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United States Food Law Update: Shrouded by Election-Year Politics, State Initiatives and Private Lawsuits Fill in the Gaps Created by Congressional and Agency Ossification

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UNITED STATES FOOD LAW UPDATE: SHROUDED BY ELECTION-YEAR POLITICS, STATE INITIATIVES AND PRIVATE LAWSUITS FILL IN THE GAPS CREATED BY CONGRESSIONAL AND AGENCY OSSIFICATION

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I. Introduction

Observers of food law in the 2012 presidential election year witnessed a dramatic slowing of federal initiatives—perhaps arising from a desire by both Congress and the administration to avoid upsetting critical constituent groups during a year seemingly dominated by campaigns and endless talking points. For example, Congress failed to take action on a unique compromise between what some had considered mortal enemies—the Humane Society of the United States and United Egg Producers—that would implement a federal animal welfare standard for laying hens in return for abandoning ballot measures in various states. Similarly, the FDA waited until the early days of 2013 to issue the proposed rules implementing the FDA Food Safety Modernization Act.[1] Recall that Congress passed this landmark statute not in 2012, but January of 2011.[2] Despite this apparent reluctance to tackle some big issues in 2012, the FDA did decide two significant food law issues: a refusal of a request seeking to rebrand high fructose corn syrup as "corn sugar," as well as promulgation of a long overdue rule on salmonella testing in shell egg production.

State and local governments, on the other hand, were exceptionally active, generating substantial changes in several food law issues ranging from outright bans on certain food products (or quantities of food as in the New York City ban on large volume sugary drinks) to animal protection initiatives. Not to be left out of the fray, various non-governmental organizations and other plaintiffs filed a string of lawsuits challenging use of the term "natural" in a variety of contexts.

As in previous editions of this update, necessity dictates that not every change is included; rather, the authors limited their analysis to significant changes within the broader context of food production, distribution, and retail. The intent behind this series of updates is to provide a starting point

1. The FDA issued two proposed regulations to implement the Food Safety Modernization Act's amendments to the Food, Drug, and Cosmetic Act. *See* FDA, *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food*, 78 Fed. Reg. 3646 (Jan. 16, 2013); FDA, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 78 Fed. Reg. 3504 (Jan. 16, 2013).

2. FDA Food Safety Modernization Act, Pub. L. 111–353, 124 Stat. 3885 (Jan. 4, 2011).

for scholars, practitioners, food scientists, and policy makers determined to understand the shaping of food law in modern society. Tracing the development of food law through these updates also builds an important historical context for the overall progression of the discipline and hopefully prompts further scholarship by others on many of these emerging issues.

II. Food Marketing

A. Food Bans

Food bans are a common tool to prevent harm to consumers. Although the results for each ban may be the same—prohibiting the consumer from purchasing the item—underlying rationales for bans vary. For example, federal and state governments ban foods harmful to human health (i.e., adulterated food) under their respective versions of the Food, Drug, and Cosmetic Act.[3] Intended to protect the public from dangerous contaminants, consumers generally support bans of this nature. Other motivations for restricting access to certain foods, however, may result in significant push back from consumers and vendors. In 2012, efforts to combat obesity, as well as environmental conservation and ethics, led to various food bans that engendered significant controversy. We discuss some of these developments below.

1. Obesity

In the United States, recent studies found that more than one-third of the adult population (37.5%) is obese.[4] Linked to heart disease, stroke, diabetes and certain types of cancer, medical costs associated with obesity were $147 billion per year in 2008, the latest data available.[5] This epidemic is not limited to adults. Since the 1980s, the number of obese children has tripled, with approximately seventeen percent of children in the U.S. currently classified as obese.[6] New York City (NYC) is acutely aware of the obesity issue, with more than fifty percent of its adult population overweight or obese, and more than twenty percent of children in

3. *See, e.g.*, 21 U.S.C. § 342 (2012) (Federal Food, Drug, and Cosmetic Act); 410 ILL. COMP. STAT. 620 (2012) (Illinois Food, Drug and Cosmetic Act).

4. CDC, Adult Obesity Facts, http://www.cdc.gov/obesity/data/adult.html (last visited Mar. 25, 2013).

5. *Id.*

6. CDC, Childhood Data and Statistics, http://www.cdc.gov/obesity/data/childhood.html (last visited Mar. 25, 2013).

kindergarten through eighth grade overweight or obese.[7] As this epidemic expands, governments such as NYC are exploring regulatory options to reduce a problem that is costing society billions a year in health care expenditures. Perhaps unsurprisingly in light of the above statistics, 2012 was a busy year for NYC government in its attempts to ban foods and incentives it deemed partly responsible for the obesity epidemic in its city, specifically targeting large sugary drinks and incentives marketed to children.

After successfully banning trans fats from foods in 2007, the New York City Board of Health set its sights on large surgery drinks. Americans consume 200-300 more calories daily than in the past, and experts largely attribute the increase to consumption of sugary drinks.[8] These drinks also are responsible for the largest source of added sugar in an American's diet.[9] In addition to an increased risk of heart disease and diabetes, health advocates associate sugary drinks with long-term weight gain for both adults and children.[10] The numbers show that New Yorkers are consuming excessive quantities of sugary drinks. Thirty percent of adults in NYC report drinking one or more sugary drinks a day, forty-four percent of children aged six to twelve consume more than one sugary drink a day, and twenty-six percent of high school students admitted to drinking two or more sugary drinks per day.[11]

It is not just consumption of sugary drinks that is on the rise; serving sizes also keep increasing, which leads to more calorie consumption. The portion size of fountain drinks at many restaurants has increased from seven to thirty-two fluid ounces since 1955—an increase of 457%.[12] Other restaurants in NYC offer sugary drinks up to sixty-four fluid ounces, which can contain up to 780 calories, fifty-four teaspoons of sugar, and no nutritional value.[13]

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7. Centers for Disease Control and Prevention. *Obesity in K-8 students – New York City, 2006-07 to 2010-11 School Years*, Morbidity and Mortality Weekly Report 2011; 60(49): 1673-78, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6049a1.htm.

8. Eric A. Finkelstein, Christopher Ruhm, & Katherine M. Kosa, *Economic Causes and Consequences of Obesity*, 26 ANN. REV. OF PUB. HEALTH 239, 242 (2005).

9. Joanne F. Guthrie & Joan F Morton, *Food Sources of Added Sweeteners in the Diets of Americans*, 100 J. AM. DIETETIC ASS'N 43, 44 (2000).

10. N.Y. CITY HEALTH CODE § 81.53 (2012), *available at* http://www.nyc.gov/html/nycrules/downloads/rules/F-DOHMH-09-13-12-a.pdf.

11. *Id.*

12. Lisa R. Young & Marion Nestle, *Portion Sizes and Obesity; Responses of Fast Food Companies*, 28 J. OF PUB. HEALTH POL'Y 238, 244 (2007).

13. N.Y. CITY HEALTH CODE § 81.53 (2012), *available at* http://www.nyc.gov/html/nycrules/downloads/rules/F-DOHMH-09-13-12-a.pdf.

In response to the above information, the New York City Board of Health adopted Mayor Michael Bloomberg's recommendation to establish a maximum serving size of sixteen ounces for sugary, non-alcoholic drinks sold at local food establishments.[14] The Board voted 8-0 to amend Article 81 of the NY City Health Code to place a size restriction on any sweetened beverage containing more than twenty-five calories per eight ounces and all self-service cups offered by food vendors.[15] The Ban goes into effect on March 13, 2013 and applies to restaurants, mobile food carts, delis, theater and stadium concessions, and any other establishment regulated by the city's Department of Health and Mental Hygiene.[16] The City is hoping that reducing the amount of sugary drinks consumed by its residents will combat obesity and the associated diseases.[17]

The sugary drink ban has created major controversy over the government's involvement in what people consume, and a group called New Yorkers for Beverage Choices announced plans to challenge the ban in court, citing the negative impact on small business owners and other companies.[18] From a legal perspective, food bans are generally based on the broad police power of the sovereign.[19] Opponents argue that these anti-obesity bans are paternalistic and unjustified.[20] Moreover, as the ban only restricts food service establishments (FSEs), owners of FSEs are quick to point out the unfair disparity in treatment between FSEs and other

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14. *Id. See also Mayor Bloomberg, Deputy Mayor Gibbs, Health Commissioner Farely and Bruce Ratner Announce Barclays Center will Voluntarily Adopt Regulations to Limit Size of Sugary* Beverages, NEWS FROM THE BLUE ROOM, http://www.nyc.gov/portal/site/nycgov/menuitem.c0935b9a57bb4ef3daf2f1c701c789a0/index.jsp?pageID=mayor_press_release&catID=1194&doc_name=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fom%2Fhtml%2F2012b%2Fpr326-12.html&cc=unused1978&rc=1194&ndi=1 (last visited Feb. 25, 2013).

15. *See Mayor Bloomberg, supra* note 14.

16. N.Y. CITY HEALTH CODE § 81.53 (2012).

17. *Id.*

18. NEW YORKERS FOR BEVERAGE CHOICES, http://nycbeveragechoices.com/ (last visited Mar. 25, 2013).

19. Alison Peck, *Revisiting the Original "Tea Party": The Historical Roots of Regulating Food Consumption in America*, 80 UMKC L. REV. 1, 6 (2011). As this article went to press, Judge Tingling of the Supreme Court of New York enjoined enforcement of the ban, finding it arbitrary and capricious. *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. NYC Dept. of Health & Mental Hygiene*, No. 653584/12 (N.Y. App. Div., order entered March 11, 2013).. The Appellate Division of the NY Supreme Court has agreed to hear the case in June 2013. *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. NYC Dept. of Health & Mental Hygiene*, No. 653584/12 (N.Y. App. Div., filed March 12, 2013)..

20. Stephanie A. McGuinness, *Time to Cut the Fat: The Case for Government Anti-Obesity Legislation*, 25 J.L. & HEALTH 41, 51 (2012).

establishments, such as grocery stores. For example, under the ban, a pizzeria will not be able to sell a two-liter bottle of Coke, but a corner deli, which is regulated as a market rather than restaurant, can.[21] As a result, FSEs complain that the new ban will hurt them economically. In January of 2013, the American Beverage Association, the NACCP and the Hispanic Federation filed a lawsuit against NYC claiming the Board of Health overstepped its power, and that the ban will disproportionately hurt small, minority owned businesses.[22]

In addition to banning large sugary drinks, the state of New York took issue against incentives (toys) associated with unhealthy food marketed to children. Specifically, the state proposed nutrition standards for restaurants that distribute incentive items aimed at children. As previously detailed, the obesity rates in children continue to rise and various jurisdictions believe breaking the link between toys and unhealthy foods will reduce the growing problem of childhood obesity. Accordingly, governments are banning toys provided with kids' meals if the meals do not meet specified nutritional requirements.[23]

New York State Senate Bill S7849-2011 would require fast food restaurants offering incentive items with children's meals to meet certain nutritional guidelines.[24] The guidelines limit the amount of fat, sugar, calories and sodium allowed per meal. If a meal intended for children falls outside of the guidelines, the restaurant will be forced to remove the incentive item. The proposed law defines an incentive item to include: "any toy, game, trading card, admission ticket or other consumer product, whether physical or digital, with particular appeal to children."[25]

San Francisco and Santa Clara, California passed similar legislation, but entrepreneurial restaurants such as McDonald's quickly found a loophole by selling the "banned" toy for an additional ten cents.[26] In response, the New York bill attempts to remove the potential loophole by stating, "a restaurant may offer an incentive item in combination with the

21. CBS NEW YORK, *New York City Lawyers, Beverage Industry Duel in Court Over Big Drink Ban*, http://newyork.cbslocal.com/2013/01/23/nyc-sugary-drink-ban-faces-first-court-test-as-opponents-question-racial-fairness/ (last visited Feb. 25, 2013).

22. Amicus brief *available at* https://iapps.courts.state.ny.us/fbem/DocumentDisplayServlet?documentId=HmpJnyM8YRf1z8GAzk9vHw==&system=prod.

23. Alexis M. Etow, *No Toy For You! The Healthy Food Incentives Ordinance: Paternalism or Consumer Protection*, 61 AM. U. L. REV. 1503 (2012).

24. N.Y. S. Res. 7849 (2011), *available at* http://open.nysenate.gov/legislation/bill/S7849-2011.

25. *Id.*

26. Etow, *supra* note 23, at 1536.

purchase of a meal, food item, or beverage, only if the meal, food item, or beverage, meets nutritional standards."[27]

At the federal level, several agencies are exploring options to reduce negative impacts from the $1.6 Billion spent annually on food ads targeting children through television commercials, social media, cell phones, and computer-based food company-branded online games.[28] The 2009 Omnibus Appropriations Act created the Interagency Working Group on Food Marketed to Children. Comprised of representatives from the FDA, FTC, USDA, and CDC, the Working Group's mission is to recommend standards for advertising food to children. The Working Group issued a Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts[29] in 2011. The proposed guidelines were met with strong opposition from food, advertising and media companies for being overly restrictive and generally inappropriate.[30] Additionally, various legal challenges based on First Amendment rights have stalled government regulation of food advertising targeted at children.[31] Although in March 2012, FTC Chairman Jon Leibowitz indicated to Congress that the Commission did not support restricting food advertising to children; the agency, in September, announced that it intended to issue a report by the end of the year detailing food industry marketing practices directed at children.[32] As of this writing, the FTC has not released the report.

2. Environmental Conservation and Ethics

At the urging of various conservationist and animal rights groups, legislatures also implemented several bans on foods. In 2012, various states banned shark fins, and California banned *foie gras*.[33] By way of

27. N.Y. S. Res. 7849.

28. Bernice Young, *US Guidelines on Food Marketing to Kids Stalls,* CALIFORNIA WATCH, (Jan. 27, 2012), http://californiawatch.org/dailyreport/us-guidelines-food-marketing-kids-stalls-14648.

29. *Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts,* Interagency Working Group on Food Marketed to Children, *available at* http://ftc.gov/os/2011/04/110428foodmarketproposedguide.pdf.

30. *US Guidelines on Food Marketing to Kids Stalls,* CALIFORNIA WATCH, http://californiawatch.org/dailyreport/us-guidelines-food-marketing-kids-stalls-14648 (last visited Mar. 28, 2013).

31. *Id.*

32. *Food Industry Braces for New Study on Marketing to Kids*, ABC WORLD NEWS, http://abcnews.go.com/blogs/business/2012/09/food-industry-braces-for-new-study-on-marketing-to-kids/ (last visited Mar. 28, 2013).

33. States with shark fin bans include Washington (WASH. REV. CODE § 77.15.770 (2012)), Oregon (OR. REV. STAT. § 509.160 (2012)), California (CAL. FISH & GAME CODE § 2021 (2012)), Hawaii (Haw. Rev. Stat. § 188-40.7 (2012)), and Illinois

background, *Foie gras* involves the forced overfeeding of geese or ducks in order to produce an exceptionally fatty liver that is eaten as a delicacy.[34] Shark Finning is an incredibly wasteful, but lucrative industry that uses five percent of the shark carcass (the fin) in order to make a traditional Chinese ceremonial soup. The practice has caused shark populations to dwindle worldwide.[35]

Foie gras bans are entrenched in arguments that the production process is inhumane. In order to make *foie gras*, huge amounts of food must be pumped into the stomachs of ducks and geese twice a day in order to obtain the fatty liver.[36] The process enlarges the birds' livers six to ten times their natural size.[37] The force-feeding lasts between twelve and thirty-one days, at which point the birds are slaughtered.[38] Animal rights groups claim the force-feeding results in painful cuts in the birds' throats and can rupture digestive tracts.[39] Currently, *foie gras* is only produced in two states, New York and California, but consumed nation-wide.[40] The debate over force-feeding birds has produced a fight with no middle ground—one side claiming the right to produce and consume the delicacy and the other claiming the process is inhumane and produces an unnecessary product.[41]

On July 1, 2012, California's ban on the production and sale of any product resulting from the force-feeding of a bird for the purpose of enlarging its liver beyond the normal size went into effect.[42] The law was

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(Illinois Public Act 97-0733). Shark fin bans have been considered in both New Jersey (proposed shark fin ban bill S1764 and A2719) and Maryland (proposed shark fin ban bill S.B. 465 and H.B. 393). California's *foie gras* ban is currently the only ban in the country (CAL. HEALTH & SAFETY CODE §§ 25980-25984 (2012)).

34. Kristin Cook, *The Inhumanity of Foie Gras Production—Perhaps California and Chicago Have the Right Idea*, 2 J. ANIMAL L. & ETHICS 263 (2007).

35. Andrew Nowell Porter, *Unraveling the Ocean from the Apex Down: The Role of the United States in Overcoming Obstacles to an International Shark Finning Moratorium*, 35 SPG ENVIRONS ENVTL. L. & POL'Y J. 231, 233-34 (Spring 2012).

36. Cook, *supra* note 34, at 264.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. Joshua I. Grant, *Hell to the Sound of Trumpets: Why Chicago's Ban on Foie Gras was Constitutional and What it Means for the Future of Animal Welfare Laws*, 2 STAN. J. ANIMAL L. & POL'Y 52, 55 (2009).

42. CAL. HEALTH & SAFETY CODE §§ 25980-25984 (2012), *available at* http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=25001-26000&file=25980-25984. *See also California's Foie Gras Ban Goes Into Effect*, ABC WORLD NEWS, http://abcnews.go.com/US/californias-foie-gras-ban-effect/story?id=16687059#.UNtYiVE2f3A (last visited Mar. 27, 2013).

initially passed in 2004, but had an eight-year delay before its effective date.[43] Not long after, a group of *foie gras* producers and restaurateurs filed a lawsuit in the United States District Court for the Central District of California. The suit claimed that the California law was unconstitutionally vague because the law does not provide fair notice of exactly what amount of food to feed a bird would be acceptable.[44] The Court denied the producer's request for an injunction.[45]

Despite the failures in court, California restaurateurs have found creative ways around the state's *foie gras* ban. The managers of the Presidio Social Club, a restaurant located in a federal enclave within San Francisco, offer *foie gras* at the restaurant by claiming the law does not apply to them because the restaurant is on land administered by a federal agency.[46] Across the state, other restaurateurs and chefs are using loopholes such as offering *foie gras* free with other orders, or preparing it for customers who bring their own *foie gras* to the restaurant.[47]

In 2006, Chicago, based on its police power to ensure the general, health, safety and welfare of its citizens, banned the sale of *foie gras*, which was met with anger from chefs, restaurant-goers and other enthusiasts.[48] Two years later, by a vote of 37 to 6, the Chicago City Council repealed the ban.[49] Influential Mayor, Richard Daley, at one point criticized the ban as "the silliest law" the City Council had ever passed.[50] Supporters of the repeal claimed the original ordinance brought negative attention to Chicago, was an embarrassment to the city, and infringed on citizen's freedom of choice.[51] The repeal occurred despite a finding by the United States District Court in the Northern Division of Illinois that the regulation did not violate the Constitution.[52] It will be interesting in future years to see if California courts follow the reasoning employed in the Illinois challenge,

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43. Cook, *supra* note 34, at 270.

44. Association des Éleveurs de Conards et d'Oies du Québec v. Harris, No. 12-5735 (U.S. Dist. Ct., C.D. Cal., W. Div., orders entered July 19, 2012 and Sept. 19, 2012).

45. *Id.*

46. Fenit Nirappil, *Foie Gras Ban: California Restaurants Duck New Law in Creative Ways*, HUFFINGTON POST, (July 17, 2012), http://www.huffingtonpost.com/2012/07/17/foie-gras-ban_n_1680200.html.

47. *Id.*

48. Grant, *supra* note 41, at 66.

49. Nick Fox, *Chicago Overturns Foie Gras Ban*, N.Y. TIMES, (May 14, 2008), http://dinersjournal.blogs.nytimes.com/2008/05/14/chicago-overturns-foie-gras-ban/.

50. Grant, *supra* note 41, at 67.

51. *Id.*

52. Illinois Restaurant Ass'n v. City of Chicago, 492 F. Supp. 2d 891 (N.D. Ill. 2007).

as well as if the ban will survive political pressure similar to that brought on the Chicago City Council.

Also in California, organizations that represent the interests of Asian Americans challenged the constitutionality of legislation that bans the "possession, sale, offer for sale, distribution, or trade of shark fins."[53] The challenge claims that the law violates their equal protection rights, unlawfully interferes with interstate commerce, preempts federal law, and violates 42 U.S.C. § 1983.[54] Additionally, the group argues that the law deprives them of rights, privileges and immunities under the U.S. Constitution.[55]

Some in the Chinese-American community use shark fins as a traditional soup—often used as a ceremonial centerpiece of banquets and served at weddings and birthdays of elders. The soup is a symbol of respect, honor and appreciation in Chinese culture.[56] The suit alleges that the ban on shark fins discriminates against people of Chinese national origin and the plaintiffs seek a declaration that the law is unenforceable and void.[57]

The Illinois legislature passed a similar ban, effective January 1, 2013.[58] The Illinois statute prohibits the possession, sale, offer for sale, trade or distribution of a shark fin on or after January 1, 2013.[59] Persons already in possession of a shark fin as of January 1, 2013 have until July 1, 2013 to dispose of the shark fin.[60]

The bans on possession of shark fins arise after a national effort to outlaw the practice of shark finning. Because shark meat is relatively inexpensive compared to other fish, such as tuna, fishermen do not want to waste precious cargo space by holding the entire shark carcass when the only lucrative portion is then fin.[61] Generally, when harvesting a shark fin, the fisher will cut the fins and tail off before throwing the animal back into the water to die.[62] The high price that shark fins can bring at market has led to a boom in the shark finning industry, and has resulted in a sharp decline in the shark population, including placing some species on the verge of

53. Chinatown Neighborhood Assn. v. Brown, No. 12-3759, 2013 WL 60919, at *1-3 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed July 18, 2012).
54. *Id.* at *3.
55. *Id.*
56. *Id.* at *1.
57. *Id.*
58. Ill. Pub. Act 97-0733 (2013).
59. *Id.*
60. *Id.*
61. Porter, *supra* note 35.
62. *Id.* at 233

extinction.[63] Depending on the size of the fin, prices generally exceed sixty dollars per kilogram, but can range in price up to seven hundred dollars.[64] In 2010, the federal government passed the Shark Conservation Act of 2010, which made it illegal for fisherman in any United States' water to keep only the shark's fin without also carrying the carcass on the ship.[65] This new round of bans, by impacting product demand via outlawing possession, seeks to indirectly reduce shark finning practices. However, while the federal act bans the practice amongst all fishermen, the new laws restricting possession only effect populations that consume shark fins, giving the organizations that filed on behalf of Asian-American's potentially solid arguments for their claims.

B. Natural Foods

1. What is Natural?

Natural is the most commonly used claim on new U.S. food products.[66] In 2009, approximately 55,000 products had the term natural on their label, and that number continues to rise.[67] Consumers have driven the trend; sixty-three percent of people who responded to a survey show preference for a product labeled natural.[68] The FDA has retained a policy statement about the term natural, but has continually refused to define the term with an official rule.[69] FDA reluctance to promulgate a firm definition

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63. *Id.* at 234.

64. *Id.* at 237.

65. 16 U.S.C. § 1857(1)(P)(i)-(iv) (2012).

66. Erik Benny, *"Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" that Includes Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1506 (2012).

67. Adam C. Schlosser, *A Healthy Diet of Preemption: The Power of the FDA and the Battle Over Restricting High Fructose Corn Syrup from Food and Beverages Labeled "Natural,"* 5 J. FOOD L. & POL'Y 145, 167 (2009).

68. GreenerChoices.Org & Consumer Reports, Food Labeling Poll 9 (July 11, 2007), *available at* http://greenerchoices.org/pdf/Food%20Labeling%20Poll-final_rev.pdf.

69. In contrast, the USDA has defined and regulates the use of the term natural in meat products. USDA, Meat and Poultry Labeling Terms, http://www.fsis.usda.gov/FACTSheets/Meat_&_Poultry_Labeling_Terms/index.asp#14 (last visited Feb. 26, 2013). In a relatively straightforward class action suit filed against Chipotle in June 2012, plaintiffs alleged that the company fraudulently misrepresented the exclusive use of naturally raised meat on their menu. Hernandez v. Chipotle Mexican Grill, Inc., No 12-5543 (U.S. Dist. Ct., C.D. Cal., filed June 26, 2012). The court denied Chipotle's motion to dismiss, holding that the plaintiff need not show actual consumption of any non-naturally raised meat because the alleged harm was paying a premium based on Chipotle's representations that non-naturally raised meat was not used at the restaurant

has led to ample private and class action litigation over "natural" claims on a variety of processed, multi-ingredient food products.[70] While the FDA policy statement generally protects producers at the federal level, multiple consumer groups have relied upon state consumer protection statutes to bring claims for deceptive and misleading use of the term "natural" on various products.[71] This trend towards litigation over claim of a product's natural characteristics is unlikely to end so long as (1) the FDA does not issue a bright line rule of the definition of natural and (2) consumers continue to be drawn to products making the natural claim.[72] In the interim, judges, on a case-by-case basis, will continue to craft what amounts to a confusing, piecemeal, state-by-state construction of what may qualify as a "natural" product.[73] While this Article features a sampling of what the authors consider are the most important cases filed this year, space constraints prevented the authors from describing several others.[74]

2. Are Products Containing Genetically Engineered Ingredients "All Natural"?

Historically, cases filed over the definition of natural involved food and beverages that contained high fructose corn syrup.[75] One novel issue in 2012 was whether or not genetically engineered ingredients warrant listing as a natural ingredient. Genetically modified organisms (GMOs) account for most of the United States' staple crops, including soybeans, corn, cotton, canola, and sugar beets.[76] From a production perspective, many farmers appreciate the insect and herbicide resistance embedded in

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chain. *Id.* The court also refused to dismiss the plaintiff's claim for fraudulent concealment, as well as the class allegations. *Id.*

70. April L. Farris, *The "Natural" Aversion: The FDA's Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403 (2010).

71. *Id.* at 404.

72. Benny, *supra* note 66, at 1504.

73. *Id.* at 1506.

74. *See generally* Shook, Hardy & Bacon, Food and Beverage Litigation Update, http://www.shb.com/fblu_newsletters.aspx (last visited Feb. 25, 2013) (detailing, on a weekly basis, several lawsuits filed over the term "natural" with food products).

75. *See* A. Bryan Endres & Nicholas R. Johnson, *United States Food Law Update: The FDA Food Safety Modernization Act, Obesity and Deceptive Labeling Enforcement*, 7 J. FOOD L. & POL'Y 135 (2011); Benny, *supra* note 66; Schlosser, *supra* note 67.

76. GENOMICS.ENERGY.GOV, *Genetically Modified Foods and Organisms*, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml (last visited Feb. 26, 2013); Benny, *supra* note 66, at 1520.)

GMOs.[77] While generally accepted by US farmers and federal agencies as safe and effective, consumers are somewhat more skeptical.[78] One consumer filed a case against Quaker Oats claiming that its Mother's Natural line of cereals advertised as "all natural" but containing GMOs, violated state unfair competition and false advertising laws.[79] Similarly, consumers filed a class action against General Mills for allegedly misleading claims that Kix cereal, advertised as containing "all natural" corn, also contains genetically modified corn.[80] Several General Mills snack foods were also subject to lawsuits for marketing as "all natural" despite containing GMOs.[81] As of this writing, the courts have not issued any dispositive orders. Although early in the process, it is certain that if the plaintiffs are successful in their claims, the ubiquitous nature of GMOs in the food supply will have a substantial impact on the ability of many large food processors to market their products as "all natural."

3. How much processing is "too much" for a "Natural" Food?

The Judicial Panel on Multidistrict Litigation consolidated six lawsuits against Tropicana alleging that the company deceptively marketed its not-from concentrate orange juice as "100% Pure & Natural," even though extensive pasteurizing and processing is used to make the juice.[82] The case will be heard before a multidistrict litigation court. In another juice-related case, a plaintiff alleged that Jamba Juice falsely misrepresented its smoothie kit as "All Natural" because the kit actually contained unnaturally processed and synthetic ingredients, including stevia.[83] The Court granted Jamba Juice's motion to dismiss in-part for plaintiff's failure to state a warranty claim under California's Magnuson-Moss Warranty Act. As of this writing, the plaintiff has not yet filed an amended claim.[84]

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77. *Id.*

78. *Id.*; Rick Blizzard, *Genetically Altered Foods: Hazard or Harmless*, GALLUP, http://www.gallup.com/poll/9034/Genetically-Altered-Foods-Hazard-Harmless.aspx (last visited Mar. 28, 2013).

79. Mitro v. The Quaker Oats Co., No. BC486882 (Cal. Superior Ct., Los Angeles Cnty., filed June 19, 2012).

80. Pfeifer v. General Mills Inc., No. 12-15157 (D.N.J., filed June 13, 2012).

81. Garcia v. General Mills Inc., No. 12-cv-22363 (S.D. Fla., filed June 26, 2012).

82. In re: Tropicana Orange Juice Mktg. & Sales Practices Litig., MDL No. 2353 (J.P.M.L, order entered June 11, 2012).

83. Anderson v. Jamba Juice Co., No. 12-1213 (U.S. Dist. Ct., N.D. Cal., Filed March 12, 2012).

84. Anderson v. Jamba Juice Co., No. 12-1213 (U.S. Dist. Ct., N.D. Cal., order entered August 25, 2012).

In an ice cream case, a federal court in California dismissed federal warranty claims, but allowed state-law claims to proceed based on allegations that the company misled consumers by labeling its products with the phrases "All Natural Flavors" and "All Natural Ice Cream."[85] The plaintiffs alleged that Dreyer's and Edy's labels should not claim "All Natural Flavors" because the products contain between one and five artificial and synthetic ingredients.[86] The court's rationale in dismissing the federal claim focused on its interpretation of the term natural as descriptive, rather than providing any assurance that the product is defect free under the Federal Magnuson-Moss Warranty Act.[87] The issue boils down to the difference between regulations of ingredients and flavorings; while the phrase natural ingredients has no federal definition, the term natural flavors does.[88] If the "All Natural Flavors" claim had been listed in the ingredient statement, rather than on the general label, the court might have sided with Dreyer's over whether the state claim was preempted by Federal labeling law.[89] Federal law requires a state law to be identical to the federal labeling requirements, and specifies how flavorings should be labeled, including the use of the term "natural flavor."[90] However, because the "All Natural Flavors" was listed as a general claim on the front of the packaging, the court decided it was possible for a consumer to see the claim and believe that entire line of ice cream was "All Natural," instead of just the flavoring ingredients.[91] A similar case was filed in September 2012 against the company that makes "All Natural Ben & Jerry's Ice Cream." Plaintiffs

85. Astiana v. Dreyer's Grand Ice Cream, Inc., No C-11-2910 EMC; Rutledge-Muhs v. Dreyer's Grand Ice Cream, Inc., No. C-11-3164 EMC (U.S. Dist. Ct., N.D. Cal., order entered July 20, 2012).

86. *Id.*

87. *Id.*

88. 21 C.F.R. § 101.22(h)(1) (2012).

89. Astiana v. Dreyer's Grand Ice Cream, Inc., No C-11-2910 EMC (Oct. 12, 2012).

90. 21 U.S.C. § 343-1(a)(3)(2012); 21 C.F.R. § 101.22(h)(1)(2012).

91. Astiana v. Dreyer's Grand Ice Cream, Inc., No C-11-2910 EMC (Oct. 12, 2012); *see also* Lam v. General Mills, Inc., No. 11-5056-SC (May, 2012) (showing the same district court denied a motion to dismiss after finding that a reasonable consumer could be deceived by the claim "made with real fruit" coupled with images of natural fruits, despite the ingredient statement listing partially hydrogenated oil and sugars, agreeing with the plaintiff that the label for Fruit Roll Ups and Fruit by the Foot were misleading). *Compare* Carrea v. Dreyer's Grand Ice Cream, Inc., No. 11-15263 (9th Cir. 2012) (displaying a similar case filed against Dreyer's Grand Ice Cream, Inc. (Dryers), where Dryers successfully argued for dismissal that a warranty claim was preempted by the Federal Food, Drug and Cosmetic Act and the Nutrition Labeling and Education Act because the use of the term "0g Trans Fat" has a federal definition that allows up to .5 grams of trans fat per serving to be listed as "0g Trans Fat" on the label).

alleged that the company's use of alkalized cocoa, corn syrup, partially hydrogenated soybean oil, and other ingredients that do not exist in nature precludes use of an "all natural" label.[92]

As previously mentioned, due to its extensive processing, high fructose corn syrup has a long history of litigation surrounding whether or not it qualifies as a natural food ingredient.[93] Most recently, plaintiffs filed a class action suit against General Mills alleging violations of California's unfair competition and false advertising laws arising from General Mill's allegedly deceptive representations that their Nature Valley products, labeled as "all natural," "natural," and "100% natural" despite incorporating highly processed ingredients such as HFCS, high maltose corn syrup, and maltodextrin.[94] The complaint also claimed that General Mills takes advantage of consumers with words and images in its marketing and labeling that depict the outdoors and natural scenes that attract consumers with preferences for natural foods.[95] As of this writing, no further action has occurred.

C. Rebranding High Fructose Corn Syrup

Aside from the typical consumer driven class action suits regarding use of the term natural with high fructose corn syrup (HFCS) discussed in the previous section, the sweet substance was also involved in broader labeling issues over the use of the term "corn sugar." The most common form of HFCS (HFCS-42 and HFCS-55) is similar to regular table sugar, except instead of sucrose, HFCS contains fructose and glucose.[96] Food manufacturers prefer HFCS to table sugar because its chemical properties provide better flavor enhancement and overall stability, consistency and texture of the food.[97] At least one scientific study, however, has linked HFCS to obesity based on ecological studies of consumption rates and obesity rates in geographic locations.[98] Proponents of the product note that the limited research available on the effects of HFCS precludes

92. Tobin v. Conopco, Inc., No. 1:33-av-00001 (U.S. Dist. Ct., D.N.J., Newark Div., filed September 13, 2012).

93. *See* Endres & Johnson, *supra* note 75, at 156; Benny, *supra* note 66, at 1512; Schlosser, *supra* note 67, at 147.

94. Janney v. General Mills Inc., No. C12-3919 (U.S. Dist. Ct., N.D. Cal., filed July 26, 2012).

95. *Id.*

96. Suzen M. Moeller et al., *The Effects of High Fructose Corn Syrup*, 28 J. OF THE AM. C. OF NUTRITION 619 (2009).

97. *Id.*

98. *Id.* at 619-20.

conclusively attaching to it the negative image portrayed in some media outlets.[99]

In an effort to side-step negative images, the Corn Refiners Association (CRA) petitioned FDA to authorize the term "corn sugar" as an alternative name for high-fructose corn syrup. Specifically, the petition had asked the agency to (1) amend the GRAS affirmation regulation for HFCS to designate corn sugar as an optional name; (2) to eliminate corn sugar as an alternate name for dextrose; and (3) to replace all references to corn sugar with dextrose in the GRAS regulations for corn sugar.[100]

The FDA cited several reasons for rejecting the proposed "re-branding" of HFCS including that (1) HFCS cannot be called sugar because sugar is a solid, dried and crystalized food; (2) for 30 years, the term corn sugar has been used as the common or usual name for dextrose; and (3) corn sugar (dextrose) is a safe ingredient for those with hereditary fructose intolerance or malabsorption, and changing the name for HFCS to corn sugar would pose a public health concern for that population.[101]

FDA's rejection of the corn sugar rebranding effort, however, does not in any way signal the end of the road for legal challenges related to HFCS. In addition to the ongoing "consumer deception" litigation, the NGO Citizens for Health filed a petition[102] with the FDA requesting that the agency amend its HFCS regulation to require food producers to identify its concentration of fructose on the product labels. For example, HFCS with 42 percent fructose would be labeled "high fructose corn syrup 42." Additionally, the petition urged that if producers manipulate the amount of fructose in HFCS to a different concentration than a standardized blend of 42 or 55, the resulting concentration should be incorporated into the ingredient name. For example, HFCS with 90 percent fructose would be labeled "high fructose corn syrup 90."[103] Citizens for Health also requested FDA enforcement against food companies using HFCS with fructose in amounts other than 42 or 55 percent blends recognized by the agency as

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99. *Id.* at 619.

100. *Response to Petition from Corn Refiners Association to Authorize "Corn Sugar" as an Alternate Common or Usual Name for High Fructose Corn Syrup*, FDA, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm305226.htm (last visited Mar. 27, 2013).

101. *Id.*; Veronica Louie, *Masquerading Behind Words: The Corn Refiners Association's Push to Rename High-Fructose Corn Syrup as "Corn Sugar,"* 4 NORTHEASTERN U. L. J. 293 (Spring 2012). (providing a more in depth discussion of the Corn Refiner's Association's attempt to rename high fructose corn syrup).

102. Citizens for Health Petition, (Aug. 15, 2012), *available at* http://www.citizens.org/http://www.citizens.org/wp-content/uploads/2012/08/CFH-Citizen-Petition-to-FDA-on-HFCS.pdf.

103. *Id.*

GRAS. Petitioners claim that scientific studies indicating that higher fructose concentrations can have negative effects on humans, thus disqualifying the product's GRAS status.[104] The FDA responded to the petition in February of 2013, informing Citizens for Health that the agency did not have time to respond to the petition within 180 days of receipt of the petition because of agency priorities, but would review the petition in the future.[105]

D. Mandatory Labeling for Genetically Modified Organisms

On the front line of the intersection between large-scale food interests (i.e., commodity agriculture, food processors, national grocery chains) and consumer labeling advocates was California's ballot initiate for the labeling of food products produced with genetically modified organisms—Proposition 37. The measure failed, with 48.6% of California voters voting yes for Proposition 37 and 51.4% voting no. Under the proposal, foods offered for retail sale that have been, or that may have been, entirely or partially produced with genetic engineering would have been required to be labeled with a statement disclosing that fact.[106] The initiative defined genetically engineered as the manipulation of an organism's genetic material through methods such as direct injection of nucleic acid into cells or fusion of cells in a way that does not occur through natural multiplication or recombination.[107]

The highly contested electoral battle attracted significant financial backing both for and against Proposition 37. Michele R. Simon, a lawyer and spokesperson for the Yes on 37 campaign speculated that the proposition failed due to "Lies, dirty tricks and $45 million" spent by industry against the proposition.[108] Others argue that the proposition failed because the scientific consensus so far has indicated that genetically engineered foods are safe for consumers, and labeling would create a

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104. *Id.*

105. FDA response to Citizens for Health, (Feb. 14, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0904-0115.

106. *Official Voter Information Guide*, CALIFORNIA GENERAL ELECTION RESULTS, http://voterguide.sos.ca.gov/propositions/37/title-summary.htm (last visited Mar. 27, 2013).

107. Proposed Proposition 37 Regulations (2012), *available* at http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf#nameddest=prop37.

108. Karl Haro von Mogel, *Why Did Proposition 37 Fail?*, FOOD SAFETY NEWS, (Nov. 19, 2012), http://www.foodsafetynews.com/2012/11/why-did-proposition-37-fail/#.UNtqclE2f3A.

tremendous burden on the food supply system resulting in increased food prices.[109]

Advocates for mandatory labeling of genetically engineered foods quickly shifted their attention to a Washington State initiative. Initiative I-522, titled the People's Right to Know Genetically Engineered Food Act, would require labeling of food products (including dietary supplements) that contain genetically modified organisms (GMO's).[110] The Initiative is similar to California's Proposition 37 in that it seeks to have the legislature require GMO labeling; specifically, labeling of foods, including raw agricultural products, processed foods, seed and seed stock offered for retail sale that have been or may have been, entirely or partially produced with genetic engineering. As of December 21, 2012, activists reported they had gathered enough signatures to send the GMO labeling initiative to the next session of the Washington legislature.[111] Under state rules, the legislature must consider whether or not to adopt the law during the next session. If the legislature declines to act, the measure will go back to the voters to decide.[112] Thus the battle over labeling food produced via use of genetic engineering continues on the West coast after several legal uproars in Ohio[113] and Vermont.[114]

Finally, at the federal level, fifty-five members of Congress sent a March 12, 2012 letter[115] to the FDA in support of a citizen petition demanding the labeling of genetically engineered foods. The petition, filed by the Center for Food Safety on behalf of the Just Label It campaign,

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109. *Id.*

110. Hank Schultz, *Organizers Confident Washington State Non-GMO Initiative will Hit Signature Goal,* FOOD NAVIGATOR-USA.COM, (Dec. 17, 2012), http://www.foodnavigator-usa.com/Regulation/Organizers-confident-Washington-state-non-GMO-initiative-will-hit-signature-goal.

111. Erik Smith, *Supporters Say They Have Signatures to Place Labeling Measure Before Legislature, Voters—Raises Possibility of Another Big-Spending Ballot Fight,* WASHINGTON STATE WIRE, (Dec. 21, 2012), http://washingtonstatewire.com/blog/fresh-from-california-a-fight-over-genetically-modified-food-comes-to-washington-i-522-will-drive-furious-debate/.

112. *Id.*

113. Int'l Dairy Foods Assoc. v. Boggs, 622 F.3d 628 (6th Cir. 2010) (striking down Ohio's regulation that prohibited dairy processors from making claims about the absence of artificial hormones (rBST) in their milk products).

114. Int'l Dairy Foods Assoc. v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996) (striking down Vermont's regulation that required dairy processors to label any product produced with the use of rBST).

115. Congressional letter to Commissioner Hamburg, (Mar. 12, 2012), *available at* http://www.leahy.senate.gov/imo/media/doc/Final%20Signed%20GE%20Labeling%20Letter.pdf.

asserts that the lack of any labeling makes GE foods misleading.[116] The letter from members of Congress urged the FDA "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."[117] As of this writing, the FDA has not yet made a determination on the petition.

III. Animal Production and Labeling Issues

In 2012, a variety of animal and livestock related legal issues generated significant attention. As discussed in more detail below, consumer interest groups appeared to make some progress in their decades-long dispute with the FDA over the subtherapeutic use of antibiotics in animal production, consumer outrage over lean finely textured beef—commonly referred to with the endearing term "pink slime"—delivered a potential death blow to the industry, animal welfare groups reached a détente with some egg producers, the Supreme Court, on preemption grounds, rejected California's attempt to prohibit downer animals from entering the human food supply chain, and the World Trade Organization rejected the Country of Origin Labeling regime for beef in the US.

116. *Press Releases: 55 Members of Congress Join in Support of Center's Legal Petition*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/2012/03/27/record-breaking-one-million-public-comments-demand-fda-label-genetically-engineered-foods/ (last visited Mar. 27, 2013).
117. *Id.*

A. Citizen and Advocacy Involvement in Long Running Dispute with FDA over Withdrawal of Subtheraputic use of Penicillin and Tetracyclines

The long-running saga regarding penicillin and tetracycline for subtherapeutic use in animal production inched ever closer to resolution in 2012 through the involvement of several citizen groups and advocacy organizations. The story begins in the mid 1950's, when the FDA approved several applications for the use of penicillin and tetracyclines for non-disease treatment purposes such as growth promotion and feed efficiency.[118] The drugs were properly approved as a new animal drug under the Food, Drug, and Cosmetic Act (FDCA), and thus also subject to the FDA's ongoing obligation to review usage and withdraw approval if new evidence shows that the drug is not safe.[119] The FDA later exercised that power by creating a task force to review antibiotic usage in animal feeds, which concluded that the practice was creating a human health hazard.[120] At the same time, the FDA issued a regulation stating that the agency would propose to withdraw all non-therapeutic uses of antibiotics in animal feed unless the agency's concerns that the drug usage had not been proven to be safe were resolved.[121] The FDA invited drug and livestock industry participants to submit data showing that the subtherapeutic use would not lead to decreased effectiveness of these important antibiotics for human usage.[122]

Subsequently, the FDA assigned a subcommittee to review the submissions from over 380 livestock and poultry producers; drug and feed manufacturers; academics; and individuals.[123] In 1973, the FDA went forward by issuing a regulation that the agency would propose to withdraw approval of antibiotics in animal feed unless conclusive evidence that no human health hazard existed from the subtherapeutic antibiotic usage.[124] By 1977, the FDA did issue proposals to amend the regulations to eliminate penicillin[125] and tetracyclines[126] for subtherapeutic use. At the same time,

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118. NRDC v. FDA, 872 F.Supp.2d 318, 322 (S.D.N.Y. June 1, 2012).

119. 21 U.S.C. § 360(b)(e), 21 C.F.R. § 514.80(a)(3).

120. Antibiotic and Sulfonamide Drugs in Animal Feeds, Proposed Statement of Policy, 37 Fed. Reg. 2,444 (Feb. 1, 1972).

121. *Id.*

122. *Id.* at 2,445.

123. Antibiotic and Sulfonamide Drugs in Animal Feeds, Proposed Statement of Policy, 38 Fed. Reg. 9,811 (Apr. 20, 1973).

124. *Id.* at 9813.

125. Penicillin in Animal Feeds; Proposed Rulemaking, 42 Fed. Reg. 43,770 (Aug. 30, 1977).

126. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264, (Oct. 21, 1977).

the FDA also issued notice of an opportunity for hearing (NOOH) in which drug companies would bear the burden of showing that such risks did not exist.

The FDA later published notice that twenty drug firms, agricultural organizations and individuals had requested a hearing and that the hearing would be scheduled "as soon as practicable."[127] Fast-forwarding thirty years, the FDA has yet to hold a hearing and withdrawal proceedings have not advanced. The FDA continued to collect data on the issue with three separate studies failing to show that continued subtheraputic use of the antibiotics was safe for the long term effectiveness of these important drugs.[128]

Industry resistance to halting subtherapeutic use has centered on increased costs due to decreased feed efficiency and the subsequent increased necessity of therapeutic antibiotics to treat disease outbreaks.[129] On the other hand, one scholar has noted that even if production drops as a result of suspending subtherapeutic antibiotic use, higher prices at the retail level for "antibiotic-free" poultry will actually result in greater industry profitability.[130] However, the lack of comprehensive data on the subtherapeutic use of antibiotics in US livestock production makes it difficult to rely on empirical data in setting public policy.[131] Further complicating the policy area, the structure of the FDCA makes for a cumbersome withdrawal process by requiring specific findings and a hearing process[132] that may not allow quick action as scientific knowledge advances.[133]

Growing consumer concern is a significant driver in the call for withdrawal of subtheraputic antibiotics. Representative Louise Slaughter (D-NY), an outspoken critic of the practice, conducted a study in early 2012 on antibiotic use policies in fast food companies, meat producers and processors, as well as grocery store chains.[134] The survey found that the majority of food producers use antibiotics in a preventative manner and that

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127. Penicillin and Tetracycline in Animal Feeds, Hearing, 43 Fed. Reg. 53,827 (Nov. 17, 1978).

128. NRDC v. FDA, No. 11 Civ. 3562 WL 983544 (S.D.N.Y. Mar. 22, 2012).

129. Terence J. Centner, *Regulating the Use of Non-Therapeutic Antibiotics in Food Animals*, 21 GEO. INT'L ENVTL L.J. 1 (Fall 2008).

130. *Id.* at 19.

131. *Id.* at 20.

132. 21 C.F.R. § 514.115 (2007).

133. Centner, *supra* note 129, at 34.

134. Congresswoman Louise M. Slaughter, "What's in the Beef?" Survey Results, (July 2, 2012), *available at* http://www.louise.house.gov/index.php?option=com_content&view=article&id=2744:survey-results-antibiotics-in-the-food-you-buy&catid=69&Itemid=59.

the laws, as currently written, fail to prevent the emergence of antibiotic resistant microbes.[135] Accordingly, Rep. Slaughter called for the FDA to combat the growing problem of antibiotic resistance resulting from the use of low levels of pharmaceuticals on otherwise healthy food-producing animals[136] and introduced a bill to phase out subtherapeutic use of antibiotics, while preserving authority to use antibiotics to treat sick animals.[137] Similarly to the FDA's thirty-year failure to hold a hearing described above, the legislative session ended without action on the bill.

The Congressional and agency atrophy in this issue, however, appears to be dislodged by the creative use of the judicial system. In May of 2011, the Natural Resources Defense Council, along with other plaintiffs, filed suit against the FDA alleging that the agency unlawfully withheld or delayed action on this issue and that the agency arbitrarily denied citizen petitions to take action on the withdrawal proceedings.[138] In December of 2011, the FDA rescinded its thirty-year old notice of opportunity for a hearing, citing the need to update the data and the agency's wish to engage in other regulatory strategies—setting the stage for a later legal challenge.[139] Accompanying the rescission, FDA unveiled a new, voluntary subtherapeutic withdrawal program, which it claimed was more effective and a better use of agency resources in meeting the goal of controlling antibiotic resistance in humans.[140] As a part of the voluntary program, FDA released three documents: (1) an industry guidance document titled, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," (2) a draft industry guidance document for removing production use of antibiotics from labels, and (3) a draft directive for the veterinary industry to oversee the use of antibiotics in animal feed.[141] Collectively, the guidance documents emphasize the use of antibiotics only

135. *Id.*

136. Helena Bottemiller, *Rep. Slaughter Calls for Greater FDA Focus on Preserving Antibiotics,* FOOD SAFETY NEWS, Sept. 26, 2012, *available at* http://www.foodsafetynews.com/2012/09/rep-slaughter-calls-for-greater-fda-focus-on-preserving-antibiotics/.

137. Preservation of Antibiotics for Medical Treatment Act of 2011, H.R. 965, 112th Cong. (2012), *available at* http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.965.IH.

138. Withdrawal of Notice of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697 (Dec. 22, 2011).

139. NRDC v. FDA, No. 11 Civ. 3562 WL 983544, 7 (S.D.N.Y. Mar. 22, 2012).

140. NRDC v. FDA, No. 11 Civ. 3562 WL 3229296, 13 (S.D.N.Y. Aug. 8, 2012).

141. Press Release, Food and Drug Administration, FDA takes steps to protect public health (Apr. 11, 2012) *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm299802.htm

for medically-necessary treatment under the supervision of a veterinarian.[142]

Despite the hearing rescission and introduction of a voluntary withdrawal program, the NRDC case filed in May 2011 progressed. In a March 2012 opinion, a federal magistrate judge held that a discrete action by the FDA had occurred when the FDA found that subtherapeutic uses should be withdrawn.[143] The holding rejected the defendant's argument that the discrete action subject to judicial review occurred in the 1970s when the agency first issued its notice of opportunity for hearings. The identification of the discrete action is important to the plaintiffs' cause of action because where the Administrative Procedure Act permits a court to "compel action unlawfully or unreasonably delayed,"[144] the Supreme Court has found that the provision only applies if an agency "failed to take a discrete action it was required to take."[145] This is also important because had the judge otherwise found that the discrete action occurred when the NOOHs were issued, the FDA may have found traction on its argument that the rescission of the NOOHs in December of 2011 mooted the plaintiffs' claim.[146]

The court further held that the FDCA unambiguously required the agency to conduct withdrawal proceedings, even before the FDA Administrator has made a finding after a formal hearing—an action the agency had failed to undertake.[147] After receiving additional briefs on the matter of a timeline for withdrawal proceedings, the judge adopted the FDA's proposed hearing schedule that calls for proceedings to be completed over a 41-month timeframe.[148] The judge also denied the government's request for a stay pending an appeal of the March order, finding that although the government has a substantial case on appeal, the likelihood of injury to the government if a stay were not granted was low.[149]

A third decision on this case added more development. Regarding the citizen petitions, the judge held in a June 2012 decision that the withdrawal of the request for hearings was more analogous to informal rulemaking than an enforcement action. As such, the withdrawal was not an issue of

142. *Id.*
143. NRDC, WL 983544 at 10.
144. 5 U.S.C. § 706(1) (2012).
145. Norton v. S. Utah Wilderness Alliance, 542 U.S. 55, 62 (2004).
146. NRDC, WL 983544 at 7.
147. *Id.* at 10
148. NRDC, WL 3229296 at 9.
149. *Id.* at 14-15.

agency discretion, but rather subject to court review.[150] The court further held that the FDA's denial of the citizen petitions and subsequent promulgation of the agency's new voluntary program was arbitrary, capricious, and in violation of the FDCA.[151]

B. Consumer Outcry Against LFBT Results in Purchasing Changes and Labeling Initiatives

In general, consumer awareness of, and influence over the agriculture industry continues to grow beyond the more traditional issues with a direct impact on human health. Consumers are demanding greater knowledge of the foods they consume—from farm to fork. The same is true of the beef industry.

Lean Finely Textured Beef (LFTB), better known after a year of infamy as "pink slime," is a key example. LFTB is a beef product developed by Beef Products, Inc. (BPI) in 1991 as a way to provide more domestic lean beef to the U.S. market.[152] The process involves heating scrap beef trimmings and sending the product through a centrifuge that separates the fat and meat. The resulting LFTB product is around 94% lean and used as a supplement in traditional ground beef to boost the final leanness of the meat products.[153] LFTB is also used in lunch meats, sausages, and canned meats.[154] To prevent contamination by E. coli, Salmonella, and other common pathogens found in beef, BPI's process also treats the LFTB with food grade ammonium gas.[155] The FDA currently lists the use of ammonium gas as "generally recognized as safe," if used according to good manufacturing practices.[156]

On March 7, 2012, ABC News broadcasted a report about the use of LFTB in retail beef products.[157] The report featured a former USDA scientist as a "whistleblower," who informed the news network that 70% of ground beef in the U.S. contains what the industry refers to as "pink slime" and that there were no requirements to label beef that contained LFTB. Not surprisingly, the news report generated widespread backlash against the use

150. NRDC v. FDA, 872 F.Supp.2d 318 (S.D.N.Y. June 1, 2012).
151. *Id.* at 339.
152. JOEL L. GREENE, LEAN FINELY TEXTURED BEEF: THE "PINK SLIME" CONTROVERSY, CONGRESSIONAL RESEARCH SERVICE, (Apr. 6, 2012), *available at* http://www.fas.org/sgp/crs/misc/R42473.pdf.
153. *Id.*
154. *Id.*
155. *Id.*
156. *Id.*
157. *Pink Slime and You*, ABC WORLD NEWS, http://abcnews.go.com/WNT/video/pink-slime-15873068 (last visited Mar. 12, 2013).

of LFTB. McDonalds, Burger King, Costco, Publix, and Whole Foods, along with several other retail grocery chains, pledged to exclude LFTB from their product offerings.[158] A survey of consumer opinions revealed that 88 percent of adults were aware of pink slime, with 76 percent ranking themselves "at least somewhat concerned" and 30 percent "extremely concerned."[159]

1. Food Libel

The steep decline in demand for LFTB took a toll on BPI, which closed three of its four processing plants following the public disclosure. BPI has since filed a $1.2 billion dollar defamation suit against ABC News, Diane Sawyer, several ABC News employees and two former USDA employees.[160] The suit, filed on September 13, 2012, claims that the defendants knowingly and intentionally published 200 false statements regarding both BPI and its LFTB product.

The ultimate success of the lawsuit is not assured. BPI filed the suit in South Dakota, likely to take advantage of the state's food libel laws.[161] Food libel laws establish an action in tort for damages resulting from falsely criticizing the safety of a perishable agricultural product.[162] South Dakota law provides recourse for producers of perishable food products for statements which are known to be false and that imply a product is not safe for public consumption.[163]

Although of questionable constitutionality,[164] application of food libel laws in the context of meat products may be exceptionally difficult to successfully pursue.[165] For example, the Texas Beef Group brought an unsuccessful suit under Texas' version of a food libel law (Tex. Civ. Prac. & Rem. § 96.001-004) against The Oprah Winfrey Show and one of its guests after claims were made on the show that American beef was unsafe

158. *BPI and Pink Slime: An Updated Timeline,* FOOD SAFETY NEWS, Sept. 26, 2012, *available at* http://www.foodsafetynews.com/2012/09/bpi-and-pink-slime-an-updated-timeline/#.USKVR1pesco.

159. *Id.*

160. Beef Prods. Inc. v. ABC Inc., No. n/a (Cir. Ct., Union Cnty., S. Dak., filed September 13, 2012).

161. S.D. Codified Laws § 20-10A-1 to 4 (2011).

162. David J. Bederman, *Limitations on Commercial Speech: The Evolution of Agricultural Disparagement Statutes*, 10 DEPAUL BUS. L.J. 169, 170-73 (Spring-Summer 1998).

163. S.D. CODIFIED LAWS § 20-10A-1 to 4 (2011).

164. *See* Bederman, *supra* note 162.

165. Sara Lunsford Kohen, *What Happened to Veggie Libel?: Why Plaintiffs Are Not Using Agricultural Product Disparagement Statutes*, 16 DRAKE J. AGRIC. L. 261, 284 (Summer 2011).

in the immediate panic over so-called mad cow disease.[166] The District Court found that ground beef was not part of the food libel law because it did not decay (i.e., it could be frozen) within a limited period of time, unlike fresh fruit and vegetables. The appellate court, however, did not discuss this issue on appeal.[167] Instead, the court affirmed the decision in favor of Oprah Winfrey based on the fact that the statements were not knowingly false at the time Oprah and her guests taped the show.[168] The South Dakota courts have not spoken on the issue of beef perishability. Further, the statute does not lay out a standard for falsity,[169] adding more doubt to the ultimate success of BPI's case.

BPI's suit may be important if the case speaks to the constitutionality of food libel laws under the First Amendment.[170] On October 30, 2012, ABC filed a motion to dismiss the suit claiming that the stories on LFTB are protected speech under the First Amendment.[171] Under current First Amendment jurisprudence, viewpoint neutrality is a key criterion.[172] If regulation of speech is viewpoint neutral, it is subject to less exacting scrutiny under a constitutional analysis.[173] If the regulation is not viewpoint neutral, it may be unconstitutional *per se*.[174] Regulation is viewpoint neutral if it discriminates on the basis of subject matter, rather than on the motivating ideology, opinion, or perspective behind the speech.[175] Food libel laws such as South Dakota's statute, are likely not viewpoint neutral. The South Dakota statute prohibits, for example, speech that states or implies that a specific food product is not safe for human consumption when it is safe.[176] Such a prohibition is specific to a certain viewpoint- whether a specific product is or is not safe- rather than prohibiting speech on the entire subject of food safety or food manufacturing practices as a whole.

Further complicating matters, if the statute regulates political speech, it is subject to an even higher standard of review.[177] In some respects, a

166. *Texas Beef Group v. Winfrey*, 201 F.3d 680 (5th Cir. Feb. 9, 2000).
167. *Id.*
168. *Id.*
169. S.D. CODIFIED LAWS § 20-10A-1(2011).
170. *Id.*
171. Beef Prods. Inc. v. Am. Broadcasting Cos., Inc., No. 2012cv04183 (U.S. Dist. Ct., D.S.D., filed October 24, 2012).
172. Rosenberger v. Rector and Visitors of the University of Virginia, 515 U.S. 819, 821 (1995).
173. *Id.* at 820.
174. *Id.* at 829.
175. *Id.*
176. S.D. CODIFIED LAWS § 20-10A-1 to 4.
177. Citizens United v. Federal Election Commission, 130 S. Ct. 879, 882 (2010).

determination necessary to assess the falsity of the speech—in this case whether LFTB is safe—may be seen as a political determination because the usage of food grade ammonia gas is regulated by government agencies.[178] If a court were to find that the regulation regards political speech, the South Dakota statute is very likely unconstitutional because "political speech must prevail against laws that would suppress it by design or inadvertence."[179]

Even if the food libel laws survive a viewpoint-based challenge, the restriction on speech must pass strict scrutiny review—a doubtful proposition in the BPI-ABC litigation.[180] Under strict scrutiny, the restrictions must advance a compelling government interest and be narrowly tailored to that interest.[181] Although a case may be made that the government has a compelling interest in managing the public's perception of the safety of the nation's food supply, the South Dakota statute is likely not narrowly tailored. For example, the statute does not regulate speech regarding non-perishable food items and thus may be under-inclusive.

In addition to consumer outcry leading to market collapse for LFTB products, legislative and agency solutions to the controversy are moving forward. On March 30, 2012, Representative Chellie Pingree (D-Maine), in response to the LFTB controversy, introduced a bill entitled the Requiring Easy and Accurate Labeling Act (REAL Act).[182] The purpose of the act is to amend the Federal Meat Inspection Act[183] to require producers to label packages of meat that contain LFTB. The House Subcommittee on Livestock, Dairy, and Poultry considered the bill, but as of this writing had not issued a report or held a vote.[184] The USDA, however, has authorized voluntary labeling of LFTB—a step that some believe if taken from the beginning, would have prevented the widespread negative response from consumers.[185]

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178. GREENE, *supra* note 152, at 5.

179. *Citizens United*, 130 S. Ct. at 882.

180. Sara Lunsford Kohen, *What Happened to Veggie Libel?: Why Plaintiffs Are Not Using Agricultural Product Disparagement Statutes*, 16 DRAKE J. AGRIC. L. 261, 272 (Summer 2011).

181. *Rosenberger*, 515 U.S. at 829.

182. REAL Beef Act, H.R. 4346, 112th Cong., Reg. Sess. (2012).

183. 21 U.S.C. § 601 et seq.

184. For up to date information on the status of the REAL Beef Act, see http://www.govtrack.us/congress/bills/112/hr4346.

185. *See* Jim Avila, *BPI Endorses USDA Voluntary Labeling of LFTB or 'Pink Slime'*, ABC NEWS (Apr. 3, 2012), http://abcnews.go.com/blogs/headlines/2012/04/bpi-endorses-usda-voluntary-labeling-of-lftb-or-pink-slime/.

2. Undercover Recording and Ag Gag Legislation

In another First Amendment-related food law development in 2012, several states considered legislation penalizing the filming or recording of animal production facilities. These so-called "Ag Gag" bills, generated significant attention after three prominent news programs broadcast undercover footage of workers mishandling and inflicting pain on live chickens, as well as failing to dispose of dead birds.[186] The broadcast resulted in a nationwide uproar that lead to McDonald's, Target, Sam's Club, and Supervalu to drop all purchasing arrangements with Sparboe, the corporate owner of the facility where the footage took place.[187] The footage in question was made by an undercover investigator working on contract with an animal rights group.[188]

In 2012, Iowa passed what may be the stiffest Ag Gag legislation in the US.[189] Individuals and organizations conducting any filming or recording without the permission of the animal facility are subject to a detailed list of possible violations.[190] Not limited to animal operations, the Iowa law applies to undercover recordings of cropping operations.[191] Of course, one could insert a joke here about how the punishment of "watching grass grow" should be a sufficient deterrent measure from recording cropping operations. Nonetheless, under the Iowa law,

186. Lewis Bollard, *Ag-Gag: The Unconstitutionality of Laws Restricting Undercover Investigations on Farms* 42 ENVTL. L. REP. NEWS & ANALYSIS 10960, (2012).

187. *Id.*

188. Mercy For Animals, Undercover Investigations: Exposing Animal Abuse, http://www.mercyforanimals.org/investigations.aspx (last visited Mar. 27, 2013). In another filming incident, an animal rights group coordinated footage of inhuman treatment of cattle at a Hanford, California slaughterhouse. The video motivated the USDA's Food Safety and Inspection Service to investigate whether downer cows entered the food supply in violation of food safety standards. Although the agency did suspend operations by removing their mark of inspection while investigating the incident, FSIS concluded that no food safety violation occurred and no recall was issued. Press Release, 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.

189. IOWA CODE ANN. § 717A (West 2013).

190. IOWA CODE ANN. § 717A.2(1) (prohibiting persons from willfully injuring an animal, exercising control over an animal facility with intent to remove an animal, or entering onto an animal facility if the facility is not open to the public with the intent to disrupt operations, among others); IOWA CODE ANN. § 717A.3 (prohibiting destroying crops and remaining on crop operations after being asked to leave, among others).

191. IOWA CODE ANN. § 717A.3.

organizations coordinating the undercover investigators in past sting operations may be prosecuted along with the actual individual conducting the recording.[192] Repeat convictions are a Class D Felony and may result in a prison sentence of five years.[193] Utah also passed an Ag Gag bill in late March, 2012.[194] Individuals who obtain employment under false pretenses to gain access to a farm facility may be charged with a serious misdemeanor under Utah law.[195] The Utah bill makes the intentional recording of an agricultural operation a Class A Misdemeanor with the possibility of up to one year in prison for each offense.[196] Kansas,[197] Montana,[198] and North Dakota[199] passed Ag Gag bills in the 1990s declaring it a misdemeanor to interfere with an animal facility by taking pictures or video.

Legislatures in Illinois,[200] Florida,[201] Indiana,[202] and Minnesota[203] also considered but did not pass Ag Gag measures in 2012. For example, the Illinois bill would have defined the offense of animal facility interfering as "creating or possessing, without the consent of the owner, a visual or sound recording made at the animal facility, which reproduces a visual or audio experience occurring at the facility."[204] Also included within the definition of animal facility interference is "exercising control over the animal facility with the intent to deprive the facility of an animal or property, and entering a facility not open to the public."[205] This offense would have been a Class A misdemeanor on the first offense and a Class 4 felony for any subsequent

192. *Id.* § 717A.3A(3)(a).
193. *Id.* § 717A.2(3)(b).
194. UTAH CODE ANN. § 76-6-112 (West 2013).
195. *Id.*§ 76-6-112(2)(a)-(d).
196. *Id.*
197. KAN. STAT. ANN. § 47-1827 (West 2013).
198. MONT. CODE ANN. § 81-30-103 (West 2013).
199. N.D. CENT. CODE § 12.1-21.1-02 (West 2013)
200. Animal Facility Offenses, Ill. H. B. 5143, 97th General Assembly (2012), *available at* http://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=84&GA=97&DocTypeId=HB&DocNum=5143&GAID=11&LegID=65244&SpecSess=&Session=.
201. Fla. S.B. 1246, Reg. Sess. (2011), *available at* http://www.flsenate.gov/Session/Bill/2011/1246/.
202. Ind. S.B. 0184, 117th Gen. Assembly (2012), *available at* http://www.in.gov/legislative/bills/2012/PDF/IN/IN0184.1.pdf.
203. Agricultural offenses penalties and remedies imposition, Minn. S.F. 1118, 87th Legislature (2012), *available at* https://www.revisor.mn.gov/bills/bill.php?b=Senate&f=SF1118&ssn=0&y=2011
204. Animal Facility Offenses, H. B. 5143, Sec. 4.3, 97th Gen. Assembly (2012).
205. *Id.*

offense.[206] It also would have modified the offense of animal facility fraud to include, "making a false statement or representation on a facility employment application, with the intent to commit an act not authorized by the facility," with felony classification.[207] The bill authorized civil damages in the amount of treble actual damages for such offenses, plus attorney fees.[208]

In advance of the failure of these four bills, the American Society for the Prevention of Cruelty to Animals released the results of a survey conducted by Lake Research Partners with the following results.[209] The report found that, "seventy-one 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." Accordingly, almost two-thirds (64 percent) of Americans oppose making undercover investigations of animal abuse on industrial farms illegal, with half of all Americans strongly opposing legislative efforts to criminalize industrial farm investigations.[210] From a constitutional perspective, Ag Gag laws, particularly the farthest-reaching laws of Iowa and Utah, may face difficulty in passing scrutiny under the First Amendment. At least one commentator argues that the newsgathering framework established by *Cohen v. Cowles Media Co.* is likely to apply in the Ag Gag context, rending such statutes unconstitutional.[211] Despite these potential constitutional infirmities, such legislation seems to be a popular trend in states with significant agricultural sectors.

C. Egg Industry and Citizen Group Agreement Reaches Congress; FDA Implements Salmonella Testing Rule

After years of acrimonious debate surrounding animal welfare ballot initiatives, the Human Society of the United States (HSUS) and the United Egg Producers (UEP) shocked many industry observers and consumers by unveiling compromise legislation designed to regulate shell egg

206. *Id.* at Sec. 5.
207. *Id.*
208. *Id.*
209. Press Release, ASPCA, 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.
210. *Id.*
211. Bollard, *supra* note 186, at 10962; *see also* Kevin C. Adam, *Shooting The Messenger: A Common-Sense Analysis Of State "Ag-Gag" Legislation Under The First Amendment* 45 SUFFOLK U. L. REV. 1129, 1137 (2012).

production.[212] The bill, sponsored by Representative Schrader (D-OR) and introduced to the House in January of 2012, sought to establish uniform standards for cage size, create labeling requirements and establish air quality, molting, and euthanasia standards for laying hens.[213] The standards would be phased in over a 15 to 18 year period.[214] Although a companion bill was introduced in the Senate as S.3239 and received a hearing; neither legislative body voted on the respective bills. A reintroduction of bill in 2013 is expected in tandem with the farm bill renewal, although no action has occurred as of this writing in late February.[215]

Industry groups, consumer advocacy organizations, and veterinary associations alike include the bill in their priority items for the 2013 legislative session.[216] The longevity, however, of this unique compromise between animal rights advocates and industry interests remains an open question for the 2013 legislative season. For its part in the compromise, HSUS withdrew its state-level ballot initiatives in Oregon and Washington, and altered its stance in support of only cage-free production.[217] The decision by the board of UEP was apparently controversial, [218] and reflects a motivation to regain public trust and join with the growing tide of public sentiment against conventional cage production.[219] After extensive

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212. Egg Products Inspection Act Amendments of 2012, H.R. 3798, 112th Cong. (2012), *available at* http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.3798.

213. *Id.* at § 7A.

214. *Id.* at § 7B.

215. Joel L. Greene & Tadlock Cowan, *Table Egg Production and Hen Welfare: Agreement and Legislative Proposals*, Congressional Research Service, January 11, 2013.

216. *See* American Veterinary Medicine Association, Issue Summaries for the 113th Congress, *available at* https://www.avma.org/Advocacy/National/Congress/Pages/AnimalWelfare-Human AnimalBond Issues.aspx; National Cattlemen's Beef Association, Legislative Watch, *available at* http://www.beefusa.org/legislativewatch.aspx; Humane Farming Association, Stop the Rotten Egg Bill, *available at* stoptherotteneggbill.org.

217. Greene & Cowan, *supra* note 215.

218. *Id.* at 8, 11.

219. The European Union has been actively regulating egg production for some time now. Beginning January 1, 1988, European Union members adopted minimum size standards, cage construction materials and watering facilities for caged laying hens. Battery cages were subsequently prohibited effective January 1, 2012 and the European Commission has taken action to enforce the prohibition. *Council for the European Communities, Laying down minimum standards for the protection of laying hens kept in battery cages, Council Directive,* March 25, 1986, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1986:095:0045:0048:EN:PDF; *Animal Welfare: Commission urges 13 Member States to implement ban on laying hen cages*, European Commission, January 26, 2012, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/47.

deliberation, the American Veterinary Medicine Association supported the compromise legislation.[220] By contrast, agriculture and livestock associations have argued that the bill sets a dangerous precedent of federal animal welfare regulation and limits local control.[221] If this compromise legislation is successful, it may pave the way for other industry groups with an eye towards consumer trends to work collaboratively with various consumer groups on a wide variety of food and animal welfare issues, including the subtherapeutic use of antibiotics, discussed above.

In a related development with respect to shell egg production, the FDA announced publication of "Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods" in the spring of 2012.[222] The guidance document is intended to guide firms that manufacture, pack, or hold human foods or direct-human-contact animal foods in testing procedures for Salmonella species contamination.[223] It also guides industry in interpreting test results for injuriousness to human health. FDA issued a second final guidance regarding Salmonella and eggs on August 20, 2012 titled "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella Enteritidis* in Shell Eggs During Production, Storage, and Transportation."[224] This document guides industry in determining whether and when producers must comply with prevention measures, sampling and testing requirements, and facility registration procedures under the egg safety rule.[225]

D. Supreme Court Invalidates California's "Downer" Animal Slaughter Law

On January 23, 2012, the U.S. Supreme Court overturned California's rule that prohibited the slaughtering or selling of non-ambulatory ("downer") animals for human consumption, holding that the Federal Meat

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220. Greene & Cowan, *supra* note 215, at 10.

221. *See id.* at 13.

222. Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods, 77 Fed. Reg. 14,022 (Mar. 8, 2012).

223. FDA, *Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods* (2012), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm295271.htm.

224. FDA, *Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation* (2012), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm313728.htm.

225. *Id.*

Inspection Act (FMIA)[226] foreclosed additional rules implemented at the state level. The case, *National Meat Association v. Harris*, pitted a trade association versus California's Attorney General—the state official charged with enforcing the statute.[227] Although confined to the scope of FMIA in relation to the California rule, the Court's holding could extend to other state efforts to regulate food safety and animal welfare at the point of slaughter.

The Department of Agriculture's Food Safety and Inspection Service (FSIS) administers the FMIA and has promulgated multiple regulations over the years regarding the inspection of animals and meat, as well as other aspects of slaughterhouse operations.[228] Under the FMIA regulations, animals that arrive at a federally inspected slaughterhouse are approved for slaughter or designated as condemned or suspect. Condemned animals must be killed and kept out of the human food supply, but suspect animals, including non-ambulatory animals, are monitored and, at the discretion of the federal inspector, eventually may be approved for human consumption.[229] California's law, codified at section 599f of the Penal Code,[230] however, prohibited the slaughtering or sale of a non-ambulatory animal for human consumption and required that slaughterhouses euthanize all non-ambulatory animals.

The National Meat Association challenged the California rule, asserting that the FMIA expressly preempted the state's regulation of animals presented for slaughter at a federally inspected slaughterhouse. The FMIA's preemption clause prohibits states from imposing any additional or different requirement concerning slaughterhouse facilities and operations that falls within the scope of the FMIA.[231] The FMIA also states, however, that it does not "preclude any State . . . from making [a] requirement or taking other action, consistent with [the FMIA], with respect to any other matters regulated under this Act."[232]

The Supreme Court unanimously reversed the Ninth Circuit's judgment that had upheld the California law. According to the Court, California imposed additional or different requirements on slaughterhouses. Under federal law, a slaughterhouse may find a non-ambulatory animal fit for human consumption, but under California's law, a slaughterhouse must euthanize all non-ambulatory animals and exclude them from the human

226. 21 U.S.C. § 601 et seq. (2012).
227. Nat'l Meat Ass'n v. Harris, 132 S. Ct. 965, 968 (2012.)
228. 9 C.F.R. § 300.1 et seq. (2012).
229. 9 C.F.R. § 313.2(d)-(e) (2012).
230. CAL. PENAL CODE § 599f (West 2013).
231. 21 U.S.C. § 678 (2012).
232. *Id.*

food supply—thereby foreclosing the discretion of the FSIS inspector to deem a non-ambulatory animal fit for slaughter and human consumption. This discrepancy was the fatal flaw in the California "downer animal" rule.

Moving forward, and with respect to other state efforts at animal welfare regulation, the Supreme Court's decision has several ramifications. First it does not completely restrict the ability of states to regulate the type of animals that can be slaughtered for human consumption in federally inspected slaughterhouses. For example, the Court explained the critical distinction between state laws prohibiting the slaughter of horses (such as the Illinois Meat Act[233]) and California's prohibition on the slaughter of non-ambulatory animals. A ban on horse slaughter does not affect the daily activities of slaughterhouses because the law prevents horses from being transported to the slaughterhouse itself. California's ban on the slaughter of non-ambulatory animals functions differently. Because animals become non-ambulatory in transit to, or after arrival at, a slaughterhouse, the ban affects the daily internal activities of slaughterhouses and thus the FMIA. California (or other states seeking to regulate downer animal slaughter) could conceivably check for and remove non-ambulatory animals at an inspection station prior to arrival at a slaughterhouse. In the alternative, a state might also regulate the types of animals that could be ordered for purchase and thus control the type of animal being transported or arriving for slaughter.[234] In sum, the Court's rejection of California's approach to resolving the ethical and food safety concerns embedded in the consumption of downer animals has thrown the issue back to the states for further creative solutions.

E. WTO Dealings Affect Labeling and Production Issues

United States labeling standards evolved on an international level as well in 2012. The World Trade Organization (WTO) issued its final ruling in the long-running Country of Origin Labeling (COOL) beef and pork products dispute between the U.S., Canada, and Mexico. Incorporated as part of the 2008 Farm Bill, the COOL rules required country of origin labeling for livestock as well as other products not subject to the WTO dispute.[235] Canada and Mexico challenged the measure in 2008, citing it as discriminatory. After the original 2011 ruling in favor of Canada and

233. 225 ILL. COMP. STAT. § 635/1 (West 2013).

234. *See* Shelly Barron, *California's Continued Struggle Against Nonambulatory Animal Slaughter and the Limits of Federal Preemption: National Meat Association v. Brown*, 4 NE U. L. J. 259, 291 (2012).

235. Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171 § 10816, 116 Stat. 134, 533-35; C.F.R. Part 60 and Part 65.

Mexico,[236] the US Trade Representative appealed, claiming that the U.S.'s COOL measures do not impose unfavorable treatment of imported products because it requires all meat, regardless of origin, to be labeled under the same set of circumstances.[237]

The WTO Appellate Body upheld parts of its initial ruling from 2011—confirming the right to require labeling—but agreed that U.S. COOL provided less favorable treatment to imported Canadian and Mexican cattle and hogs.[238] Citing extensive paperwork and recordkeeping requirements that were outsized in relationship to the amount of information conveyed to the consumer, the Appellate Body found that the labeling requirements were discriminatory in effect. However, the Appellate Body did not reject the objectives of COOL. Instead, it found that providing consumers with origin information was reasonable, and did not violate Article 2.2 of the Technical Barriers to Trade (TBT) Agreement. However, it made no conclusion as to whether COOL is more restrictive than necessary regarding its objectives.[239]

In an even older WTO dispute relating to beef products, the U.S and Canada reached an agreement with the European Union (EU) on the treatment of imported beef. The U.S. and Canada have been in a disagreement with the EU over the importation of beef produced with added growth hormones as far back as 1988 and, despite a 1997 WTO ruling that the ban violated world trade rules, it remains in effect. In response to the EU ban, the U.S. and Canada imposed costly trade sanctions, such as $125 million a year on unique cheeses (Roquefort and Stilton), truffles, chocolates, and other luxury food products imported from the EU. In 2009, the U.S. agreed to gradually lift its sanctions in exchange for an increase in the EU's duty-free import quotas of hormone free beef from North America. In March of 2012, the European Parliament approved

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236. United States- Certain Country of Origin Labeling (COOL) Requirements- Final Reports of the Panel, Doc # 11-5865. WT/DS384/R, Nov. 11, 2011, *available at* https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds384/r*%20not%20rw*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#.

237. United States- Certain Country of Origin Labeling Requirements (2011), *available at* http://www.ustr.gov/sites/default/files/US.AppellantSub.fin_.pdf.

238. United States- Certain Country of Origin Labeling (COOL) Requirements- Arb-2012-1/26 Arbitration under Article 21.3(c), Doc # 12-6679, WT/DS384/24 (2012), *available at* https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds384/24*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#.

239. World Trade Organization Decision, *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds384_e.htm.

a deal between the EU, Canada, and the U.S. that lifts all import duties on targeted European luxury foods in exchange for the increase of the annual quota on imports of hormone free beef to 48,000 metric tons while maintaining its ban on imports of hormone treated beef.[240] Although temporarily relieving the pressure on beef imports and resulting tariffs, the recent announcement of talks regarding an EU-US free trade agreement may reopen this sensitive area.[241]

IV. Concluding Thoughts

From various food bans to criminalizing undercover recording of animal production facilities, 2012 proved to be an important year in the evolution of food law. Consumer interest in food, from the production processes at the farm level, to the various claims made at retail venues, may be at an all-time high despite, fortunately, the absence of a major outbreak of a food borne illness. This may signal a movement away from crisis-based consumer attention in food to a more systematic and steady focus on broader issues related to the food supply chain. Private litigation, in the form of various consumer protection claims, gained considerable traction, especially in the context of "natural" claims. On the other hand, industrial interests pushed back on this wider consumer scrutiny of the supply chain with the introduction of various Ag Gag bills, a successful court challenge to the downer animal prohibition in California, an important food libel suit associated with the disclosure of pink slime in ground beef, and the defeat of mandatory labeling measures for food produced with genetic engineering. In sum, these tensions among the various market forces are likely to continue, along with greater government involvement in the next years as the nation moves beyond the 2012 election season.

240. *Vote Ends EU-U.S. Hormone-Treated Beef Row,* REUTERS, http://www.reuters.com/article/2012/03/14/eu-trade-beef-idUSL5E8EE50620120314 (last visited Mar. 27, 2013).

241. *Statement from United States President Barack Obama, European Council President Herman Van Rompuy and European Commission President José Manuel Barroso,* THE WHITE HOUSE, OFFICE OF THE PRESS SECRETARY, February 13, 2013, *available at* http://www.ustr.gov/about-us/press-office/press-releases/2013/february/statement-US-EU-Presidents (last visited Feb. 27, 2013).