Journal of Food Law & Policy

Volume 7 | Number 2 Article 7

2011

United States Food Law Update: Moving Toward a More Balanced Food Regulatory Regime

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UNITED STATES FOOD LAW UPDATE: MOVING TOWARD A MORE BALANCED FOOD REGULATORY REGIME

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For decades, the federal government has played a significant role in promoting healthy eating. In the early 1900s, the United States Department of Agriculture (USDA) promoted a foundational diet of milk, proteins, fruits and vegetables, and grains.[1] Most Americans are at least somewhat familiar, although perhaps confused, with the more nuanced healthy eating recommendations contained in the food pyramid – first employed in 1992.[2] And virtually every American has experienced the federally supported school lunch program. In the first half of 2011, these two iconic programs underwent significant change as part of a stepped-up effort to improve the health of the country through better food choices. Part I of this article describes the "MyPlate" initiative that replaces the iconic USDA food pyramid and menu revisions to the national school lunch and school breakfast programs. This section also profiles administrative decisions in two school districts to ban, on health grounds, brown-bag lunches in favor of school-provided lunches. Finally, this section describes some of the challenges of implementing a rule for chain restaurant menu labeling under the Patient Protection and Affordable Care Act.

Part II of this article discusses several food safety issues, both legislative and administrative, intended to minimize consumer vulnerability to the increasing complex food supply chain.

Part III profiles four developments in food-related litigation. The first, *Seaside Farms v. United States*, seeks compensation from the government for negligently identifying tomatoes as the source of a 2008 *Salmonella* outbreak eventually traced to jalapeno peppers. Other litigation

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1. *See* Jeanne P. Goldberg, et al., *The Obesity Crisis: Don't Blame it on the Pyramid*, 104 J. AM. DIET. ASSOC. 1141, 1142 (2004) (describing history of dietary guidance at the federal level).

2. *See id.* at 1141 (noting general awareness of the pyramid); John M. Kinney, *The US Department of Agriculture Food Pyramid; the birth and aging of an idea*, 6 CURRENT OPINION IN CLINICAL NUTRITION AND METABOLIC CARE 9, 11-12 (2003) (noting confusing recommendations).

described below includes a claim for exposure to diacetyl through daily consumption of microwave popcorn; a failure to label meat analogues containing mycoprotein sourced from the cell protoplasm of the fungus *Fusarium venenatum,* an alleged allergen; and a settlement in a multi-district class action dispute regarding baby products containing Bisphenol A.

This article concludes with a discussion of two significant developments relating to biotechnology: the resolution of an injunction prohibiting the planting of genetically engineered alfalfa and a multi-million dollar settlement in the Liberty Link rice contamination class action arising from the unauthorized commingling of genetically engineered rice.

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 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.

I. HEALTH INITIATIVES

A. USDA's MyPlate

With substantial backing from Michelle Obama, the USDA recently replaced its longstanding (and often maligned) food pyramid with a new nutrition guide aimed at giving consumers easy-to-understand information about daily food choices. The guide, called MyPlate, depicts a typical consumer's daily food intake in the form of a dinner plate that graphically illustrates the recommended daily proportions of grains, proteins, dairy products, and fruits and veggies. If the consumer's actual plate mirrors that of the MyPlate icon, then – in the words of the First Lady – "we're good; it's as simple as that."[3]

The MyPlate icon already has garnered praise from nutrition advocates for being much easier to use than the old food pyramid system. A companion USDA website, www.choosemyplate.gov, elaborates upon the MyPlate icon using simple, pithy directives: "[e]njoy your food, but eat less," "[m]ake half your plate fruits and vegetables," and "[d]rink water

3. William Neuman, *Nutrition Plate Unveiled, Replacing Food Pyramid,* N.Y. TIMES, June 2, 2011, B3, *available at* http://www.nytimes.com/2011/06/03/business/03plate.html?_r=1&scp=4&sq=myplate&st=cse.

instead of sugary drinks."[4] The website's section on "empty calories" helpfully juxtaposes foods with some empty calories (e.g., sweetened applesauce; regular ground beef; whole milk) against companion foods that have few or no empty calories (e.g., unsweetened applesauce; extra lean ground beef; fat-free milk).[5]

B. FDA's Menu Labeling Rules

While the USDA's MyPlate icon is perhaps nothing more than a breezy effort to make consumers think more about the foods they eat on a daily basis, the United States Food and Drug Administration (FDA) recently engaged in formal rulemaking that aims to accomplish essentially the same goal. The FDA's efforts will have real consequences for chain restaurants throughout the United States, who will soon be required to place calorie information on menus and display cases.[6] These menu labeling requirements are part of a long-running effort by health and nutrition advocates to curb the growing obesity epidemic in the United States. About a third of the average American's daily caloric intake now comes from food prepared outside the home, and studies have shown that consumers often badly underestimate the number of calories in these prepared foods.[7] But that is not to say that consumers do not *want* to know how many calories are in their Big Macs and Whoppers: to the contrary, a national telephone survey revealed that more than 70% of U.S. adults supported the idea of listing calorie counts on restaurant menus.[8] Responding to this demand, some states and municipalities have enacted menu labeling requirements for the chain restaurants within their jurisdictions, but the laws' differing requirements have proven burdensome for the chain restaurants that must comply with them.[9]

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4. *See* CHOOSEMYPLATE.GOV, U.S. Department of Agriculture, http://www.choosemyplate.gov/index.html (last visted Dec. 20, 2011).

5. *Empty Calories,* CHOOSEMYPLATE.GOV, U.S. Department of Agriculture, http://www.choosemyplate.gov/foodgroups/emptycalories.html (last visited Dec 19, 2011).

6. *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,192 (Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11 and 101).

7. *See id.*

8. *Id.* at 19,193.

9. *See id.* (noting that "[s]ome jurisdictions required only calories on menus and menu boards while others required additional nutrient declarations (e.g., variations of the following: total grams of *trans* fat, grams of saturated fat, grams of carbohydrates, and milligrams of sodium). Some State and local laws required a statement on menus and menu boards regarding daily intake amounts for calories and other nutrients and other laws did not require such a statement.").

In response, the Patient Protection and Affordable Care Act[10] amends section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to require "restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items . . . to provide calorie information for standard menu items, including food on display and self-service food."[11] "Calorie information" means the number of calories contained in each menu item as it is usually prepared, as well as a statement suggesting daily caloric intake for contextual purposes.[12] If this information is not on the menu, then the food is misbranded under the FFDCA.[13]

The menu labeling provisions of the Affordable Care Act went into effect upon the law's enactment in 2010, but the FDA has said that it does not intend to enforce the self-executing provisions of the law until it promulgates final regulations that more clearly delineate the scope of the labeling requirements.[14] This is perhaps a smart move, given the definitional complexities that lay hidden beneath what appears to be a rather simple requirement. Take, for example, an issue tackled by the FDA's recent round of draft rulemaking: the definition of "retail food establishment." The menu labeling provisions of the Affordable Care Act apply only to foods offered for sale "*in a restaurant or similar retail food establishment* that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items."[15] But what sort of places does Congress view as being a restaurant or similar to it? Acknowledging that the term is ambiguous, FDA proposes to define the phrase as "a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment."[16] The "primary business activity" requirement would be met if the establishment has either (1) held itself out to the public as a restaurant, or (2) devotes more than 50% of its gross floor

10. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).

11. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed Reg. 19,192, 19,193(Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11 and 101).

12. *See id.*

13. *See id.*

14. *See id.* at 19,194 (noting that "[a]lthough these provisions became requirements at the time the law was signed, FDA has previously announced that we intend to exercise our enforcement discretion until the final rule is published and in effect.").

15. 21 U.S.C. § 343(q)(5)(H)(i) (2011) (emphasis added).

16. Food Labeling, Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,192, 19,197 (Apr. 6, 2011) (to be codified at 21 C.F.R. pts. 11 and 101).

area to the preparation, purchase, service, consumption, or storage of food.[17]

This proposed definition seems sensible enough, but there is a linguistic point worth emphasizing: FDA's proposed definition turns on an establishment's sale of food in general, *regardless* of whether that food is prepared restaurant-style. That means, for example, that grocery stores and convenience stores would fall within the proposed definition of "restaurant or similar retail food establishment" because, while they might not hold themselves out as restaurants, more than 50% of their gross floor space is devoted to the preparation, purchase, service, consumption, or storage of food.[18] Therefore, any "restaurant-type food" (generally defined by the FDA as ready-to-eat food that is prepared in the establishment in question and not for sale outside of it[19]) offered in grocery stores and convenience stores that otherwise meet the law's requirements must label those items with calorie information. As a less-inclusive alternative to its proposed definition, the FDA has suggested "to define 'restaurant or similar retail food establishment' to mean a retail establishment where the sale of *restaurant or restaurant-type food* – as opposed to food in general – is the primary business activity of that establishment."[20] That would by and large exclude grocery and convenience stores, whose primary business activity is selling food products to be prepared by consumers. The FDA seeks comment on which of these definitions it should adopt.

If the FDA sticks with its proposed definition of "restaurant or similar retail establishment," the result may be some thinly split hairs. The FDA anticipates that "most movie theaters, amusement parks, general merchandise stores with in-house concession stands, hotels, and transportation carriers such as trains and airplanes" will not meet the definition because they do not present themselves to the public as restaurants (and they likely also would not meet the 50% floor space requirement).[21] Furthermore, it is equally clear that chain restaurants within larger establishments (e.g., Subway in a Walmart or Starbucks inside a Barnes & Noble) will need to label their menu items with calorie information, because they have locations outside of that larger establishment.[22] But what of the Target or Walmart Café – the little sit-down dining area that serves hot dogs, nachos, and Icees? In its draft

17. *See id.*
18. *See id.* at 19,198.
19. *See* 21 U.S.C. § 343(q)(5)(A)(ii) (2011).
20. Food Labeling, Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,198.
21. *See id.* at 19,197.
22. *See id.* at 19,198.

guidance, FDA suggests that these restaurant-style areas would fall outside of the menu labeling requirements because they are not part of a chain with locations outside of the Target or Walmart.[23] FDA would, therefore, consider these eating areas to be part of the Target or Walmart itself, and the question is whether the big-box store has presented itself as a restaurant or devotes more than 50% of its floor space to food (likely not, on both counts).[24] The FDA has asked for comments on whether these establishments should fall within the scope of the labeling rule.

In any case, the definition of "restaurant or similar retail establishment" matters, because once the FDA's menu labeling requirements apply, they are quite broad. For example, FDA proposes to define the "menu" or "menu board" that contains calorie information as the "primary writing . . . from which a consumer makes an order selection," no matter where the consumer is physically located in proximity to the restaurant.[25] That means that affected restaurants will need to put calorie information not only on primary menus and menu boards inside the restaurant, but also on drive-through menus, express window menus, take-out menus, and even menus on the restaurant's website if consumers can place orders via phone, fax, or online.[26]

The FDA further proposes to define "restaurant-type food" broadly to include not only standard menu items,[27] but also items routinely contained in standing self-serve displays – for example, "[p]otato salad that is routinely offered at a salad bar, pancakes that are routinely offered at a buffet, and pudding that is routinely offered at a cafeteria line."[28] Under the proposed rules, restaurants will need to place a sign next to each one of these salad bar or buffet items stating the number of calories either per item (e.g., a muffin or a baked potato) or per serving (e.g., potato salad or ice cream).[29] The same would go for pastries, ready-made sandwiches, or

23. *See id.* ("If . . . a facility selling restaurant or restaurant-type food is not part of a chain with locations outside of the chain of the larger retail establishment, the facility would be considered part of the larger retail establishment. For example, if Superstore XYZ has a café that appears only in the other locations of Superstore XYZ chain, the café would be considered part of Superstore XYZ.").

24. *See id.*

25. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,201-202.

26. *See id.* at 19,201.

27. *See id.* at 19,202 (defining standard menu items to include "combination meals, variable menu items, self-service food, and food on display," but not custom orders, daily specials, foods being test-marketed, and temporary menu items).

28. *Id.* at 19,203.

29. *See id.* at 19,215. Per serving measurements can be done using the serving utensil as the measure (e.g., 400 calories per scoop) or by common household measurements (e.g., 400 calories per cup). *Id.*

similar items for purchase from a display case.[30] The labeling rule even reaches self-serve soda dispensers, which "must have calorie declarations for each flavor or variety offered" and in amounts corresponding to the size of the drink purchased (e.g., "140 calories per 12 ounces").[31]

Given these requirements, it is interesting to examine FDA's cost-benefit analysis of the proposed regulations. The agency estimates that its new menu labeling rules would affect about 278,600 establishments organized under 1,640 chains.[32] The mean aggregated start-up cost of compliance with the regulations would be $315 million – or roughly $1,100 per restaurant – with mean ongoing costs of $44 million.[33] But will these substantial costs be offset by lowered obesity rates? FDA admits that "[f]ood choice and consumption decisions are complex," and that it is "unaware of comprehensive data allowing accurate predictions of the effect of the proposed requirements on consumer choice and establishment menus."[34] Nevertheless, the agency has offered a ballpark break-even estimate: FDA estimates that at least 0.06 percent of the adult obese population would need to reduce their caloric intake by at least 100 calories per week to break even on the mean annualized cost of the regulations.[35] Current U.S. Centers for Disease Control and Prevention (CDC) data indicate that 34% of the U.S. population – or roughly 105 million people – are obese,[36] which means that if only 6,300 obese Americans reduce their caloric intake by 100 each week each year, the economy won't lose a dime on FDA's menu-labeling investment. While such bureaucratic number-crunching is often impossible to objectively confirm, the menu-labeling rules are a positive step forward in shifting consumer preferences toward more healthy fare at chain restaurants. When a McDonald's patron sees "790 calories" prominently displayed next to the Angus Bacon and Cheese burger on the menu board, she may pick the company's 290-calorie southwest grilled chicken salad instead,[37] and McDonald's may alter its menu offerings accordingly in the face of this evolving demand.

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30. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,215.

31. *See id.* at 19,216.

32. *See id.* at 19,222.

33. *See id.*

34. *Id.* at 19,223.

35. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,223.

36. *See id.* at 19,192.

37. *See McDonald's USA Nutrition Facts for Popular Menu Items,* MCDONALD'S, http://nutrition.mcdonalds.com/getnutrition/nutritionfacts.pdf (last visited Dec. 20, 2011).

C. USDA's Revisions to the National School Lunch and School Breakfast Programs

The federal government has long targeted obesity as a national concern, but it has recently focused on combating that problem in children.[38] CDC data suggest that about 32% of children and adolescents aged 2 to 19 are overweight, and countless studies have linked childhood obesity to adulthood health problems like heart disease, diabetes, strokes, and high blood pressure.[39] Naturally, one of the key risk factors associated with obesity at any age is caloric intake, and for children, one of the main daily sources of calories – whether good or bad – is the breakfast and lunch programs in the nation's school systems. The problem is these meals do not always provide children with the healthy food needed to combat obesity. A 2007 report by the USDA indicates that under current school menu planning, fewer than one-third of school lunches offered in the 2004-2005 school year met program requirements of less than 10% of total calories from saturated fat.[40] A report by the Institute of Medicine (IOM) found that "children's consumption of whole grains is extremely low in comparison with the Dietary Guidelines recommendation that half of all grains consumed [should be] whole grains."[41] Current school lunch regulations allow schools to serve whole and reduced-fat (2%) milk without restriction, but do not require schools to offer the quantities of fruits and vegetables recommended by the 2005 Dietary Guidelines for Americans.[42] Finally, school meals also have extremely high levels of sodium–lunches in particular average 1,400 mg of sodium, according to one report.[43]

Therefore, the USDA issued significant draft revisions to its National School Lunch Program (NLSP) and School Breakfast Program (SBP) in

38. *See, e.g.*, 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, 139-41 (2011) (outlining key provisions of the Healthy, Hunger-Free Kids Act of 2010).

39. *See* Food Labeling, Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. at 19,192.

40. Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. 2494, 2496 (Jan. 13, 2011) (to be codified at 7 C.F.R. pts. 210 and 220).

41. *Id.*

42. *See id.* at 2495-96.

43. *Id.* at 2502 (noting that the average sodium content of all school lunches is more than 1,400 mg).

order to align them with the recommendations set forth by the 2005 Dietary Guidelines for Americans.[44] In particular:

> The proposed standards for menu planning improve the school meals' alignment with the 2005 Dietary Guidelines by offering more fruits at breakfast; increasing the amount and variety of vegetables at lunch; offering more whole-grain rich foods; limiting fluid milk choices to fat-free (unflavored or flavored) and unflavored fluid low-fat milk; establishing minimum and maximum calorie levels for each age/grade group; increasing the emphasis on limiting saturated fat; seeking gradual but major reductions in the sodium content; and minimizing *trans* fat.[45]

To help it implement the 2005 Dietary Guidelines into the NSLP and the SBP, USDA turned to the IOM, an independent, nonprofit arm of the National Academy of Sciences that provides "unbiased and authoritative" health advice to the public and policymakers.[46] At USDA's request, IOM conducted an independent review of the nutritional needs of school-aged children in the U.S. using both the 2005 Dietary Guidelines and its own Dietary Reference Intake (DRI) reports.[47] Based on this review, IOM "set targets for 24 nutrients and other dietary components that serve as a scientific basis for the proposed standards for menu planning."[48] However, schools will not use these nutrient targets to plan their own menus; rather, the crux of the revamped program are the new "food-based meal patterns" (FBMP) developed by IOM that incorporate the 24 nutritional targets.[49] There are two main patterns – one for breakfast and one for lunch – and each sets minimum daily values for fruits, vegetables, grains, meats, and fluid milk, while also capping the total number of calories per meal.[50] The daily values vary by three different age groups: Grades K-5, Grades 6-8, and Grades 9-12.[51] So long as school menu planners stick within the

44. *See id.* at 2494.

45. Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. at 2496-97.

46. *See About the IOM,* INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, http://www.iom.edu/About-IOM.aspx (last visited July 19, 2011).

47. *See* Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. at 2496.

48. *Id.* at 2497.

49. *See id.* at 2497-98.

50. *See id.* at 2498.

51. *Id.*

patterns recommended by IOM, they should be in compliance with USDA's nutritional requirements.

In order to carry out these new FBMPs, the proposed rule recommends a significant change in how the NSLP and NBP are operated. Currently, there are five menu planning approaches schools may use when planning school breakfasts and lunches: two follow the FBMP approach, two follow the nutrient standard menu planning (NSMP) approach (which uses computer modeling), and one allows for individualized modification of either the FBMP or the NSMP.[52] The proposed regulations eliminate the NSMP approaches in favor of a FBMP-only approach; no other menu planning approaches would be permitted.[53] USDA estimates that a single menu plan will not only simplify operations (70% of U.S. schools already use the FBMP approach), but will also better effect USDA's goals by requiring schools to stay within the new dietary guidelines established by IOM.[54]

In setting calorie limits for its school meal programs, USDA noted that it was "mindful of the childhood obesity trend and the food choices available to school children outside of [school meals]."[55] Therefore, the minimum and maximum calorie levels for school lunches and breakfasts take into consideration the meals and snacks kids eat when they are not in school – food that in many cases is less healthy than what the government prescribes for breakfast and lunch. The recommended calorie ranges are fairly narrow – there's a 100-calorie variance between the upper and lower limits at lunch, and a 150-calorie range at breakfast.[56] The USDA states that the goal of the calorie ranges "is not to reduce children's intake of food, but to avoid excessive calories," and that its guidelines "leave relatively few discretionary calories for fats and added sugars."[57]

52. *See* Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. at 2495.

53. *Id.* at 2499.

54. *See id.*

55. *Id.* at 2501.

56. *See id.*

57. Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. at 2501.

D. Wanna Brown-Bag It? Not At This Chicago School

The upshot of the USDA's revised school meal guidelines seems clear: less wiggle room for school administrators to fill breakfasts and lunches with unhealthy food choices. Of course, there is another way for kids to get all the bologna, potato chips, and Twinkies they want – pack a bag lunch. And that is why one Chicago school has taken the drastic step of banning all homemade lunches, instead requiring its pupils to sign on to the federally-funded school meal programs.[58] Chicago Public Schools has no formal policy on brown bag lunches, leaving the decision up to the principal at each school.[59] The principal at Little Village Academy on Chicago's West Side enacted the homemade lunch ban after she saw students "bring 'bottles of soda and flaming hot chips' on field trips for their lunch."[60] Another school on Chicago's South Side allows students to bring bag lunches but apparently dispatches the food constabulary to "confiscate any snacks loaded with sugar or salt."[61] A spokeswoman for Chicago Public Schools defended Little Village's policy in the *Chicago Tribune,* stating that the school's principal "is encouraging the healthier choices and attempting to make an impact that extends beyond the classroom."[62]

However, not everyone is thrilled with the policy. For parents who do not qualify for free or reduced-price school meals, homemade lunches can be less expensive than the fixed-price school programs.[63] And for picky eaters, no home lunches may mean no lunch at all: the *Chicago Tribune* described a lunchtime scene at Little Village in which "dozens of students took the [required school] lunch but threw most of it into the garbage uneaten."[64] But the rottenest tomato that can be lobbed at homemade lunch bans is that they do not allow kids and their parents to make *good* food decisions. Vegans and vegetarians certainly suffer – the NSLP and NBP mandate servings of protein but do not allow for tofu because it does not have a federal standard of identity.[65] Children with food allergies may

58. *See* Monica Eng and Joel Hood, *Chicago School Bans Some Lunches Brought From Home,* CHICAGO TRIBUNE Apr. 11, 2001, http://www.chicagotribune.com/news/education/ct-met-school-lunch-restrictions-041120110410,0,4567867.story.

59. *See id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *See* Eng and Hood, *supra* note 58.

64. *Id.*

65. *See* Nutrition Standards in the National School Lunch and School Breakfast Programs, 76 Fed. Reg. at 2501.

have to wrangle with school administrators for an exception to the policy.[66] And finally, the brown-bag lunch ban does not allow children to learn to take responsibility for making wise food choices. When asked by a reporter what he would bring for lunch if he were able, Little Village student Gerardo Ramos – only a second-grader – responded: "I would bring a banana, orange, and some grapes."[67]

II. FOOD SAFETY INITIATIVES

Food safety has been a long-running topic in these Food Law Updates, and the Government Accountability Office (GAO) has continued to include the topic in its "High Risk Series" reports.[68] But the issue has taken on new resonance in light of an *E. coli* outbreak that spread throughout Europe in May and June, killing 49 people and sickening at least 4,100 more.[69] The outbreak involved a rare, mutated strain of *E. coli* that officials suspect originated from organic fenugreek seeds shipped from Egypt and used to grow sprouts in Germany.[70] The European outbreak also laid bare the formidable food safety challenges posed by an increasingly global and industrialized food system. First, the *E. coli* strain proved highly resistant to antibiotic treatment, suggesting it had originated in growing fields with the high levels of antibiotic use often found in industrial-scale farming.[71] Second, global supply chains have made traceback vexingly difficult. Eleven tons of the suspect seeds were shipped from Egypt to a distributor in Germany that resold the seeds to 54 companies in Germany and 16 companies in 11 other European countries, and officials still had not accounted for another five tons of the seeds as of late July.[72]

Though the European outbreak largely spared the United States, it illustrates the need for continuing food safety efforts in all corners of the globe. Following on the passage of the Food Safety Modernization Act in

66. *See* Eng and Hood, *supra* note 58.

67. *Id.*

68. *See* U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-99-184, HIGH-RISK SERIES: AN UPDATE 111 (Feb. 2011), *available at* http://www.gao.gov/new.items/d11278.pdf.

69. *See* William Neuman, *A Search Is Underway For Tainted Sprout Seeds,* N.Y. TIMES, July 6, 2011, B3, *available at* http://www.nytimes.com/2011/07/06/business/06seeds.html?_r=1&ref=foodsafety.

70. *See id.*

71. *See* Tom Randall and Catherine Larkin, *Europe E. Coli Is Deadliest Outbreak as Rare Strain Causes Kidney Failure,* BLOOMBERG NEWS (June 3, 2011), http://www.bloomberg.com/news/2011-06-03/e-coli-outbreak-in-europe-reaches-deadliest-on-record-with-kidney-failure.html.

72. *See* Neuman, *supra* note 69.

early 2011, U.S. policymakers have continued their efforts to ensure the safety and integrity of the U.S. food supply. A few of these efforts are detailed briefly below.

A. Senate passes bill that would increase penalties for willful food safety violators

In the midst of a *Salmonella* outbreak investigation at his company, Peanut Corporation of America (PCA) president Stewart Parnell sent an email to FDA officials begging them to allow the company to stay in business, noting that PCA "desperately at least need[s] to turn the raw peanuts on our floor into money."[73] The company subsequently went bankrupt – a direct consequence of the outbreak that FDA traced to unsanitary conditions at PCA's plant, which killed eight people and sickened nearly 600 more.[74] Reaction in Congress to the flagrant food safety violations in PCA's plants was justifiably harsh: "I'd like to see some people go to jail," Senator Patrick Leahy (D-VT) told the *Los Angeles Times.*[75]

Now, thanks to Senator Leahy, prison time may be a possibility for those who willfully or recklessly disregard food safety laws. Senate Bill 216, introduced by the Senator and several co-sponsors in April, amends Section 333 of Federal Food, Drug and Cosmetic Act to prescribe prison time for knowing or reckless violations of the Act's prohibitions on adulterated or misbranded food.[76] Violations of the Act with intent to defraud or mislead are already punishable by prison time under § 333,[77] but Senator Leahy's bill increases the penalty for such violations from a three-year maximum to a ten-year maximum.[78] The bill also reduces the level of *mens rea* necessary for imprisonment under § 333 by providing that those who act "with conscious or reckless disregard of death or serious bodily injury" may also go to prison for up to ten years.[79] The bill passed the

73. Gardiner Harris, *Peanut Products Sent Out Before Tests,* N.Y TIMES, Feb. 12, 2009, A24, *available at* http://www.nytimes.com/2009/02/12/health/policy/12peanut.html?hp.

74. Ben Meyerson, *Senators Rebuke Federal Regulators in Peanut-Borne Salmonella Outbreak,* L.A. TIMES, Feb. 6, 2009, http://articles.latimes.com/2009/feb/06/nation/na-peanut-fda6.

75. *Id.*

76. *See* S. 216, 112th Cong. (2011).

77. *See* 21 U.S.C. § 333(a)(2) (2011).

78. S. 216, 112th Cong., § 2 (2011).

79. *See id.*

Senate by unanimous consent in April, but the House has yet to act on the legislation as of this writing.[80]

B. FDA issues first administrative regulations under FSMA

The FDA has issued its first administrative regulations under the watershed Food Safety Modernization Act signed into law by President Obama in early 2011.[81] The first regulation involves a change to the criteria by which FDA can order administrative detention of food that it suspects to be adulterated or misbranded. The Bioterrorism Act of 2002[82] gave FDA the authority to order administrative detention of any article of food "if during an inspection, examination, or investigation an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious health consequences or death to humans or animals."[83] Section 207 of the FSMA, however, loosens that language and an FDA official may now administratively detain food during an inspection "if there is reason to believe that an article of food is adulterated or misbranded."[84] The substantive changes thus are twofold: (1) the "credible information or evidence" has been substituted for the mushier "reason to believe" as sufficient knowledge to trigger detention; and (2) the inspector need not show a threat of "serious health consequences or death" – just that the food may violate the law.

The actual consequences of this change, however, are so far unknown – in large part because FDA has yet to exercise its administrative detention authority in the nine years since the Bioterrorism Act's passage.[85] Nevertheless, under the new standard, FDA believes that it will be more likely to use its administrative detention powers – and especially in situations where "the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."[86] In

80. *See Bill Summary & Status Search*, THE LIBRARY OF CONGRESS, http://thomas.loc.gov/cgi-bin/bdquery/D?d112:1:./temp/~bdBDGm:@@@X|/home/LegislativeData.php| (last visited Dec. 20, 2011).

81. *See*, e.g., Endres & Johnson, *supra* note 38, at 136-39 (outlining the major food safety provisions of the FSMA).

82. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188 (2002).

83. Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption, 76 Fed. Reg. 25,538, 25,539 (May 5, 2011) (to be codified at 21 C.F.R. pt. 1).

84. *Id.* at 25,538.

85. *See id.* at 25,540.

86. *Id.*

other words, the new FSMA provisions give FDA the authority to go further out on a limb to address less serious–but still *potentially* harmful–violations of the FDCA. That approach is consistent with the policy goals of the FSMA, which are to enable "FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur."[87]

The second regulation involves a change to FDA's imported food notification procedures. Section 801(m) of the FDCA requires anyone importing food into the United States to submit to the FDA prior notice of that importation so that the agency may inspect the food before it enters the U.S.[88] Before the FSMA's passage, that notice was to include a description of: (1) the article of food itself; (2) the manufacturer and shipper of the article; (3) the grower of the article; (4) the country of origin; (5) the county from which the article is shipped; and (6) the anticipated port of entry.[89] Current FDA regulations add a number of detailed requirements to the statutory list.[90] Section 304 of the FSMA adds a seventh statutory requirement: "any country to which the article has been refused entry,"[91] and so FDA's Interim Final Rule simply amends the agency's own regulations to reflect that change. FDA expects that requiring notice of prior refusals will help the agency to "better identify imported food shipments that may pose safety and security risks to U.S. consumers."[92]

C. New FDA recall search engine allows consumers to track product recalls

In April, FDA completed another one of its FSMA mandated tasks. Specifically, Section 206 of the FSMA required FDA to add a "consumer-friendly" search engine that tracks both ongoing and completed recalls.[93] FDA consulted with consumer groups such as the Consumers Union, Food Marketing Institute, Grocery Manufacturers Association, and the Pew Health Group on ways to easily communicate recall information to consumers.[94] The result is a searchable online database that organizes

87. *Id.* at 25,538.

88. 21 U.S.C. § 381(m) (2011).

89. *Id.*

90. *See* Food and Drug Administration, Department of Health and Human Services, 21 C.F.R. § 1.281 (2010).

91. Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption, 76 Fed. Reg. at 25,542.

92. *Id.* at 25,543.

93. *See* FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 206 (2011).

94. *See* Press Release, U.S. Food and Drug Administration, FDA Launches Consumer-Friendly Web Search for Consumers During Recalls (Apr. 4, 2011),

recalls by date, product brand name, product description, and the reason for recall.[95] Consumers can view all FDA recalls, or they can click on different tabs to see recalls for food, drugs, animal health, biologics, and medical devices.[96] Helpfully, most food product recall notices also include a picture of the recalled product's label and a link to a company-issued press release announcing the recall.[97]

D. USDA proposes new "test and hold" procedure for meat and poultry

The USDA has introduced a proposed rule that would change the way the agency inspects meat and poultry products for harmful pathogens under the Federal Meat Inspection Act (FMIA)[98] and the Poultry Products Inspection Act (PPIA).[99] Under current law, the USDA's Food Safety and Inspection Service (FSIS) periodically tests sample lots of meat and poultry at federally-inspected slaughterhouses for the presence of *Salmonella, E. coli, Listeria monocytogenes,* and other harmful pathogens.[100] The FMIA and PPIA require meat and poultry products to bear a certification mark before they are introduced into interstate commerce; that mark signifies that the meat has been inspected and is free from adulteration.[101] Currently, FSIS recommends, but does not require, that individual slaughterhouses hold all meat products sampled by FSIS until negative test results are received.[102] But because producers may ship meat before sample test results are available, meat products contaminated with harmful pathogens may, in some cases, enter into the food supply.

In fact, that situation is precisely what led FSIS to change its rule. Although the agency has considered a "test and hold" requirement since

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available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249437.htm.

95. *See Recalls, Market Withdrawals, & Safety Alerts*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Safety/Recalls/default.htm (last visited Dec. 20, 2011).

96. *See id.*

97. *See id.*

98. The Federal Meat Inspection Act (FMIA) authorizes the USDA to license and inspect meat production facilities that ship in interstate commerce. *See* Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (2011).

99. The Poultry Products Inspection Act (PPIA) authorizes the USDA to license and inspect poultry production facilities that ship in interstate commerce. *See* Poultry Products Inspection Act, 21 U.S.C. §§ 451-471 (2011).

100. *See* Not Applying the Mark of Inspection Pending Certain Test Results, 76 Fed. Reg. 19,952, 19,953 (Apr. 11, 2011).

101. *See id.*

102. *Id.*

2002,[103] recent recall data appears to have been the catalyst for change. FSIS reports that as a result of its testing procedures, there were 14 recalls in 2007, 19 in 2008, and 11 in 2009, with the bulk of them involving *E. coli* and *Listeria monocytogenes* bacteria.[104] Apparently, "[t]hese recalls occurred because the establishments that produced the product that tested positive released the product into commerce while test results were pending."[105]

The agency's own numbers suggests that the problem is not quite epidemic: across establishment size, "between 79 percent and 100 percent of establishments already hold product pending test results."[106] The agency's proposed mandatory test-and-hold requirement therefore represents an effort to corral the laggards in the bottom twenty percent. Nevertheless, FSIS's data show that many of the establishments not voluntarily holding meat and poultry pending testing results qualify as small and very small establishments,[107] and the National Meat Association (NMA) has asked FSIS to analyze the consequences of its rule on these producers in two contexts: (1) in cases where the establishment's products have a shelf life less than the amount of time required to complete testing, and (2) in cases where the establishment makes same-day deliveries to buyers.[108] FSIS believes it can minimize hardship in those cases by giving establishments advance notice of inspection (something it already does) so that they can produce and set aside an adequate amount of meat for testing.[109]

E. FSIS announces final rules for cooperative state meat and poultry inspection programs

USDA's Food Safety and Inspection Service (FSIS) promulgated final regulations that will allow certain state-inspected meat and poultry processors to ship their products in interstate commerce. Qualifying state-inspected establishments must meet all Federal standards under the FMIA and PPIA.

FSIS's rule adds a third cooperative state-federal meat inspection regime to the agency's already-existing procedures. Generally, the FMIA and the PPIA authorize FSIS to work with state agencies to develop meat

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103. *See id.*
104. *See id.* at 19,954.
105. Not Applying the Mark of Inspection Pending Certain Test Results, 76 Fed. Reg. at 19,954
106. *Id.* at 19,959.
107. *See id.* (Table 3).
108. *See id.* at 19,955.
109. *See id.*

or poultry inspection programs.[110] These cooperative inspection regimes require standards "at least equal to" Federal programs, and they apply to meat and poultry produced and sold within the State.[111] In addition, the Talmadge-Aiken Act authorizes FSIS to enter into separate agreements with State agencies to conduct meat, poultry, and egg inspections on behalf of FSIS.[112] These programs also operate only intrastate.[113] The 2008 Farm Bill[114] amendments to the FMIA and PPIA added new sections that "supplement the existing cooperative State meat and poultry inspection programs by establishing a new cooperative program under which certain State-inspected establishments would be permitted to ship meat and poultry products in interstate commerce,"[115] and bear the USDA's federally-inspected certification mark.[116]

The FSIS final rule describes the requirements for this voluntary cooperative interstate inspection regime.[117] In general, a meat or poultry processor may participate in the State-inspected interstate shipment program if it: (1) submits a request to be considered for the program;[118] (2) employs no more than 25 employees as that term is defined in the regulations;[119] (3) is in compliance with all the requirements under the cooperative State inspection programs authorized by the FMIA and PPIA;[120] and (4) is otherwise in compliance with the implementing regulations for the interstate shipping program.[121]

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110. *See* 21 U.S.C. § 661 (2011); 21 U.S.C. § 454 (2011); *see also* Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products, 74 Fed. Reg. 47,648, 47,648 (Sept. 16, 2009) (to be codified at 9 C.F.R. pts. 321, 332, and 381).

111. 21 U.S.C. § 661(a)(1) and § 454(a)(1).

112. *See* 7 U.S.C. § 450 (2011); U.S. DEPARTMENT OF AGRICULTURE, FSIS DIRECTIVE, 5720.2 REVISION 3, STATE COOPERATIVE INSPECTION PROGRAMS (NOV. 16, 2004).

113. *See* Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products, 74 Fed. Reg. at 47,648 (noting that under the Talmadge-Aiken Act, FSIS "enters into a separate agreement with a State agency for the State program to conduct meat, poultry, or eggs products inspection or other regulatory activities on behalf of FSIS.").

114. The Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, 112 Stat. 1651 (June 18, 2008).

115. Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products, 74 Fed. Reg. at 47,648.

116. *Id.*

117. *See* Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Product; Final Rule, 76 Fed. Reg. 24,714, 24,715 (May 2, 2011)(to be codified at 9 CFR Parts 321, 332, and 381).

118. *See id.* at 24,753-54; 24, 757.

119. *See id.* at 24,753-54; 24756-57.

120. *See id.* at 24,754; 24,757.

121. *See id.*

The new inspection regime seems aimed at encouraging more small businesses to ship their meat and poultry across state lines by increasing the number of available slaughtering facilities. Establishments that already ship their products interstate may not participate in the new cooperative program.[122] However, though the new interstate inspection program is separate from the intrastate cooperative programs, the proposed FSIS regulations allow a facility to participate in both, so long as "the establishment implements and maintains written procedures for complete physical separation of product and process for each operation by time or space."[123]

III. LITIGATION

A. Tomato producer alleges FDA was negligent in implicating tomatoes in 2008 Salmonella *outbreak*

The regulatory developments outlined in section II of this Food Law Update suggest that FDA plans to exercise an abundance of caution when it comes to food safety outbreaks. The problem with acting in the face of uncertainty and incomplete information is that sometimes the agency gets it wrong and innocent parties get blamed. At least that is the general idea behind a complaint filed in South Carolina federal court by Seaside Farms, a tomato producer that alleges the FDA acted negligently in fingering tomatoes as the source of a 2008 *Salmonella* outbreak eventually traced to jalapeno peppers.[124]

The complaint, filed under the Federal Tort Claims Act,[125] pleads several causes of action, including negligence, defamation, and a Fifth Amendment takings claim – as well as violations of South Carolina consumer protection laws.[126] The crux of the negligence claim is that the FDA owes a duty to Seaside to act in a way that is not reckless, and that the FDA was "negligent, grossly negligent, and reckless" in, *inter alia*: (1) failing to identify any contaminated tomatoes in South Carolina before issuing a nationwide recall for tomatoes;[127] (2) failing to verify reports of *Salmonella* due to consumption of tomatoes before issuing a nationwide

122. *See* Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products, 74 Fed. Reg. at 47,649.

123. *See* Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Product; Final Rule, 76 Fed. Reg. at 24,755, 24,759.

124. Complaint at 6-7, Seaside Farms v. United States, No. 11-cv-1199-CWH (D.S.C. May 18, 2011) [hereinafter *Complaint*].

125. *See* 28 U.S.C. § 2671 *et seq.*; *Complaint supra* note 124, at 1.

126. *See Complaint, supra* note 124, at 5, 7-8.

127. *Id.* at 6.

tomato recall;[128] (3) "failing to follow FDA standards and practices with regard to tomatoes and without regard to the processes of food supervision;"[129] and (4) issuing a nationwide tomato recall and then subsequently identifying tomatoes from 41 states as safe.[130] The complaint alleges that Seaside has always been in cooperation with FDA audits and did not source any contaminated tomatoes at any time during the recall.[131]

Commentators have cited the 2008 *Salmonella* Saintpaul outbreak as a communications failure between the CDC, FDA, and state departments of health.[132] On May 31, 2008, the CDC first informed FDA about an outbreak of *Salmonella* thought to be associated with tomatoes. FDA's investigation therefore initially focused on raw tomatoes, and its early public statements suggested that "raw red plum, red Roma and round red tomatoes [were] the likely suspect food."[133] But by mid-July, jalapeno peppers linked to a single Texas distributor had been pinpointed as the source of the outbreak.[134] Though FDA had lifted its warning on eating tomatoes by this time, the damage to the tomato industry had been done – to the tune of an estimated $200 million in economic losses.[135] One postmortem analysis concluded that "[t]he outbreak response was marked by a lack of organization, capacity, and coordination that calls into the question the public-health effectiveness of the response. Finally, messages to the public were often mixed, if not contradictory."[136]

But from a liability perspective, the picture is muddy. It is not just that other actors besides the FDA, such as the CDC and state departments of public health, were involved – it is also the fact that none of these

128. *See id.*
129. *Id.*
130. *Id.*
131. *Complaint, supra* note 124, at 3.
132. *See* Nathan M. Trexler, *"Market" Regulation: Confronting Industrial Agriculture's Food Safety Failures,* 17 WIDENER L. REV. 311, 335 (2011); Sara M. Benson, *Guidance for Improving the Federal Response to Foodborne Illness Outbreaks Associated With Fresh Produce,* 65 FOOD & DRUG. L.J. 503, 510 (2010); Elizabeth A. Trachtman, Note, *Food-Borne Illnesses Strike U.S. Food Supply: A Discussion of Inadequate Safety Procedures and Regulations in the U.S. and Abroad,* 20 IND. INT'L & COMP. L. REV. 385, 404 (2010); Produce Safety Project, *Breakdown: Lessons To Be Learned From the 2008 Salmonella Saintpaul Outbreak* (Nov. 17, 2008), *available at* http://www.producesafetyproject.org/admin/assets/files/0015.pdf. [hereinafter *Produce Safety Project*].
133. *Produce Safety Project, supra* note 132, at 10.
134. *See* Benson, *supra* note 132, at 510.
135. *Id.*
136. *Produce Safety Project, supra* note 132, at 17.

organizations can control the market reaction to the recall.[137] One report noted that, given the agencies' lack of consistent messaging as to the source and scope of the contamination, "[i]t should not have been surprising . . . that several large retail outlets pulled tomatoes off their shelves and out of their menu items in the middle of the outbreak, and consumers stopped eating all types of tomatoes," even though FDA had consistently said that certain types of tomatoes were safe to eat.[138] This type of market overreaction is typical in the early stages of foodborne illness outbreaks: during the 2006 *E. coli* outbreak in fresh spinach, the bottom dropped out of the entire spinach market even though the FDA later clarified that canned and frozen spinach was safe to eat;[139] during the 2011 *E. coli* outbreak in Europe, Russia announced a complete ban on *all* produce sourced from Europe.[140]

To the extent that it reaches the merits, the viability of the *Seaside* litigation will likely turn upon the discovery process: What did the government know about tomato contamination, and when? How did it communicate this information to other food safety officials? Did those actions or non-actions amount to negligence? The *Seaside* case is an interesting illustration of what happens when the interests of commodity producers collide with the precautionary principle that underlies safety regulation. In the regulation context, risk management often involves making complex judgments about the available science, the underlying harm, and the number of lives that may be put at risk if regulation does not occur. Agencies weigh these factors and then come up with the appropriate "amount" of proactive regulation to address the harm. The problem with the U.S. food safety regime, however, is that it is largely *reactive* rather than proactive. Given limited agency resources and the sporadic nature of pathogenic outbreaks, FDA and CDC can only scramble to put out fires, sometimes applying water cannons to problems that need only fire extinguishers.

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137. For a good introduction to the topic of so-called "veggie libel" laws designed to protect the economic interests of small agricultural producers, see David J. Bederman, et. al., *Of Banana Bills and Veggie Hate Crimes: The Constitutionality of Agricultural Disparagement Statutes,* 34 HARV. J. ON LEGIS. 135 (1997).

138. *Produce Safety Project*, *supra* note 132, at 11.

139. *See* A. Bryan Endres & Nicholas R. Johnson, *Integrating Stakeholder Roles in Food Production, Marketing, and Safety Systems: An Evolving Multi-Jurisdictional Approach,* 26 J. ENVTL. L. & LITIG. 29,56, n. 137 (2011) (describing the FDA's contradictory messages throughout the spinach recall).

140. *See Russia bans fresh European produce, state media report*, CNN WORLD (Jun. 2, 2011), http://articles.cnn.com/2011-06-02/world/russia.e.coli_1_russia-bans-coli-vegetables?_s=PM:WORLD.

The recent developments discussed in this Update – in particular, the provisions that allow FDA to detain food if it has "reason to believe" that it violates the FDCA, as well as FSIS's new "test-and-hold" procedures – are incremental steps toward a more proactive food safety regime. So long as they are bolstered by adequate funding for enforcement, these new procedures may help food safety officials stop contaminated jalapenos from ever being released into the marketplace, or prevent an entire commodity industry from bearing the consequences of the actions of a minor segment.

B. Federal district judge denies summary judgment in consumer's diacetyl microwave popcorn suit

A federal district judge in Colorado has denied the defendant's motion for summary judgment in a suit by a consumer who alleges that microwave popcorn caused his respiratory ailments. According to the complaint in *Watson v. Dillon Companies, Inc.*,[141] Wayne Watson ate two to three bags of the defendants' microwave popcorn at his home on a daily basis for about seven years.[142] Doctors subsequently diagnosed him with a rare lung condition called brochiolitis obliterans, which is primarily characterized by small airway obstruction that causes shortness of breath even upon mild exertion and does not respond to the use of an inhaled bronchodilator.[143] Watson filed his claim under the Colorado Consumer Protection Act, alleging that the defendants either knew or should have known that their microwave popcorn was unreasonably dangerous, and they failed to provide material facts about the risks of the product to the popcorn-consuming public.[144]

The basis for the claim is a series of studies linking exposure to vapors from the flavorings used in microwave popcorn production – and in particular diacetyl, a chemical used in artificial butter flavoring – to decreased lung functioning in popcorn plant workers.[145] These studies have shown that "the highest levels of [diacetyl] release occur when opening the bag after popping,"[146] and researchers have "issued recommendations for reducing exposures in the workplace, including better exhaust and ventilation, closed production systems, personal protective

141. 2011 WL 2490963 (D. Colo. June 22, 2011) (slip. op.).
142. *Id.* at *1.
143. *See id.* at *5.
144. *Id.* at *18.
145. *Id.* at *3. For a comprehensive history of the so-called "popcorn lung crisis" and a critique of the regulatory response to it, *see* Andrew Scott Dulberg, *The Popcorn Lung Case Study: A Recipe for Regulation?*, 33 N.Y.U. REV. L. & SOC. CHANGE 87 (2009).
146. *Watson*, 2011 WL 2490963 at *3.

equipment, and removal of diacetyl as an ingredient in butter flavoring."[147] Put generally, Watson claims that his respiratory condition was caused by his excessive consumption of microwave popcorn,[148] and that the evidence of respiratory problems in microwave popcorn plant workers should have put the defendants on notice that their product was unreasonably dangerous for consumers.[149]

The bulk of the court's analysis consisted of a *Daubert* analysis[150] of the plaintiffs' medical experts, which it resolved largely in the plaintiffs' favor.[151] Based mainly on the strength of the proffered expert testimony, the court also concluded that the plaintiffs had offered enough evidence to survive a motion for summary judgment on the issue of causation.[152] That being said, however, causation may yet be an issue if and when the case (or others like it) comes before a jury. Although the studies that examined diacetyl exposure in microwave popcorn plant workers have established a clear relationship between butter flavorings and respiratory conditions, the *Watson* court noted that "there remain numerous unanswered questions about what level of exposure triggers health effects and whether such effects are caused by peak or by cumulative exposures."[153] Many of the studies cited by the plaintiffs had examined the effects of diacetyl exposure on plant quality control workers who popped and then opened bags of microwave popcorn to determine the number of unpopped kernels and other quality issues.[154] The plaintiff in the *Watson* case claims that his exposure "is more similar to that of QC workers, who pop and open popcorn in the same manner as consumers, albeit at much greater rates."[155] The defendants in *Watson* argue that "the studies of QC workers are inapplicable because of the significantly higher number of bags popped per day (often a hundred or more compared to Mr. Watson's two or three) and variations in the workplace assignments and environments."[156]

While that argument was not a winning one for purposes of a *Daubert* expert testimony analysis, it could very well sway a jury. Indeed, at least two other consumer lawsuits alleging injury from diacetyl exposure in

147. *Id.* at *4.
148. *See id.* at *16
149. *Id.* at *19.
150. The standard for admissibility of expert testimony is primarily governed by the Supreme Court's holding in *Daubert v. Merrill Dow Pharmaceuticals,* 509 U.S. 579 (1993).
151. *See Watson,* 2011 WL 2490963 at *9-*17.
152. *Id.* at *18.
153. *Id.* at *4.
154. *Id.* at *1.
155. *Id.* at *4.
156. *Watson,* 2011 WL 2490963, at *12.

microwave popcorn have been litigated; one was dismissed on motions[157] and the other resulted in the jury verdict for the defendant corporation.[158] The district court in *Newkirk v. ConAgra Foods* excluded broad swaths of testimony from Dr. David Egilman, an expert upon whom the *Watson* plaintiffs rely, on grounds that it was not sufficiently reliable and then dismissed the case on summary judgment motions;[159] the Ninth Circuit Court of Appeals affirmed that decision in June.[160]

While juries in several states have awarded multimillion dollar verdicts to popcorn plant workers who claimed that their respiratory conditions were caused by exposure to diacetyl,[161] they have not been so generous to consumers making the same claims. The first such claim to reach a jury, *Khoury v. ConAgra Foods,* resulted in a verdict for ConAgra on all counts.[162] After the verdict, a defense attorney in the *Khoury* case opined that plaintiffs' attorneys in consumer diacetyl cases are "trying to take the regular popcorn consumer and turn them into a popcorn worker . . . . Some enterprising attorneys got involved and decided to bring it into your kitchen whether the science is there or not."[163]

C. State court judge rules that mycoprotein allergy claims are preempted by federal labeling rules

A circuit court judge in Connecticut has dismissed a suit by a consumer who claims that a maker of vegetarian chicken patties should

157. *See* Newkirk v. ConAgra Foods, 727 F. Supp. 2d 1006 (E.D. Wash. 2010); *aff'd,* 2011 WL 2421144 (9th Cir. June 17, 2011) (unpublished).

158. *See* Khoury v. ConAgra Foods, Inc., No. 0816-cv-31620 (Mo. Cir. Ct., Jackson County Aug. 2, 2010).

159. *See* Newkirk, 727 F. Supp. 2d at 1029 ("There is simply too great an analytical gap between the existing data, indicating that exposure to butter flavoring vapors in the occupational setting can cause bronchiolitis obliterans, and Dr. Egilman's opinion that a consumer of microwave popcorn is exposed to a vaporized substance equivalent to production plant butter flavoring vapors at levels sufficient to cause bronchiolitis obliterans . . . . His opinion testimony, therefore, is inadmissible under *Daubert* and Fed.R.Evid. 702.").

160. Newkirk v. ConAgra Foods, 2011 WL 2421144 (9th Cir. June 17, 2011).

161. *See* Alyson E. Raletz, *Regular Popcorn Snacker's Lawsuit Over Lung Condition Starts In,* FINDARTICLES (July 6, 2010), http://findarticles.com/p/articles/mi_7992/is_20100706/ai_n54413207/; *see also* Jeff Lehr, *Illinois Worker Wins $30 Million Verdict in Diacetyl Popcorn Chemical Lawsuit,* THE JOPLIN GLOBE (Aug. 16, 2010), http://www.joplinglobe.com/local/x369041172/Illinois-worker-wins-30-million-verdict-in-diacetyl-popcorn-chemical-lawsuit.

162. *Khoury,* No. 0816-cv-31620.

163. Alyson E. Raletz, *In Jackson County Circuit Court, Consumer Loses 'Popcorn Lung' Case,* FINDARTICLES (July 30, 2010), http://findarticles.com/p/articles/mi_7992/is_20100730/ai_n55294593/.

have warned her that the product contained a food allergen. Plaintiff Kathy Cardinale filed a lawsuit against defendant Quorn Foods, claiming the mycoprotein in the company's vegetarian "Chik'n Patties" was the cause of her food-allergy-related injuries.[164] The suit alleged violations of Connecticut's Unfair Trade Practices Act (CUTPA),[165] which prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."[166]

Mycoprotein is sourced from the cell protoplasm of the fungus *Fusarium venenatum,* which is fermented in vats that use glucose syrup as food.[167] Quorn Foods uses mycoprotein as a meat analogue for its frozen meat-free food products, including the Chik'n patties that allegedly sickened the plaintiff.[168] The FFDCA at 21 U.S.C. § 321(qq) lists major food allergens that must be labeled as prescribed by the statute at § 343(w), but mycoprotein is not on that list.[169] Nevertheless, the plaintiff alleged that Quorn's "failure to warn consumers on their product labels of the 'allergenicity' of mycoprotein" made her "unaware of the possible health risks . . . when she purchased the Chik'n Patties."[170] The plaintiff in the *Cardinale* case alleged that she experienced vomiting and dizziness within hours of eating Quorn Chik'n patties, and she was apparently able to isolate the patties as the cause by eating them multiple times and experiencing the same symptoms each time.[171]

The court, in an unpublished opinion, found that the allergen labeling requirements codified at § 321 of the FFDCA preempted the plaintiff's claims.[172] The court reasoned that by enacting uniform allergen labeling requirements, "Congress expressed a federal intent to occupy the field of labeling of products with potential food allergens."[173] The court noted that FDA currently is reviewing mycoprotein's status as a food allergen, but that "Congress has not yet acted on any recommendation from the FDA to add [mycoprotein] to the list of allergens it believes consumers should be warned about in the interests of public health."[174] The court further noted

164. *See* Cardinale v. Quorn Foods, Inc., 2011 WL 2418628 (Conn. Super. filed May 19, 2011).
165. *See id.* at 1.
166. Connecticut Unfair Trade Practices Act, CONN. GEN. STAT. § 42-110b (2010).
167. *See How Mycoprotein is made*, MYCOPROTEIN (2008), http://www.mycoprotein.org/what_is_mycoprotein/product_process.html.
168. *Cardinale,* 2011 WL 2418628 at *1.
169. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321, 343 (2010).
170. *Cardinale,* 2011 WL 2418628 at *1.
171. *See id.*
172. *See id.* at 4-5.
173. *Id.* at *8.
174. *Id.*

that the FDA, "with its staff of food scientists, nutrition experts and vast regulatory authority over our nation's food supply is in a far better position and possessed of more adequate resources to properly assess the pros and cons of additional or specific labeling for the food product at issue here."[175]

Though the *Cardinale* opinion is an unpublished state court decision, it is significant for two reasons: (1) it is the first court case (as the authors are aware) to address the allergenic properties of mycoprotein; and (2) it represents yet another setback for consumer advocates who have long argued that the fungus can cause serious allergic reactions and is, therefore, unsafe. The parent company of Quorn, Marlow Foods, is a British company that has been selling meat-free mycoprotein products in the UK since the mid-1980s.[176] The UK's Ministry of Agriculture, Fisheries, and Food (the British equivalent of the FDA) approved mycoprotein as safe to eat in 1985,[177] but Marlow nonetheless faced serious opposition from the Center for Science in the Public Interest (CPSI) when it began selling Quorn products in the U.S. in 2002. CPSI claimed that hundreds of people in the UK had had serious adverse allergic reactions to Quorn products with mycoprotein – including hives, vomiting, fainting, and shortness of breath – and argued that these products "should not be allowed to remain in our food supply either as a GRAS substance or a food additive."[178] Nonetheless, FDA stated that it had "no questions" about Marlow Foods' own determination that mycoprotein is GRAS – which is essentially the agency's position to date.[179] CPSI's crusade against the company was dismissed by food pundits and scientists as "puzzlingly tenacious"[180] and "overblown,"[181] and Marlow's retail sales zoomed to $200 million in 2004.[182] But after nearly ten years on the market, the *Cardinale* complaint

175. *Id.* at *5.

176. *See* Kate Jackson, *Once-Scorned Quorn Still Alive and Kicking,* TODAY'S DIETICIAN (Aug. 2004), http://www.todaysdietitian.com/newarchives/td_0804 p32.shtml.

177. *See id.*

178. Letter from Michael F. Jacobson, Ph.D., Executive Director, Center for Science in the Public Interest, to Dr. Mark McClellan, Commissioner, U.S. Food and Drug Administration (Apr. 21, 2003), *available at* http://www.cspinet.org/new/pdf/quorn_ mcclellan_letter_4-23.pdf.

179. Letter from Alan M. Rulis, Ph.D., Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, to Stuart M. Pape, Patton Boggs LLP (Jan. 7, 2002), *available at* http://www.fda.gov/Food/FoodIngredientsPackaging/ GenerallyRecognizedasSafeGRAS/GRASListings/ucm154623.htm.

180. Jackson, *supra* note 176.

181. Joe Lewandowski, *Quorn Dogged: Scientists Call Advocacy Group's Complaints Unfounded,* NEWHOPE360.COM (Apr. 24, 2008), http://newhope360.com/ quorn-dogged-scientists-call-advocacy-groups-complaints-unfounded.

182. *See* Jackson, *supra* note 176.

again raises the question of whether FDA should add mycoprotein to its list of recognized food allergens.

D. Settlement in BPA Litigation

Bisphenol-A (BPA) is a chemical commonly used in polycarbonate plastics and epoxy resins.[183] Whether low concentrations of BPA cause adverse endocrine-related effects in humans – primarily exposed through food packaging – remains subject to considerable debate.[184] Although food contact materials fall under FDA jurisdiction, approximately 85 to 90 percent of BPA use in the United States is in products under EPA's Toxic Substances Control Act (TSCA) authority.[185] Accordingly, the EPA requested public comment on a toxicity testing and environmental sampling study of BPA's potential environmental impacts.[186] This study would complement existing efforts at FDA to study the potential human health issues associated with BPA consumption via food packaging.[187]

Earlier in 2011, Philips Electronics North America Corporation (Philips), the successor to Avent America, Inc., settled a series of putative class actions arising from the sale of baby products containing BPA.[188] In January 2011, the parties agreed to a settlement whereby Philips agreed to not sell baby bottles or "sippy" cups containing BPA.[189] However, if a competitor began selling these products containing BPA, then Philips could resume sales of the products so long as it disclosed the presence of BPA in the product material.[190] This disclosure mandate would last for one year.[191] The settlement also provided class members a refund for purchased

183. *Bisphenol A Action Plan*, U.S. ENVIRONMENTAL PROTECTION AGENCY, 1 (Mar. 2010), http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa_action_plan.pdf.

184. *See id.* at 1-2 (noting that "BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic," which leads to questions about the impact on children's health).

185. *See id.* at 3.

186. *See* EPA. *Testing of Bisphenol A, Advance notice of proposed rulemaking*, 76 Fed. Reg. 44535 (July 26, 2011) (to be codified at 40 C.F.R. pt. 799).

187. *See Update on Bisphenol A for Use in Food Contact Applications: January 2010*, FOOD AND DRUG ADMINISTRATION (Mar. 22, 2010), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm [hereinafter *FDA*].

188. *In re* Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation, Master Case NO. 4:08-1967-MD-W-ODS, MDL No. 1967 (W.D. Mo. 2011).

189. *See* Stipulation of Class Action Settlement, In re Bisphenol-A (BPA) Polycarbonate Plastic ProductsLiability Litigation, Master Case NO. 4:08-1967-MD-W-ODS, MDL No. 1967 (W.D. Mo. 2011), *available at* http://www.wdklaw.com/images/FE/chain232siteType8/site201/client/Stipulation%20of%20Settlement.pdf.

190. *See id.* at 16.

191. *Id.* at 16.

products sold by Philips that contained BPA.[192] The injunctive relief, however, may have little market impact as according to the FDA, major manufacturers of bottles and infant feeding cups have stopped selling polycarbonate products containing BPA in the US market – switching back to more traditional glass and polypropylene bottles and disposable bag liners.[193]

IV. BIOTECHNOLOGY LITIGATION AND REGULATORY UPDATE

A. Alfalfa

In 2004, Monsanto Co. and Forage Genetics International petitioned the USDA to deregulate an alfalfa variety resistant to the herbicide glyphosate.[194] A coalition of alfalfa farmers and environmental NGOs challenged USDA's decision to deregulate the genetically engineered alfalfa.[195] The court entered an injunction prohibiting future planting of the alfalfa variety pending completion by USDA of a full Environmental Impact Statement.[196] The initial problem with the agency's deregulation decision was the failure to consider the potential impacts of pollen drift on non-GM farmers as well as the cumulative environmental impact of another crop resistant to the glyphosate herbicide.[197] The Supreme Court subsequently reversed this injunction on procedural grounds – leaving intact the requirement for further agency review of potential environmental impacts.[198]

USDA issued a final Environmental Impact Statement for GM Alfalfa in December 2010.[199] In a shift from the agency's previous environmental assessments, the agency proposed an option of partial deregulation in addition to the usually proffered preferred alternative of full deregulation.[200] The partial deregulation alternative envisioned production zones to minimize the potential for unwanted cross-pollination and thereby

192. *Id.* at 17-18.

193. *See FDA*, *supra* note 187 (noting Interim Public Health Recommendations).

194. *See Petition for Determination of Nonregulated Status for Roundup Ready® Alfalfa (Medicago Sativa L.) Events J101 and J163, 19 (2004),* APHIS (Apr. 16, 2004), http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf.

195. *See* Geertson Seed Farms v. Johanns, 2007 WL 518624 at *12 (N.D. Cal. Feb. 13, 2007).

196. *See id.* at 12.

197. *See id.*

198. *See* Monsanto Co. v. Geertson Seed Farms, 130 S.Ct. 2743 (2010).

199. *See* USDA, GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS; FINAL ENVIRONMENTAL IMPACT STATEMENT (Dec. 2010).

200. *See id.* at iv.

facilitate coexistence between GM and non-GM alfalfa. Although the agency eventually settled on the full deregulation alternative,[201] the consideration of a partial deregulation decision to facilitate coexistence was a significant signal by the agency that it may seriously consider coexistence impacts in future regulatory decisions.

B. GM Rice Lawsuit

In 1998, Aventis CropScience (Aventis) began field testing a genetically engineered rice variety resistant to the Liberty Link brand herbicide. At the time, Aventis (later purchased by Bayer CropScience), did not seek regulatory approval for the rice variety.[202] In January 2006, Riceland Foods, Inc. (Riceland), the largest rice cooperative in the United States, discovered trace amounts of genetically engineered DNA in the 2005 rice harvest.[203] USDA publically confirmed the stray genetic material as LLRice601 (Liberty Link Rice) in August 2006.[204] Importers in Japan and the European Union subsequently banned long-grain rice imports from the US and implemented genetic testing regimes.[205] The first lawsuits were filed against Bayer and Riceland within days of the USDA announcement.[206]

1. Duty to Defend

Riceland, a successful plaintiff (jury verdict of more than $136 million) in an Arkansas state case against Bayer CropScience (Bayer) in the Liberty Link Rice contamination litigation,[207] is also a defendant in over 170 lawsuits brought by rice farmers over the contamination of their conventional crops with the genetically engineered Liberty Link variety.[208] Liberty Mutual Insurance Co., the issuer of a commercial general liability

201. *See Record of Decision, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status,* APHIS (Jan 27, 2011), http://www.regulations.gov/#!documentDetail;D=APHIS-2007-0044-12941.

202. *See* AgrEvo USA Co., Availability of Determination of Nonregulated Status for Rice Genetically Engineered for Glufosinate Herbicide Tolerance, 64 Fed. Reg. 22595, 22595 (April 27, 1999) (USDA approval of petition for nonregulated status for two related GE rice events - LLRice06 and LLRice 62 – but not LLRice 601).

203. See Bayer Crop Science v. Schafer, 2011 Ark. 518 at 3.

204. *See id.*

205. *See id* at 4.

206. *See id.*

207. *See* Martinne Geller, *Bayer ordered to pay $136.8 mln in U.S. rice case,* RUETERS (Mar. 2, 2011), http://www.reuters.com/article/2011/03/21/idUSN2129802520110321.

208. *See* Riceland Foods, Inc. v. Liberty Mut. Ins. Co., 2011 WL 2262932 (E.D. Ark. 2011).

policy for Riceland, refused coverage, arguing that the policy expressly precluded liability from cross-pollination.[209] The court, however, found for Riceland, holding that because the policy was silent regarding liability for the physical mixing of the GE crop with conventional rice during harvest, processing, transportation, or storage – allegations made by plaintiff farmers in addition to cross-pollination – Liberty Mutual had a duty to defend the entire action brought against Riceland.[210]

2. Settlement

During the Riceland-Liberty Mutual insurance coverage litigation, a number of plaintiffs brought successful claims against Bayer. In the first federal case, a jury awarded two Missouri farmers approximately $2 million in compensatory damages for the economic loss arising from the contamination of the rice supply.[211] Three farmers from Arkansas and Mississippi obtained a $1.5 million federal verdict a month later.[212] In April 2010, 14 farmer-plaintiffs obtained a state verdict of approximately $6 million in compensatory damages and $42 million in punitive damages.[213] An informal survey of jury verdicts and settlements with farmers indicated an average compensatory damage award of over $434,000, [214] not including the Riceland victory noted above.

In July 2011, Bayer agreed to a $750 million settlement in an attempt to end any future threat of litigation.[215] The settlement allows rice farmers to opt into one of three settlement pools. Pool one compensates for "market losses" and is available to any farmer who planted rice between

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209. *See Id.* at 3-4.

210. *See Id.* at 3-5.

211. *See* Joe Whittington & Andrew M. Harris, Bayer Must Pay Farmers for Contaminated Rice Crop (Update 5), BLOOMBERG (Dec. 4, 2009), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=adGubJZ21Uzo.

212. *See* Allison Retka, *Second contaminated rice trial nets another plaintiff's verdict*, MISSOURI LAWYERS WEEKLY (Mar. 1, 2010) *available at* http://www.grgpc.com/News-PDFs/GRG48.pdf.

213. Margaret Cronin Fisk & Joe Whittington, *Bayer Loses Fifth Straight Trial over U.S. Rice Crops*, THE WASHINGTON POST (July 14, 2010), http://www.washingtonpost.com/wp-yn/content/article/2010/07/14/AR2010071404574.

214. *See id.*; Margaret Cronin Fisk & Joe Whittington, Ba*yer Settles Texas Suits Alleging its GM Seed Contaminated Rice Fields,* BLOOMBERG (Oct. 18, 2010), http://www.bloomberg.com/news/2010-10-18/bayer-settles-suits-with-texas-farmers-over-genetically-engineered-rice.html (3 famers settle for $270,000); *Rice Famers Settle with Bayer* BIZJOURNALS (Jan 14, 2011), http://www.bizjournals.com/stlouis/news/2011/01/14/rice-farmers-settle-with-bayer.html (4 farmers settle for $873,000).

215. *See* David Bennett, *GM rice: settlement construction and farmer options*, DELTA FARM PRESS (July 3, 2011), http://deltafarmpress.com/print/rice/gm-rice-settlement-construction-and-farmer-options.

2006 and 2010.[216] The pool establishes a damages schedule that compensates farmers on a per acre basis for economic damages incurred as a result of decreased export demand for US-grown rice.[217] Farmers who suffered damages beyond the market losses covered by the first pool can recover by opting into one of two other settlement pools with more complex filing requirements.

The second settlement pool compensates farmers who planted two contaminated seed varieties later banned by the government – Cheniere and Clearfield 131.[218] In an effort to prevent further contamination of the rice seed supply, farmers were instructed not to plant any variety of rice on land planted with the Cheniere or Clearfield 131 variety the previous year. In response, those farmers either planted less lucrative soybeans or let the land lay fallow. The settlement will compensate those farmers $100 per acre.[219] Farmers experiencing other losses, such as cleaning expenses or any other documented losses may claim actual losses under the third settlement pool, up to a cumulative cap of $100 million.[220]

The voluntary settlement as a whole is premised upon one big condition: farmers who farmed at least 85% of the total acres of rice planted in the United States between 2006 and 2009 must participate in the settlement, and if that 85% threshold is not achieved, then Bayer reserves the right to opt out.[221] Of course, this would result in additional, individualized litigation in state and federal courts – litigation in which Bayer has yet to prevail in any of the previous trials.

The Bayer LibertyLink settlement is reminiscent of the 2002 settlement between Aventis Crop Science and thousands of corn farmers affected by contamination of StarLink GM corn with corn intended for food and export channels.[222] In 1998 and 1999, Aventis received EPA approval, subject to several restrictions, to market the StarLink variety of seed corn.[223] In 2000, numerous reports surfaced that human food products

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216. *See id.*

217. Farmers can prove their damages simply by producing FSA Form 578 (which lists the number of rice acres planted by that farmer in a given year). *See id.* Damages start at $120 per acre for rice planted in 2006, declining to $10 per acre for rice planted in 2010. *Id.*

218. *See* Bennett, *supra* note 215.

219. *See id.*

220. *See id.*

221. *See id.*

222. *See* D.L. Uchtmann & Gary Hoff, *Non-StarLink Farmer Litigation: Where is MY Settlement Payment? How Much Is It? What Do I Do When It Arrives? How Is It Taxed?*, AGRIC. L. & TAX'N BRIEFS 04-12 (Nov. 4, 2004).

223. *See* D.L. Uchtmann, *StarlinkTM – A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 162 (2002).

had tested positive for the GM protein found in the StarLink corn variety.[224] Manufacturers issued recalls for products containing corn and fear of contamination convinced some food processors to replace domestically produced corn with imports.[225] The market price for corn fell and many members of the supply chain required testing of all corn shipments for the presence of StarLink DNA.[226] In subsequent class-action litigation, a federal district court in Illinois ruled that Aventis had a duty to ensure that its GM variety did not enter the food supply (i.e., a duty to abide by the EPA's permit restrictions) and that Aventis breached several of these obligations, which caused the plaintiffs' corn to be contaminated.[227] The court then approved a $110 million class-action settlement designed to compensate farmers for their losses.[228]

The settlement in the GM Liberty Link rice litigation is almost seven times the amount in the StarLink corn class action. Considered together, these two GM contamination cases have established additional certainty in the evolving common law of biotechnology – crop developers will be held responsible for the market losses resulting from the unauthorized commingling of their regulated GM products with conventional crops. Moreover, the economic loss rule may not insulate firms in contractual privity with impacted farmers. Accordingly, firms should take particular precautions to develop and implement coexistence strategies that prevent unwanted commingling.

V. CONCLUDING THOUGHTS

Governments walk a fine line between public protection and nannying, and the optimal level of regulation is often frustratingly difficult to obtain. The developments described in this Update suggest that the federal government is still tinkering with its health and food safety regulations but has, in some cases, decided that it needs to be more proactive about protecting the public from unhealthy and dangerous food. While the tort system has in many cases moved to fill in perceived gaps in this system of federal oversight (e.g., diacetyl and mycoprotein labeling), it has at the same time pushed back when federal agencies take proactive

224. *See id.* at 182.

225. Thomas P. Redick & Donald L. Uchtmann, *Coexistence Through Contracts: Export-Oriented Stewardship in Agricultural Biotechnology vs. California's Precautionary Containment*, 7 DRAKE J. AGRIC. L. 207, 213-14 (2008).

226. *In re* StarLink Corn Products Liability Litigation, 212 F. Supp. 2d 828, 833-35.

227. *Id.* at 843.

228. Redick & Uchtmann, supra note 225, at 214 (citing *In re* StarLink Corn Products Liability Litigation, 152 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001)) (this class action suit was settled for $110,000,000).

(some would say reactive) steps to protect the public (e.g., the *Seaside Farms* lawsuit). This inter-branch tug-of-war has played out in the midst of secondary, but very relevant, political concerns such as a sagging economy that threatens federal funding for food safety programs, as well as a burgeoning local foods movement that demands less regulation of food production. In the near term, then, we can probably expect much of the same: a federal government that addresses food safety issues in fits and starts, and a tort system that opportunistically provides a backstop when regulatory efforts amount to a swing and a miss.