2012 DEVELOPMENTS IN FOOD LAW AND POLICY†

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† This Article is based on the 2012 Food Law update prepared for and presented at the American Agricultural Law Association's Annual meeting in October 2012. The information contained herein generally reflects the law as of the date of the presentation, with limited exceptions. Updates have been added when significant events (such as an election or a suspension of a regulation) have taken place in the interim.

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I. INTRODUCTION

Hardly a day seemed to pass in 2012 without a morsel of food news making headlines. Although some of the widely covered stories were silly and sensational (the end of Twinkies, worldwide bacon shortages, etc.), many others were sobering and have complicated, contested, legal dimensions. Americans, for example, reacted with horror upon learning that many of their iconic foods might not be as wholesome as they believed: hamburgers made of so-called "pink

slime," rice products with alarming levels of arsenic, killer cantaloupes laced with *Listeria*, and *Salmonella*-tainted peanut butter. Unsated school children mounted a musical protest against USDA's attempts to improve the nutritional profile of school food, prompting the Agency to reconsider some of its new regulations. And consumers clamored for additional information about the contents of food products and packaging, taking their concerns to both FDA and the polls.

This Article reviews significant developments in 2012 across the broad field of Food Law. Part II provides detail about some of 2012's most widely-reported and controversial food stories, but it goes far beyond the headline news. This Article examines recent developments about (III) food safety and foodborne illness, (IV) food adulteration and food additives, (V) food marketing, labeling, and advertising, (VI) food biotechnology, (VII) organics and alternative agriculture, (VIII) food insecurity and nutrition programs, (IX) livestock and meat production, (X) farm and food labor, and (XI) obesity and food-related chronic disease.

II. FOOD FIGHTS: WIDELY COVERED CONTROVERSIES

A. *Arsenic in Foods Containing Rice*

On the heels of the controversies regarding arsenic levels in apple juice and chicken that received widespread media attention in 2011, researchers at Dartmouth College found elevated arsenic levels in foods that use brown rice syrup and other rice-based ingredients, including infant formula, cereal bars, energy bars, and energy shots.[1] The peer-reviewed study, published in the *Environmental Health Perspectives* journal, found:

- Two of seventeen infant formulas tested listed organic brown rice syrup as the primary ingredient.[2] One had a total arsenic concentration (including both inorganic and organic arsenic) that was six times the federal limit of ten parts per billion (ppb) for total arsenic in bottled or public drinking water.[3] The standard of ten ppb for drinking water was used as a reference limit because FDA has not defined limits for the amount of arsenic in food.[4]

1. Brian P. Jackson et al., *Arsenic, Organic Foods, and Brown Rice Syrup*, 120 ENVTL. HEALTH PERSP. 623 (2012).
2. *Id.* at 624.
3. *Id.* at 624 tbl.1.
4. *Id.* at 625.

- Cereal bars that did not list organic brown rice syrup, rice flour, rice grain, or rice flakes among the top five ingredients had arsenic levels ranging from eight to twenty-seven ppb.[5] Bars containing rice, whether as syrup or in an alternate form, had arsenic levels ranging from twenty-three to 128 ppb.[6]

- "Energy shots" typically used by endurance athletes contained eighty-four and 171 ppb of total arsenic respectively.[7]

In response to this study, FDA stated that it was expanding its surveillance activities of rice and rice products to determine the level and types of arsenic typically found in such products.[8] The FDA report was scheduled to be completed in spring 2012, but that timeframe passed without the report being issued.[9]

Even more recently, *Consumer Reports*, which drew attention last year for its coverage of arsenic in apple and grape juice,[10] added to the public concern over arsenic in rice by reporting the alarming results of its test of more than 200 rice-based food items, including baby cereals, crackers, milk, pasta, flour, and an array of brown, white, and basmati rice.[11] Levels of total arsenic, both organic and inorganic, observed in the *Consumer Reports* study were consistently far in excess of the federal arsenic-in-drinking-water limit of ten ppb.[12] On the heels of the *Consumer Reports* publication, FDA reiterated that it had been actively investigating arsenic levels in rice and expected to complete its data collection by the end of the 2012 calendar year.[13] FDA noted that, to date, its results have been consistent with *Consumer Reports'* published findings.[14]

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5. *Id.* at 625 tbl.2.
6. *Id.*
7. *Id.* at 625.
8. Press Release, U.S. Food & Drug Admin., FDA Statement on Arsenic in Brown Rice Syrup (Feb. 17, 2012), *available at* http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm292531.htm.
9. *See id.*
10. *See Results of Our Apple Juice and Grape Juice Tests*, CONSUMER REP., Jan. 2012, http://news.consumerreports.org/Consumer%20Reports%20Arsenic%20Test%20Results%20January%202012.pdf.
11. *Arsenic in Your Food: Our Findings Show a Real Need for Federal Standards for This Toxin*, CONSUMER REP., Nov. 2012, http://www.consumerreports.org/cro/arsenic1112.htm.
12. *Id.*; *see also* 40 C.F.R. § 141.62 (2012) (setting maximum contaminant levels for inorganic contaminants).
13. Press Release, U.S. Food & Drug Admin., FDA Releases Preliminary Data on Arsenic Levels in Rice and Rice Products (Sept. 19, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm319972.htm.
14. *Id.*

The USA Rice Federation issued a statement criticizing the *Consumer Reports* article as

> incomplete and inaccurate on many levels [because] it employs an 'arsenic content standard' that simply doesn't exist in federal law. It cites federal health data to allege health risk from arsenic ingestion when that data is based on arsenic *excreted from*, rather than *absorbed by*, the body. It offers consumption advice without addressing all of the relevant public health issues that must be taken into account.[15]

This trade association also set up an informational website regarding arsenic levels in rice.[16] Days after the *Consumer Reports* story broke, Representatives Rosa Delauro (D-Conn.), Frank Pallone (D-N.J.), and Nita Lowey (D-N.Y.) announced their intent to introduce legislation that would require FDA to implement a maximum level of arsenic allowed in rice or foods containing rice, regardless of whether the results of the Agency's study match the findings reported by *Consumer Reports*.[17] The proposed legislation has, not surprisingly, been given a catchy title: Reducing Food-Based Inorganic and Organic Compounds Exposure Act of 2012 (RICE).[18]

While the possibility that a plant-based food that is widely regarded as healthy, affordable, and nutritious may also be full of a carcinogenic compound is troubling, responding myopically by focusing solely on controlling the levels of harmful substances in one agricultural product will not do much to improve the overall safety of our food supply. Rather, the arsenic in rice scare should prompt "a more holistic assessment of agricultural production methods—an assessment that takes into account the full spectrum of considerations and not just product-specific economic justifications."[19]

B. *Lean Finely Textured Beef / "Pink Slime"*

Lean Finely Textured Beef (LFTB) is a food product made by recovering tiny shards of lean beef from the fatty scraps of bovine carcasses that have al-

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15. Press Release, USA Rice Fed'n, Rice Is an Important, Nutritional and Safe Part of a Healthy Diet (Sept. 19, 2012), *available at* http://www.usarice.com/doclib/230/6245.pdf.

16. *An Online Resource for Information on Arsenic in Rice*, USA RICE FED'N, http://www.arsenicfacts.usarice.com/ (last visited May 10, 2013).

17. Press Release, Office of Congressman Frank Pallone, Jr., DeLauro, Pallone, Lowey Introduce Legislation to Limit Arsenic in Rice (Sept. 21, 2012), *available at* http://pallone.house.gov/press-release/delauro-pallone-lowey-introduce-legislation-limit-arsenic-rice.

18. RICE Act, H.R. 6509, 112th Cong. (2012).

19. Susan A. Schneider, *Arsenic and Rice*, AGRIC. L. (Sept. 22, 2012, 12:37 PM), http://aglaw.blogspot.com/2012/09/arsenic-and-rice.html.

ready been cut into steaks and roasts.[20] Reclaiming the meat scraps used for LFTB requires a multi-step process of heating carcass parts that would not otherwise have been used for human food, separating the lean from the fat in a centrifuge, and treating the recovered lean pieces with ammonium hydroxide gas to rid the product of *E. coli* and other pathogens.[21] This advanced process results in the creation of a substance that has come to be known in the popular press and consumer consciousness as "pink slime."[22] LFTB was widely used as filler in some seventy percent of ground beef sold in the United States until media attention generated public outcry and widespread backlash against the product, which is technically safe but admittedly unappetizing.[23] For comprehensive coverage of the LFTB/pink slime controversy, see the extensive collection of relevant articles at FoodSafetyNews.com.[24] Other consequences of recent attention to LFTB include:

- *REAL Beef Act*: The "Requiring Easy and Accurate Labeling of Beef Act," or "REAL Beef Act," which would require manufacturers to accurately label products containing LFTB trimmings was introduced in the House by Representative Chellie Pingree (D-Me.).[25] The proposed legislation, introduced in direct response to the "pink slime" controversy, would mandate LFTB labels "at the final point of sale."[26] The bill, which was introduced in March 30, 2012, was referred to the House Committee on Agriculture but was never passed out of committee.[27]

- *USDA Allows Voluntary Labeling of LFTB*: USDA is granting manufacturers' requests to voluntarily label LFTB trimmings in their products.[28] LFTB producers and marketers expressed interest in voluntary labeling

20. *BPI and Pink Slime: An Updated Timeline*, FOOD SAFETY NEWS (Sept. 17, 2012), http://www.foodsafetynews.com/2012/09/bpi-and-pink-slime-an-updated-timeline/.
21. *Id.*
22. *Id.*
23. *See id.*
24. *See generally Pink Slime*, FOOD SAFETY NEWS, http://www.foodsafetynews.com/tag/pink-slime/ (last visited May 10, 2013) (providing links to articles on the pink slime controversy).
25. REAL Beef Act, H.R. 4346, 112th Cong. (2012).
26. *Id.*
27. 158 CONG. REC. H1811 (daily ed. Mar. 30, 2012).
28. Rita Jane Gabbett, *Exclusive: USDA Will Approve LFTB Label Requests*, MEATINGPLACE, Apr. 2, 2012, http://www.meatingplace.com/Industry/News/Details/31955?item=31955&allowguest=true.

because they believe that consumers would not have been outraged about the product if it had been more precisely labeled in the first place.[29]

- *Effect on the Ground Beef Market*: AFA Foods, a ground-beef processor owned by Yucaipa Cos., sought Chapter 11 bankruptcy protection with a plan to sell some assets after the media revealed "pink slime" and ensuing consumer revulsion "dramatically reduced the demand for all ground beef products."[30] AFA's assets throughout the country have been purchased by major industry players including Cargill, CTI Foods, FPL Food, and Tri West Investments.[31]

- *BPI Sues for Defamation*: ABC News, Diane Sawyer, several ABC News employees, and two former USDA employees are the targets of a defamation suit filed by Beef Products, Inc. (BPI), the infamous maker of LFTB.[32] In its lengthy, 256 page complaint, BPI alleges the "[d]efendants knowingly and intentionally published nearly 200 false and disparaging statements regarding BPI and its product, lean finely textured beef ('LFTB')" and seeks some $1.2 billion in damages.[33] BPI filed its case in South Dakota, likely to take advantage of the state's food libel law, which may provide an alternate cause of action in the event that the common law defamation claims do not survive.[34]

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29. JoNel Aleccia, *'Pink Slime' in Your Meat? Labels to Tell You, USDA Says*, NBC NEWS (Apr. 4, 2012), http://vitals.nbcnews.com/_news/2012/04/04/11006836-pink-slime-in-your-meat-labels-to-tell-you-usda-says?lite.

30. Phil Milford & Shruti Date Singh, *AFA Foods Files Bankruptcy Citing 'Pink Slime' Coverage*, BLOOMBERG (Apr. 2, 2012), http://www.bloomberg.com/news/2012-04-02/afa-foods-files-bankruptcy-citing-pink-slime-coverage.html (quoting AFA interim CEO Ron Allen in court papers).

31. *Fourth AFA Foods Plant Sold*, NAT'L PROVISIONER, July 16, 2012, http://www.provisioneronline.com/articles/print/98134-fourth-afa-foods-plant-sold.

32. Beef Prods., Inc. v. ABC, Inc., No. 4:12-cv-04183 (D.S.D. Oct. 24, 2012).

33. *Id.* at ¶¶1, 24, 701; *see also* Kat Kinsman & Sarah LeTrent, *'Pink Slime' Manufacturer Sues ABC News for $1.2 Billion in Damages*, CNN EATOCRACY BLOG (Sept. 13, 2012, 2:00 PM), http://eatocracy.cnn.com/2012/09/13/pink-slime-manufacturer-sues-abc-news-for-1-2-billon-in-damages/ (discussing the lawsuit).

34. Nate Robson, *Experts: BPI Defamation Lawsuit Faces Legal Hurdles*, SIOUX CITY J., Sept. 13, 2012, http://siouxcityjournal.com/news/local/experts-bpi-defamation-lawsuit-faces-legal-hurdles/article_7743ee82-0f31-5fd7-af58-95619e6c6ad8.html.

In an effort to improve its standing in the court of public opinion, BPI has launched and is aggressively advertising BeefisBeef.com, a promotional website aimed at rehabilitating the reputation of its LFTB products.[35]

C. *Labeling of Genetically Engineered Foods*

1. *California Proposition 37*

California voters had the opportunity to decide whether genetically engineered food sold in their state must be labeled as such.[36] Although Proposition 37 enjoyed wide margins of support early in the election cycle, the ballot initiative was roundly defeated after the food industry mounted an extremely well-financed (and, according to some, unscrupulous) campaign against it.[37] Proposition 37 would have required non-exempt foods offered for retail sale that have been, or that may have been, entirely or partially produced with genetic engineering be labeled with a statement disclosing that fact.[38] As the term is used in the ballot initiative, "genetically engineered" means the manipulation of an organism's genetic material through methods such as "direct injection of nucleic acid into cells or organelles, or . . . fusion of cells . . . in a way that does not occur through natural multiplication or natural recombination" such as standard methods of plant hybridization.[39]

Had it been enacted, genetically engineered foods sold at retail in California would have been deemed "misbranded" unless they complied with certain requirements. For raw agricultural products, the words "Genetically Engineered" would have been required on the front of the package or, for food not separately packaged, on a label appearing on the retail display shelf or bin; and for *proc-*

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35. *The Facts on Lean Finely Textured Beef*, BEEFISBEEF, http://www.beefisbeef.com/ (last visited May 10, 2013).

36. *The California Right to Know Genetically Engineered Food Act*, *in* CALIFORNIA GENERAL ELECTION TUESDAY, NOVEMBER 6, 2012: OFFICIAL VOTER INFORMATION GUIDE 110 [hereinafter *Genetically Engineered Food Act*], *available at* http://vig.cdn.sos.ca.gov/2012/general/pdf/complete-vig=v2.pdf.

37. *See, e.g.*, Michele Simon, *Lies, Dirty Tricks, and $45 Million Kill GMO Labeling in California*, APPETITE FOR PROFIT, Nov. 7, 2012, http://www.appetiteforprofit.com/2012/11/07/lies-dirty-tricks-and-45-million-kill-gmo-labeling-in-california/ (discussing the campaign against Proposition 37).

38. *Genetically Engineered Food Act*, *supra* note 36, at 111 § 110809(a). *See generally* Lauren E. Handel, *Labeling of Genetically Engineered Foods: A Constitutional Analysis of California's Proposition 37*, 1 CULINARIA 1 (2012) (analyzing of the text of Proposition 37, the potential First Amendment and Preemption challenges to the initiative, and practical implications for food producers).

39. *Id.* at 111 § 110808(c).

essed foods, the words "Partially Produced with Genetic Engineering" or "May Be Partially Produced with Genetic Engineering" would have been required on the front or back of the package.[40]

In addition to requiring affirmative disclosure of GE ingredients, the proposed law would have prohibited the marketing of genetically engineered foods as "natural."[41] As written, the prohibition on "natural" claims would have applied not only to genetically engineered foods, but also to all foods meeting the initiative's broad definition of "processed," which encompasses "any food other than a raw agricultural commodity, and includes any food produced from a raw agricultural commodity that has been subject to processing such as canning, smoking, pressing, cooking, freezing, dehydration, fermentation, or milling."[42]

The following categories of foods would have been exempt from the labeling requirements and prohibition on "natural" claims:

- Food from an animal that has not itself been genetically engineered, even if it was fed genetically engineered food or injected with a genetically engineered drug;

- Food grown, raised, or produced without knowing and intentional use of genetic engineering (subject to additional requirements);

- Processed foods that include only genetically engineered processing aids or enzymes;

- Alcoholic beverages;

- Until July 1, 2019, foods that contain relatively small amounts of genetically engineered ingredients, as long as "no single such ingredient accounts for more than one-half of one percent of the total weight of such processed food; and . . . the processed food does not contain more than 10 such ingredients.";

- Food lawfully certified as "organic" under federal law;

- Food sold in a restaurant or otherwise prepared and packaged for immediate consumption; and

40. *Id.* at 54–55.
41. *Id.* at 112 § 110809.1.
42. *Id.* at 111 § 110808(d).

- Medical food.[43]

2. *Washington State Initiative I-522*

The group "Label it WA" filed and gathered signatures for an initiative proposed to the Washington State legislature to establish mandatory labeling of foods produced through genetic engineering.[44] The initiative, I-522, appears to be based on California's Proposition 37. Like Proposition 37, I-522 would require disclosure labeling of foods, including raw agricultural products, processed foods, seeds, and seed stock, "offered for retail sale . . . [that have been,] or may have been, entirely or partly produced with genetic engineering," subject to the same list of exceptions.[45] Unlike its California counterpart, however, I-522 does not contain a section on "Misbranding of Genetically Engineered Foods as 'Natural'" and makes no effort to restrict the use of the term "natural" on the labels of processed foods.[46] Proponents of the initiative succeeded in collecting over 350,000 valid signatures (significantly more than the 241,153 required) by the December 31, 2012 deadline.[47] Thus, the Washington legislature will consider adopting I-522 during the next scheduled legislative session.[48] If the legislature does not adopt it, the measure will be placed on the November 2013 ballot.[49]

3. *FDA Urged to Label Genetically Engineered Foods*

Fifty-five members of Congress (ten senators and forty-five representatives) sent a March 12, 2012 letter to FDA in support of an October 2011 petition demanding the labeling of GE foods.[50] The petition, which was filed by the Center for Food Safety on behalf of the Just Label It campaign,[51] asserts, among other

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43. *Id.* at 112 § 110809.2.

44. *See I-522 "The People's Right to Know Genetically Engineered Act*,*"* LABEL IT WA, http://www.labelitwa.org/read_i_522 (last visited May 10, 2013) [hereinafter *I-522*].

45. *Id.* § 3(1).

46. *Compare Genetically Engineered Food Act*, *supra* note 36, at 112 § 110809.1, *with I-522*, *supra* note 44.

47. *Thank You I-522 Petition Signing Locations!*, LABEL IT WA, http://www.labelitwa.org/where_to_sign_i_522 (last visited May 10, 2013); *Frequently Asked Questions*, LABEL IT WA, http://www.labelitwa.org/resources (last visited May 10, 2013).

48. *Frequently Asked Questions*, *supra* note 47.

49. *Id.*

50. Letter from Barbara Boxer, U.S. Sen., et al., to Margaret Hamburg, FDA Comm'r (Mar. 12, 2012) [hereinafter Sen. Boxer Letter], *available at* http://www.leahy.senate.gov/imo/media/doc/Final%20Signed%20GE%20Labeling%20Letter.pdf.

51. *See* JUST LABEL IT, http://justlabelit.org/ (last visited May 10, 2013) (explaining position of consumer's right to know).

legal and scientific rationales, that "the absence of mandatory labeling disclosures for GE foods is misleading to consumers."[52] The letter from members of Congress emphasized FDA's responsibility "to protect a consumer's right to know, the freedom to choose what we feed our families, and the integrity of our free and open markets."[53]

D. *U.S. Department of Labor's Attempt to Regulate Child Agricultural Labor*

In 2011, the U.S. Department of Labor (DOL), sought to update a forty-year old rule regarding child agricultural labor in light of data showing that "children are significantly more likely to be killed while performing agricultural work than while working in all other industries combined."[54] The proposed rule would have prohibited children younger than sixteen from using power-driven equipment deemed hazardous and children younger than eighteen from working in feed lots, grain bins, and stockyards.[55] Additional restrictions applied to children working with certain animals deemed dangerous.[56]

Concern about the impact of the rule and a general opposition to government regulation fueled the proliferation of negative publicity about the rule, some accurate and some wildly inaccurate.[57] Extreme opposition from lawmakers and the agricultural sector led DOL to withdraw the proposed rule with no plan to resubmit.[58] The DOL and USDA pledged to "work with rural stakeholders—such as the American Farm Bureau Federation, the National Farmers Union, the Future Farmers of America, and 4-H—to develop an educational program to reduce accidents to young workers and promote safer agricultural working practices."[59]

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52. Petition at 2, Ctr. for Food Safety v. Sebelius, FDA-2011-P-0723-0001 (Oct. 12, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0723-0001.

53. Sen. Boxer Letter, *supra* note 50.

54. Press Release, U.S. Dept. of Labor, U.S. Labor Department to Re-Propose 'Parental Exemption' of Child Labor in Agriculture Rule (Feb.1, 2012), *available at* http://www.dol.gov/opa/media/press/whd/WHD20120203.htm; *see also* Child Labor Regulations, Orders & Statements of Interpretation, 76 Fed. Reg. 54,836 (proposed Sept. 2, 2011) (to be codified at 29 C.F.R. pts. 570 and 579).

55. Press Release, U.S. Dep't of Labor, U.S. Labor Department Proposes Updates to Child Labor Regulations (Aug. 31, 2011) [hereinafter DOL Proposes Updates], *available at* http://www.dol.gov/opa/media/press/whd/WHD20111250.htm; *see also* 76 Fed. Reg. at 54,875–81.

56. DOL Proposes Updates, *supra* note 55; *see also* 76 Fed. Reg. at 54,879.

57. Press Release, U.S. Dept. of Labor, Labor Department Statement on Withdrawal of Proposed Rule Dealing with Children Who Work in Agricultural Vocations (Apr. 26, 2012), *available at* http://www.dol.gov/whd/media/press/whdpressvB3.asp?Pressdoc=national/20120426.xml.

58. *Id.*; *see also* 77 Fed. Reg. 31,549–51 (May 29, 2012) (withdrawing proposed rules).

59. *Id.*

E. *School Lunch*

USDA issued—and then temporarily suspended—an interim rule regarding nutrition standards in the National School Lunch and School Breakfast Programs.[60] In January 2012, USDA issued a final rule that updated the "meal patterns and nutrition standards for the National School Lunch and School Breakfast Programs to align them with the Dietary Guidelines for Americans."[61] The final rule requires most schools to "increase the availability of fruits, vegetables, whole grains, and fat-free and low-fat fluid milk in school meals; reduce the levels of sodium, saturated fat and *trans* fat in meals; and meet the nutrition needs of school children within their calorie requirements."[62] The changes to the school meal programs were largely based on recommendations made by the Institute of Medicine of the National Academies, and "are expected to enhance the diet and health of school children, and help mitigate the childhood obesity trend."[63] The new regulations provide both calorie minimums and maximums for school lunches,[64] whereas the prior regulations only set a caloric floor.[65] The permissible caloric ranges rise with student age: a maximum of 650 calories for grades K–5, 700 calories for middle school students, and 850 calories for high school students.[66] The rule also imposes new weekly grain/meat limits and mandates the serving of an increased quantity of fruits and vegetables, which may be served in excess of the caloric limitations upon student request.[67] The rule became effective March 26, 2012 and generally required compliance on or before July 1, 2012.[68]

The caloric restrictions have generated significant controversy since their implementation at the start of the school year. The chief complaint is that an 850 calorie lunch does not provide enough energy for high school athletes, who can

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60. National School Lunch Program: School Food Service Account Revenue Amendments Related to the Healthy Hunger-Free Kids Act of 2010, 76 Fed. Reg. 35,301 (June 17, 2011) (to be codified at 7 C.F.R. pt. 210).

61. Nutrition Standards in the National School Lunch and School Breakfast Programs, 77 Fed. Reg. 4087, 4088 (Jan. 26, 2012) (to be codified at 7 C.F.R. pts. 210, 220).

62. *Id.*

63. *Id.*

64. Memorandum from Food & Nutrition Serv., USDA, to the Regional Directors of Special Nutrition Programs and State Directors of Child Nutrition Programs (Dec. 20, 2012), *available at* http://www.fns.usda.gov/cnd/Governance/Policy-Memos/2013/SP11-2013os.pdf.

65. 7 C.F.R. § 210.10(c) (2011) (setting minimum calorie levels for school lunches).

66. 77 Fed. Reg. at 4146.

67. *Id.* at 4091–95.

68. *Id.* at 4088.

burn an average of 3000 calories a day.[69] Additional criticism came from school lunch advocates who were frustrated that, by limiting meal planning flexibility and food choice, the new rules were making it more difficult to offer healthy options.[70] Moreover, because the calorie restrictions have been championed by First Lady Michelle Obama, they have predictably become a partisan issue.[71] House Republican Steve King (R-Iowa) introduced H.R. 6418, the No Hungry Kids Act, which would repeal USDA's new rule on nutrition standards in school lunches.[72] This bill was referred to the House Committee on Education and the Workforce.[73]

A few months after the new rules were implemented, USDA agreed to partially suspend them for the remainder of the 2012–2013 school year.[74] In a December 7, 2012 letter, Secretary of Agriculture Tom Vilsack identified the meat and grain portion limits as the "top operational challenge" for states and schools in implementing the new standards and announced USDA would enforce the minimum, but not the maximum, serving limits for meat and grains.[75] This temporary suspension is designed to "allow more time for the development of products that fit within the new standards while granting schools additional weekly menu planning options to help ensure that children receive a wholesome, nutritious meal every day of the week."[76]

F. *Energy Drinks*

Energy drinks containing high levels of caffeine and other stimulants continue to concern lawmakers. Energy beverages are often marketed as dietary

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69. Dan Flynn, *Rebellion in the Heartland over School Lunch Calorie Reductions*, FOOD SAFETY NEWS (Sept. 26, 2012), http://www.foodsafetynews.com/2012/09/rebellion-in-the-heartland-over-calorie-reductions-at-lunch/.

70. Dana Woldow, *New USDA School Lunch Rules Limit Even Healthy Choices*, BEYONDCHRON (Aug. 7, 2012), http://www.beyondchron.org/news/index.php?itemid=10381.

71. Bettina Elias Siegel, *The Right Wing and the School Food Calorie Kerfuffle*, THE LUNCH TRAY (Sept. 28, 2012), http://www.thelunchtray.com/the-right-wing-and-the-school-food-calorie-kerfuffle/.

72. No Hungry Kids Act, H.R. 6418, 112th Cong. (2012).

73. 158 CONG. REC. H6060 (daily ed. Sept. 14, 2012).

74. Susan Heavy, *U.S. Loosens Rules Aimed at Healthier School Meals*, REUTERS (Dec. 10, 2012), http://www.reuters.com/article/2012/12/10/usa-health-schoolmeals-idUSL1E8NA2B020121210.

75. Letter from Thomas J. Vilsack, Sec'y of Agric., to John Hoeven, U.S. Sen. (Dec. 7, 2012), *available at* http://www.hagstromreport.com/assets/2012/2012_1207_VilsackHoevenLtr.pdf.

76. *Id.*

supplements; thus, they receive less FDA scrutiny than regular beverages.[77] While the caffeine in energy drinks is generally less than that contained in a cup of brewed coffee, the beverages typically contain three times more caffeine than soft drinks.[78] Such beverages also typically contain additional stimulants which often escape regulatory restriction because manufacturers claim these substances are used as part of a drink's "energy blend."[79]

Mounting concern regarding energy drinks and their consumption by youth was heightened by the December 2011 caffeine toxicity-related death of fourteen-year-old Anais Fournier.[80] Fournier died after consuming two energy drinks in succession; the two beverages contained as much caffeine as fourteen cans of Coca-Cola.[81]

- Senator Richard J. Durbin (D-Ill.) has twice urged FDA to take regulatory action to address the rising health concerns around energy drinks purportedly containing high levels of caffeine and other ingredients such as taurine, guarana, and ginseng.[82] Durbin's initial April 2012 letter was met with what he deemed an unsatisfactory response by FDA,[83] which focused narrowly on caffeine consumption and did not specifically address two primary areas of concern: "potential interactions and cumulative effects of additives with stimulant properties in energy drinks with high levels of

77. Gretchen Goetz, *Five U.S. Consumers Drank Same Energy Drink Before Death, Records Show*, FOOD SAFETY NEWS (Oct. 23, 2012), http://www.foodsafetynews.com/2012/10/energy-drinks-implicated-in-hospitalizations-and-deaths/.

78. *Caffeine Content of Food and Drugs*, CTR. FOR SCI. IN THE PUB. INTEREST, http://www.cspinet.org/new/cafchart.htm (last visited May 10, 2013).

79. Berry Meier, *Safety Becomes a Concern with High-Caffeine Drinks*, N.Y. TIMES, Oct. 23, 2012, http://www.nytimes.com/2012/10/24/business/safety-becomes-a-concern-with-energy-drinks.html; *Youth & Energy Drinks*, NAT'L COUNCIL ON STRENGTH & FITNESS, http://www.ncsf.org/enew/articles/articles-youthenergydrinks.aspx (last visited May 10, 2013).

80. *Anais Fournier, 14-Year-Old Girl, Dies After Drinking 2 Energy Drinks*, HUFFINGTON POST (Mar. 25, 2012), http://www.huffingtonpost.com/2012/03/24/anais-fournier-energy-drinks-caffeine-toxicity-poisoning_n_1373655.html.

81. *Id.*

82. Letter from Richard J. Durbin & Richard Blumenthal, U.S. Senators, to Margaret Hamburg, Comm'r, U.S. Food & Drug Admin. (Sept. 11, 2012), *available at* http://www.durbin.senate.gov/public/index.cfm/pressreleases? ID=0ff54c20-7fa3-4398-9b53-cc55800b9360; Letter from Richard J. Durbin, U.S. Sen., to Margaret Hamburg, Comm'r, U.S. Food & Drug Admin. (Apr. 3, 2012), *available at* http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=035e7993-a1e2-4e2c-b1a1-b4f5348eb0cb.

83. *See generally* Letter from Jeanne Ireland, Assistant Comm'r for Legislation, U.S. Food & Drug Admin., to Richard J. Durbin, U.S. Sen. (Aug. 10, 2012), *available at* http://durbin.senate.gov/public/index.cfm/files/serve?File_id=17eadaa1-85e7-4ceb-a827-be244fbddfa5.

caffeine," and "the unique health risks associated with consuming high levels of caffeine among young people."[84]

- Senator Richard Blumenthal (D-Conn.) joined Sen. Durbin in the second attempt to prompt regulatory action.[85] They urged FDA to take a more searching look at the identified issues and to "assert its authority to regulate the level of caffeine in energy drinks marketed as beverages."[86] In 2011, Senators Durbin and Blumenthal co-sponsored The Dietary Supplement Labeling Act to strengthen warnings on product labels, but the bill stalled in Congress.[87]

- FDA indicated that it intends to release final guidance distinguishing liquid dietary supplements from beverages.[88] FDA's "generally recognized as safe" regulation for caffeine applies to cola-type beverages; the Agency "has not challenged the use of caffeine in other beverages at levels comparable to the prior-sanctioned use level of 200 ppm."[89] According to FDA, caffeine intake up to 400 mg per day is not associated with untoward health effects.[90]

- New York's Attorney General Eric T. Schneiderman is investigating energy drink ingredient and health claims.[91] Schneiderman issued subpoenas in July 2012 to Monster Beverage Corp., PepsiCo Inc. (which markets Amp Energy Drinks) and Living Essentials, LLC (which makes 5-Hour Energy drink), seeking information on the companies' advertising, marketing, ingredients, and sale of their energy beverages.[92]

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84. Letter from Richard J. Durbin to Margaret Hamburg, *supra* note 82.
85. *Id.*
86. *Id.*
87. Dietary Supplement Labeling Act of 2011, S. 1310, 112th Cong. (2011).
88. Letter from Jeanne Ireland to Richard Durbin, *supra* note 83.
89. *Id.*; *see also* 21 C.F.R. § 182.1180 (2012).
90. *Id.*
91. Nelson D. Schwartz, *New York State Is Investigating Energy Drink Makers*, N.Y. TIMES, Aug. 28, 2012, http://www.nytimes.com/2012/08/29/business/new-york-state-is-investigating-energy-drinks.html.
92. Reed Albergotti & Mike Esterl, *New York Probes Energy-Drink Makers*, WALL ST. J., Aug. 28, 2012, http://online.wsj.com/article/SB10008723963904442305045776156902491231 50.html.

III. FOOD SAFETY: OVERSIGHT & OUTBREAKS

A. *Federal Food Safety Oversight*

1. *FDA Sued for Delayed FSMA Implementation*

The Center for Food Safety and Center for Environmental Health filed a complaint for declaratory and injunctive relief against FDA alleging that the agency has unlawfully delayed adopting and implementing regulations under the Food Safety Modernization Act (FSMA) in violation of both FSMA and the Administrative Procedures Act (APA).[93] Plaintiffs allege FDA has abdicated responsibility, put lives at risk, and failed to implement FSMA's major food safety regulations by missing seven statutory deadlines.[94] Specifically, plaintiffs allege that FDA failed (i) to establish "science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls and documenting the implementation of preventive controls"; (ii) to address "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership . . . and on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership"; (iii) to "establish science-based minimum standards for the safe production and harvesting of fruits and vegetables"; (iv) to "protect against the intentional adulteration of food"; (v) to impose sanitary transportation practices on shippers and carriers; (vi) to create a foreign supplier verification program; and (vii) to create a program to "ensure the neutrality and independence of third-party audits."[95] The complaint also challenges FDA's policy not to "enforce provisions that are self-executing . . . even if [the agency] has not promulgated final regulations."[96] The Office of Management and Budget has also been named as a defendant for allegedly failing to approve the implementing regulations that FDA submitted for its review.[97] Plaintiffs seek a declaratory and injunctive relief requiring FDA and OMB to promul-

93. Complaint at 2–3, 5, Ctr. for Food Safety v. Hamburg, No. 12-4529 (N.D. Cal., Aug. 29, 2012) [hereinafter Ctr. for Food Safety Complaint]; *see also* Press Release, Ctr. for Food Safety, Center for Food Safety Lawsuit Targets FDA, OMB on Stalled Food Safety Act (Aug. 30, 2012), *available at* http://www.centerforfoodsafety.org/press-releases/723/center-for-food-safety-lawsuit-targets-fda-omb-on-stalled-food-safety-act.

94. *See* Ctr. for Food Safety Complaint, *supra* note 93, at 2–3.

95. *Id.* at 8–11.

96. *Id.* at 11.

97. *Id.* at 15.

gate and approve all FSMA regulations "as soon as reasonably practicable" and pursuant to a court-imposed timeline.[98]

2. *FDA Collaborates on Public Foodborne Bacteria Genome Database*

FDA is participating in a public-private collaboration (along with University of California-Davis, Agilent Technologies Inc., and the Centers for Disease Control and Prevention) to create a public database that will contain 100,000 foodborne pathogen genomes to help facilitate the identification of those responsible for outbreaks involving bacteria such as *Salmonella*, *Listeria*, and *E. coli.*[99] Called "The 100K Genome Project," the undertaking is slated to be a five-year genetic sequencing program openly accessible to researchers and others helping to develop tests that would identify the type of bacteria present in a sample within days or hours.[100] "The FDA is providing more than 500 already completed *Salmonella* whole-genome draft sequences, thousands of additional important food pathogen strains for sequencing, and bioinformatic support. FDA scientists also will participate in guiding the project and providing technical assistance when needed."[101]

3. *FDA Focuses on Global Cooperation for Product Safety*

On April 23, 2012, FDA formalized its effort to "transform from a domestic to a global public health agency" by releasing a Global Engagement Report, which details "the steps the agency is taking to ensure that imported food, drugs, medical devices, and other regulated products meet the same rigorous standards for safety and quality as those manufactured domestically."[102] According to FDA,

> FDA-regulated products originate from more than 150 countries, 130,000 importers, and 300,000 foreign facilities. Each year from 2005–2011, food imports have grown by an average of 10 percent . . . . Approximately 50 percent of fresh fruits

98. *Id.* at 16.

99. Press Release, U.S. Food & Drug Admin., FDA, UC Davis, Agilent Technologies and CDC to Create Publicly Available Food Pathogen Genome Database (July 12, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm311661.htm.

100. *Id.*

101. *Id.*

102. Press Release, U.S. Food & Drug Admin., FDA Strengthens International Collaboration to Ensure Quality, Safety of Imported Products (Apr. 23, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm301191.htm; *see also* U.S. FOOD & DRUG ADMIN., GLOBAL ENGAGEMENT (2012) [hereinafter GLOBAL ENGAGEMENT], *available at* http://www.fda.gov/AboutFDA/Reports ManualsForms/Reports/ucm298576.htm.

> and 20 percent of fresh vegetables, as well as 80 percent of the seafood consumed in America come from abroad.[103]

FDA's efforts to increase its global reach include coalition building, regulatory capacity-building efforts in other countries, development and harmonization of science-based regulatory standards, increased awareness of the importance of regulatory systems, and information and data sharing to "facilitate rapid identification of and response to public health emergencies."[104]

Relatedly, in March 2012, the Centers for Disease Control and Prevention (CDC) released an analysis of data collected by the Foodborne Disease Outbreak Surveillance System from 2005 to 2010 showing that disease outbreaks linked to imported foods increased in 2009 and 2010.[105] The report also found thirty-nine outbreaks and 2348 illnesses were tied to imported foods from fifteen countries.[106] Foods from Asia accounted for nearly forty-five percent of imported foods causing outbreaks.[107]

4. *Amended Final Rule on Compounds of Carcinogenic Concern Used in Food-Producing Animals*

FDA issued an amended final rule, effective September 21, 2012, which amends regulations regarding concentrations of compounds of carcinogenic concern in the diet of food-producing animals, and residues of carcinogenic concern in specific edible tissues.[108] The changes clarify certain definitions "to enable the Center for Veterinary Medicine to consider allowing the use of alternative procedures to satisfy the DES [Diethylstilbestrol] Proviso . . . without requiring the development of a second, alternative set of terminology."[109] FDA has changed the existing emphasis in 21 C.F.R. part 500 on how to measure the carcinogenic risk from a standard that required "the specific 1 in 1 million risk of cancer to the test animals approach" to a primary standard that requires "no significant increase in the risk of cancer to the human consumer" and retains the "1 in 1 million risk" as a secondary standard.[110] This change is intended to "enable the Cen-

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103. FDA Strengthens International Collaboration, *supra* note 102.

104. GLOBAL ENGAGEMENT, *supra* note 102, at 4.

105. Press Release, Ctrs. for Disease Control and Prevention, CDC Research Shows Outbreaks Linked to Imported Foods Increasing (Mar. 14, 2012), *available at* http://www.cdc.gov/media/releases/2012/p0314_foodborne.html.

106. *Id.*

107. *Id.*

108. Regulation of Carcinogenic Compounds in Food-Producing Animals, 77 Fed. Reg. 50,591, 50,591 (Aug. 22, 2012) (to be codified at 21 C.F.R. pt. 500).

109. *Id.*

110. *Id.*

ter for Veterinary Medicine to consider allowing the use of alternative procedures to satisfy the DES Proviso."[111]

5. *FDA-Issued Guidelines for Preventing* Salmonella *in Eggs*

FDA issued final "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation," on August 20, 2012.[112] The guidance document addresses questions regarding the requirements under the Egg Safety Rule including how to determine whether and when producers must comply with the requirements, *Salmonella* Enteritidis prevention measures, sampling and testing requirements, facility registration, and enforcement and compliance.[113] Draft guidance for producers who provide their laying hens with outdoor access is expected to be forthcoming.

6. *FDA Takes Enforcement Action Against California Fish Processor*

In a complaint filed by the Department of Justice, FDA sought a permanent injunction to stop the processing and distribution of fish products by Fujino Enterprises Inc., doing business as Blue Ocean Smokehouse, of Half Moon Bay, California, because of a risk of botulism, listeriosis, scombrotoxin, and other food hazards.[114] The complaint alleged that "the company's fish and fish products are adulterated, because they are processed under conditions that do not comply with the agency's Hazard Analysis Critical Control Point (HACCP) regulations," and the conditions under which fish are "prepared, packed, and held fail to conform to the Current Good Manufacturing Practice requirements for food established to ensure that food is processed in a safe and sanitary manner."[115] Blue Ocean Smokehouse allegedly ignored repeated warnings by FDA before the lawsuit was filed.[116]

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111. *Id.*

112. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING THE FINAL RULE, PREVENTION OF *SALMONELLA* ENTERITIDIS IN SHELL EGGS DURING PRODUCTION, STORAGE, AND TRANSPORTATION (2012).

113. *Id.*

114. Press Release, U.S. Food & Drug Admin., FDA Pursues Enforcement Action Against California Fish Processor (Mar. 29, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm297809.htm.

115. *Id.*

116. *Id.*

7. *FDA Reportable Food Registry*

FDA's Second Annual Reportable Food Registry Report summarizes information submitted between September 8, 2010 to September 7, 2011 by manufacturers, processors, packers, and holders through the online Reportable Food Registry Portal.[117] The report encompasses all human and animal food regulated by FDA but excludes infant formula and dietary supplements.[118] The purpose of the report is to track patterns of adulteration to help FDA administer inspection resources more effectively.[119]

8. *FDA Will Not Alter Rule on Irradiation in Food Processing & Handling*

FDA denied a petition seeking a hearing and changes to the final rule on the use of irradiation in processing and handling food.[120] FDA concluded that the petitioners failed to "establish[] that FDA overlooked significant information contained within the record in reaching its conclusion that the use of irradiation for microbial control of pathogens in seeds for sprouting is safe."[121]

9. *USDA & FDA Co-Issue Food Safety Information Booklets*

USDA, FDA, and the Food Safety Inspection Service (FSIS) partnered to create six booklets providing "food safety advice for populations that are most susceptible to foodborne illness. The booklets in this 'at-risk series' are tailored to help older adults, transplant recipients, pregnant women, and people with cancer, diabetes or HIV/AIDS reduce their risk for foodborne illness."[122] In addition to five booklets previously published in 2006, a sixth booklet targets pregnant women, a population particularly at risk for listeriosis.[123]

As part of a multi-faceted approach to prevent foodborne illness, USDA and FDA joined the CDC and the Ad Council to launch *Food Safe Families*, a

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117. *See* U.S. FOOD & DRUG ADMIN., FOODS AND VETERINARY MED. PROGRAM, THE REPORTABLE FOOD REGISTRY: TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION 3 (2012).

118. *Id.*

119. *Id.*

120. Irradiation in the Production, Processing and Handling of Food, 77 Fed. Reg. 27,586 (May 11, 2012) (to be codified at 21 C.F.R. pt. 179).

121. *Id.* at 27,590.

122. Press Release, U.S. Food & Drug Admin., Food Safety Guides for Groups Most Vulnerable to Foodborne Illness Now Available (Aug. 1, 2012), *available at* http://www.fsis.usda.gov/news/NR_080112_01/index.asp.

123. *Id.*

consumer food safety education campaign.[124] It is the first joint public service campaign to empower families to further reduce their risk of foodborne illness at home by completing key food safety steps: clean, separate, cook, and chill.[125]

10. *New USDA Safeguards to Protect Against Foodborne Illness*

On May 2, 2012, USDA announced "series of prevention-based policy measures" designed to "better protect consumers from foodborne illness in meat and poultry products."[126] This initiative featured traceback measures designed to identify potentially contaminated products more quickly after contamination is detected.[127]

11. *FSIS Implements Routine Screening for Six Additional STEC Strains*

FSIS began sampling for six Shiga toxin-producing *E. coli* (STEC) (serogroups O26, O45, O103, O111, O121, and O145), which are now identified as adulterants of non-intact raw beef products and product components within the meaning of the Federal Meat Inspection Act (FMIA).[128] As of June 4, 2012, FSIS is routinely testing raw beef manufacturing trim, a major component of ground beef.[129] Trim found to be contaminated with any of these six additional pathogens will not be allowed into commerce and will be subject to recall.[130]

12. *GAO Report Criticizes FDA Food Recall Process*

The Government Accountability Office (GAO) issued a July 26, 2012 report criticizing FDA's efforts to implement a comprehensive food advisory and recall process pursuant to authority granted to FDA under FMSA.[131] The GAO assessed FDA's ability to order recalls and effectively inform consumers and

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124. Tom Vilsack, *New Multimedia Campaign Aims to Reduce Food Poisoning*, FOODSAFETY.GOV (June 28, 2011), http://www.foodsafety.gov/blog/foodsafefamilies.html.

125. *Id.*

126. Press Release, Food Safety & Inspection Serv., USDA, USDA Announces New Safeguards to Protect Consumers from Foodborne Illness (May 2, 2012), *available at* http://www.fsis.usda.gov/news/NR_050212_01/index.asp.

127. *Id.*

128. Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products, 77 Fed. Reg. 31,975 (May 31, 2012) (to be codified at 9 C.F.R. pts. 416, 417, 430).

129. *Id.*

130. *See id.*

131. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-589, FOOD SAFETY: FDA's FOOD ADVISORY AND RECALL PROCESS NEEDS STRENGTHENING 19 (2012), *available at* http://www.gao.gov/assets/600/593031.pdf.

retailers about food safety issues, and concluded that although FDA has established internal procedures describing the steps it will take to order a food recall, these "procedures have not yet been made public, and [] the agency has not issued regulations or industry guidance clarifying its procedures for ordering food recalls."[132]

13. *GAO Issued a Report Regarding Pre-slaughter Interventions To Reduce* E. coli *in Cattle*

The U.S. beef industry recalled more than 23 million pounds of beef between 2006 and 2012 due to *Escherichia coli* (STEC) bacterial contamination.[133] *E. coli* does not harm cattle but can cause potentially fatal illness in humans.[134] GAO reviewed (1) interventions before slaughter that may help reduce STEC in cattle; (2) USDA's role in approving STEC vaccines; (3) the extent to which STEC strains have been determined to be adulterants in beef and the status of tests to detect them; and (4) practices other countries have employed that could reduce STEC in cattle.[135] In its March 9, 2012 report, GAO recommended, among other things, that USDA "provide more specific public guidance on the license approval requirements for STEC vaccines."[136]

B. *Foodborne Illness Outbreaks*

Highlighted below are just a few of the year's major foodborne illness outbreaks.[137]

- A Canadian beef recall because of possible *E. coli* O157:H7 contamination, encompassing more than 200 products, was extended to beef trim

132. *Id.* at 37.

133. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-527, FOOD SAFETY: PRESLAUGHTER INTERVENTIONS COULD REDUCE *E. COLI* IN CATTLE 1 (2012), *available at* http://www.gao.gov/assets/590/589160.pdf.

134. *Id.*

135. *Id.* at 8–22.

136. *Id.* at 22.

137. *See Foodborne Illness Outbreaks*, FOOD SAFETY NEWS, http://www.foodsafetynews.com/sections/foodborne-illness-outbreaks/ (last visited May 10, 2013); *see also CDC Current Outbreak List*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/outbreaks/index.html (last visited May 10, 2013).

products sold in the United States, specifically in Montana, Oregon, and Washington.[138]

- A rare strain of *Salmonella* Bredeney contaminated many popular brands of peanut butter manufactured by Sunland Inc. of Portales, New Mexico.[139]

- Mexican mangoes contaminated with *Salmonella* Braenderup were linked to infections of at least 121 people in fifteen states.[140]

- An outbreak of *E. coli* at the Saginaw Correctional Facility sickened eighty-nine inmates and seven prison guards.[141]

- An August 2012 nationwide *Salmonella* Typhimurium outbreak, as well as two subsequent infectious *Salmonella* clusters, were linked to cantaloupes from Chamberlain Farms of Owensville, Indiana.[142]

- At least 163 people were sickened by *Salmonella* traced to chicks and ducklings from an Ohio mail order hatchery.[143]

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138. Dan Flynn, *Ground Beef Made with XL Trim Recalled by Safeway in 3 States*, FOOD SAFETY NEWS (Sept. 22, 2012), http://www.foodsafetynews.com/2012/09/canadas-big-beef-recall-the-one/.

139. Dan Flynn, *Peanut Butter Recall Expands Beyond Trader Joe's*, FOOD SAFETY NEWS (Sept. 24, 2012), http://www.foodsafetynews.com/2012/09/peanut-butter-recall-expands-beyond-trader-joes/.

140. Helena Bottemiller, *CDC: 121 Ill in 15 States Linked to Imported Mangoes*, FOOD SAFETY NEWS (Sept. 14, 2012), http://www.foodsafetynews.com/2012/09/cdc-121-ill-in-15-states-linked-to-imported-mangoes/.

141. *Apparent* E. Coli *Outbreak at Saginaw Prison Sickens 96*, FOOD SAFETY NEWS (Sept. 6, 2012), http://www.foodsafetynews.com/2012/09/apparent-e-coli-outbreak-at-saginaw-prison-sickens-96/.

142. Gretchen Goetz, *Farm Linked to Cantaloupe Outbreak Is Likely Source of One, Possibly Two More Outbreaks*, FOOD SAFETY NEWS (Sept. 13, 2012), http://www.foodsafetynews.com/2012/09/farm-linked-to-cantaloupe-outbreak-is-likely-source-of-1-and-maybe-2-more-outbreaks/.

143. *More Salmonella Cases Linked to Chicks and Ducklings*, FOOD SAFETY NEWS (Aug. 21, 2012), http://www.foodsafetynews.com/2012/08/more-salmonella-cases-linked-to-chicks-and-ducklings/.

IV. ADULTERATION & ADDITIVES

A. *Food Ingredient Fraud Database*

The U.S. Pharmacopeial Convention (USP), "a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements,"[144] has developed a searchable online database of food ingredient fraud reports and associated analytical detection methods.[145] Researchers from USP and Michigan State University published an article in the *Journal of Food Science* discussing the database and the food products that appear most prone to fraud.[146] Based on data collected to date, they have concluded that olive oil, milk, honey, saffron, orange juice, coffee, and apple juice are the most frequently adulterated ingredients.[147] The category of "spices" is another area of concern, being "mentioned in over ten percent of the records of each dataset."[148]

B. *BPA in Food Packaging*

Bisphenol A (BPA) is an organic compound used to make polycarbonate polymers, epoxy resins, and plastics.[149] Since the middle of the twentieth century, BPA has been incorporated into plastics (commonly used for baby bottles and beverage containers) and epoxy linings used to extend the shelf life for comestibles sold in cans and glass jars with metal lids.[150] BPA is presently approved for use in the production of polycarbonate polymers and epoxy-based enamels and coatings.[151]

Because BPA exhibits hormone-like properties in the body and is believed to be an endocrine disruptor, concerns have been raised about its suitabil-

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144. *About USP*, U.S. PHARMACOPEIAL CONVENTION, http://www.usp.org/about-usp (last visited May 10, 2013).

145. *USP Food Fraud Database*, U.S. PHARMACOPEIAL CONVENTION, http://www.foodfraud.org/ (last visited May 10, 2013).

146. *See* Jeffery C. Moore et al., *Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010*, 77 J. OF FOOD SCI. R108 (2012).

147. *Id.* at R111.

148. *Id.* at R111.

149. *Bispenol A (BPA)*, NAT'L. INST. OF ENVTL. HEALTH SCI., http://www.niehs.nih.gov/health/topics/agents/sya-bpa/ (last visited May 10, 2013).

150. *Bisphenol A (BPA) Information for Parents,* U.S. DEP'T OF HEALTH & HUMAN SERVS. http://www.hhs.gov/safety/bpa (last visited May 10, 2013).

151. *See, e.g.*, 21 C.F.R. §§ 175.300(b)(3)(viii), 177.1440, 177.1580, 177.2280 (2012) (4,4'-isopropylenediphenol is the chemical name for bisphenol A) .

ity in food and cosmetic packaging, as well as other consumer products.[152] Worldwide, an estimated eight billion pounds of BPA are produced each year.[153] The compound has been detected in the urine of nearly every adult and child tested in the United States.[154] The past year's developments in light of this new knowledge include:

- *FDA Bans BPA in Baby Bottles*: FDA issued a final rule, effective July 17, 2012, amending the food additive regulations in 21 C.F.R. part 177 "to no longer provide for the use of polycarbonate (PC) resins," including BPA, in infant feeding bottles or spill-proof sippy cups.[155] The "BPA-Baby Bottle Ban" was issued in response to a petition by the American Chemistry Council (ACC) that requested an amendment to food additive regulations to no longer allow for the use of BPA-based resins in these products.[156] The ACC claimed that baby bottles and sippy cups manufactured from PC resins are no longer being introduced into the U.S. market and manufacturers of baby bottles and sippy cups have abandoned the use of PC resins in making these products.[157] FDA concluded that the use of PC resins in these products has been "completely and permanently abandoned," and agreed to amend the regulations accordingly.[158]

- *Petition to Ban BPA in Infant Formula Packaging*: U.S. Representative Edward Markey (D-Mass.) asked FDA to amend its food additive regulations to prohibit the use of BPA-based epoxy resins as coatings in packaging for infant formula.[159] The Markey petition is based on the same ra-

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152. *Bisphenol A*, *supra* note 149.

153. Mike Verespej, *Health Canada: BPA Is Safe in Food Packaging*, PLASTICS NEWS, Oct. 1, 2012, www.plasticsnews.com/article/20121001/News/310019968/health-canada-bpa-is-safe-in-food-packaging.

154. *See generally* Antonia M. Calafat et al., *Exposure of the U.S. Population to Bisephenol A and 4*-tertiary-*Octylphenol: 2003-2004*, 116 ENVTL. HEALTH PERSP. 39 (2008) (discussing the test results the impact of BPA exposure on humans).

155. Indirect Food Additives: Polymers, 77 Fed. Reg. 41,899 (July 17, 2012) (to be codified at 21 C.F.R. pt. 177).

156. *Id.*

157. Letter from Steven G. Hentges, Polycarbonate/BPA Global Grp., Am. Chemistry Council, to Dr. Francis Lin, Dir., Div. of Food Contact Substance Notification Rev., U.S. Food & Drug Admin. (Sept. 19, 2011), *available at* http://plastics.americanchemistry.com/Product-Groups-and-Stats/PolycarbonateBPA-Global-Group/FDA-Petition-Letter-ACC.pdf.

158. 77 Fed. Reg. at 41,901.

159. Letter from Edward J. Markey, U.S. Rep., to Dr. Francis Lin, Dir., Div. of Food Contact Substance Notifications Rev., U.S. Food & Drug Admin. (Mar. 16, 2012), *available at* http://markey.house.gov/sites/markey.house.gov/files/documents/03-16-12%20BPA%20petition%20infant%20formula%20and%20baby%20food%5B1%5D.pdf.

tionale that led to the BPA-Baby Bottle Ban; namely, that such use has been abandoned by the industry.[160] Markey received letters signed by sixty-two non-governmental organizations in support of his petition.[161] FDA requested comments by September 17, 2012 that address, among other things, (i) "whether these uses of BPA-based epoxy resins have been completely abandoned" and (ii) "whether the uses that are the subject of the petition . . . have been adequately defined."[162]

- *FDA Refuses to Prohibit BPA in Food Packaging*: FDA rejected a 2008 Natural Resources Defense Council (NRDC) petition[163] to ban BPA in food packaging and confirmed the compound's continued use, finding that the scientific evidence cited by the NRDC in its petition cannot readily be applied to humans because it involved non-oral routes of exposure, small sample size, inappropriate statistical analysis, and failure to demonstrate the relevance of these studies on animals to human health effects.[164] FDA determined that "as a matter of science and regulatory policy, [] the best course of action . . . is to continue our review and study of emerging data on BPA."[165]

- *Washington Extends BPA Ban to Sports Bottles*: Sport bottles with a capacity of up to sixty-four ounces containing BPA can no longer be made, sold, or distributed in the state of Washington, in accordance with a 2010 law passed by the state legislature which bans the sale of certain products containing BPA.[166] The first phase of the law, implemented July 1, 2011, prohibited BPAs in bottles, cups, or other containers intended for children under age three.[167] The second phase of the ban, covering sports bottles,

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160. *Id.* at 4–8.

161. *See, e.g.*, Letter from Alaska Cmty. Action on Toxics et al. to Edward Markey, U.S. Rep. (March 14, 2012), *available at* http://markey.house.gov/sites/markey.house.gov/files/documents/ALL%20support%20letters%20BPA%20petition.pdf.

162. 77 Fed. Reg. 41,953, 41,954 (July 17, 2012) (to be codified at 21 C.F.R. pt. 175).

163. Petition for Nat'l Res. Defense Council, No. FDA-2008-P-0577 (Oct. 21, 2008); Letter from David H. Dorsey, Acting Assoc. Comm'r for Policy and Planning, U.S. Food & Drug Admin., to Sarah Janssen and Aaron Colangelo, Nat'l Res. Defense Council (Mar. 30, 2012) [hereinafter Dorsey Letter], *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0577-0007.

164. Dorsey Letter, *supra* note 163, at 7.

165. *Id.* at 15.

166. WASH REV. CODE ANN. § 70.280.020 (West 2011); *see also Waste 2 Resources, Bisphenol A*, WASH. DEP'T OF ECOLOGY, http://www.ecy.wa.gov/programs/swfa/bpa.html (last visited May 10, 2013).

167. WASH REV. CODE ANN. § 70.280.020(1).

became effective on July 1, 2012.[168] Metal cans designed to hold or pack food may still contain BPA.[169]

- *Association Between BPA Exposure and Coronary Artery Disease*: Researchers have repeatedly raised concerns about the ability of BPA to interfere with the body's hormonal system and affect brain development, behavior, and the prostate gland.[170] Emerging research indicates that BPA exposure may also contribute to coronary artery disease.[171] U.K. researchers observed elevated urinary BPA concentrations in 591 study participants "with intermediate or severe stenoses compared to those graded as having no coronary artery disease."[172]

C. *Pesticide Residues on Foods: Environmental Working Group (EWG) Updates Its Guide to Pesticides in Produce*

The EWG released its "2012 Shopper's Guide to Pesticides in Produce," which "ranks pesticide contamination for 45 popular fruits and vegetables based on an analysis of more than 60,700 samples" taken from USDA and FDA data collected between 2000 to 2010.[173] Almost all of the studies on which the guide is based tested produce after it had been washed or peeled.[174] The updated report identifies a "Dirty Dozen" (plus two bonus crops added this year) and a "Clean 15" list.[175]

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168. *Id.* § 70.280.020(2).

169. *Waste 2 Resources*, *supra* note 166.

170. CTR. FOR THE EVALUATION OF RISKS TO HUMAN REPROD., U.S. DEP'T OF HEALTH AND HUMAN SERVS., PUBL'N NO. 08-5994, NTP-CERHR MONOGRAPH ON THE POTENTIAL HUMAN REPRODUCTIVE AND DEVELOPMENTAL EFFECTS OF BISPHENOL A, at 8 fig.3 (2008).

171. DAVID MELZER ET AL., *Urinary Bisphenol A Concentration and Angiography-Defined Coronary Artery Stenosis*, 7 PLoS ONE (Aug. 15, 2012).

172. *Id.*

173. *EWG's 2012 Shopper's Guide to Pesticides in Produce: Methodology*, ENVTL. WORKING GRP. (June 19, 2012), http://www.ewg.org/foodnews/methodology/.

174. *Id.*

175. *EWG's 2012 Shopper's Guide to Pesticides in Produce: Summary*, ENVTL. WORKING GRP. (June 19, 2012), http://www.ewg.org/foodnews/summary/.

V. FOOD MARKETING: LABELING & ADVERTISING

A. *Labeling Claim Litigation*

1. *Second Circuit Upholds New York's Kosher Law*

In *Commack Self-Service Kosher Meats, Inc. v. Hooker*, the Second Circuit Court of Appeals upheld New York's Kosher Law Protection Act of 2004 against constitutional challenges based on the Free Exercise and Establishment Clauses of the First Amendment.[176] "The Kosher Act merely requires food products marketed as kosher to be labeled as kosher," U.S. Circuit Judge Christopher Droney wrote.[177] "Thus, the Kosher Act does not entangle the State with religion because it does not require the State to enforce laws based on religious doctrine or to inquire into the religious content or religious nature of the products sold."[178] Notably, unlike an earlier version of the act found to violate the Establishment Clause, the 2004 Kosher Act does not improperly "define kosher or authorize state inspectors to determine the kosher nature of the products."[179] Rather, it is a labeling law with the "secular purpose of protecting against fraud by informing a consumer that a particular seller believes a product is kosher."[180]

2. *Lucerne "Greek Yogurt"*

A putative class of all consumers who purchased Lucerne® Brand Greek yogurt from its parent company's Safeway grocery stores has alleged that the product is mislabeled and adulterated because it is thickened by the addition of milk protein concentrate, not by straining.[181] The complaint alleges that milk protein concentrate, a blend of dry dairy ingredients, is not among "generally regarded as safe" food additives listed by FDA.[182] The complaint further alleges that the product does not meet FDA's standard of identity for yogurt products.[183]

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176. 680 F.3d 194, 214 (2d Cir. 2012).
177. *Id.* at 207.
178. *Id.*
179. *Id.* at 201.
180. *Id.* at 206–07.
181. Complaint at 3, Tamas v. Safeway, Inc., RIC 1206341 (Cal. Super. Ct. Apr. 27, 2012).
182. *Id.* at 12.
183. *Id.* at 11.

3. *Starbucks Faces Putative Class Action Over Bug-Based Coloring*

Starbucks stands accused of violating the California Unfair Business Practices Act and False Advertising Act, unjust enrichment, fraud by omission/concealment, and violation of California's Consumers Legal Remedies Act stemming from its failure to disclose that some of its products contained cochineal extract, a common food-coloring made from crushed insects.[184] On behalf of a putative consumer class, the plaintiff claims that, if the presence of cochineal extract had been disclosed, members of the class would not have purchased Starbucks' products because of objections to consuming animal products, allergic responses to the ingredient, or "sheer disgust."[185]

4. *High Fructose Corn Syrup Labeling*

FDA unequivocally rejected a petition by the Corn Refiners' Association (CRA) seeking approval for usage of the term "corn sugar" as an alternate common or usual name for the controversial sweetener, high-fructose corn syrup (HFCS).[186] FDA cited several reasons for disallowing what many have viewed as the proposed "re-branding" of HFCS, including: (1) HFCS cannot be referred to as a sugar because "sugar" is defined as "a solid, dried, and crystallized food; whereas syrup is an aqueous solution or liquid food;" (2) the term "corn sugar" has, for the past thirty years, been used as the common or usual name for dextrose; (3) "corn sugar" (dextrose) is a safe ingredient for individuals with hereditary fructose intolerance or fructose malabsorption, who must avoid ingredients that contain fructose; and (4) changing the name for HFCS to "corn sugar" would pose a public health concern and endanger this vulnerable population.[187]

In an August 2012 petition, Citizens for Health requested that FDA amend its high-fructose corn syrup regulations to require that food producers using HFCS identify the concentration of fructose on product labels.[188] This re-

184. Complaint at 11–20, Anderson v. Starbucks Corp., No. BC485438 (Cal. Super. Ct. May 25, 2012).

185. *Id.* at 7.

186. Citizen Petition from Audrae Erickson, President, Corn Refiners Ass'n, to U.S. Food & Drug Admin., Docket No. FDA-2010-P-0491 (Sept. 14, 2010); Letter from Michael M. Landa, Dir., Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Audrea Erickson, President, Corn Refiners Ass'n (May 30, 2012) [hereinafter Corn Refiners Ass'n Letter], *available at* http://www.fda.gov/default.htm (search "high-fructose corn syrup"; then select "Response to Petition from Corn Refiners Association" hyperlink) (rejecting petition to label high-fructose corn syrup as corn sugar).

187. Corn Refiners Ass'n Letter, *supra* note 186.

188. Petition from Citizens for Health to U.S. Food & Drug Admin., Docket No. FDA-2012-P-0904 (Aug. 15, 2012).

quirement would apply to food producers who use both standardized blends (forty-two and fifty-five percent fructose) and those who manipulate the amount of fructose in HFCS "to a different concentration" (for example, under the proposed addition to the rule HFCS with a ninety percent fructose, which is commonly used in sodas, salad dressings, jams, jellies, desserts and so-called light foods, would be labeled "high fructose corn syrup 90").[189] Additionally, the petitioners have asked FDA to use its enforcement authority against food companies using HFCS with fructose in amounts other than the forty-two or fifty-five percent blends, which FDA has generally regarded as safe.[190]

B. *"Natural" Foods*

As in the recent past, FDA's repeated refusal to define the term "natural" continued to keep judges and litigants throughout the country very busy in 2012.[191] What follows is but a small sample of recent cases regarding the use of the ubiquitous and contentious term.

- *"100% Pure & Natural" Tropicana Orange Juice*: Multi-district litigation alleging that, despite extensive pasteurizing and processing, Tropicana deceptively markets its not-from-concentrate orange juice as "100% Pure & Natural."[192]

- *"All Natural" Jamba Juice Smoothie Kits*: On behalf of a putative class, plaintiff alleges that Jamba Juice falsely misrepresents its smoothie kits as "All Natural" when they actually contain "unnaturally processed, synthetic and/or non-natural ingredients," such as ascorbic acid, citric acid, xanthan gum, and steviol glycosides.[193] The District Court recently granted a partial dismissal with leave to amend, reasoning that, "[t]he

189. *Id.* at 2.

190. *Id.*

191. Two of the "all natural" cases covered in last year's AALA update are proceeding after partial dismissals of federal warranty claims. Thurston v. Bear Naked, Inc., No. 11-CV-02890-H-BGS (S.D. Cal. Sept. 21, 2011), *partially dismissed* (July 13, 2012) (alleging "100% Pure and Natural" claim was false because of inclusion of synthetic ingredients such as hexane-processed soy ingredients, glycerin, and tocopherols); Bates v. Kashi Co., No. 11-CV-1967-H-BGS (S.D. Cal., Aug. 24, 2011), *partially dismissed* (July 16, 2012) (alleging false labeling as "all natural" when the products actually contain processed and synthetic ingredients, including sodium selenite which has not been designated by FDA as "generally recognized as safe").

192. In re Tropicana Orange Juice Mktg. & Sales Practices Litig., 867 F. Supp. 2d 1341 (2012) (consolidating six separate suits before a multidistrict litigation court).

193. Anderson v. Jamba Juice Co., No. 12-CV-01213, 2012 U.S. Dist. LEXIS 120723, at *3 (N.D. Cal. Mar. 12, 2012), *partially dismissed* (Aug. 25, 2012).

statement 'All Natural' is a general product description rather than a promise that the product is defect free," under the Magnuson-Moss Warranty Act.[194]

- *Chipotle Meat: Natural or Not?*: A California District Court judge ruled putative class claims regarding fraudulent misrepresentation of exclusive use of naturally raised meat in menu items can proceed against Chipotle Mexican Grill.[195] In denying the restaurant chain's Motion to Dismiss, the District Court observed, "Plaintiff need not show that he consumed non-naturally raised meat on one of his visits to Chipotle. The harm alleged [is that] . . . Plaintiff purchased food at Chipotle, at a premium, based on Defendant's representations that non-naturally raised meat was not used there."[196] The Plaintiff's claim for fraudulent concealment was also adequately alleged.[197]

- *"All Natural Flavors" & "All Natural Ice Cream"*: Despite obtaining dismissal of federal warranty claims, popular ice cream manufacturer Dreyer's will have to defend itself against state law warranty claims based on allegations that the company misled consumers by labeling its products with the phrases "All Natural Flavors" and "All Natural Ice Cream."[198]

- *"All Natural" Genetically Modified Cereals and Snacks*: Disgruntled consumers are challenging Quaker Oats and General Mills for labeling breakfast cereals and other snack foods made with genetically engineered ingredients as "All Natural."[199]

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194. *Id.* at *10.

195. Order Denying Motion to Dismiss at 1, Hernandez v. Chipotle Mexican Grill, Inc., No. CV 12-5543 DSF (C.D. Cal. Aug. 23, 2012).

196. *Id.*; *see also* Complaint at 7, Hernandez v. Chipotle Mexican Grill, Inc., No. 12-05543, (C.D. Cal. June 26, 2012).

197. Order Denying Motion to Dismiss at 1, Hernandez v. Chipotle Mexican Grill, Inc., No. CV 12-5543 DSF (C.D. Cal. Aug. 23, 2012).

198. Order Granting in Part and Denying in Part Defendant's Motion to Dismiss at 13, 19, Astiana v. Dreyer's Grand Ice Cream, Inc., No. C-11-2910 EMC (N.D. Cal. July 20, 2012).

199. First Amended Class Action Complaint and Demand for Jury Trial at 2–3, Pfeifer v. Gen. Mills, Inc., No. 12-cv-03567 (D.N.J. July 23, 2012) (claiming Kix cereal, advertised as made with all natural corn, is not all natural because it contains genetically modified corn); Class Action Complaint for Equitable Relief and Damages at 1, Garcia v. Gen. Mills, Inc., No. 12-cv-22363 (S.D. Fla. June 26, 2012) (claiming GMO-containing snack foods marketed as "natural" are not "natural"); Complaint and Demand for Jury Trial at 1, Mirto v. Quaker Oats Co., No. BC486882 (Cal. Sup. Ct. June 19, 2012) (claiming that cereal was misadvertised as "all natural" because it contained genetically modified ingredients).

- *"All Natural" Nature Valley Products Made with HFCS*: Putative class action alleging violations of California's unfair competition and false advertising laws based on General Mills' representations of "All Natural," "Natural," and "100% Natural" on its Nature Valley® products. The Class Action alleges the labeling is deceptive because the brand is made with HFCS, high-maltose corn syrup, maltodextrin, and rice maltodextrin, ingredients which are allegedly not "minimally processed."[200] The Complaint further alleges that General Mills "takes wrongful advantage of consumers' strong preference for foods made entirely of natural ingredients" with words and images in its marketing and on product labels evocative of the outdoors and nature.[201]

C. *Country of Origin Labeling: Dispute Before the WTO*

The WTO has issued a final ruling in the dispute between the United States, Canada, and Mexico over country of origin labeling (COOL) for beef and pork products.[202] In November 2011, the WTO's Dispute Panel determined that specific provisions of the U.S. COOL program provided Canadian livestock less favorable treatment than domestic livestock.[203] The U.S. Trade Representative appealed, asserting that the U.S. COOL measure does not impose unfavorable treatment of imported products because "retailers must label meat derived from both domestic and imported livestock in the same conditions."[204] The WTO's Appellate Body upheld the Dispute Panel's assessment, concluding that "the COOL measure treats imported livestock differently than domestic livestock," in part because its recordkeeping requirements create an "incentive in favour of processing exclusively domestic livestock and a disincentive against handling imported livestock."[205] Additionally, the Appellate Body stated that the COOL measure lacks even-handedness because "its recordkeeping and verification re-

200. Class Action Complaint at 2, Janney v. Gen. Mills, No. C12-3919 (N.D. Cal. July 26, 2012).

201. *Id.* at 3.

202. *See generally* Panel Report, *United States—Certain Country of Origin Labelling (COOL) Requirements*, WT/DS 384/R, WT/DS386/R (Nov. 18, 2011), *available at* http://www.wto.org/english/tratop_e/dispu_e/384_386r_e.pdf (finding that the United States' implementation of COOL did not completely comply with WTO obligations).

203. *Id.* at 214A.

204. Appellate Body Report, *United States—Certain Country of Origin Labelling (COOL) Requirements*, II, WT/DS384/AB/R, WT/DS3861 AB/R (June 29, 2012), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds386_e.htm (select "Appellate Body Report" hyperlink).

205. *Id.* ¶ 496(a)(i), (ii).

quirements impose a disproportionate burden on upstream producers and processors" of livestock as compared to the "information conveyed to consumers through the mandatory labeling requirements" for meat sold at the retail level.[206]

Nevertheless, the Appellate Body determined that, as a general matter, the United States has the right to enact COOL regulations. The initial finding that COOL was "inconsistent" with Article 2.2 of the Technical Barriers to Trade (TBT) Agreement by being more trade-restrictive than necessary was reversed.[207] The United States is free to implement COOL in a manner consistent with the TBT agreement and will have a reasonable period of time to do so.[208]

D. *Advertising Issues*

1. *Food Marketing to Children*

A Federal Trade Commission (FTC) report found in 2009 companies spent $1.79 billion on ads targeting kids through TV commercials, social media, mobile phones, and recently via computer-based "advergames," food company-branded and themed online games.[209] As reported in the *Wall Street Journal*, food advertisers continue to develop new and ever-more effective ways to market directly to children using mobile technology.[210] Despite growing concern about marketing directed at children, regulatory and litigated efforts to limit the ways that food products can be marketed to children lost steam this year.

The effort by the Interagency Working Group on Food Marketed to Children (comprised of the FDA, FTC, USDA, and CDC) to create voluntary guidelines that would limit the marketing of certain foods to children stalled in

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206. *Id.* ¶ 349.

207. *Id.* ¶ 468.

208. Arbitrators Report, *United States – Certain Country of Origin Labelling (COOL) Requirements*, ¶ 122 WT/DS384/24, TW/D5386/23 (Dec. 4, 2012), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds386_e.htm (select "Article 21.3(c) Arbitration Report" hyperlink).

209. FED. TRADE COMM'N, A REVIEW OF FOOD MARKETING TO CHILDREN AND ADOLESCENTS: FOLLOW-UP REPORT 5, 70–71 (2012) [hereinafter FOLLOW-UP REPORT], *available at* http://www.ftc.gov/os/2012/12/121221foodmarketingreport.pdf. This constitutes an increase from the $1.6 billion spent targeting kids in 2006 as announced in the 2008 report. *See* FED. TRADE COMM'N, MARKETING FOOD TO CHILDREN AND ADOLESCENTS: A REVIEW OF INDUSTRY EXPENDITURES, ACTIVITIES, AND SELF-REGULATION 7 (2012), *available at* http://www.ftc.gov/os/2008/07/P064504foodmktingreport.pdf.

210. Anton Troianovski, *Child's Play: Food Makers Hook Kids on Mobile Games*, WALL ST. J., Sept. 17, 2012, http://online.wsj.com/article/SB10000872396390444812704577605263654758948.html#articleTabs%3Darticle.

2012.[211] The Interagency Working Group, which was created by Congress in 2009 to recommend standards for advertising food to kids, issued its "Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts" in 2011.[212] The draft guidelines were well received by public health advocates but sharply criticized by food and beverage industry lobbyists, who argued that the guidelines restricted commercial speech in violation of the First Amendment.[213] In March 2012, FTC Chairman Jon Leibowitz reportedly indicated to Congress that "'it's probably time to move on'" from the effort and later clarified, "The Commission does not support legislation restricting food advertising to children."[214] Nevertheless, as recently as September 2012, Chairman Leibowitz informed the *Wall Street Journal* that the FTC intends to "release a report by the end of the year detailing how dozens of food companies market their products to children" with the aim of "mak[ing] sure we have sunshine on industry practices."[215]

2. *No Injunction to Stop McDonald's from Selling Happy Meals with Toys*

Efforts by the Center for Science in the Public Interest, on behalf of a putative class, to enjoin McDonald's from advertising its Happy Meals® featuring toys to children have been stymied by a California Superior Court, which dismissed the case with prejudice.[216]

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211. FED. TRADE COMM'N ET AL., INTERAGENCY WORKING GROUP ON FOOD MARKETED TO CHILDREN, PRELIMINARY PROPOSED NUTRITION PRINCIPLES TO GUIDE INDUSTRY SELF-REGULATORY EFFORTS 1 (2011), *available at* http://www.ftc.gov/os/2011/04/110428foodmarketproposed guide.pdf.

212. *Id.*

213. *See, e.g.*, Letter from Julie Ralston Aoki, Staff Attorney, Public Health Law Ctr., & Elizabeth Moore, Project Consultant and Co-Principal, to Jon Leibowitz, Chairman, Fed. Trade Comm'n, et al. (July 8, 2011), *available at* http://publichealthlawcenter.org/sites/default/files/resources/phlc-comments-iwg-nutritionstdsandmarketingdefs-2011.pdf (in support); Letter from Carter Keithley, Pres., Toy Indus. Ass'n, to Office of Sec'y, Fed. Trade Comm'n (July 14, 2011), *available at* http://www.ftc.gov/os/comments/foodmarketedchildren/07840-80008.pdf (in opposition).

214. Jon Leibowitz, Op-Ed., *Food Marketing to Children Policies*, WALL ST. J., Apr. 30, 2012, http://online.wsj.com/article/SB10001424052702304811304577366090570130800.html.

215. Anton Troianovski, *FTC Shines Light on Food Ads, Kids*, WALL ST. J., Sept. 19, 2012, http://online.wsj.com/article/SB10000872396390443720204578004680626535230.html; *see* FOLLOW-UP REPORT, *supra* note 209 (anticipated report).

216. *Parham v. McDonald's Corp.*, No. CGC-10-506178 (Cal. Super. Ct. Dec. 15, 2010), *dismissed with prejudice* (Cal. Super. Ct. Apr. 4, 2010).

3. *N.Y. Considers Legislation to Limit the Marketing of Children's Meals with Incentive Items*

New York State Senate Bill S7849-2011 would require fast-food restaurants offering incentive items with children's meals to meet certain nutritional guidelines.[217] The nutritional guidelines would be established by the state health commissioner to limit the amount of fat, sugar, calories, and sodium per meal.[218] "Incentive items" regulated by the proposed legislation would include toys, games, trading cards, admission tickets, "or other consumer product[s], whether physical or digital, with particular appeal to children."[219] Moreover, the nutritional standards for meals would also apply whenever any "any coupon, voucher, ticket, token, code or password which is provided directly by the restaurant and is redeemable for or grants digital or other access to any toy, game, trading card, admission ticket, or other consumer product" appealing to children.[220]

San Francisco enacted a city ordinance banning restaurants from offering free toys with meals unless the meals met specific dietary guidelines in 2010,[221] but McDonald's quickly found a loophole. Instead of altering the contents of the food to meet the requirements or removing free toys from its Happy Meals, McDonald's started charging customers who wanted the toys an extra ten cents, which the company then donated to its Ronald McDonald House charity.[222] The proposed New York legislation appears to have been drafted in a way that would prohibit the discounted tying of an incentive item; it specifically states that a "restaurant may offer an incentive item in combination with the purchase of a meal, food item, or beverage, only if the meal, food item, or beverage, meets nutritional standards."[223]

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217. S.B. 7849, 2012 Gen. Assemb., Reg. Sess. (N.Y. 2012).
218. *Id.*
219. *Id.*
220. *Id.*
221. *See* S.F., CAL., HEALTH CODE art. 8, § 471.4 (2010).
222. Robin Wilkey, *San Francisco Happy Meal Toy Ban Takes Effect, Sidestepped by McDonald's*, HUFFINGTON POST (Dec. 1, 2011), http://www.huffingtonpost.com/2011/11/30/san-francisco-happy-meal-ban_n_1121186.html.
223. *See* S.B. 7849, *supra* note 217.

VI. BIOTECHNOLOGY & FOOD

A. *Genetically Engineered Crops & Livestock*

1. *Seralini Study on the Long-Term Toxicity of Roundup Ready Corn*

A widely-covered two-year study, published in the peer-reviewed journal *Food and Chemical Toxicology*, found that a commonly-grown genetically engineered corn variety, Monsanto's Roundup-tolerant NK603, raised the rate of cancer and increased the risk of kidney and liver problems in rats.[224] Opponents of genetic engineering have been quick to praise the study and point to its findings as a compelling reason to require labeling of genetically modified ingredients.[225] At the same time, the study has drawn significant criticism for purported design flaws, including insufficient sample sizes, use of a breed of rats that is prone to tumor growth, and a lead researcher who has a record of bias against genetic engineering.[226]

2. *Organic Farmers Seek to Stop GE Canola Crops in Oregon*

After issuing a temporary rule (without notice or opportunity for comment) that would open 1.7 million acres of previously restricted Oregon land to genetically engineered canola plants, the Oregon Department of Agriculture (ODA) found itself in court opposing a motion for a stay brought by Friends of Family Farmers, the Center for Food Safety, and several seed companies.[227] The court was persuaded by the Plaintiffs' claim that opening formerly protected Willamette Valley acreage to genetically engineered crops without requiring buffers could result in irreparable harm by virtue of inevitable cross-pollination, seed crop contamination, increased pests and disease, and escaped canola weeds.[228] Finding that the Plaintiffs demonstrated both a "sufficient likelihood of severe

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224. Gilles-Eric Séralini et al., *Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize*, 50 FOOD CHEM. TOXICOLOGY 4221, 4224–27 (2012), http://research.sustainablefoodtrust.org/wp-content/uploads/2012/09/Final-Paper.pdf; *see also* Lynne Peeples, *GMO Debate Heats Up: Critics Say Biotech Industry Manipulating Genes, and Science*, HUFFINGTON POST, Sept. 24, 2012, http://www.huffingtonpost.com/2012/09/21/gmo-proposition-37-study-funding-research_n_1904535.html?utm_hp_ref=email_share.

225. Peeples, *supra* note 224.

226. Steven Salzberg, *Does Genetically Modified Corn Cause Cancer? A Flawed Study Fails to Convince*, FORBES, Sept. 24, 2012, http://www.forbes.com/sites/stevensalzberg/2012/09/24/does-genetically-modified-corn-cause-cancer-a-flawed-study/.

227. Order Granting Motion to Stay, Friends of Family Farmers v. Or. Dep't of Agric., No. A152202 (Or. Ct. App. Aug. 31, 2012).

228. *Id.*

and irremediable harm" and a "very substantial likelihood of prevailing on the merits," the court renewed the temporary stay placed in effect August 16, 2012.[229] A September 28, 2012 hearing on ODA's permanent rule was attended by more than 100 concerned citizens, including organic farmers and seed companies against opening the acreage in question and grain and grass seed growers in favor of the rule.[230] In February 2013, ODA struck a compromise by adopting an administrative rule that allows some canola production in the Willamette Valley but establishes a "rapeseed exclusion zone" covering the area where the majority of specialty seed production occurs.[231] The rule further limits "how much canola can be grown in the Willamette Valley, where it can be grown, and requires significant management practices for production by controlling inadvertent spread of canola seed."[232]

3. *Genetically Engineered Salmon*

In 1995, AquaBounty Technologies filed an application to produce AquAdvantage Salmon, an Atlantic salmon containing Chinook genes that accelerate maturation.[233] In the autumn of 2010, FDA held highly anticipated public meetings on AquAdvantage Salmon, the first genetically engineered animal intended to be consumed as food.[234] Since that time, the application has been reviewed by FDA's Center for Veterinary Medicine.[235] In February 2012, Food and Water Watch, Consumers Union, and the Center for Food Safety filed a petition with the Office of Food Additive safety of FDA's Center for Food Safety and Applied Nutrition requesting that the AquAdvantage application be reviewed

229. *Id.*

230. Bennett Hall, *Valley Divided on Canola Plan*, CORVALLIS GAZETTE-TIMES, Sept. 29, 2012, http://www.gazettetimes.com/news/local/valley-divided-on-canola-plan/article_d384548c-09bb-11e2-8752-0019bb2963f4.html?comment_form=true; *see also, e.g.*, Declaration of Frank Morton in Support of Petitioner's Motion, Friends of Family Farmers v. Or. Dept. of Agric., No. 152262 (Or. Ct. App. Aug. 14, 2012).

231. Press Release, Or. Dep't of Agric., ODA Adopts Willamette Valley Canola Control Area Rule (Feb. 7, 2013), *available at* http://www.oregon.gov/ODA/Pages/news/130205canola_rule.aspx.

232. *Id.*

233. *See* CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., AQUADVANTAGE SALMON: DRAFT ENVIRONMENTAL ASSESSMENT 100 (2012), *available at* http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineGenet/GeneticallyEngineeredAnimals/UCM333102.pdf.

234. *Id.* at 102.

235. *Id.*

under the food additive provisions of the Food, Drug, and Cosmetic Act. [236] According to the petitioners, the genetic modifications made by AquaBounty "significantly alter[] the salmon's composition . . . in a way that is reasonably expected to alter its nutritive value or concentration of constituents, and the new substance raises safety concerns."[237] Thus, the salmon "must be treated as a food additive and the Agency must make a closer inquiry into the safety of its consumption, including, but not limited to, subjecting it to extensive pre-market testing."[238]

4. *Genetically Engineered Apples*

On July 13, 2012, USDA's Animal and Plant Health Inspection Service (APHIS) published a notice in the Federal Register announcing receipt of a petition from Okanagan Specialty Fruits, Inc. seeking deregulation of an apple genetically engineered to resist browning.[239] Comments were to be submitted until September 11, 2012.[240] The U.S. Apple Association opposes the petition, expressing concern about consumer acceptance and the potential effect on overall apple consumption.[241]

5. *APHIS Determinations of Nonregulated Status*

USDA's APHIS approved several genetically engineered crop varieties for non-regulated status based on determinations that the varieties in question are "unlikely to pose a plant pest risk."[242] These deregulation decisions allow farmers and distributors to freely move and plant the specified crops without further regulatory oversight from APHIS. Deregulated varieties include:

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236. Petition from Food & Water Watch et al. to Office of Food Additive Safety, U.S. Food & Drug Admin. (Feb. 7, 2012), *available at* http://www.centerforfoodsafety.org/up-content/uploads/2012/02/FDAFoodAdditivePetitionGEsalmon.pdf.

237. *Id.* at 1.

238. *Id.*

239. Availability of Petition for Determination of Nonregulated Status of Apples Genetically Engineered to Resist Browning 77 Fed. Reg. 41,362 (July 13, 2012) (notice of petition).

240. *Id.*

241. Andrew Pollack, *That Fresh Look, Genetically Buffed*, N.Y. TIMES, July 12, 2012, http://www.nytimes.com/2012/07/13/business/growers-fret-over-a-new-apple-that-wont-turn-brown.html?pagewanted=all.

242. Press Release, Animal & Plant Health Insp. Serv., USDA, USDA Announces Biotechnology Regulatory Actions (Dec. 21, 2011) [hereinafter Biotechnology Regulatory Actions], *available at* http://www.aphis.usda.gov/newsroom/2011/12/brs_actions.shtml.

- *H7-1 Sugar Beets*: APHIS deregulated Monsanto's Roundup Ready sugar beet genetically engineered to be resistant to the herbicide glyphosate.[243]

- *MON 87769 Soybean*: Monsanto has genetically engineered this soybean variety "to produce stearidonic acid, an omega-3 fatty acid not found in conventional soybeans."[244]

- *MON 87460 Corn*: Monsanto genetically engineered this corn variety to be tolerant of drought. [245] This is APHIS' "first determination of non-regulated status of a product that has been genetically engineered to increase drought tolerance." [246] The December 2011 deregulation decision was "[b]ased on the data submitted by Monsanto with its petition for deregulation, APHIS' risk assessment and evaluation of scientific information, and review of the public comments received."[247]

- *MON 87705 Soybean*: Monsanto genetically engineered these soybeans to have a "modified fatty acid profile and for tolerance to the herbicide glyphosate."[248]

- *J101 and J163 Alfalfa*: On January 27, 2011, APHIS announced its controversial decision to grant non-regulated status for alfalfa that has been genetically engineered to be glyphosate resistant.[249] This is the first deregulation of a GE perennial crop by USDA.[250] APHIS originally deregulated the lines of Roundup Ready alfalfa in June 2005,[251] and a lawsuit was subsequently filed in the United States District Court for the Northern

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243. 77 Fed. Reg. 42,693 (July 20, 2012).
244. 77 Fed. Reg. 41,350 (July 13, 2012).
245. 76 Fed. Reg. 80,869 (Dec. 27, 2011).
246. Biotechnology Regulatory Actions, *supra* note 242.
247. *Id.*
248. 76 Fed. Reg. 78,232 (Dec. 16, 2011).
249. ANIMAL & PLANT HEALTH INSP. SERV., USDA, RECORD OF DECISION: GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS (2011), *available at* http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_rod.pdf (describing the deregulation process for these genetically modified lines of alfalfa, including a summary of the litigation through December 2010).
250. *American Beekeeping Federation Passes Resolution Opposing USDA's Deregulation of GE Alfalfa*, CORNUCOPIA INST. (Jan. 11, 2011), http://www.cornucopia.org/2011/01/ american-beekeeping-federation-passes-resolution-opposing-usda%E2%80%99s-deregulation-of-ge-alfalfa/.
251. 70 Fed. Reg. 36,917, 36,918 (June 27, 2005).

District of California.[252] In February 2007, the court vacated APHIS' 2005 decision to deregulate Roundup Ready alfalfa and ordered APHIS to prepare an Environmental Impact Statement (EIS) in support of a regulatory determination regarding Roundup Ready alfalfa.[253] This time APHIS made its decision to deregulate "after conducting a thorough and transparent examination of alfalfa through a multi-alternative EIS and several public comment opportunities, and determining that [Roundup Ready] alfalfa does not pose a plant pest risk."[254] A variety of advocacy groups have actively opposed the deregulation of GE Roundup Ready alfalfa. Following APHIS's most recent deregulation decision, the Center for Food Safety and Earthjustice filed another action in the Northern District of California alleging USDA had failed to provide proper oversight for the biotech crop.[255] The challenge was unsuccessful.[256] Plaintiffs note that, according to USDA's own data, prior to the deregulation of Roundup Ready alfalfa, "93% of all the alfalfa planted by farmers in the U.S. is grown without the use of any herbicides.[257] With the full deregulation of GE alfalfa, "USDA estimates that up to 23 million more pounds of toxic herbicides will be released into the environment each year."[258] Opponents of GE crops are especially concerned about the potential for Roundup Ready alfalfa to be cross pollinated with and contaminate natural alfalfa.[259] This risk is especially acute because perennial alfalfa "remains in the ground for 3–6 years and is widely prevalent in wild or feral form throughout America, further increasing the likelihood and extent of transgenic contamination."[260]

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252. Geertson Seed Farms v. Johanns (Alfalfa I), No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

253. *Id.* at *12.

254. *Roundup Ready Alfalfa*, ANIMAL & PLANT HEALTH INSP. SERV., USDA, http://www.aphis.usda.gov/biotechnology/alfalfa.shtml (last visited May 10, 2013).

255. Ctr. for Food Safety v. Vilsack (Alfalfa II), 844 F. Supp. 2d 1006, 1022 (N.D. Cal. 2012).

256. *Id.* at 1024 (holding agency took requisite "hard look" and allowing deregulation). An appeal has been filed. Ctr. for Food Safety v. Vilsack, No. 12-15052 (N.D. Cal. Jan. 6, 2012).

257. Press Release, Ctr. for Food Safety, Farmers and Consumer Groups File Lawsuit Challenging Genetically Engineered Alfalfa Approval (Mar. 18, 2011), *available at* http://www.centerforfoodsafety.org/press-releases/753/farmers-and-consumer-groups-file-lawsuit-challenging-genetically-engineered-alfalfa-approval.

258. *Id.*

259. *Id.*

260. *Id.*

6. *AMA Amends Policy on GE Foods*

The American Medical Association's (AMA) House of Delegates has reportedly updated its policy on genetically engineered foods, voting at its 2012 Annual Meeting to adopt a statement that supports pre-market product testing but opposes special labeling.[261] The AMA has apparently concluded that "there is no scientific justification for special labeling of bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education."[262] At the same time, however, the association has backed "mandatory pre-market systematic safety assessments of bioengineered foods."[263]

7. *AC21 Committee Issues Final Report, Urges Coexistence*

USDA Advisory Committee on Biotechnology and 21st Century Agriculture (AC21),[264] which is tasked with the difficult job of resolving conflicts between genetically engineered and non-genetically engineered crops, held its last plenary session on August 27–28, 2012 to discuss the draft of the highly-anticipated AC21 Report.[265] The committee, which nearly reached consensus, issued its report, *Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture*, with the signatures of all but one member attached.[266] The report acknowledges that America is a nation that employs diverse agricultural practices and aims to preserve the ability of individual farmers to make their own decisions about how and what to cultivate on their land.[267] The committee suggests advancing the concept of crop coexistence through five recommendations:

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261. Rosie Mestel, *GMO Foods Don't Need Special Label, American Medical Assn. Says*, L.A. TIMES, June. 21, 2012, http://articles.latimes.com/2012/jun/21/news/la-heb-gmo-foods-medical-association-20120620.

262. *H-480.958 Bioenginnered (Genetically Engineered) Crops and Foods*, AM. MED. ASS'N, http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-480.958.HTM (last visited May 10, 2013).

263. *Id.*

264. ADVISORY COMM. ON BIOTECHNOLOGY & 21ST CENTURY AGRIC. (AC21), ENHANCING COEXISTENCE: A REPORT OF THE AC21 TO THE SECRETARY OF AGRICULTURE (2012) [hereinafter ENHANCING COEXISTENCE], *available at* http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf.

265. *See Advisory Committee on Biotechnology and 21st Century Agriculture (AC21)*, USDA, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=AC21Main.xml (last visited May 10, 2012).

266. Dan Flynn, *AC21 Wants USDA to Investigate Crop Insurance for Genetic Harm to Organic Crops*, FOOD SAFETY NEWS (Nov. 21, 2012), http://www.foodsafetynews.com/2012/11/ac21-wants-usda-to-investigate-crop-insurance-for-genetic-harm-to-organic-crops/.

267. ENHANCING COEXISTENCE, *supra* note 264, at 4.

- Developing a crop-insurance-based mechanism to compensate for economic losses suffered when an organic crop is contaminated by a genetically engineered or conventional crop;

- Spearheading and funding a broad-based education and outreach initiative regarding coexistence;

- Working with all stakeholders to foster good crop stewardship and mitigate potential economic risks from unintended gene flow between crop varieties;

- Funding research relevant to coexistence in American agriculture; and

- Working with seed suppliers to ensure a diverse and high quality commercial seed supply.[268]

The first recommendation, using crop-insurance to compensate for genetic drift, generated significant controversy and sparked disappointment among proponents of organic, sustainable, and non-GE agriculture.[269] The recommendation places the financial burden of contamination on organic and non-GE farmers who would be responsible for purchasing insurance to cover any potential losses and allows the biotechnology companies that created and profit handsomely from GE technology to avoid any responsibility for contamination.[270] Indeed, this recommendation prompted the dissenting member of the committee not to add her name to the report.[271] The USDA is presently working to review and implement AC21 recommendations.[272]

8. *Development of Genetically Engineered "Enviropig" Halted*

Canadian researchers have reportedly stopped pursuing the development of genetically engineered pigs after the project's sponsor, Ontario Pork, pulled its

268. *Id.* at 14–25.
269. Flynn, *supra* note 266.
270. *Id.*
271. *Id.*
272. Press Release, USDA, Summary of USDA Efforts to Address Final Recommendations by the Advisory Committee on Biotechnology & 21st Century Agriculture (AC21) (Feb. 21, 2013), *available at* http://www.usda.gov/documents/usda-factsheet-ac21-final-recommendations.pdf.

funding.[273] Created in 1999 by scientists at the University of Guelph, the Enviropig was engineered with genes from mice and an *E. coli* bacterium to digest plant phosphorus more efficiently and, consequently, to produce manure that has a less deleterious environmental impact, as compared to conventional Yorkshire pigs.[274] The Enviropig met heavy resistance from consumer and environmental groups opposed to the introduction of transgenic livestock into the food supply.[275]

B. *Nanotechnology*

Nanotechnology, which is highly anticipated in the agricultural and food sectors for its potential to increase yield, improve nutrition, and decrease perishability, is poised be the next controversial scientific frontier in agricultural and food science.[276] Government attention is beginning to focus on this emerging area.

1. *CRS Policy Primer on Nanotechnology*

Nanomaterials were the subject of an April 13, 2012 Congressional Research Service (CRS) report addressing topics concerning efforts to move nanotech from research laboratories to commercial products, including "federal research and development [] investments under the National Nanotechnology Initiative []; U.S. international competitiveness; and environmental, health, and safety [] concerns," but also "nanomanufacturing and public attitudes toward, and understanding of nanotechnology."[277] The report acknowledges that (1) there is "widespread uncertainty" regarding the environmental, health, and safety implications of nanotechnology, and (2) "new and unique technologies, tools, instruments, measurement science, and standards for nanomanufacturing," may be

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273. Rod Nickel, *Death Knell May Sound for Canada's GMO Pigs*, REUTERS (Apr. 2, 2012), http://www.reuters.com/article/2012/04/03/us-gmo-canada-pigs-idUSBRE83110320120403.

274. *See Enviropig*, UNIV. OF GUELPH, http://www.uoguelph.ca/enviropig/ (last visited May 10, 2013); *see also* Anne Minard, *Gene Altered "Enviropig" to Reduce Dead Zones?*, NAT'L GEOGRAPHIC NEWS, March 30, 2010, http://news.nationalgeographic.com/news/2010/03/100330-bacon-pigs-enviropig-dead-zones/.

275. *See* Press Release, Canadian Biotechnology Action Network, Genetically Modified Pig Shelved (Apr. 2, 2012), *available at* http://www.cban.ca/Press/Press-Releases/Genetically-Modified-Pig-Shelved.

276. *See generally* JOHN F. SARGENT, JR., CONG. RESEARCH SERV., RL 34511, NANOTECHNOLOGY: A POLICY PRIMER (2012) (discussing nanotechnology), *available at* http://www.fas.org/sgp/crs/misc/RL34511.pdf.

277. *Id.* at 1.

needed to bring nanotech products "into safe, reliable, effective, and affordable commercial-scale production in a factory environment."[278]

2. *GAO Report Regarding Nanotechnology Research*

The GAO issued a May 2012 report regarding nanotechnology, which emphasizes the need for improved performance information and cost analysis for environmental, health, and safety research (EHS).[279] GAO reviewed its own nanotechnology research conducted in 2010 by seven National Nanotechnology Initiative (NNI) member agencies, including FDA.[280] GAO concluded that the Office of Science and Technology Policy should facilitate development of performance measures for NNI EHS research needs, make this information available in public reports, and approximate the costs and resources required to meet research needs.[281]

3. *Nanomaterials Lawsuit Against FDA Dismissed; Draft Guidance Issued*

In December 2011 a group of NGOs, including the International Center for Technology Assessment, Friends of the Earth, The Action Group on Erosion, Technology and Concentration, The Center for Environmental Health, Food and Water Watch, and the Institute for Agriculture and Trade Policy, sued FDA for allegedly failing to respond to their 2006 petition asking for regulation of nanomaterials in food.[282] Approximately four months later, FDA responded by issuing draft guidance,[283] mooting the issue and prompting plaintiffs to voluntarily

278. *Id.* at 12–13.

279. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-427, NANOTECHNOLOGY: IMPROVED PERFORMANCE INFORMATION NEEDED FOR ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH 2–3 (2012), *available at* http://www.gao.gov/assets/600/591007.pdf.

280. *Id.* at 5.

281. *Id.* at 51–52.

282. *See* Complaint for Declaratory and Injunctive Relief, Int'l. Ctr. for Tech. Assessment v. Hamburg, No. C 11-6592 MEJ (N.D. Cal. Dec. 21, 2011); Petition Requesting FDA Amend Its Regulations for Prods. Composed of Engineered Nanoparticles Generally & Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically, Int'l Ctr. for Tech. Assessment v. Eschenbach, No. FDA-2006-P-0213 (2006).

283. U.S. FOOD & DRUG ADMIN., U.S. DEPT. OF HEALTH & HUMAN SERV., DRAFT GUIDANCE FOR INDUSTRY: ASSESSING THE EFFECTS OF SIGNIFICANT MANUFACTURING PROCESS CHANGES, INCLUDING EMERGING TECHNOLOGIES, ON THE SAFETY AND REGULATORY STATUS OF FOOD INGREDIENTS AND FOOD CONTACT SUBSTANCES, INCLUDING FOOD INGREDIENTS THAT ARE COLOR ADDITIVES (2012) [hereinafter DRAFT GUIDANCE], *available at* http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM300927.pdf.

dismiss the action.[284] FDA has taken the position that although nanomaterials may have unusual characteristics compared to their larger counterparts, regulating them as new substances is outside of the Agency's regulatory authority.[285] FDA will evaluate nanomaterials based on their effects on regulated products and engage in pre-market review in all cases where the Agency has such authority (for example, new drugs, new animal drugs, biologics, food additives, color additives, certain human devices, and certain new dietary ingredients in dietary supplements).[286] FDA rejected the groups' request to develop a new testing regime for nanomaterials saying the agency considers "the current framework for safety assessments sufficiently robust and flexible."[287] At this time, FDA is not considering mandatory labeling for all products that contain nanoparticles, as requested by the petitioners; instead, FDA plans to make case-by-case evaluations of the best way to convey information about nanomaterials.[288]

C. *Synthetic Agriculture*

University of Kansas School of Law Professor Andrew Torrance examined the promises and perils of genetic engineering taken to the ultimate level—designing organisms from scratch—a process that has been dubbed "synagriculture."[289] According to Torrance, synagriculture is presently part of the do-it-yourself biology movement and, in contrast to the genetic engineering practiced to date, represents a democratization of GE crop and livestock development.[290] Torrance urges the legal community to prepare for the next frontier in engineered agriculture.[291]

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284. Int'l Ctr. for Tech. Assessment v. Hamburg, No. C 11-6592 MEJ (N.D. Cal. May 11, 2012) (granting dismissal).

285. DRAFT GUIDANCE, *supra* note 283, at 12–14.

286. *Id.*

287. *Fact Sheet: Nanotechnology*, U.S. FOOD & DRUG ADMIN. (Apr. 2012), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm300914.htm.

288. DRAFT GUIDANCE, *supra* note 283, at 13.

289. Andrew W. Torrance, *Planted Obsolescence: Synagriculture and the Law*, 48 IDAHO L. REV. 321, 322 (2012).

290. *Id.* at 346.

291. *Id.* at 350.

VII. ORGANICS & ALTERNATIVE AGRICULTURE

A. *Stanford Meta-Analysis of Studies Assessing the Health Benefits of Organic Food*

By conducting a systematic review of prior studies, including seventeen studies in humans and 223 studies of nutrient and contaminant levels in foods, regarding the health benefits of organically grown food, a team of researchers affiliated with Stanford University set out to answer the question: "Are organic foods safer or healthier than conventional alternatives?"[292] The press release announcing the findings began with a headline proclaiming they found "little evidence of health benefits from organic foods."[293] This viral sound-bite was repeated over and over throughout the media. According to the Stanford study:

> [n]o consistent differences were seen in the vitamin content of organic products, and only one nutrient—phosphorus—was significantly higher in organic versus conventionally grown produce (and the researchers note that because few people have phosphorous deficiency, this has little clinical significance). There was also no difference in protein or fat content between organic and conventional milk, [but a few studies indicated] that organic milk may contain significantly higher levels of omega-3 fatty acids.[294]

Proponents of organic production and sustainable agriculture have been quick to point out the limitations in the study, the narrow conclusions, and the attention-grabbing way in which the findings were disseminated. Some have suggested that the researchers were not sufficiently objective.[295] Others note that the conclusions regarding pesticide exposure fail to address the synergistic, "cocktail effect" of multiple pesticide exposure, especially for vulnerable populations including pregnant women, developing fetuses, and children.[296] Still, others emphasized that a narrow focus on health benefits does not capture the myriad of

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292. Crystal Smith-Spangler et al., Are Organic Foods Safer or Healthier Than Conventional Alternatives?: A Systematic Review, 157 ANNALS INTERNAL MED. 348, 348–66 (2012).

293. Press Release, Michelle Brandt, Stanford Sch. of Med., *Little Evidence of Health Benefits from Organic Foods, Stanford Study Finds* (Sept. 3, 2012), *available at* http://med.stanford.edu/ism/2012/september/organic.html.

294. *Id.*; *see also* Smith-Spangler et al., *supra* note 292, at 357–59.

295. *See* Lynne Peeples, *Stanford Organics Study: Have Faulty Methods, Political Motivations Threatened Kids' Health?*, HUFFINGTON POST (Sept. 13, 2012), http://www.huffingtonpost.com/2012/09/13/stanford-organics-study-public-health_n_1880441.html (noting recent donation by Cargill to Stanford University).

296. Tom Philpott, *5 Ways the Stanford Study Sells Organics Short*, MOTHER JONES, Sept. 5, 2012, http://www.motherjones.com/tom-philpott/2012/09/five-ways-stanford-study-underestimates-organic-food.

reasons to prefer organic food and support organic production, including a desire to avoid antibiotic residue (and microbial resistance) and concerns about consuming genetically modified food, as well as a desire to promote sustainable and environmentally responsible production methods.[297]

B. *USDA National Organic Program Revises National List of Allowed and Prohibited Substances*

USDA's National Organic Program (NOP) issued a final rule, effective August 3, 2012, revising the National List of Allowed and Prohibited Substances with regard to the use of tetracycline, formic acid, and attapulgite during the production and processing of organic crops and food ingredients.[298] The previous iteration of the list permitted the use of tetracycline "for fire blight control only" in apple, pear, and other organic fruit crops until October 21, 2012.[299] As amended, the final rule specifies that permissible tetracycline use is limited to controlling fire blight in apple and pear crops only, and such use must be phased out by October 21, 2014.[300] Additionally, formic acid was added to the National List; permissible use of formic acid is sharply limited to suppress infestations of mites in honeybee colonies.[301] NOP has also approved the use of attapulgite, a substance generally regarded as safe by FDA when used as an adjuvant for pesticide chemicals "as a processing aid in the handling of plant and animal oils."[302]

VIII. FOOD INSECURITY & NUTRITION PROGRAMS

A. *Food Insecurity*

According to the USDA Economic Research Service (ERS), 14.9% of American households—home to a staggering 50.1 million Americans—experienced food insecurity during 2011.[303] Of these households, 5.7% had "very

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297. Rosie Mestel, *Lots of Chatter, Anger over Stanford Organic Food Study*, L.A. TIMES, Sept. 12, 2012, http://www.latimes.com/health/boostershots/la-heb-stanford-organic-food-study-controversy-20120911,0,173210.story.

298. National Organic Program; Amendments to the National List of Allowed and Prohibited Substances, 77 Fed. Reg. 45,903 (Aug. 2, 2012) (to be codified at 7 C.F.R. pt. 205).

299. *Id.* at 45,903.

300. *Id.* at 45,907 (to be codified at 7 C.F.R. § 205.601(12)).

301. *Id.* at 45,904, 45,907 (to be codified at 7 C.F.R. § 205.603(b)(2)).

302. *Id.* at 45,907 (to be codified at 7 C.F.R. § 205.605(a)).

303. ALISHA COLEMAN-JENSEN ET AL., ECON. RESEARCH SERV., USDA, HOUSEHOLD FOOD SECURITY IN THE UNITED STATES IN 2011, at 6 tbl.1A (2012), *available at* http://www.ers.usda.gov/publications/err-economic-research-report/err141.aspx.

low food security."[304] Such designation means household members "were food insecure to the extent that eating patterns of one or more household members were disrupted and their food intake reduced."[305] Another USDA report focused on food and nutrition assistance program trends through 2011 and summarized ERS research reports on WIC-related topics (topics related to women, infants, and children) that were released in fiscal year 2011.[306]

B. *USDA ERS Evaluates the Real Cost of Healthy Food*

It is widely, though largely incorrectly, assumed that healthy foods cost more than their less health-promoting counterparts (such as foods that are high in saturated fat, added sugar, and/or sodium, or that contribute little to meeting dietary recommendations). In a May 2012 report, the ERS endeavored to put some concrete numbers on the cost of healthy food.[307] They compared the prices of healthy and less healthy foods using three different metrics to get a better sense of whether healthier foods are really more expensive than less healthy options.[308] The metrics used were (1) price per calorie, or food energy ($/calorie), price per edible weight ($/100 edible grams), and (3) price per average-portion size.[309] ERS also "estimate[d] the daily cost of meeting dietary recommendations for each of the five major food groups," and stated that "it is not possible to conclude that healthy foods are more expensive than less healthy foods," finding different outcomes depending the metric used.[310]

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304. *Id.*
305. *Id.* at 5.
306. *See* ECON. RESEARCH SERV., USDA, ECON. INFO. BULLETIN NO. 93, THE FOOD ASSISTANCE LANDSCAPE: FY 2011 ANNUAL REPORT (2012), *available at* http://www.ers.usda.gov/media/376910/eib93_1_.pdf.
307. *See* ANDREA CARLSON & ELIZABETH FRAZÃO, ECON. RESEARCH SERV., USDA, ECON. INFO. BULLETIN NO. 96, ARE HEALTHY FOODS REALLY MORE EXPENSIVE? IT DEPENDS ON HOW YOU MEASURE THE PRICE (2012), *available at* http://www.ers.usda.gov/media/600474/eib96_1_.pdf.
308. *Id.* at 30.
309. *Id.*
310. *Id.* at 2, 30.

IX. LIVESTOCK AND MEAT

A. *USDA Livestock Regulation*

1. *FSIS Issues Notice on Final Rule Regarding Misbranded Meat, Poultry*

In May 2012, FSIS issued a final rule, and a related Notice to Inspectors, on misbranded meat and poultry.[311] The rule requires establishments to prepare and maintain recall procedures, notify FSIS within twenty-four hours when adulterated or misbranded meat and poultry products which could harm consumers have entered the marketplace, and document their Hazard Analysis and Critical Control Point system food safety plans.[312]

2. *FSIS Amends Poultry Classes*

In an effort to "ensure that the labeling of poultry products is truthful and not misleading," FSIS issued a final rule, effective January 1, 2014, amending the definitions and standards for classes of poultry in the market.[313] To date, poultry classes have been defined by the bird's age and sex, but because of improved "grow-out" rates, today's birds tend to be ready for market much sooner.[314] Thus, the new classifications lower the age of five classes of poultry for market—roaster or roasting chickens, broiler or fryer chickens, Rock Cornish game hens, capons, and fryer-roaster turkeys.[315]

3. *Supreme Court Invalidates California's Downer Livestock Law*

A California law that aimed to prohibit slaughterhouses from receiving, processing, or selling nonambulatory animals[316] failed to survive the National Meat Association's preemption challenge.[317] The United States Supreme Court relied on the express preemption language in the Federal Meat Inspection Act (FMIA) to overrule the Ninth Circuit Court of Appeals, which previously held

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311. Requirements for Official Establishment to Notify FSIS of Adulterated or Misbranded Product, 77 Fed. Reg. 26,929 (May 8, 2012) (to be codified at 9 C.F.R. pts. 304, 381, 417, 418).

312. *Id.* at 26,936–37.

313. Classes of Poultry, 76 Fed. Reg. 68,058, 68,058 (Nov. 3, 2011) (to be codified at 9 C.F.R. pt. 381).

314. *Id.*

315. *Id.* at 68,064.

316. CAL. PENAL CODE § 599f (West 2010).

317. Nat'l Meat Ass'n v. Harris, 132 S. Ct. 965, 970, 975 (2012) (holding the FMIA expressly preempts the state law).

that the states may regulate "the kind of animal that may be slaughtered."[318] The Supreme Court reasoned,

> The FMIA regulates slaughterhouses' handling and treatment of nonambulatory pigs from the moment of their delivery though the end of the meat production process. California's [law] endeavors to regulate the same thing, at the same time, in the same place except by imposing different requirements. The FMIA expressly preempts such a state law.[319]

B. *Central Valley Meat Suspension*

Less than a year after the FSIS issued a final compliance guide regarding the use of video recording in federally inspected slaughtering establishments,[320] the agency received disturbing video footage from Compassion Over Killing, an animal welfare organization.[321] The footage documented unacceptable treatment of cattle at Central Valley Meat Company in Hanford, California.[322] Upon investigation, FSIS found humane handling infractions and probable violations of the Humane Methods of Slaughter Act.[323] Accordingly, FSIS suspended both the facility's mark of inspection and the assignment of the inspectors stationed at the facility.[324] In the August 21, 2012 press release, FSIS emphasized that "while some of the footage provided shows unacceptable treatment of cattle, it does not show anything that would compromise food safety."[325] At the time of publication, FSIS's investigation is ongoing; to date, no food safety violations have been substantiated.[326]

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318. *Id.* at 970.

319. *Id.* at 975.

320. FOOD SAFETY AND INSPECTION SERV., USDA, COMPLIANCE GUIDELINES FOR USE OF VIDEO OR OTHER ELECTRONIC MONITORING OR RECORDING EQUIPMENT IN FEDERALLY INSPECTED ESTABLISHMENTS (2011), *available at* http://www.fsis.usda.gov/Significant_Guidance/index.asp.

321. David Zahniser, *Central Valley Slaughterhouse Closed over Inhumane Treatment*, L.A. TIMES, Aug. 22, 2012, http://articles.latimes.com/2012/aug/22/local/la-me-0822-slaughterhouse-20120822.

322. *Id.*

323. *See* Press Release, Food Safety & Inspection Serv., USDA, USDA Suspends Central Valley Meat for Humane Handling Violations (Aug. 21, 2012), *available at* http://www.fsis.usda.gov/news/NR_082112_01/index.asp.

324. *Id.*

325. *Id.*

326. *Id.*

C. *Undercover Livestock Surveillance Prohibitions: "Ag-Gag" Bills Pass in Iowa & Utah; Debated in Several Other States*

Iowa and Utah have amended their criminal codes to discourage the taking of undercover photos, video, and audio recordings at agricultural operations without permission.[327] In Iowa, it is now a serious misdemeanor to obtain employment under false pretenses so as to obtain access to a farm facility.[328] A first offense is punishable with up to one year in prison and a fine of up to $1875.[329] A second conviction will be treated as an aggravated misdemeanor and may carry a sentence of up to two years in prison and fine of up to $6250.[330] In Utah, the knowing or intentional recording of images and/or sound from an agricultural operation is now a Class A misdemeanor, which carries the possibility of up to one year in jail for each offense.[331]

In the early 1990s, several other farm states enacted laws specifically designed to block undercover whistleblowers from exposing practices and conditions in livestock production facilities. North Dakota,[332] Montana,[333] and Kansas[334] all presently make it a misdemeanor to interfere with an animal facility by taking pictures or video.

This year, ag-gag bills were also introduced, but failed to pass, in Florida, Illinois, Indiana, and Minnesota.[335] Similar bills were pending in Missouri, Nebraska, New York, and Tennessee.[336] According to an opinion poll by Lake Research Partners (commissioned by the ASPCA), "71 percent of Americans support undercover investigative efforts by animal welfare organizations to expose animal abuse on industrial farms, including 54 percent who *strongly support* the efforts."[337] Additionally, 64% "of Americans oppose making undercover

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327. IOWA CODE § 717A.3A (2013); UTAH CODE ANN. § 76-6-112 (LexisNexis 2012).

328. IOWA CODE § 717A.3A(1)–(2).

329. *Id.* § 903.1(1)(b).

330. *Id.* §§717A.3A(2)(b), 903.1(2).

331. UTAH CODE ANN. §§ 76-6-112(3), 76-3-204(1) (LexisNexis 2012).

332. N.D. CENT. CODE ANN. §§ 12.1-21.1-01-02, -04 (West 2012).

333. MONT. CODE ANN. §§ 81-30-103, -105 (2011).

334. KAN. STAT. ANN. § 47-1827 (West 2012).

335. S.B. 1184, Reg. Sess. (Fla. 2012); H.B. 5143, 97th Gen. Assemb., Reg. Sess. (Ill. 2012); S.B. 0184, 117th Gen. Assemb., 2d Reg. Sess. (Ind. 2012); S.F. 1118 & H.F. 1369, 87th Leg. Sess. (Minn. 2012).

336. S.B. 695, 96th Gen. Assemb., 2d Reg. Sess. (Mo. 2012); L.B. 915, 102d Leg., 2d Reg. Sess. (Neb. 2012); H.B. 3620 & S.B. 3460, 107th Gen. Assemb., Reg. Sess. (Tenn. 2012); S.B. 5172, 2011–2012 Reg. Sess. (N.Y. 2011).

337. Press Release, Am. Soc'y for the Prevention of Cruelty to Animals, ASPCA Research Shows Americans Overwhelmingly Support Investigations to Expose Animal Abuse on Industrial Farms (Feb. 17, 2012), *available at* http://www.aspca.org/Pressroom/press-releases/021712.aspx.

investigations of animal abuse on industrial farms illegal, with half of all Americans *strongly oppose*[*d*]."[338]

D. *Antibiotic Use, Exposure, & Resistance*

Mounting concerns regarding the widespread use of antibiotics and antimicrobial agents in production of livestock, and the rise of antibiotic resistant strains of bacteria have resulted in a flurry of legal, political, and regulatory action. Grassroots efforts, such as the "Supermoms Against Superbugs" rally in Washington D.C. brought additional attention to the tragic, sometimes deadly consequences of antibiotic resistant infections, particularly those connected with foodborne illness outbreaks.[339]

1. *Litigation to Force FDA Action*

The United States District Court for the Southern District of New York determined that FDA arbitrarily denied petitions filed by advocacy organizations in 1999 and 2005 seeking the withdrawal of FDA's approval of the use of certain antibiotics in livestock for non-therapeutic purposes.[340] The court ordered FDA to begin proceedings on FDA's proposed timeline (which is longer than the timeline advanced by Plaintiffs) and denied FDA's request for a stay while the matter is appealed to the Second Circuit.[341] FDA must issue revised notices of opportunity for public hearing regarding the use of penicillin and tetracyclines as growth promotants in livestock in seventeen months; the agency will have an additional forty-one months to hold the necessary hearings.[342]

2. *FDA Voluntary Initiative to Decrease Antimicrobial Use in Agricultural Animals*

In April 2012, FDA launched a new voluntary initiative intended to decrease the use of antimicrobials in agricultural animals.[343] The centerpiece of

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338. *Id.*

339. *See* Helena Bottemiller, *'Supermoms Against Superbugs' Take Their Message to Washington*, FOOD SAFETY NEWS (May 16, 2012), http://www.foodsafetynews.com/2012/05/supermoms-against-superbugs-take-their-message-to-washington/.

340. Natural Res. Def. Council v. FDA, 872 F. Supp. 2d 318, 342 (S.D.N.Y. 2012).

341. Natural Res. Def. Council v. FDA, 884 F. Supp. 2d 108, 120, 126 (S.D.N.Y. 2012).

342. *Id.* at 121.

343. Press Release, U.S. Food & Drug Admin., FDA Takes Steps to Protect Public Health (Apr. 11, 2012), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm299802.htm; *see* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #209, THE JUDICIOUS

FDA's effort is final guidance for industry entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," which is based on two principles: (1) limiting "medically important antimicrobial drugs in food-producing animals . . . to [] uses that are considered necessary for assuring animal health,"[344] and (2) limiting medically important antimicrobial drugs to uses in food producing animals "to those uses that include veterinary oversight or consultation."[345] Additionally, FDA put forth draft guidance urging animal pharmaceutical companies to voluntarily remove "production uses of antibiotics from their FDA-approved product labels" and, "where appropriate," to add "scientifically-supported disease prevention, control, and treatment uses."[346] Finally, the Agency also proposed a veterinary feed directive which sets forth methods that can be used by veterinarians to authorize the use of certain animal drugs in feed and to provide oversight in a feasible and efficient manner.[347]

3. *Food Industry Survey on Antibiotic Use*

In February 2012, U.S. Representative Louise Slaughter (D-N.Y.) sent a letter to sixty food producers and retailers requesting they disclose their policies on antibiotic use in meat and poultry production.[348] After receiving and analyzing the responses, Representative Slaughter, the only microbiologist serving in Congress, concluded that "while a small number of industry leaders provide antibiotic-free meat and poultry products, an overwhelming majority of food production companies routinely feed low-doses of antibiotics to healthy food-animals."[349] Representative Slaughter is the author of H.R. 965, the "Preservation of Antibiotics for Medical Treatment Act" (PAMTA), which aims to end the

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USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS (2012) [hereinafter JUDICIOUS USE], *available at* http://www.fda.gov/downloads/AnimalVeterinary/Guidancefor Industry/UCM216936.pdf; *see also* Guidance for Industry on the Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals, 77 Fed. Reg. 22,328 (Apr. 13, 2012).

344. JUDICIOUS USE, *supra* note 343, at 21.

345. *Id.* at 22.

346. *See* FDA Takes Steps, *supra* note 343; *see also* Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals, 77 Fed. Reg. 22,327 (Apr. 13, 2012).

347. Veterinary Feed Directive; Draft Text for Proposed Regulation, 77 Fed. Reg. 22,247, 22,248 (Apr. 13, 2012).

348. Letter from Louise M. Slaughter, U.S. Rep., to Food Industry (Feb. 16, 2012), *available at* http://www.louise.house.gov/images/stories/Fast_Food_Letter.pdf.

349. *Id.*; Press Release, Office of Congresswoman Louise M. Slaughter, As July 4th Approaches, Slaughter Reveals "What's in the Beef" (July 3, 2012), *available at* http://www.louise.house.gov/index.php?option=com_content&task=view&id=2749&Itemid=100069.

routine use of antibiotics on healthy animals, curb the growing threat of superbugs, and preserve the effectiveness of medically important antibiotics by phasing out the use of these drugs in healthy food-producing animals, while allowing their use for treatment of sick animals.[350]

4. *FDA Prohibits Extra-Label Uses of Cephalosporins in Livestock Production*

Effective April 5, 2012, FDA has prohibited "extralabel" or unapproved uses of cephalosporins in cattle, swine, chickens and turkeys, the so-called major species of food-producing animals.[351] Cephalosporins (with the exception of cephapirin, an older drug) may no longer be used at "unapproved dose levels, frequencies, durations, or routes of administration," in unapproved species, or for the purpose of disease prevention.[352] Veterinarians may, however, still use or prescribe cephalosporins for limited extra-label use in cattle, swine, chickens or turkeys as long as they follow the dose, frequency, duration, and route of administration that is on the label.[353] Use of cephalosporins in other livestock, such as ducks and rabbits, remains unrestricted.[354] Cephalosporins are a class of antibiotics (including Keflex and Ceclor) commonly used in humans for the treatment of pneumonia, skin and soft tissue infections, pelvic inflammatory disease, diabetic foot infections, and urinary tract infections.[355]

5. *NYU Study Indicates that Early Antibiotic Exposure to Antibiotics Associated with Increase in BMI*

Low-dose antibiotics are routinely administered to poultry and livestock to increase feed efficiency and hasten weight gain; similar effects are now being observed in human children.[356] After evaluating data in a longitudinal study of more than 11,000 children, New York University researchers have observed a consistent association between antibiotic exposure in the first six months of life with "elevations in body mass index and with overweight and obesity from ages

350. Preservation of Antibiotics for Medical Treatment Act, H.R. 965, 112th Cong. (1st Sess. 2011).

351. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition, 77 Fed. Reg. 735, 736 (Jan. 16, 2012) (to be codified at 21 C.F.R. pt. 530).

352. *Id.* at 736.

353. *Id.*

354. *Id.* at 742.

355. *Id.* at 737.

356. L. Trasande et al., *Infant Antibiotic Exposures and Early-Life Body Mass*, 37 INT'L J. OF OBESITY 16–17 (2012).

10 to 38 months."[357] Researchers concluded that the administration of antibiotics during early life when the gut is being colonized may disrupt "ancient patterns of intestinal colonization."[358] Specifically, the study found that "[a]t 38 months, children who had been exposed to antibiotics during this earliest period had significantly higher standardized BMI scores, and were 22% more likely to be overweight than children who had not been exposed."[359]

E. *Hormones in Meat: U.S., Canada, & EU Reach Agreement Regarding Beef Growth Hormone Usage*

For twenty years, the United States and Canada, on the one hand, and the European Union (EU), on the other, have been at odds regarding the EU's prohibition on the importation of beef treated with growth hormones.[360] In response to the EU's prohibition, the United States and Canada imposed trade sanctions amounting to hundreds of millions of dollars of duties on EU exports of Roquefort cheese, truffles, chocolates, and other specialty comestibles.[361] In March 2012, however, in exchange for a complete removal of the *ad valorem* duty against EU products, the EU agreed to increase quotas on imports of hormone-free beef to 48,200 metric tons, while maintaining the categorical ban on imports of hormone-treated beef.[362]

F. *Selective Meat & Seafood Bans*

1. *California Foie Gras Ban*

California's ban on the sale of any product that is the result of force-feeding a bird for the purpose of enlarging its liver beyond normal size went into effect on July 1, 2012.[363] Shortly thereafter, *foie gras* producers mounted a legal challenge in the United States District Court for the Central District of California.[364] The court denied the producers' *ex parte* request for a temporary injunc-

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357. *Id.* at 17, 18.

358. *Id.* at 16 (citing A.R. Bedford Russell & S.H. Murch, *Could Peripartum Antibiotics Have Delayed Health Consequences for the Infant?*, 113 BJOG 758 (2006)).

359. *Id.* at 20.

360. Press Release, Eur. Parliament, Win-Win Ending to the "Hormone Beef Trade War" (Mar. 14, 2012), *available at* http://www.europarl.europa.eu/news/en/pressroom/content/20120314IPR40752/html/Win-win-ending-to-the-hormone-beef-trade-war.

361. *Id.*

362. *Id.*

363. CAL. HEALTH & SAFETY CODE § 25982 (West 2010).

364. Complaint, Assoc. des Éleveurs de Canards et d'Oies du Québec v. Harris, No. CV 12-5735-SVW-RZ, 2012 WL 2944490 (C.D. Cal. July 2, 2012).

tion,[365] as well as a subsequent request for a preliminary injunction,[366] against California's enforcement of the ban.

Nevertheless, California restaurateurs have found ways around the state's foie gras ban.[367] For example, a restaurant located in the Presidio, a federal enclave within the geographic boundaries of the city of San Francisco, began offering foie gras on its menu, claiming that its location in a national park makes it exempt from state regulation.[368] Several Los Angeles restaurants are offering foie gras for free with other orders, and some chefs are reportedly preparing it for customers who bring their own.[369]

2. *Constitutional Challenge to California's Shark Fin Ban*

Chinese-Americans who use shark fins to make a traditional, ceremonial soup are challenging the constitutionality of legislation that went into effect January 1, 2012 making it illegal "to possess, sell, offer for sale, trade, or distribute a shark fin."[370] In a complaint filed in the United States District Court for the Northern District of California, an advocacy organization representing Asian Americans sought a declaration that the shark fin ban violates their members' equal protection rights, unlawfully interferes with interstate commerce, "preempts federal law," and deprives them of "rights, privileges and immunities under the United States Constitution."[371] Plaintiffs allege that because other parts of a legally fished shark may be used, the ban discriminates against people of Chinese national origin.[372] Plaintiffs further allege that the ban interferes with the power of the U.S. Congress to regulate interstate commerce, unlawfully preempts

365. Assoc. des Éleveurs de Canards et d'Oies du Québec v. Harris, No. 2:12-CV-05735-SVW-RZ (C.D. Cal. July 18, 2012) (denying ex parte application for temporary restraining order).

366. Assoc. des Éleveurs de Canards et d'Oies du Québec v. Harris, No. 2:12-CV-05735-SVW-RZ (C.D. Cal. Sept. 19, 2012) (denying motion for preliminary injunction).

367. *See* Norimitsu Onishi, *Some in California Skirt a Ban on Foie Gras*, N.Y. TIMES, Aug. 12, 2012, http://www.nytimes.com/2012/08/13/us/some-california-restaurants-skirt-foie-gras-ban.html?_r=1&.

368. Stacy Finz & Paolo Lucchesi, *Presidio Restaurant Says It Can Serve Foie Gras*, S.F. GATE, July 10, 2012, http://www.sfgate.com/restaurants/article/Presidio-restaurant-says-it-can-serve-foie-gras-3694610.php.

369. Fenit Nirappil, *Calif. Restaurants Duck Weak State Foie Gras Ban*, YAHOO! NEWS, July 17, 2012, http://news.yahoo.com/calif-restaurants-duck-weak-state-foie-gras-ban-170233787.html.

370. CAL. FISH & GAME CODE § 2021(b) (West 2012).

371. Complaint at 2, Chinatown Neighborhood Ass'n v. Brown, No. CV 12-3759 PJH (N.D. Cal. July 18, 2012).

372. *Id.* at 7.

federal law, and violates 42 U.S.C. section 1983.[373] Plaintiff's motion for a preliminary injunction was denied.[374]

X. Labor in the Farm & Food Sectors

A. *Food Sector Workers Report*

Food Chain Workers Alliance issued a report titled, "The Hands That Feed Us: Challenges and Opportunities for Workers Along the Food Chain," which analyzes the circumstances of U.S. workers in all areas of the food sector—production, processing, distribution, retail, and service.[375] The survey-based report finds that the vast majority of workers in the sector, which employs 20 million people—or one-sixth of the U.S. workforce—earn low wages and have minimal health benefits.[376] Of the workers surveyed:

- More than 86% reported "earning low or poverty wages";[377]
- 79% said they either "[d]o not have paid sick days or do not know if they do";[378]
- 83% do not receive employer-sponsored health benefits;[379]
- 53% admitted to having "worked while sick";[380]
- 57% reported a work-related injury or health problem;[381]
- 52% said they did not receive any health and safety training from their employer;[382]
- 35% reported using the emergency room for primary health care;[383] and

373. *Id.*
374. Chinatown Neighborhood Ass'n v. Brown, No. CV 12-3759 PJH, 2012 U.S. Dist. LEXIS 439 (N.D. Cal. Jan. 2, 2013).
375. Food Chain Workers Alliance, The Hands That Feeds Us: Challenges and Opportunities for Workers Along the Food Chain 9 (2012).
376. *Id.* at 9, 12.
377. *Id.* at 23, 37.
378. *Id.* at 24.
379. *Id.*
380. *Id.*
381. *Id.* at 27.
382. *Id.*

- 33% said they were not always provided the necessary equipment to do their jobs.[384]

To alleviate some of these problems and conditions, the Food Chain Workers Alliance advocates for an increase in the minimum wage for tipped workers.[385] To improve food safety and public health, the Alliance calls for the provision of health benefits, access to health care, and paid sick days.[386] The report also notes that food justice advocates should "include sustainable working conditions for food workers within the definition of sustainable food."[387]

B. *Food & Water at the Borderlands*

An August 2012 report, "Hungry for Change: Borderlands Food and Water in the Balance," poses and attempts to answer questions about our inherently bi-national (U.S.-Mexican) food system.[388] It also illustrates how much of the U.S. food supply is dependent upon labor, expertise, ingenuity, seeds, seafood, and water originating in Mexico.[389] According to the report sixty to seventy percent of all fresh produce eaten in the U.S. is grown in Mexico.[390] With regard to seafood, 150,000 to 170,000 tons are exported from Mexico to the U.S. each year.[391] Moreover, three-quarters of all farmworkers involved in harvesting in the U.S. were born in Mexico.[392] Since 2009, as the immigration debate in the U.S. has intensified, many have returned to Mexico.[393] In 2012, a 30% to 40% worker shortage meant that hand-picked fruits and vegetables in California would remain unpicked.[394] Economic conditions on both sides of the border have flip-flopped:

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383. *Id.* at 65.
384. *Id.* at 27.
385. *Id.* at 77.
386. *Id.*
387. *Id.* at 78.
388. Gary Paul Nabhan, *A Brief History of Cross-Border Food Trade*, *in* SW CENTER'S KELLOGG PROGRAM IN SUSTAINABLE FOOD SYS., HUNGRY FOR CHANGE: BORDERLANDS FOOD AND WATER IN THE BALANCE (2012) [hereinafter HUNGRY FOR CHANGE], *available at* http://swc.arizona.edu/sites/swc.arizona.edu/files/Hungry%20final-Composite_08.14.12_LoRez.pdf.
389. *See id.* at 28–31.
390. *Id.* at 28.
391. *Id.* at 31.
392. Gary Nabhan et al., *Introduction*, *in* HUNGRY FOR CHANGE, *supra* note 388, at 4.
393. Gary Nabhan, *A Meal Without a Mexican? Your Food has Already Migrated!*, CIVIL EATS (Aug. 30, 2012), http://civileats.com/2012/08/30/a-meal-without-a-mexican-your-food-has-already-migrated/.
394. *Id.*

U.S. border counties now suffer poverty levels twice as high as the country as a whole, while residents of Mexico's northern states have average incomes 75% higher than those throughout the rest of Mexico.[395]

C. *Overtime Wages to Agricultural Workers in Minnesota*

Federal labor law provides the minimum protections afforded to workers.[396] Some states, however, have laws that provide additional rights and protections.[397] Under the Fair Labor Standards Act (FLSA), agricultural laborers are categorically exempted from FLSA overtime wage protection.[398] In Minnesota, the Court of Appeals ruled that under the Minnesota Fair Labor Standards Act, agricultural workers who are paid an hourly rate are subject to the overtime pay requirements.[399]

XI. FOOD, OBESITY, & CHRONIC DISEASE

Obesity continues to be considered the number one health problem facing the U.S. population, and increasingly, economic concerns regarding the health impact of this problem are making their way into budgetary and policy debates.

A. *Obesity Forecast*

The Trust for America's Health and the Robert Wood Johnson Foundation released a joint report that forecasts "by the year 2030, more than 44 percent of adults could be obese, which could lead to major increases in obesity-related disease rates and health care costs."[400] The report also suggests obesity-related diseases and the attendant health care costs can be reduced if states de-

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395. Nabhan, *supra* note 392, at 3; Nabhan, *supra* note 393.

396. 29 U.S.C. § 206 (2006).

397. *See id.* § 218(a) (permitting states to establish higher minimum wages than federal requirements).

398. *Id.* § 213(a)(6).

399. In re Order to Comply: Labor Law Violation of Dailey Farm of Lewiston, No. A11-1788 (Minn. Ct. App. July 9, 2012); *see also* MINN. STAT. § 177.25 (2012); Angela Rud & Jeffrey Peterson, *Agribusiness Alert: All Agricultural Workers in the State of Minnesota that Are Paid an Hourly Rate Are Now Entitled to Overtime Pay*, GRAY, PLANT, MOOTY LAW FIRM, July 23, 2012, http://www.gpmlaw.com/resources/newsletters/agribusiness-alert-overtime-pay.aspx.

400. TRUST FOR AMERICA'S HEALTH & ROBERT WOOD JOHNSON FOUND., F AS IN FAT: HOW OBESITY THREATENS AMERICA'S FUTURE 2012, at 23 (2012), *available at* http://www.healthyamericans.org/assets/files/TFAH2012FasInFatFnlRv.pdf.

crease the average body mass index of their residents by 5% in the next seventeen years.[401] According to this report:

- If obesity rates continue climbing according to current trajectories, by 2030, thirteen states could have adult obesity rates above 60%, thirty-nine states could have rates above 50%, and all fifty states could have rates above 44%.[402]

- "[N]ew cases of type 2 diabetes, coronary heart disease and stroke, hypertension, and arthritis could increase 10 times between 2010 and 2020—and then double again by 2030."[403]

- Current estimates of the medical costs of adult obesity in the United States "range from $147 billion to nearly $210 billion per year."[404]

- "[M]edical costs associated with treating preventable obesity-related diseases are estimated to increase [] between $48 billion and $66 billion per year in the United States by 2030—while the loss in economic productivity could be between $390 billion and $580 billion annually by 2030." [405]

B. *Obesity as a Threat to National Security*

Mission: Readiness, a "nonpartisan national security organization of senior retired military leaders calling for smart investments in America's children," has identified childhood obesity as a significant barrier to military recruitment.[406] The organization points out that "[c]urrently, 75 percent of 17- to 24-year olds in the US cannot serve in the military, primarily because they are physically unfit, have not graduated from high school, or have a criminal record."[407]

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401. *Id.* at 23, 25.
402. *Id.* at 23.
403. *Id.* at 3.
404. *Id.* at 32 (citing John Cawley & Chad Meyerhoefer, *The Medical Care Costs of Obesity: An Instrumental Variables Approach*, 31 J. HEALTH ECON. 219 (2012); Eric A. Finkelstein et al., *Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates*, HEALTH AFFAIRS., at w822 (2009)).
405. *Id.* at 28 (citing Y. Claire Wang et al., *Health and Economic Burden of the Projected Obesity Trends in the USA and the UK*, 378 LANCET 815 (2011)).
406. *About Us*, MISSION: READINESS, http://www.missionreadiness.org/about-us/ (last visited May 10, 2013).
407. *Id.*

C. *Obesity as a Protected Disability*

In answer to a certified question from the United States District Court for the District of Montana, a divided Montana Supreme Court ruled that obesity, which is not the symptom of a physiological condition, may be a "'physical or mental impairment'" as the terms are used in the Montana Human Rights Act.[408] Taking a cue from federal disability discrimination law and, specifically, Congress's stated intention that "the definition of disability [under the Americans With Disabilities Act] . . . shall be construed in favor of broad coverage . . . to the maximum extent permitted," the court determined that the condition of being obese, separate and apart from another medical condition, is a protected disability under state law.[409] The ruling was based in part on non-binding interpretive guidance from the federal Equal Employment Opportunity Commission, which provides that "'severe obesity, which has been defined as body weight more than 100% over the norm . . . is clearly [a protected] impairment.'"[410] As the Montana Supreme Court notes, "most federal courts to have considered the issue have held that obesity is not an impairment unless it is the result of a physiological disorder or condition."[411]

D. *Alabama Prohibits "Fat Suits"*

Alabama is the latest state to ban "made-me-fat" lawsuits. The Alabama State Legislature passed the Commonsense Consumption Act, which prohibits lawsuits "based on claims arising out of weight gain, obesity, a health condition associated with weight gain or obesity, or other generally known condition allegedly caused by or allegedly likely to result from long-term consumption of food," brought against "packers, distributors, carriers, holders, sellers, marketers, or advertisers of food products that comply with applicable statutory or regulatory requirements."[412]

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408. BNSF Ry. Co. v. Feit, 281 P.3d 225, 231 (Mont. 2012); *see also* MONT. CODE ANN. § 49-2-101(19)(a) (2011) (defining "physical or mental disability").

409. *BNSF Ry. Co.*, 281 P.3d at 228, 231 (citing ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (2008)).

410. *Id.* at 230 (citing EEOC Compliance Manual § 902.2(c)(5)(ii)).

411. *Id.* at 229 (citing EEOC v. Watkins Motor Lines, Inc., 463 F.3d 436, 443 (6th Cir. 2006); Andrews v. Ohio, 104 F.3d 803, 810 (6th Cir. 1997); Francis v. City of Meriden, 129 F.3d 281, 286–87 (2d Cir. 1997)).

412. Commonsense Consumption Act, H.B. 242, 2012 Reg. Sess. (Ala. 2012) (codified as amended at ALA. CODE 55 §§ 6-5-730 to -736).

E. *Using Alcohol-Control Policies to Address Obesity*

An article in the peer-reviewed journal, *Preventing Chronic Disease*, likens the drivers of the obesity epidemic to problematic alcohol consumption and advocates the use of alcohol-control policies in societal management of obesity.[413] The authors suggest regulating access to low-nutrient foods through five legislative and regulatory tools including: (1) zoning and licensing restrictions on the density of food outlets; (2) displays and sales restrictions aimed at discouraging impulse buying; (3) regulations on portion sizes; (4) pricing and taxation strategies (for example, higher taxes on foods high in calories and low in nutritional value); and (5) use of warning labels and ads to discourage people from over-consumption of nutritionally impoverished comestibles.[414]

F. *Request for Surgeon General's Report on Sugar-Sweetened Beverages*

The American Cancer Society Cancer Action Network has urged the U.S. Surgeon General to "prepare a Report on the health effects of sugary drinks and to issue a Call to Action to spur national efforts to reduce sugary drink consumption."[415] The July 19, 2012 letter seeks a report addressing the

> specific ingredients of sugary drinks: the biology, pharmacology, and physiological effects of sugars; addictive mechanisms associated with sugar use or other ingredients contained in sugary drinks; epidemiological data on consumption of these products and their health-damaging effects including obesity; trends in consumption for all age groups; and the gender, racial, and ethnic disparities in the effects of sugary drink consumption on health.[416]

G. *Sugar Purportedly as Addictive & Toxic as High Fructose Corn Syrup*

A University of California, San Francisco endocrinologist and professor of clinical pediatrics, Dr. Robert Lustig,[417] asserts that Americans' consumption

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413. Deborah Cohen & Lila Rabinovich, *Addressing the Proximal Causes of Obesity: The Relevance of Alcohol Control Policies*, 9 PREVENTING CHRONIC DISEASE 247 (2012).

414. *Id.*

415. Letter from Alameda Cnty. Pub. Health Dep't et al. to Kathleen Sebelius, Sec'y, U.S. Dept. of Health & Human Servs. (July 19, 2012), *available at* http://cspinet.org/new/pdf/letter-to-sec-sebelius.pdf (emphasis removed).

416. *Id.*

417. Lustig gained notoriety through his 2000 lecture, "Sugar: The Bitter Truth," that has had more than three million views on YouTube. UCTV, *Sugar: The Bitter Truth*, YOUTUBE (July 30, 2009), http://www.youtube.com/watch?v=dBnniua6-oM.

of sugar amounts to a public health crisis.[418] He concludes that sugar is as "equally toxic" as high-fructose corn syrup, and recommends that men consume no more than 150 calories of added sugars daily and women no more than 100, which is less than the amount in one can of soda.[419]

The L.A. Times reported on the anti-sugar movement, linking it to "some of the biggest names in nutrition, including Harvard's Dr. Walter Willett and Yale's Dr. Kelly Brownell," in addition to Dr. Lustig.[420]

> Lustig says that sweets in processed food—whether it's high-fructose corn syrup in a soda or cane sugar in a candy bar—are the leading cause of metabolic syndrome, a dangerous collection of complications that includes high blood sugar, high blood pressure and decreased sensitivity to insulin. By some estimates, the syndrome more than doubles the risk of heart attack or stroke. And that's bad news, because about 1 in 4 U.S. adults—including many sugar junkies who look lean and fit—already have the syndrome. "Everyone needs to be aware of the danger," he says.
>
> Of course, sugar has plenty of defenders. Or, depending on your viewpoint, co-conspirators. "Lustig doesn't know the science," says Andy Briscoe, president and chief executive of the Sugar Assn. People ate a lot of sugar back in the early 1970s, he says, "and we didn't have all these problems with obesity or with this metabolic stuff."[421]

H. *Food, Obesity, & Addiction*

The issue of food and addiction received unprecedented attention from an array of perspectives this year. A thorough review of this topic is beyond the scope of this overview, but practitioners should be mindful of this developing area.

- *Food and Addiction: A Comprehensive Handbook*: Published by Yale University Psychology Professors Kelly Brownell and Mark Gold, this book aims to bring scientific understanding to the issue of food and addiction.[422] This multi-disciplinary collection includes the perspectives of experts in nutrition, addiction, psychology, epidemiology, and public health

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418. *60 Minutes: Is Sugar Toxic?* (CBS television broadcast Apr. 1, 2012), *available at* http://www.cbsnews.com/video/watch/?id=7403942n.

419. *Id.*

420. Chris Woolston, *Sounding the Sugar Alarms*, L.A. TIMES, Apr. 14, 2012, http://articles.latimes.com/2012/apr/14/health/la-he-sugar-20120414.

421. *Id.*

422. KELLY D. BROWNELL & MARK S. GOLD, FOOD AND ADDICTION: A COMPREHENSIVE HANDBOOK (2012).

to explore and analyze the scientific evidence for the addictive properties of food.[423]

- *Treatment for Obesity Through Brain's "Addiction" Center*: FDA approved the use of brain pacemakers as an obesity treatment in connection with a study being conducted at Ohio State University.[424] Deep-brain stimulation was previously approved for use in the treatment of disorders including Parkinson's disease, tremors, dystonia, and obsessive-compulsive disorder.[425] Researchers aim to stimulate the region of the brain linked to addictive behavior to improve its "function, regulation, and control."[426]

- *"Food Addiction" Assessment Quiz*: *The New York Times* Well blog featured a food addiction assessment module based on the Yale Food Addiction Scale created by researchers at the Rudd Center for Food Policy and Obesity.[427] Based on responses to statements and questions such as, "I find myself consuming certain foods even though I am no longer hungry" and, "I keep consuming the same types or amounts of food despite significant emotional and/or physical problems related to my eating," the quiz provides a food addiction score of "not addicted" or "possible food addiction."[428]

1. *Correlation Between BPA Levels & Obesity in White Children*

Although they admit that they are far from establishing a causal link between BPA levels and obesity in white children, researchers at New York University observed that "[c]ompared with children and teens with the lowest appar-

423. *Id.*

424. Press Release, Ohio State Univ., Targeting Brain's Addiction Center Could Be Answer to Obesity (Aug. 27, 2012), *available at* http://medicalcenter.osu.edu/Mediaroom/releases/Pages/Obesity-and-DBS.aspx.

425. *Id.*

426. *Id.*

427. Tara Parker-Pope, *Quiz: Are You Addicted to Food?*, N.Y. TIMES WELL BLOG (Sept. 20, 2012, 4:02 P.M.), http://well.blogs.nytimes.com/2012/09/20/quiz-are-you-addicted-to-food/; *see also* PAM PEEKE & MARISKA VAN AALST, THE HUNGER FIX: THE THREE-STAGE DETOX AND RECOVERY PLAN FOR OVEREATING AND FOOD ADDICTION 303 (2012) (detailing neurological processes and the addiction assessment model to demonstrate overeating as an addiction).

428. Parker-Pope, *supra* note 427; *see also* PEEKE & VAN AALST, *supra* note 427, at 303.

ent exposure to the ubiquitous chemical [BPA], those with the highest exposure were roughly 2.5 times more likely to be obese."[429]

2. *NYC Ban on Large Sugary Drinks*

The New York City Board of Health "approved a ban on the sale of large sodas and other sugary drinks at restaurants, street carts and movie theaters."[430] Slated to go into effect on March 12, 2013, the New York City government was enjoined and permanently restrained from implementing or enforcing the measure by a New York Supreme Court, which found the ban to be "arbitrary and capricious."[431] According to the *New York Times*, the ban would have effected "establishments that receive inspection grades from the health department, including movie theaters and stadium concession stands,"[432] Convenience stores, vending machines, and some newsstands were exempted from the ban.[433] Additionally, the *New York Times* reported that the "restrictions would not affect fruit juices, dairy-based drinks like milkshakes, or alcoholic beverages; no-calorie diet sodas would not be affected, but establishments with self-service drink fountains, like many fast-food restaurants, would not be allowed to stock cups larger than 16 ounces."[434] The sugary drink ban—the first restriction of its kind in the country—generated significant controversy. Mayor Michael Bloomberg, the primary champion of the ban, called it "'the single biggest step any city . . . has ever taken to curb obesity.'"[435] Opponents of the ban included New Yorkers for Beverage Choices, a group financed by the soft-drink industry.[436] After the ruling, Mayor Bloomberg announced he believed "the judge's decision was clearly in error, and

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429. Melissa Healy, *Study Links Chemical BPA to Obesity in White Children*, L.A. TIMES, Sept. 18, 2012, http://articles.latimes.com/2012/sep/18/science/la-sci-bpa-obesity-20120919.

430. N.Y.C. DEP'T OF HEALTH & MENTAL HYGIENE, BD. OF HEALTH, NOTICE OF ADOPTION OF AN AMENDMENT (§ 81.53) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE (2012), *available at* http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article81.pdf; *see also* Michael M. Grynbaum, *Health Panel Approves Restriction on Sale of Large Sugary Drinks*, N.Y. TIMES, Sept. 13, 2012, http://www.nytimes.com/2012/09/14/nyregion/health-board-approves-bloombergs-soda-ban.html?_r=0.

431. N.Y. Statewide Coalition of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health, No. 653584/12 (N.Y. Sup. Ct. Mar. 11, 2013) (granting motion to enjoin and permanently restrain the Department of Health from implementing the law).

432. Grynbaum, *supra* note 430.

433. *Id.*

434. *Id.*

435. *Id.*

436. *Board of Health Rubberstamps Mayor's Ban, Goes Against Wishes of New Yorkers*, NEW YORKERS FOR BEVERAGE CHOICES (Sept. 13, 2012), http://www.prnewswire.com/news-releases/board-of-health-rubberstamps-mayors-ban-goes-against-wishes-of-new-yorkers-16927466.html.

[that they would] win on appeal."[437] Appellate arguments are scheduled for the first week of June 2013.[438]

3. *The Weight of the Nation*

HBO and the Institute of Medicine, in association with the National Institutes of Health, the Centers for Disease Control and Prevention, Kaiser Permanente, and the Michael and Susan Dell Foundation, produced a four-part documentary series, *The Weight of the Nation*, which investigates the obesity epidemic through interviews with both experts and ordinary Americans struggling with obesity.[439]

XII. CONCLUSION

As the realities and politics associated with food production and consumption capture the attention and stimulate concern in a growing portion of the population, the role that the law plays in shaping our food system becomes increasingly apparent and important. Going forward, agricultural and food lawyers will have the opportunity to both advise farmers and food producers, and to participate in the increasingly important dialog about the public health, national security, and environmental implications of food law and policy. Thus, it is essential that such practitioners keep abreast of developments not just within, but also *around* the law so that they can provide informed, strategic advice to their clients in the agricultural and food sectors.

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437. Michael M. Grynbaum, *Judge Blocks New York City's Limits on Big Sugary Drinks*, N.Y. TIMES, Mar. 11, 2013, http://www.nytimes.com/2013/03/12/nyregion/judge-invalidates-bloombergs-soda-ban.html?pagewanted=all.

438. Joseph Ax, *New York City's Appeal of Soda Ban Ruling to be Heard in June*, REUTERS, Mar. 13, 2013, http://www.reuters.com/article/2013/03/13/us-sodaban-lawsuit-appeal-idUSBRE92C1GF20130313.

439. *The Weight of the Nation* (HBO television broadcast 2012), *available at* http://theweightofthenation.hbo.com; *About the Project*, WEIGHT OF THE NATION, http://theweightofthenation.hbo.com/about-the-project (last visited May 10, 2013).