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Food Law Update

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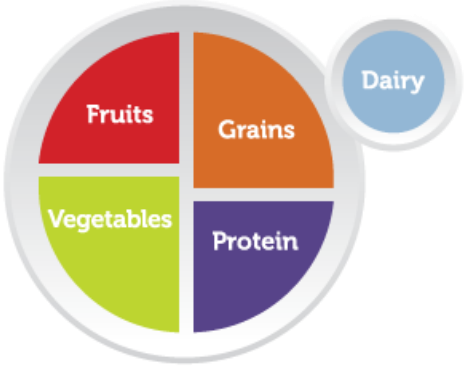
Introduction

An increasing number of legal and policy issues reflect some aspect of our food system. Environmental regulations and incentives intended to protect the soil and water that our food systems depend on; labor and employment law issues concerning the people who work along the path from farm to fork; government subsidies that reward those who produce certain crops; and land tenure issues involving who controls the land needed for food production are but a few examples. Then there are the traditional food law issues that span the breadth of the mainstays of food regulation: misbranding and adulteration.

This selected food law update focuses on traditional food law issues, but it also attempts to include items that seem particularly important in the context of developing trends, changing expectations, and emerging issues of importance, even when they push the boundaries of food law. Generally excluded from coverage are reports on pending litigation, regulation and litigation involving wine, beer, and spirits, and regulation issues in involving foreign jurisdictions and international trade. Also excluded are reports on the USDA nutrition programs and their impact on food security. These are worthy of their own analysis.



This outline is organized by food group, in a tip of the hat to USDA Secretary Vilsack's "My Plate" initiative. Old time foodies will

recall the food pyramid, but for the past 8 years, the graphic depiction has been a plate intended to show us how much of that plate should be devoted to which foods for a balanced diet. As though it was really that simple. . . before we even consider our plate, our discussion begins with a look at the new Dietary Guidelines released in January 2016.

Dietary Guidelines

The USDA and HHS published the 2015-2020 Dietary Guidelines for Americans, as required under the 1990 National Nutrition Monitoring and Related Research Act, based on the preponderance of current scientific and medical knowledge. The 2015-2020 edition of the Dietary Guidelines builds from the 2010 edition with revisions based on the Scientific Report of the 2015 Dietary Guidelines Advisory Committee and consideration of Federal agency and public comments.

The guidelines offer the following "overarching" recommendations:

1. Follow a healthy eating pattern across the lifespan";
2. Focus on variety, nutrient density, and amount [in an effort to stay within calorie limits];
3. Limit calories from added sugars and saturated fats and reduce sodium intake
4. Shift to healthier foods and beverage choices; and
5. Support healthy eating patterns for all.

The Guidelines note that a "healthy eating pattern" includes a "variety of vegetables from all of the sub-groups;" "fruits, especially whole fruits;" "grains, at least half of which are whole grains;" "fat-free or low-fat dairy products and/or fortified soy beverages; a "variety of proteins, such as seafood, lean meats, poultry, eggs, legumes, nuts, seeds, and soy;" and oils. Saturated fats and *trans* fats, added sugars and sodium are to be limited.

- Consume less than 10 percent of calories per day from added sugars
- Consume less than 10 percent of calories per day from saturated fats
- Consume less than 2,300 milligrams (mg) per day of sodium
- If alcohol is consumed, it should be consumed in moderation—up to one drink per day for women and up to two drinks per day for men—and only by adults of legal drinking age.

The Scientific Report of the 2015 Dietary Guidelines Advisory Committee had advocated for reduced meat consumption (particularly red and processed meats) and to factor in the sustainability of food production as a factor for consideration in a healthy and sustainable diet. These recommendations were rejected in the final report.

I. Fruits & Vegetables

POM Wonderful LLC v. FTC,

The U.S. Supreme Court denied certiorari in the FTC lawsuit against POM Wonderful LLC and Roll Global LLC alleging the companies made false or misleading health claims about their pomegranate-derived products. *POM Wonderful LLC v. FTC*, No. 15-525 (U.S., certiorari denied May 2, 2016). The U.S. Court of Appeals for the District of Columbia previously upheld a Commission decision finding POM misled consumers by claiming its products treat, prevent or reduce the risk of heart disease and prostate cancer, with some claims purported to be supported by clinical studies. *Pom LLC v. FTC*, 777 F3d 478 (9th Cir. 2015).

FSMA Produce Safety Rule Finalized

On November 27, 2015, the FDA published final rules "establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption." *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 80 Fed. Reg. 74,354 (final rule to be codified at 21 C.F.R. pts. 11, 16, 112) (Nov. 27, 2015). FDA's authority is based on the Food Safety and Modernization Act. These standards do not apply to "produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity." Produce that receives commercial processing to adequately reduce the presence of harmful pathogens is eligible for exemption from the requirements of the standards. The standards require "procedures, processes, and practices to minimize the risk of serious adverse health consequences or death." Areas affected include water used in production; personnel health, training and practices; handling and use of manure; access of animals to crop production; processes used in harvesting, packing, and holding produce; and sanitation standards for equipment, tools, and buildings. An exemption is provided for very small operations. For more information, the FDA maintains a website that tracks all FSMA implementation activities. There are training materials, fact sheets, and webinars available with other educational activities under development. Compliance dates generally range from 2-4 years depending the provision and the size of the farming operation.

Potatoes and Acrylamide

The FDA finalized its *Guidance for Industry: Acrylamide in Foods*, a document in draft form since 2013. The Guidance provides information on reducing acrylamide at all stages of production and processing and provides suggestions to consumers. It does not set a maximum recommended level for food products.

Acrylamide was first recognized in foods in 2002, particularly during high-temperature cooking. Acrylamide has been identified as a "human health concern" and is "reasonably expected to be a carcinogen." While there are a variety of sources, it was most notably identified in potato products such as french fries.

II. Grains

A. Rice

The FDA proposed a limit of 100 parts per billion (ppb) for inorganic arsenic in infant rice cereal in order to reduce infant exposure to inorganic arsenic. This limitation is not regulatory but comes as an "action level" and is expressed in the *Draft Guidance for Industry [on] Inorganic Arsenic in Rice Cereals for Infants: Action Level*.

The Guidance was announced by Federal Register notice, *Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document forAction Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability*, 81 Fed. Reg. 19,976 (Apr. 6, 2016).

Since 2013, in response to an alarming Consumer Reports survey on arsenic levels in rice, the FDA has been gathering data. On April 1, 2016, the FDA released data on the levels of arsenic in infant rice cereals. FDA's data show that only 47% of infant rice cereals sampled from retail stores in 2014 would meet the proposed action level of 100 ppb inorganic arsenic but that 78% was at or below 110 ppb inorganic arsenic. The agency states that it "expects manufacturers can produce infant rice cereal that meet or are below the proposed limit with the use of good manufacturing practices, such as sourcing rice with lower inorganic arsenic levels." *See*, FDA webpage, *Arsenic in Rice and Rice Products*.

III. Proteins

A. Alternative Proteins

Just Mayo Controversy Resolved

In 2014-15, a controversy arose regarding the labeling of a new sandwich spread called "Just Mayo." The controversy stemmed from the manufacturer's use of pea protein instead of egg protein, the latter being required under the standards of identity for "mayonnaise." FDA sent a warning letter challenging the name of the product; Hampton Creek, the manufacturer refused, alleging that its new recipe was more environmentally sustainable and the standards should change. In late 2015, the FDA and Hampton Creek reached a settlement. A new label would be used to highlight the egg-free nature of the product; and explanation would be provided that "just" referred to social justice and not "the same as." Pictured below is the old label, immediately followed by the new label.

B. Beef

Prison Terms and Judgments Ordered Against Midamar Founder, Midamar, ISA, and Sons

In February 2016, the U.S. Attorney's Office for the Northern District of Iowa announced the sentencing of William B. Aossey, Jr. of Cedar Rapids Iowa, the founder of Midamar Corporation and ISA, Inc. to two years in federal prison and a fine of $60,000. He was also ordered to forfeit $184,983 in proceeds of the fraud and to pay certain costs. Midmar was fined $20,000 and ordered to forfeit $600,000. ISA was fined $60,000 and ordered to forfeit $600,000. In March, it was also announced that Aossey's two sons were also sentenced. Jalel Aossey was sentenced to 12 months on one day of imprisonment and fined $30,000. Yahya Aossey was sentence to a 3 year term of probation and fined $5,000.

Sentences relate to multiple counts of conspiracy, making false statements on export certificates, and wire fraud involving a sophisticated scheme to sell beef that was fraudulently marketed as Halal.

Settlement in Canadian E.coli Beef Case

An Alberta court approved a settlement agreement in a class action law suit against XL Foods based on an E. coli outbreak that resulted in the recall of nearly 4 million pounds of beef in Canada and the United States, noted to be to the largest meat recall in Canadian history. XL Foods Inc. agreed to pay $4 million to consumers in Canada and the U.S. and in costs. Harrison v. XL Foods Inc., No. 1203-14727 (Can.

Alta. Q.B., order entered February 17, 2016). Consumers in Canada and the U.S. who either purchased XL Foods Inc.'s beef, thereby suffering an economic injury, or consumed it, causing them to contract an illness are eligible for payment. A Settlement website explains the terms.

WHO Report Characterizes Red and Processed Meat as Carcinogenic

The World Health Organization's (WHO's) International Agency for Research on Cancer (IARC) released a monograph that evaluated the potential link between red and processed meat consumption and cancer. Twenty-two experts from 10 countries reviewed more than 800 different studies and concluded that red meat is "probably carcinogenic . . .based on limited evidence that the consumption of red meat causes cancer in humans and strong mechanistic evidence supporting a carcinogenic effect." Stronger evidence was alleged with regard to the conclusion that processed meats (salted, cured, fermented, smoked) "are carcinogenic."

C. Chicken, Turkey and Other Poultry Products

Federal Preemption of State "Slack-Fill" Laws As Applied to Meat & Poultry

The Ninth Circuit affirmed a lower court's decision that California state law regulating the empty space between a product and its packaging is preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) with regard to actions against producers of meat and poultry products. *Del Real v. Harris*, No. 13-16893 (9th Cir., order entered February 12, 2016).

USDA Publishes New Salmonella and Camphylobacter Standards for Poultry
The USDA finalized new standards regarding Salmonella and Campylobacter levels in ground chicken and turkey products, as well as raw chicken breasts, legs and wings in an attempt to reduce the levels of the pathogens in poultry sold to consumers. The new rules were published at They require routine sampling throughout the year and allow publication of the results by establishment online. *See also*, Data Release in Meat – Generally section.

Poultry Products Inspection Act Preempts State Law Challenge to "Humanely Raised"

The Ohio Court of Appeals dismissed a challenge to the Kroger Company for its sale of chicken labeled "humanely raised." The plaintiffs based their challenge on two Ohio state consumer fraud and deceptive trade practices laws. The lower court dismissed the claims as preempted under the federal Poultry Products Inspection Act (PPIA), and the Court of Appeals agreed. At issue were poultry products marketed under Kroger's "Simple Truth" brand, sold for a premium price. The plaintiffs alleged that the chickens were raised "no differently than any other chicken mass produced by its supplier, Perdue." Under the PPIA, however, the USDA

FSIS is given authority over misbranding and adulteration of poultry products and poultry labels are approved for use by the FSIS. The court found there to be express preemption that precluded the plaintiff's claims.

Challenge to New Poultry Inspection System Dismissed

The D.C. Circuit Appeals Court affirmed a lower court's dismissal a challenge to the New Poultry Inspection System. *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905 (2015). The complaint alleged that the new system would increase the risk of foodborne pathogens in poultry and that it failed to comply with the Poultry Products Inspection Act. The lower court found that the plaintiffs did not have standing to sue because they were unable to show that the increased risk and probability of harm was substantial enough.

D. Eggs

Prison Sentences for Egg Executives Upheld

The 8th Circuit Court of Appeals upheld the legality of the 3 month prison sentences handed down to Austin "Jack" DeCoster and his son Peter, former executives at Quality Egg, LLC, the company found responsible for a nationwide 2010 Salmonella outbreak traced to its Iowa egg farms. *United States v. Quality Egg, LLC*, No. 15-1890 (8th Cir., order entered July 6, 2016). The DeCosters pled guilty to shipping and selling contaminated eggs as "responsible corporate officers" of Quality Egg. Quality Egg pled guilty to bribery of a public official, sale of misbranded food with the intent to defraud of mislead, and sale of adulterated food. The DeCosters were sentenced to 3 months incarceration, and they appealed their sentences alleging they were unconstitutional or in the alternative, procedurally and substantively unreasonable. The 8th Circuit rejected their allegations and affirmed the sentences.

American Egg Board Investigated Over Just Mayo Activities

A USDA OIG investigation continues into whether the American Egg Board improperly lobbied against Hampton Creeks' alternative protein product, "Just Mayo." Check-off organizations such as AEB are limited in their activities to product promotion & advertising, consumer education, and research with lobbying and other political activities prohibited. *See*, Alternative Proteins.
Organic Egg Production: Cornucopia Report

A new Cornucopia Institute report, *Scrambled Eggs: Separating Factory Farm Egg Production from Authentic Organic Agriculture* examines different methods of organic egg production and provides a "scorecard" on various brands of eggs based on 28 criteria.

E. Fish & Seafood

Genetically Engineered Salmon

Senator Lisa Murkowski (Alaska) is attempting to require FDA to mandate GE salmon labeling through a provision added to appropriations bills currently under consideration.

Health Canada and the Canadian Food Inspection Agency announced its finding that AquAdvantage Salmon, the genetically engineered salmon, "is as safe and nutritious for humans and livestock as conventional salmon" and approved its sale in Canada. *Health Canada and Canadian Food Inspection Agency approve AquAdvantage Salmon*, Gov't of Canada Statement (May 19, 2016).

There is at least one law suit that still is attempting to challenge the approval, *Inst. For Fisheries Res. V. Burwell*, No. 13-1574 (N.D. Cal., filed Mar. 30, 2016). Some retailers have indicated that they will not sell GE salmon in their stores.

The FDA issued Import Alert 99-40 on January 29, 2016 prohibiting the entry into commerce of genetically engineered salmon. The reason for the alert was listed as follows:

> The Fiscal Year (FY) 2016 Omnibus Appropriations Act covering the funding of the federal government during fiscal year 2016 (FY16) was signed into law by the President on December 18, 2015 becoming Public Law No: 114-113. In part, this law directs that during FY16 the FDA shall not allow the introduction or delivery for introduction into interstate commerce of any food that contains genetically engineered salmon, until FDA publishes final labeling guidelines for informing consumers of such content.

Senator Lisa Murkowski of Alaska, a fierce advocate for mandatory labeling, is credited with the appropriations act provision. As AquaAdvantage is produced in Canada and Panama, this import ban temporarily precludes its U.S. sale.

The FDA announced its decision that AquAdvantage Salmon is safe to eat, *FDA Has Determined That the AquAdvantage Salmon is as Safe to Eat as Non-GE Salmon* (Nov. 19, 2015). AquaAdvantage was approved under the FDA's authority to approve new animal drugs.

At the same time, it released a *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon* and provided notice of it via the Federal Register. 80 Fed. Reg. 73,193 (Nov. 24, 2015). The draft guidance requires no special labeling for genetically engineered salmon or its products and provides guidance as to how non-genetically engineered products can be labeled to indicate its status as non-GMO.

Seafood Company Shut Down Amid Concerns of Botulism and Listeria

U.S. Department of Justice obtained a a permanent injunction against Mill Stream Corp., a seafood company for the alleged processing and sale of adulterated seafood, specifically failing to take measures preventing the formation and growth of Clostridium botulinum or Listeria monocytogenes. *U.S. v. Mill Stream Corp*., No. 16-0080 (D. Me., order entered February 12, 2016). The injunction prevents the company and its employees operating until a number of sanitary conditions have been met.

F. Meat: Generally

New Publication: Leftovers for Livestock

In *Leftovers for Livestock: A Legal Guide for Using Excess Food as Animal Feed*, the University of Arkansas School of Law's Food Recovery Project and the Harvard Food Law and Policy Clinic provide the a catalogue of the different state regulations and requirements for feeding food scraps to animals. It is designed to serve as an resource for businesses with food scraps that could go to animals, livestock farmers, and other interested stakeholders.

Leftovers for Livestock also describes the federal and state laws and regulations regarding the practice of feeding food scraps to animals, and offers useful suggestions for both generators of food scraps and animal feeding operations. The federal government creates a floor, or base level of regulations for the feeding of food scraps to animals; however, states can apply more strict regulations than the federal baseline. Indeed, forty-eight states plus Puerto Rico more tightly regulate the feeding of food scraps to animals; some even have outright bans on the use of certain types of food scraps as animal feed.

Shortly after the release of Leftovers for Livestock, the FDA announced a new Draft Guidance for Industry: Human Food By-Products for Use as Animal Food. *Notice of Availability of Draft Guidance for Industry; Human Food By-Products for Use as Animal Food*, 81 Fed. Reg. 58,521 (Aug. 25, 2016).

Data Release

The USDA FSIS has planned to provide greater access to its data collection on pathogens for some time. In January, 2015, it published a notice announcing its intent to share data on federally inspected meat, poultry, and processed egg product establishments. 80 Fed. Reg. 2092 (Jan. 15, 2015). After receiving comments, FSIS released its final strategic plan for this establishment-specific data release by notice at 81 Fed. Reg. 45,451 (July 14, 2016).

Annual FDA Report on Antibiotic Use Finds Increase

The FDA published its annual report of overall sales and distribution data for antimicrobial drugs used in food-producing animals, *2014 Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals*. Observed trends that were reported included:

- Domestic sales and distribution of antimicrobials approved for use in food-producing animals increased by 22% from 2009 through 2014, and increased by 4% from 2013 through 2014.

- In 2014, domestic sales and distribution of medically important antimicrobials accounted for 62% of the domestic sales of all antimicrobials approved for use in food-producing animals.

- Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals increased by 23% from 2009 through 2014, and increased by 3% from 2013 through 2014.

Updated Guidance for Meat and Poultry Product Allergens

USDA FSIS issued a revised Guidance Industry for identifying, controlling and labeling allergens and other ingredients of public health concern in meat and poultry products through hazard analysis and critical control point (HACCP) plans, sanitation standard operating procedures (SOPs) or related programs in compliance with federal ingredient labeling requirements. *FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling* (Nov. 2015).

IV. Dairy

Fine Assessed for 2015 Listeria Outbreak in Ice Cream

The Texas Department of State Health Services fined BlueBell Creameries $850,000 for the 2015 outbreak of Listeria monocytogenes associated with its ice cream manufacturing facilities. Under the terms of the fine, however, only $175,000 is to be paid within 30 days, and the balance of $675,000 will be waved in 18 months if Blue Bell complies with an agreement that specifies certain food safety protocols and notification requirements. Included is a requirement that Blue Bell maintain "test and hold" procedures, through which the company must ensure that its ice cream is free of pathogens before shipping. See Texas Dept. of State Health Services, Press Release: Texas Finalizes Agreement With Blue Bell (July 29, 2016).

Report on Health Effects of Butter

A new meta-analysis of the effect of dairy fats on health was released. The report relied on nine different studies and found a small increase in overall risk of death but a 4-percent lower incidence of type 2 diabetes and no association with stroke, heart disease, or overall cardio-vascular disease. Laura Pimpin, et al., *Is Butter Back? A Systematic Reviewand Meta-Analysis of Butter Consumption and Risk of Cardiovascular Disease, Diabetes, and Total Mortality*, PLoS One, (June 2016).

Questions Raised About Use of "Soy Milk"

The Good Food Institute (GFI) has filed a lawsuit against the FDAS seeking to disclose all records "related to FDA's regulatory treatment of the common and usual name 'soy milk' to refer to a liquid food derived from the cooking and processing of whole soybeans with water." Good Food Inst. v. FDA, No. 16-1052 (D.D.C., filed June 6, 2016). The organization asserts that FDA has been inconsistent in its allowance of the label "soy milk," citing two warning letters to soy-milk producers requesting them to use "soy beverage" or "soy drink" instead, while some brands of soy milk continue to label their products as 'soy milk' or 'soymilk.' GFI submitted Freedom of Information Act requests to FDA in April 2016 and asserts that it only received a partial response.

Definition of Skim Milk Unsuccessfully Challenged

A Florida federal court rejected a dairy farmer's claim that he had a First Amendment right to sell his non-fat milk as "skim milk" in violation of the state's standard of identity for skim milk. *Ocheesee Creamery v. Putnam*, No. 14-0621 (N.D. Fla., Tallahassee Div., order entered Mar. 30, 2016). Under state law, and the law elsewhere, when cream (butterfat) is removed, the Vitamin A that is lost must be replaced so that the milk still has the expected nutrient content. The court held that the state standard of identity that defined "skim milk" and the associated federal provisions under the federal Food, Drug, and Cosmetic Act, passed muster under the First Amendment test for commercial speech.

Cheese Companies and Executive Plead Guilty to Misbranded Cheese

The Department of Justice brought charges against cheese companies who sold Parmesan and Romano cheeses into interstate commerce that were alleged to be misbranded and adulterated. Charges included conspiracy to introduce misbranded cheese and to commit money laundering. At issue was the addition of filler in violation of the standards of identity for the cheese product. Universal Cheese & Drying Inc., International Packing LLC, pled guilty and an executive with Castle Cheese pled guilty to a misdemeanor count of aiding and abetting the introduction of misbranded cheese. News of the prosecution triggered a Bloomberg Business News investigation into parmesan cheese, finding inflated amounts of cellulose (aka wood pulp) in a number of brands. Cellulose is permitted in foods, with an

acceptable level reported to be 2-4%. It is used in Parmesan Cheese to prevent caking. However, it must be included in the ingredient list, and the levels found were excessive.

> Essential Everyday 100% Grated Parmesan Cheese, from Jewel-Osco, was 8.8 percent cellulose, while Wal-Mart Stores Inc.'s Great Value 100% Grated Parmesan Cheese registered 7.8 percent, according to test results. Whole Foods 365 brand didn't list cellulose as an ingredient on the label, but still tested at 0.3 percent. Kraft had 3.8 percent.

Lydia Mulvany, *The Parmesan Cheese You Sprinkle on Your Penne Could Be Wood*, BLOOMBERG PURSUITS (Feb. 16, 2016).

Cheese Company and Two Officers Plead Guilty to Adulteration Charges

The Justice Department announced that a Delaware Cheese Company, Roos Foods pled guilty to misdemeanor violations of the Food, Drug & Cosmetic Act. It's principals agreed to a consent decree of permanent injunction regarding a civil complaint that was also filed. Both were filed in connection with the 2014 outbreak of Listeria Monocytogenes (L. Mono) associated with cheese products produced by the company. According to the criminal information:

> [T]he FDA inspection revealed significant sanitation deficiencies, such as widespread roof leaks in the manufacturing area, including over open manufacturing equipment; rust flakes on the manufacturing equipment from corroded roof trusses and metal roofing; un-cleanable surfaces on walls, floors and ceilings and product residue on equipment that had purportedly been cleaned. In addition, as alleged in the information, FDA collected environmental samples and found L. mono on 12 surfaces in the facility.

Evidencing the recent increase in criminal investigations and charges, the Justice Department announcement states that:

> The Department of Justice will use all of the tools available to us – criminal and civil – to ensure that the food we buy is free from dangerous bacteria and is safe to eat. . . We will continue to work aggressively with the Food and Drug Administration (FDA) to combat and deter conduct leading to the distribution of adulterated food to consumers.

V. Off the Plate

A. Salt

Voluntary Salt Reduction Targets

FDA issued a Request for Comments, *Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods*, 81 Fed. Reg. 35,363 (notice) (June 21, 2016). This guidance is intended to articulate voluntary short-term and long-term goals for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared in order to address the excessive intake of sodium and promote improvements in public health. The comment period was extended to Oct. 17, 2016 for food categories with 2-year target dates and Dec. 2, 2016 for foods with 10-year target dates.

B. Soda

Pepsi Settles 4-MeI Case

PepsiCo agreed to a settlement in another case claiming that its products contained levels of 4-Methylimidazole (4-MeI) in violation of the California Safe Drinking Water and Toxic Enforcement Act. As in a similar case, Pepsi agreed "to require its caramel coloring suppliers to meet certain 4-MeI levels in products shipped for
sale in the United States, ensuring the 4-MeI concentration levels will not exceed the level of 100 parts per billion, and to test the covered products pursuant to an agreed protocol." The California federal court granted preliminary approval of the settlement agreement. *Sciortino v. PepsiCo Inc.*, No. 14-0478 (N.D. Cal., order entered June 28, 2016).

C. Sugar

The American Heart Association issued a *Scientific Statement on Added Sugars and Cardiovascular Disease Risk in Children*. Added sugars are "energy dense but nutrient poor" and their consumption increases the risk of developing obesity, cardiovascular disease, hypertension, obesity-related cancers, and dental caries. This Statement concludes that

> Associations between added sugars and increased cardiovascular disease risk factors among US children are present at levels far below current consumption levels. Strong evidence supports the association of added sugars with increased cardiovascular disease risk in children through increased energy intake, increased adiposity, and dyslipidemia. The committee found that it is reasonable to recommend that children consume ≤25 g (100 cal or ≈6 teaspoons) of added sugars per day and to avoid added sugars for children <2 years of age. Although added sugars most likely can be safely consumed in low amounts as part of a healthy diet, few children achieve such levels, making this an important public health target.

VI. General & Systemic Issues

A. Food Additives, GRAS, and other Food Constitutents

Nanotechnology Primer

The Congressional Research Service issued an overview report, *Nanotechnology: A Policy Primer*, addressing federal funding of R&D in nanotechnology; U.S. competitiveness, and environmental, health, and safety concerns. This report also discusses nano-manufacturing and public perceptions of nanotechnology. There is little regulation of nanotechnology and nano-manufacturing, including its use in food products.

Database of BPA Packaging

The Environmental Working Group (EWG) released a searchable database of nearly 16,000 processed food and drink products that are packaged in materials that may contain the chemical bispherol A (BPA). The database is available on the EWG website and is titled, *BPA Bombshell: Industry Database Reveals 16,000 Foods with Toxic Chemical in Packaging*.

FDA Finalizes Rule for GRAS Process

As was reported last year, the Center for Food Safety sued the FDA over its 15+ year reliance on a streamlined GRAS process that was set forth in a 1997 proposed rule. The case was settled Oct. 20, 2014, with the FDA promising to finalize the rule no later than Aug. 31, 2016. The FDA met its deadline, filing a final rule on August 17. *Substances Generally Recognized as Safe*, 81 Fed. Reg. 54,960 (final rule to be codified at 21 C.F.R. pts. 20, 25, 170) (Aug. 17, 2016). The new rule adopts much of the process in use under the long-standing proposed rule, confirming that companies can use their own experts to determine whether a substance is considered GRAS and thus not subject to premarket review by the agency. The FDA "strongly encourages" companies to inform them of their GRAS determinations using a voluntary notification process. The rule was met with support by industry and criticism from consumer groups. *See*, Dan Flynn, *FDA Continues to Trust Industry Under GRAS Substance Rule,* FOOD SAFETY NEWS (Aug. 16, 2016).

B. Food Safety

The FDA issued its final rule for the *Sanitary Transportation of Human and Animal Food*, 81 Fed. Reg. 20,092 (Apr. 6, 2016). This rule, enacted pursuant to the Sanitary Food Transportation Act and the Food Safety Modernization Act,

establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. The rule became effective June 6, 2016.

The FDA published three final rules under the Food Safety Modernization Act on November 27, 2015: produce safety, foreign supplier verification programs (FSVPs) and accredited third-party certification.

- *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 80 Fed. Reg. 74,354 (final rule to be codified at 21 C.F.R. pts. 11, 16, 112) (Nov. 27, 2015). (See section on Fruits and Vegetables for more information)

- *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*, 80 Fed. Reg. 74,226 (final rule to be codified at 21 C.F.R. pts. 1. 11, 111) (Nov. 27, 2015).

- *Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications*, 80 Fed. Reg. 74,570 (final rule to be codified at 21 C.F.R. pts. 1, 11, 16) (Nov. 27, 2015).

- For information on recent foodborne illness outbreaks, see:

    - FDA website *Outbreaks: Investigation, Response & Evaluation;*
    - FDA website *Recalls of Foods & Dietary Supplements;*
    - FoodSafety.gov (coordinated site by FDA and USDA);
    - FSIS website, *Recalls*.

- Consult the following resources for ongoing reporting on food safety issues:
    - Food Safety News, an online daily newspaper;
    - Marlerblog.com , an award winning legal blog by food poisoning attorney Bill Marler.

C. Genetic Engineering of Food Products & Ingredients

Federal Legislation on GMO Labeling Enacted

Congress enacted and the President signed a law amending the Agricultural Marketing Act to include a new section, National Bioengineered Food Disclosure Standard. The new law preempts state law regulation of GMO labeling such as that enacted in Vermont, and it directs the Secretary of Agriculture to establish a mandatory system for the disclosure of GMO ingredients by "text, symbol, or

electronic or digital link" such as a QR code within the next two years. Proponents of GMO labeling have expressed concerns about the USDA's authority to define the types of technologies that will be subject to labeling and to set the threshold amount of GMO-derived ingredients that will trigger labeling. The food industry was generally relieved to no longer be faced with different state approaches to labeling. *See* Lauren Handel, *Congress Passes GMO Labeling Law*, HANDEL FOOD LAW (July 14, 2016).

FDA Guidance for Industry: Voluntary Labeling

On Nov. 24, 2015, in conjunction with its announcements regarding GE Salmon, the FDA announced its final *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants*. The Guidance is available on FDA's website and notice of its availability was published at 80 Fed. Reg. 73,194 (Nov. 24, 2015). It confirms FDA's position that labeling for GMO or non-GMO status should voluntary . As it predates the federal legislation referenced above, it will be subject to future revision.

D. "Healthy" as a Labeling Term

On May 10, 2016, FDA announced in a statement that it would be reevaluating regulations concerning nutrient content claims, including the term "healthy." FDA stated that public comments would be requested.

E. Menu Labeling

The FDA published it Guide for Industry, A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance With FDA's Food Labeling Regulations).'' The guidance is directed to restaurants and similar retail food establishments to assist them with compliance with the menu labeling requirements, including the requirements to provide calorie and other nutrition information for standard menu items. Enforcement of the final rule for Nutrition Labeling of Standard Menu Items was extended and will commence on May 1, 2017 (one year after this publication). *A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II*, 81 Fed. Reg. 27,067 (notice) (May 5, 2016).

F. "Natural" in Food Labeling

FDA requests comments on definition of "natural"

80 Fed. Reg. 69,905 (notice) (Nov. 12, 2015); 80 Fed. Reg. 80,718 (Dec. 28, 2015) (extending the comment period to May 10, 2016). FDA published a notice asking for comments on the definition of "natural" in food labeling. FDA's failure to define the term has contributed to many lawsuits. At least three Citizen Petitions and some Federal courts called for the agency to issue a definition. Particular items in controversy include ingredients produced using genetic engineering, high fructose corn syrup, and pesticide residues. The notice indicated potential collaboration with USDA on the definition, potentially affecting the use of the term in meat, poultry, and egg products. The comment is now closed, and of this writing no FDA announcement has been made. *See, Natural on Food Labeling* (FDA website).

The Ninth Circuit affirmed the dismissal of a lawsuit against Costco over its "natural" label on its VitaRain Tropical Mango Vitamin Enhanced Water Beverage. The plaintiff admitted to not reading the label. *Maple v. Costco,* No. 13-36089 (9th Cir. May 9, 2016).

G. Nutrition Facts Label

FDA Announces Changes to Nutrition Facts Panel

On May 20, 2016, FDA announced its decision regarding proposed changes to the Nutrition Facts Label that is required to appear on almost all food products. The changes were submitted as a final rule published at *Food Labeling: Revision of the Nutrition and Supplement Facts Labels* , 81 Fed. Reg. 33,742 (final rule to be codified at 21 C.F.R. pt. 101) (May 27, 2016).

The FDA also announced companion changes to the regulatory serving sizes that form the basis of the information on the Nutrition Facts Label. *Food Labeling: Serving Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments*, 81 Fed. Reg. 34,000 (final rule to be codified at 21 C.F.R. pt. 101) (May 27, 2016).

Report on Consumer Survey of Nutrition Labeling

The FDA released the results of its *2014 FDA Health and Diet Survey* (May 6, 2916), with a variety of interesting information about consumer habits and perceptions. For example:

- Seventy-seven percent (77%) of U.S. adults reported using the Nutrition Facts label always, most of the time, or sometimes when buying a food product.

- Seventy-nine percent (79%) used the label ("often or sometimes) when buying a food for the first time.

- Almost nine in ten said they used claims such as "low in sodium," "rich in antioxidants," "contains no added sugar," and "no sugar added" when buying food products, but only a third of those thought that the claims accurately described the products.

- While nine in ten had heard of trans fat or omega 3 fatty acids, a quarter of those could not tell if the fat raises, lowers, or has no relationship with the risk of heart disease.

H. Obesity Epidemic

Report on Potential Relationship Between Chemical Exposures and Obesity

The National Academies Press (NAP) published *The Interplay Between Environmental Chemical Exposures and Obesity*, a report that summarizes human and non-human epidemiological studies allegedly linking exposure to environmental chemicals "to weight gain and to glucose tolerance, insulin sensitivity, inflammation, and other aspects of the metabolic syndrome." The report focuses on endocrine disruptors studying the increase in chemical production alongside obesity rates. The report raises questions about the metabolic effects of chemicals with wide exposure rates including "organophosphates and carbamates; polychlorinated biphenyls (PCBs); polybrominated biphenyls and fire retardants; heavy metals; solvents; and plastics, such as phthalates and bisphenol A (BPA)." The report also considers the potential role of infectious diseases and treatments, including antibiotics, in childhood obesity.

Report Links Artificially Sweetened Beverages During Pregnancy and Increased Infant BMI

New research claims that the daily consumption of artificially sweetened beverages (ASBs) during pregnancy is associated with increased infant body mass index (BMI). Meghan Azad, et al., *Association Between Artificially Sweetened Beverage Consumption During Pregnancy and Infant Body Mass Index*, JAMA PEDIATRICS, (May 2016).

I. Organic Foods

Courts Rule (and disagree) on Preemptive Effect of Organic Standards

Marentette v.Abbott Labs., No. 15-2837 (E.D.N.Y., order entered August 23, 2016) (order dismissing the state law claims as preempted by the Organic Foods Production Act of 1990 (OPFA). This case involved Similac® Advance® organic infant formula, a product that contains ingredients impermissible under the National Organic Standards listing, but nevertheless was certified as organic by an accredited organic certifier. Citing *In re Aurora Dairy Corp. Organic Milk Mktg & Sales Practices Litig.*, 621 F.3d 781 (8th Cir. 2010), the court held that state challenges to the certification of a product itself are preempted, but "state law challenges to the facts underlying certification" are not. The court notes conflicting interpretations of OFPA preemption by other district courts.

Quesada v. Herb Thyme Farms, Inc., 361 P.3d 868 (Cal. 2015) (holding that OPFA does *not* preempt state law claims involving produce that is intentionally mislabeled as organic).

Organic Fertilizer Rule Sent Back to USDA

A California federal court has invalidated a guidance document (NOP 5016) that allowed organic producers to use compost materials containing synthetic pesticides present in the environment, referring to them as "Unavoidable Residual Environmental Contamination" (UREC). The court held that the USDA violated the Administrative Procedures Act (APA) by failing to subject the amendment to public notice and comment before it took effect. USDA had alleged that NOP 5016 was either a general statement of policy or an interpretive rule under the APA and thus not subject to the notice and comment requirement. The court rejected the USDA's arguments, finding that the policy was a legislative rule change. Ctr. for Envtl. Health v. Vilsack, No. 15-1690 (N.D. Cal., order entered June 20, 2016). After a lengthy consideration of the environmental and economic impacts the court vacated NOP 5016 effective August 22, 2016. Any green waste compost purchased or used between 2010 and August 22, 2016 was grandfathered in and not subject to this Order.

On August 18, 2016, USDA announced its plans to conduct a notice and comment rulemaking on this issue, stating that a proposed rule was "under development."

Proposed Changes to Organic Livestock and Poultry Practices

The USDA AMS published a proposed rule to amend the organic livestock and poultry production requirements by: adding new provisions for livestock handling and transport for slaughter and avian living conditions; and expanding and clarifying existing requirements covering livestock health care practices and living conditions. *National Organic Program; Organic Livestock and Poultry Practices*, 81 Fed. Reg. 21,956 (proposed rule)(Apr. 13, 2016).

Guidelines for National List Process Released

The National List of Allowed and Prohibited Substances identifies the synthetic substances that may be used and the non-synthetic substances that may not be used in organic production and handling. In March 2016, the USDA issued *Procedure: National List Guidelines* to explain the petition process for adding and deleting items from the National List.

Notice of 2016 Sunset Review Published

The USDA AMS published its results of the review of seven items on the National List of Allowed and Prohibited Substances pursuant to its sunset review procedures. All seven substances were renewed for approval. *National Organic Program: USDA Organic Regulations*, 81 Fed. Reg. 8,821 (notice)(Feb.23, 2016).

Guidance Published on Substances Used Post-Harvest

The National Organic Program (NOP) announced the availability of a final guidance document intended for use by accredited certifying agents, and certified and exempt organic operations. *Substances Used in Post-Harvest Handling of Organic Products* (NOP 5023), 81 Fed. Reg. 2067 (notice) (Jan. 15, 2016). According to the NOP, this Guidance clarifies:

1) what substances may be used for post-harvest handling;
2) the difference between "post-harvest handling of raw agricultural commodities" and "further processing"; and
3) the regulatory requirements for facility pest management.

J. Pet Food

Cornucopia Institute released a new report on pet foods, Decoding Pet Food: Adulteration, Toxic Ingredients, and the Best Choices for Your Companion Animals, accompanied by a product buying guide.