (other than persons who transport food within the United States), and certain other entities are excluded from the rule, which also allows for special exceptions for the makers of food contact substances.[131]

The guidance document is designed to help FDA field the large number of questions regarding the recordkeeping final rule.[132] The document follows a question-and-answer format that will periodically be updated as FDA receives and responds to additional questions.[133]

VI. RECENT DEVELOPMENTS

A. GAO Report Criticizes the FDA's BSE Feed Testing Program

In October 2005, the General Accounting Office (GAO) released a report citing several flaws in the small feed testing program the United Stated Food and Drug Administration (FDA) implemented in 2003.[134] The October 2005 GAO report acknowledged that the small feed testing program "is a small part of [the] FDA's BSE oversight effort and is one of several methods FDA uses to monitor for compliance with the feed-ban rule."[135] The GAO report further notes, however, that the program vies for the FDA's limited BSE oversight resources and has several weaknesses in design and implementation that need to be addressed to improve its effective-

129. *See* Press Release, FDA, FDA Issues Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply Under the Bioterrorism Act (Dec. 6, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01143.html.

130. Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. at 71,562.

131. *Id.*

132. Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; Availability, 70 Fed. Reg. 53,728 (Sept. 12, 2005) (to be codified at 21 C.F.R. pt. 1).

133. *Id.*

134. *See* GAO, *Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 with Recommendations for Making the Program a Better Oversight Tool*, GAO-06-157R, Oct. 2005, at 1-2, *available at* http://www.gao.gov/new.items/d06157r.pdf.

135. *Id.* at 3.

ness.[136] The purpose of the small feed testing program is to "collect and analyze cattle and other types of animal feed and feed ingredients to determine whether feed that could be fed to cattle might contain material prohibited by [the] FDA's feed-ban rule."[137]

The GAO report specifically faults the program for three failures: first, not requiring the FDA district offices to document their follow-up reviews or the basis for their final determinations on samples that the laboratories identified as potentially containing banned protein products; second, taking longer than thirty days from the date the sample was collected until the date the laboratory completed its analysis for over half the samples tested, including twenty-one samples that took longer than 100 days; and third, the FDA managers not adequately overseeing the feed testing program.[138]

The GAO report recommends several steps for FDA to take to improve the effectiveness of the program, including implementation of an internal field management directive and an assignment memorandum, enforcement of proper periods of time for testing samples and follow-up activities, and increased oversight by headquarter managers.[139]

In comments included in the GAO report, FDA expressed concern with the report's undue emphasis on "one small aspect of BSE oversight efforts."[140] The GAO report did note that FDA plans to fully implement the directive and guidance issued earlier in 2005.[141]

136. *See id.*
137. *Id.* at 2.
138. *Id.* at 4, 7-13.
139. *Id* at 15.
140. *Id.*
141. *Id.*