2013 NAFFS CONVENTION[1]

THE UNITED STATES AND JAPAN ENTER INTO AN ORGANIC EQUIVALENCE ARRANGEMENT

On September 26th the USDA announced that the United States entered into an Organic Equivalence Agreement with Japan. U.S. officials attending the signing ceremony stated that the Organic Equivalence Agreement entered into would reopen the Japanese consumer market for United States organic producers of all sizes, and would create jobs and business opportunities for the United States organic food and farming sector. The agreement was strongly supported by the U.S. based Organic Trade Association.

Prior to the signing of this agreement, both countries conducted independent assessments to confirm that organic management, certification, accreditation, and enforcement programs were not only in place in both countries, but would conform to each other's respective programs. This trade agreement with Japan also marks the first organic equivalency arrangement without organic standards exceptions. As a result, certified organic products, as of January 1, 2014, will be able to move freely between Japan and the United States. Japan has agreed to recognize the USDA's National Organic Program as the equivalent to the Japanese Agricultural Standards Program, and will allow products produced and certified as meeting the USDA's standards to be marketed as organic in Japan. The same will be true here in the United States. It will be required in both countries that the accredited certifier must be identified on the product label.

FDA GIVES APPROVAL TO A PETITION FOR A QUALIFIED

[1] This seminar provides general information only and does not constitute legal advice. No attorney-client relationship has been created. If legal advice or other expert assistance is required, the services of a competent professional should be sought. We recommend that you consult with an attorney familiar with your specific situation before taking any action.

HEALTH CLAIM LINKING WHOLE GRAIN CONSUMPTION TO RISK OF DEVELOPING TYPE II DIABETES

In January 2012 ConAgra Foods filed a petition with the FDA which proposed a qualified health claim characterizing the relationship between the consumption of whole grains and a reduction of the risk of Type II Diabetes. The FDA accepted the petition and, following the public comment period, reviewed comments from eleven different submissions from industry, academia, food and health organizations, and individual consumers. As explained in its letter, a copy of which is included on the CD, the FDA determined that the current evidence supported a qualified health claim in the labeling of whole grain containing conventional foods concerning the relationship between whole grains and Type II Diabetes.

In justifying its position, the FDA noted it relied not only upon the material submitted by ConAgra, but numerous other sources of data and studies focusing on the scientific issues about the substance, the disease in reviewing the health claim and as background about the substance – disease relationship. The report went on to provide a summary of the various studies and analyses that had been relied upon by the FDA from various sources in conducting its analysis. In addition, the FDA also reviewed information as part of the development of the Dietary Guidelines For Americans issued in 2010 by the USDA. Based on that information, the Dietary Guidelines information justified a lowest grade of evidence assigned by the Dietary Guidelines.

Upon completing its review, the FDA announced it agreed with the Dietary Guidelines For Americans that the limitations of the evidence suggesting a relationship between whole grain intake and reduced risk of Type II Diabetes justified the lowest grade for strength of evidence. Based on this the FDA concluded that there was "very limited credible evidence for a relationship between whole grain consumption and reduced risk of Type II Diabetes." In sum, the FDA intends to consider exercising its discretion for the following qualified health claims:

1. "Whole grains may reduce the risk of Type II Diabetes, although the FDA has concluded there is very limited scientific evidence for this claim."

2. "Whole grains may reduce the risk of Type II Diabetes. FDA has concluded that there is very limited scientific evidence for this claim."

TYLENOL BOTTLES TO CONTAIN NEW LABELS

Starting this month, Tylenol now has its bottles labeled on the cap with the words "Contains Acetaminophen" and "Always Read The Label" in bold letters. This is designed to alert Tylenol users of the potentially fatal side effects caused by liver damage. The goal of the new labeling is to encourage people who normally don't read the warning labels not to miss them. According to the Center for Disease Control and the FDA, at least five hundred people die each year as a result of overdosing on Acetaminophen. It is used in over six hundred other types of over the counter products including popular brands such as Nyquil cold medicine and Sudafed sinus medication. This evolved out of a class action lawsuit that was consolidated in April of this year in the Federal District Court in the Eastern District of Pennsylvania, where the maker of Tylenol, Johnson & Johnson, is defending some eight-five lawsuits alleging that the pain reliever is responsible for liver injuries and death. The lawsuits alleged that Johnson & Johnson failed to adequately warn about the risk of liver damage or liver failure associated with the pain medication. The FDA is in the process of drafting new safety measures that could potentially limit the strength of various Acetaminophen-containing products.

CHOCOLATE MAKERS CLASS ACTION LAWSUIT IN CANADA SETTLED

In September it was announced that Mars and Nestle had opted to settle and resolve a class action lawsuit filed in 2008 by the Canadian Competition Bureau, alleging that they and numerous other chocolate manufacturers, along with Hershey, Cadbury and Canadian National

Distribution Network ITWAL, Ltd., had conspired to fix prices of their products in Canada. Settlement of this class action, however, does not get Nestle and Mars Canada out of the courthouse, since both companies are still facing criminal charges from Canada's Competition Bureau. The allegations are that the pricing fixing scheme was started between various company executives dating back to the summer of 2007. When Hershey settled out of the case, it admitted, as part of the settlement, that it had conspired to arrange to fix the price of chocolate in Canada in 2007.

CLASS ACTION SETTLEMENT BY CARGILL OVER ALLEGATIONS OF MISLEADING SHOPPERS

Cargill has entered into a potential settlement of a class action lawsuit which alleged it was misleading consumers by marketing its Truvia consumer product as "natural." The lawsuit was filed in Federal Court in Minnesota by two plaintiffs, alleging that they could certify a class of people who were misled by statements on the labels describing the Truvia consumer products and their ingredients, including Stevia Leaf Extract and Erythritol as "natural." The plaintiffs alleged that the consumer products from Truvia were not natural because they contained ingredients that were highly processed or derived from genetically modified organisms, and that the descriptions violated the Minnesota Prevention of Consumer Fraud Act, Minnesota's Unlawful Trade Practices Act, the State's Deceptive Trade Practices Act and False Advertising Statute. The plaintiffs sought damages and injunctive relief and sought to represent one class of Truvia product consumers from California, as well as other multi-state consumers. The proposed settlement recites the claims by the plaintiffs under both Minnesota and California laws, as well as reliance upon various states' breach of warranty laws regarding the advertising, labeling and marketing of Cargill's Truvia consumer products.

In response to the lawsuit, Cargill has denied and continues to deny that it violated any of the alleged statutes relied upon by the plaintiffs or that their marketing, advertising or labeling of the products was false, deceptive or misleading to consumers. The resulting settlement agreement came out of a summer long effort to mediate the matter under the supervision of a retired federal judge. Cargill agreed to the class action being certified by the Court solely for the purpose of resolving all the claims on a single class basis. A copy of the settlement agreement, which runs about seventy-three pages, is included on the CD. As part of the resolution of the case, Cargill is creating a five million dollar fund to cover either cash refunds or vouchers for consumers who bought selected Truvia products. The resolution of this case would resolve claims that have been brought in other states against Cargill with the same types of allegations.

Cargill also agreed, as part of the agreement, to make some modifications to its labeling. It also agreed to update its website to address the GMO issue. Specifically, in response to a question "Does Truvia Natural Sweetener contain GMO?" "Is it genetically modified?", the website will now state as follows: "No. Truvia Natural Sweetener is not GMO, and does not contain any genetically modified ingredients." It will also go on to say that: "Although genetically enhanced corn and non-transgenic corn are grown in the US today, Erythritol is not derived from corn or dextrose feed stock; it is derived from the yeast organism. Erythritol is not genetically modified, and does not contain any genetically modified proteins."

FOOD LABELING MODERNIZATION ACT OF 2013

Congressman Frank Pallone of New Jersey, Congresswoman Rose Delauro of Connecticut and Richard Bloomenthal of Connecticut have co-sponsored this legislation, a copy of which is included on the CD. The Bill would require the FDA to establish a front of the package nutrition labeling system for all products, make ingredient labels easier to read, and

make firms label any added sugar or caffeine on the product. The legislation also says that manufacturers should not describe products as "natural" that contain artificial ingredients or ingredients that have undergone "chemical changes", such as chemically modified starch, cocoa process with alkali, or corn syrup. The legislation, however, does not make any reference to labeling with regard to genetically modified organisms. The proposed legislation would also address what are commonly referred to as "healthy claims" with regard to foods containing grains or whole grains. It would require listing calories on a per serving basis; it would require disclosing caffeine levels containing more than ten milligrams of caffeine per serving; and also disclose whether there are any trans fats in any product. At this point it is too early to predict whether this legislation has any chance of moving through the Congress.

FDA ANNOUNCEMENT REGARDING GLUTEN LABELING

As of August 5, 2014, manufacturers using the term "gluten free" on food labels, must adhere to new regulations issued by the FDA that set a gluten limit at 20 parts per million. The parties have been following a draft set of regulations that had been issued by the FDA dating back to 2007. The regulation also requires foods where the labeling claims "free of gluten", "without gluten" or "no gluten" to meet the definition for "gluten-free." The FDA rule stated that the proposed level at 20 parts per million was low enough; the agency found that it would be far more difficult for manufacturers to make food products that could be labeled as gluten-free, thus reducing food choices for individuals with Celiac Disease.

J.M. SMUCKERS LITIGATION

This is one in a series of cases that has been brought in the state of California where plaintiffs have been seeking to certify a class action, claiming that various types of labels, especially those making claims regarding "natural" ingredients, may be violative of various state

laws or involve issues concerning GMO's. In this case, Smuckers sought to dismiss the case filed in the Federal District Court in the Northern District of California, where the allegation is that the plaintiffs purchased various types of vegetable oil, canola oil, corn oil or natural blend oil on which the label "all natural" is next to the oil's name on the packaging. The plaintiffs allege this is not the case and that the products in question include genetically modified crops. Plaintiffs allege violations of California's Consumer Legal Remedies Act; unfair competition law; and breach of express warranty. Smuckers sought to dismiss the lawsuit on the grounds that the pleadings were insufficient in detail to justify the lawsuit and that the plaintiff does not explain how the manufacturing process renders the oils "chemically altered" as alleged in the complaint. Smuckers also tried to argue that the claims should be pre-empted because they conflict with FDA policies on bioengineered foods and Federal food labeling regulations. The Court denied the motions to dismiss the various counts of the complaint. The Court concluded that "it cannot as a matter of law conclude, as the defendant urges, that reasonable consumers would all understand that packaged, non-organic foods may contain bioengineered ingredients and that the only way to avoid such ingredients completely is to buy only certified organic products. Plaintiffs has alleged that a reasonable consumer would read the "all natural label, assume that such a product contained no bioengineered or chemically altered ingredients, and would then be misled if the product did in fact contain such things". The Court found that "since the reasonable consumer issue cannot be resolved as a matter of law at this point", the plaintiff had sufficiently stated enough of a claim to proceed and the motion was denied as to the statutes from California. The Court also found the plaintiff had alleged sufficient facts to make out a claim for breach of express warranty because of the label.

LYON RICHARDS V. SAFEWAY

In a lawsuit filed on September 18, 2013, Safeway was sued as part of a class action being brought where the plaintiffs were seeking to certify a class action involving the purchase of "Open Nature 100% Natural Multi-Grain Waffles and Open Nature 100% Natural Home Style Waffles". The plaintiffs allege the advertising and labeling was misleading because the products contain sodium acid pyrophosphate, which is a commonly used preservative. The plaintiffs are seeking a certification of a class action for both California residents under state law, and national class for anyone who purchased the products from September 18, 2009 going forward. A copy of the complaint and jury demand is included on the CD.

MONIQUE MANCHOUCK V. MONDELEZ INTERNATIONAL A/B/A NABISCO

In this case, the plaintiff sought to certify a class action, claiming that there was misinformation in the labeling on Newton cookies, because the strawberry and raspberry type cookies were filled with fruit puree, which she alleged is not "real fruit". Apparently the label on the cookie package said that the cookies were "made with real fruit". Plaintiff sought to certify a class action based on allegations that Nabisco violated the California Business and Professions Code, engaged in unfair fraudulent business practices, unlawful business practices, false and misleading advertising. Mondelez/Nabisco succeeded with a motion to dismiss the case; the Court found that the plaintiff had failed to state a claim as alleged. The Court held that "plaintiff has not plausibly alleged by the statement 'made with real fruit' would not include mechanically separated fruit puree". The Court ruled that this decision agrees with the numerous decisions that have dismissed similar food labeling claims at the pleading stage. The Court said in one case where the word "apple" was used on an apple straw product that contained pureed apples was cited as precedent; that case, Sensible Foods v. World Gourmet, was decided in the Northern

District of California in February 2012. The Court found that the claims made by the plaintiff strained credibility. The Court noted that the complaint failed to dispute that the cookies contained real fruit in puree form, that even the most narrow definition of "real fruit" does not exclude fruit that has been strained or blended in pureed form. The Court also noted that the amended complaint admitted that the list of ingredients on the package serves notice to consumers that the products contain both raspberry puree and strawberry puree. The Court even went so far as to state as follows: "It is ridiculous to say consumers would expect snack food 'made with real fruit' to contain only actual strawberries or raspberries", rather than these fruits in a form amenable to being squeezed inside a Newton". The Court even went so far as to deny the plaintiff leave to file yet another amended complaint.

FRITO LAY LITIGATION

Pepsico is the target of an attempt to certify a class action by purchasers of various Tostitos, Sun Chips, Frito's bean dip products, again claiming that the "all natural" label that was on these products violates various laws, including taking a national class action; they allege violations of the Magnuson Moss Warranty Act; and various common laws of both California and New York. They were also seeking to have certification for a class of Florida residents since one of the plaintiffs was a state resident. There were a total of 13 causes of action named in the complaint. The Court found that, as filed, the first amended complaint failed to allege sufficient facts to support liability against Pepsico. The Court also dismissed certain claims under New York law, but gave the plaintiff the opportunity to refile the complaint with the intentional misrepresentation claims based on California and Florida law. A copy of the Court's ruling is on the CD.

ELIZABETH COX V. GRUMA CORPORATION

This is another attempt at a class action suit, again in the Northern District of Federal Court in California, where the allegation is that the plaintiffs purchased products made by Gruma, specifically all natural tortilla triangles, that had the "all natural" label on it. In a surprising ruling, the judge, Yvonne Gonzalez Rogers, stayed the action for six months pending a review of the issues raised by the Federal Food and Drug Administration ("FDA"). The FDA was not a party to the case. This was something done by the judge to seek guidance from the FDA with regard to food labeling enforcement. The Court noted that the parties were in agreement that the FDA has not addressed, even informally, the question of whether foods containing genetically modified organisms or bioengineered ingredients may be labeled as "natural" or "all natural" or whether GMO or bioengineered ingredients would be considered artificial or synthetic. The Court found that under the circumstances, deference to the FDA's regulatory authority was the appropriate course of action. This Court ruling is clearly contrary to the numerous cases that are being brought out in California and at this point there is no prediction as to how there will ever be a reconciliation between the two, especially since many of these claims are being brought in part based on alleged violations of state laws rather than Federal.

STATE OF WASHINGTON BALLOT INITIATIVE ON GMO's

The state of Washington has a ballot measure to be put before the voters in November that would require new disclosures on foods produced through genetic engineering. It has strong national interest as many companies in the food industry have spent millions in an effort to defeat this ballot initiative. A copy of the ballot initiative is on the CD. If adopted, it would go

into effect on July 1, 2015. It would require the words "genetically engineered" be stated clearly and conspicuously on the front of the package of any food offered for retail sale. It also provides that in the case of any processed food, on the front of the package of the food the label "partially produced with genetic engineering" or in the alternative "may be partially produced with genetic engineering" must be stated clearly and conspicuously. It also provides enforcement mechanisms for the state which would allow civil penalties to be assessed, as well as allowing private citizens to bring such an action after giving 60 days advance notice to the State Attorney General and the alleged violator. And, of course, any prevailing plaintiff would be allowed to recover court costs and legal fees.

FLAVORS AND ELECTRONIC CIGARETTES

As of now, the FDA has yet to issue regulations regarding electronic cigarettes. In the absence of regulations from the FDA, at least 12 states have passed statutes limiting their sale or prohibiting their sale to minors. Previously the FDA had tried to classify electronic cigarettes as drug delivery devices and subject them to regulation under the Food Drug and Cosmetic Act before importation and sale into the United States. This effort was successfully challenged in Court, under a ruling by Federal District Court Judge Richard Leon in January 2010. The Court held that the devices should be regulated as tobacco products rather than as drug or medical products. The Court specifically ordered the FDA to end its blocking of the importation of the electronic cigarettes from China and indicated the devices should be regulated as tobacco products rather than medical devices. The FDA was unsuccessful in appealing this ruling to the US Court of Appeals for the District of Columbia, which issued a unanimous decision in December 2010, again ruling the FDA could only regulate electronic cigarettes as tobacco products, and thus could not block their import.

On a related note, a statement has been issued by the Flavor and Extract Manufacturers Association on the safety assessment and regulatory authority to use flavors regarding electronic cigarettes. The statement noted that there is no apparent direct regulatory authority in the United States to use flavors in products like e-cigarettes that involve inhalation exposure. The statement also noted that none of the primary "safety assessment programs for flavors, including the GRAS Program sponsored by FEMA, evaluate flavor ingredients for use in products other than human food". The GRAS process for a flavor ingredient does not provide regulatory authority to use flavor ingredients in electronic cigarettes in the US. The statement also went on to note that the FEMA expert panel evaluates the safety of flavoring substances only under their conditions of intended use in human food, including drinks and chewing gum. To quote from the statement "The expert panel only evaluates flavor ingredients for exposure through ingestion. The expert panel does not evaluate flavor ingredients for use in tobacco products or other products that are not human food, or products that result in inhalation exposure or exposures other than by ingestion". A copy of the statement in included on the CD.

O'SHEA V. CAMPBELL SOUP COMPANY

On August 13th a complaint was filed in Federal Court in New Jersey by Kerry O'Shea and other plaintiffs seeking class certification against Campbell Soup Company and the American Heart Association alleging that both defendants allowed the misrepresentative labeling of "heart healthy" and the nationally recognized "heart-check mark" authorized by the American Heart Association to be misused and result in unfair, deceptive and misleading advertising. The allegation claims that the American Heart Association, for a fee, abandoned its non-commercial, dietary and nutritional guidelines agrees to certify as heart healthy products that merely meet the minimum standards for certain FDA regulated health claims, rather than the "more demanding

standards" of the American Heart Association. The plaintiff is a California citizen who resides in Huntington Beach. She allegedly purchased a number of different types of soup from Campbell's in numerous locations throughout Orange County, California from 2009 through 2013. The focus is on the amount of sodium in the product. It is alleged by the plaintiffs that Campbell's has purchased American Heart Association certification for at least 97 of its products, ranging from soups, juices, breads and sauces, and pays annual fees to maintain these certifications. In addition to seeking class action certification, the complaint alleges violations of the New Jersey Consumer Fraud Act, breach of express warranty, and unjust enrichment. The relief sought in the lawsuit asks for treble damages, restitution and disgorgement of all amounts wrongfully charged, and of course, legal fees and costs of suit. A copy of the complaint is included in the CD.

UPDATED DRAFT GUIDANCE FROM FDA ON MEDICAL FOODS

In August the FDA issued an updated version of its draft guidance for industry regarding medical foods. It updates an edition issued in May 2007, noting there are several new questions and answers and amended responses provided in the "frequently asked questions" portion of the document, a copy of which is included on the CD. The FDA considers the statutory definition of medical foods to narrowly constrain the type of product to fit within this category of foods. They are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or a condition. Medical foods are those that are specifically formulated and processed for a patient who is seriously ill or requires use of the product as a major component of a disease or condition for specific dietary management.

Medical foods are not considered drugs by the FDA and, as such, are not subject to those respective regulatory requirements. There is also a compliance program manual entitled "Medical Foods Program – Import and Domestic", which can be downloaded from the FDA website.

NOTICE FROM FDA ON USE OF BPA

In March the FDA issued an update regarding the use of BPA in various types of hard plastic bottles or metal based food and beverage cans. The summary, which is included on the disk, notes that the FDA is supporting actions by the industry to stop producing BPA-containing baby bottles and infant feeding cups for the United States market, facilitating alternatives to BPA for the linings of infant formula cans, and supporting efforts to replace or minimize BPA levels in other food can linings. The FDA noted that there are still ongoing studies being conducted by the Agency's National Center for Toxicological Research to produce information that should enhance the ability of the FDA to evaluate the safety of BPA.

EXHIBIT LIST

1. Petition for qualified health claim for whole grains and reduced risk of diabetes type II by ConAgra Foods

2. Ballot initiative in the state of Washington regarding the labeling of genetically modified foods

3. Copy of complaint – Molly Martin and Lauren Barry, et al. v. Cargill, US District Court for the District of Minnesota, filed September 19, 2013

4. House Resolution 3147 – Food Labeling Modernization Act of 2013

5. Copy of complaint and notice of tentative ruling in Elizabeth Cox, et al. v. Gruma Corporation, filed December 21, 2012, notice of tentative ruling dated June 11, 2013

6. In RE: Frito Lay North America, Inc. all natural litigation, US District Court, Eastern District of New York, order issued by the Court August 29, 2013

7. Monique Manchouck v. Mondelez International a/k/a Nabisco, order granting defendant's motion to dismiss September 26, 2013

8. Ryan Richards, et al. v. Safeway, class action complaint filed in US District Court, Northern District of California, September 18, 2013

9. Diana Parker v. J.M. Smuckers, US District Court, Northern District of California, order denying motion to dismiss lawsuit dated August 23, 2013

10. Correspondence from the USFDA to the Electronic Cigarette Association dated September 8, 2010 regarding efforts at regulating electronic cigarettes

11. Statement issued by Flavor and Extract Manufacturer's Association entitled "Safety Assessment and Regulatory Authority to Use Flavors: Focus on E-Cigarettes"

12. Complaint filed in US District Court of New Jersey by Kerry O'Shea and others v. Campbell Soup Company and American Hearth Association, filed August 13, 2013

13. Draft guidance for industry: frequently asked questions about medical foods, revised August 2013 by the USFDA

14. Updated news and events statement from the USFDA, updated March 2013 regarding the use of bisphenol A ("BPA")

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