Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Obama to Appoint Key Food Safety Official

President Barack Obama (D) recently announced his intention to "recess appoint" Elisabeth Hagen as the U.S. Department of Agriculture's (USDA's) under secretary for food safety. According to a White House press release, Hagen is among four key administrative nominees who have waited an average of 303 days for Senate confirmation. Obama said he chose to appoint all the nominees while Congress was away on its August recess in accordance with his "authority to do what is best for the American people. At a time when our nation faces so many pressing challenges, I urge members of the Senate to stop playing politics with our highly qualified nominees and fulfill their responsibilities of advice and consent."

Hagen is currently the USDA's chief medical officer and senior executive within USDA's Food Safety and Inspection Service. USDA Secretary Tom Vilsack was quoted as saying that Hagen's background "will enable her to successfully lead the effort to develop and execute the agency's scientific and public health agenda, and continue to build the coordination with public health partners at federal, state, and local level[s] needed to achieve the objectives of President Obama's Food Safety Working Group." *See White House Press Release* and *USDA Press Release*, August 19, 2010.

House Members Seek Documents, Schedule Hearing on Tainted-Egg Recall

Representative Rosa DeLauro (D-Conn.), who chairs the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) appropriations subcommittee, is **seeking** information from the agencies about the unfolding *Salmonella* outbreak linked to two Iowa egg producers. Representatives Henry Waxman (D-Calif.) and Bart Stupak (D-Mich.) have also stepped into the massive egg recall, **requesting** information from the same agencies and **demanding** documents and information from the egg company owners. Stupak's oversight subcommittee of the House Committee on Energy and Commerce has scheduled a September 14, 2010, hearing into the matter and has apparently invited Wright County Egg owner Austin "Jack" DeCoster and Hillandale Farms owner Orland Bethel to testify.

More than a half-billion eggs, representing less than 1 percent of the U.S. egg supply, have been recalled after an upswing in *Salmonella* cases came to the attention of state regulators and the Centers for Disease Control and Prevention beginning in May. FDA has reportedly confirmed that the same strain sickening

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more than 1,500 consumers in some 22 states has contaminated the two Iowa farms, locating the bacterium in two barns at Wright County Egg and in feed the company produces for its own chickens and supplies to Hillandale. According to a news source, agency officials are not certain how the feed or barns became contaminated, although they apparently suspect that the chicken feed is the source. An FDA official was quoted as saying, "This contamination can come in through numerous routes—including rodents, shared equipment, workers—so we are looking into all those possibilities in our investigation."

The eggs that continue to be produced at the facilities will reportedly be sold as liquid eggs for use in cookies, cakes, egg substitutes, and pet food. Because liquid eggs are pasteurized, the *Salmonella* bacteria are destroyed, and animal science experts say they are safe to eat.

Meanwhile, plaintiffs' lawyer William Marler has already filed two lawsuits against Quality Egg, LLC, one of DeCoster's egg-producing companies. One suit involves an 11-year-old California girl who was allegedly hospitalized after consuming eggs in early July; the other was filed on behalf of a Wisconsin woman. Marler has reportedly indicated that his firm may already have 30 viable cases linked to the egg recall and is considering filing litigation in federal court in Iowa and consolidating the claims.

News articles about the outbreak have proliferated, covering (i) the fragmented nature of egg and poultry regulation in the United States and the fact that FDA had never once visited the suspected Iowa facilities; (ii) egg industry concentration, which has reduced the number of producers from 2,500 in 1987 to just 192 today that own some 95 percent of U.S. laying hens, a circumstance contributing to the potential for widespread outbreaks; (iii) the need for the enhanced FDA authority contained in food safety legislation currently languishing in the Senate; (iv) potential impact on exports to Russia, which only recently reopened its borders following a dispute over U.S. poultry meat processed in chlorine solutions; (v) the efficacy of chicken vaccinations that have purportedly drastically reduced the incidence of *Salmonella* outbreaks in Great Britain; (vi) doubts among FDA scientists that the agency can adequately protect consumers from food-borne illness in eggs; and (vii) egg-production practices that some consider inhumane and conducive to contamination.

A number of news outlets have also revealed in recent days that DeCoster has an alleged history of flouting employment, immigration, environmental, and health and safety laws. The Occupational Safety and Health Administration reportedly fined DeCoster $3.6 million in 1996 after finding workers "many of whom are immigrants from Latin America, handling manure and dead chickens with their bare hands, and living amid rats and cockroaches in the company's trailer park." He also apparently paid $5 million in 1999 to settle a class-action lawsuit alleging unpaid overtime for thousands of workers and paid $2.1 million in 2003 for hiring 100 undocumented immigrants. He has not evidently indicated whether he will appear before Congress, but a company spokesperson has said that the company is working to respond to the requests for information. Hinda Mitchell was quoted as saying, "We will approach it in

the same forthright manner as we have in our cooperation with FDA to date." *See OMB Watch*, August 20, 2010; *Christian Science Monitor,* August 22, 2010; *DeLauro Press Release*, August 23, 2010; *Committee on Energy and Commerce Press Releases*, August 23 and 25, 2010; *The Wall Street Journal*, August 23 and 26, 2010; *The New York Times, The Los Angeles Times, Food Safety News, The Pump Handle, Slate.com*, August 24, 2010; *The Washington Post, meatingplace.com*, August 24 and 26, 2010; *AlterNet, msnbc.com*, August 25, 2010; *The Hill, La Vida Locavore, Agency France Presse*, August 26, 2010.

FDA to Hold Public Consultations for GE Salmon

The Food and Drug Administration (FDA) has announced two public meetings to consider the labeling of food derived from genetically engineered (GE) salmon. During the first **meeting** slated for September 19-20, 2010, the Veterinary Medicine Advisory Committee will address general scientific issues surrounding GE animals, statutory and regulatory constraints, and "a new animal drug application (NADA) concerning AquAdvantage salmon produced by AquaBounty Technologies, Inc.," which has inserted Chinook and ocean pout genes into Atlantic salmon to accelerate maturation.

In addition, FDA has called a September 21, 2010, public **hearing** to explain "the relevant legal principles for food labeling and to solicit information and views from interested persons on the application of these principles to food derived from AquAdvantage Salmon." FDA has specifically invited participants to consider the following: (i) "Which facts about the AquAdvantage Salmon seem most pertinent for FDA's consideration of whether there are any 'material' differences between foods from this salmon and foods from other Atlantic salmon[?]"; and (ii) "If FDA determined there are 'material' differences, how would that difference be described on a food label in a way that is truthful and nonmisleading[?]." The agency has further noted that information about changes "in the attributes of the food itself, such as its nutritional value, functional properties (e.g., storage), and 'organoleptic' qualities (e.g., texture and aroma) could be material." FDA will accept comments on the hearing until November 22, 2010. More information about the NADA process for AquAdvantage salmon appears in **background** documents provided by FDA as well as **Issue 355** of this *Update*. *See FDA Press Release* and *Federal Register,* August 26, 2010.

Because it is the first GE animal to undergo FDA review, AquAdvantage salmon has long attracted attention from several media outlets. In particular, *The Guardian* recently registered the concern of some critics who deem the product "frankenfish." Among those campaigning against the technology, the International Salmon Farmers Association has expressed reservations that FDA approval "will undermine the popularity of salmon, which commands high prices in the U.S." *See UPI.com,* August 23, 2010; *The Guardian,* August 25, 2010.

FDA Issues Draft and Final Guidance for Menu Labeling Laws

The Food and Drug Administration (FDA) has released **draft** and **final** guidance to assist restaurateurs and vending machine operators in implementing

the labeling provisions set out in section 4205 of the Patient Protection and Affordable Care Act of 2010. The Act requires food retail establishments with 20 or more locations to post the calorie content for standard items on menus and menu boards; provide additional nutrition information in writing; and post calorie information for self-serve items and foods on display. The draft **document** offers proposed guidance on the execution of these standards, while the **final** explains the impact of the federal measure on state and local laws.

According to an August 24, 2010, FDA press release, the agency "realizes that industry may need additional information and time to comply with the new provisions, and that the agency expects to refrain from enforcement action for a time period that will be provided in the guidance once it is finalized." FDA will accept comments on this timeline and the draft guidance until October 12, 2010. *See Federal Register,* August 25, 2010.

FDA Advises Consumers to Discard Fruit Pulp on Typhoid Outbreak Fears

Linking a *Salmonella Typhi* outbreak to frozen mamey fruit pulp, the Food and Drug Administration (FDA) has urged consumers to discard La Nuestra® or Goya® fruit products in their possession and find out what brand is in use by street vendors before purchasing the mamey fruit-based juices and fruit shakes they sell. At least nine consumers in California and Nevada have apparently developed typhoid fever from the outbreak. FDA has also indicated that it will increase its border sampling to prevent contaminated product from entering the United States. *See Product Liability Law 360*, August 20, 2010.

USDA Approves Continued Methionine Use in Organic Poultry Production

The U.S. Department of Agriculture's National Organic Program (NOP) has issued an interim final **rule** that extends until October 1, 2012, the allowance for methionine in organic poultry production. Effective October 1, 2010, the interim rule allows organic operations to use synthetic methionine at the following maximum limits per ton of poultry feed: (i) four pounds for laying chickens; (ii) five pounds for broiler chickens; and (iii) six pounds for turkeys and all other poultry.

According to an August 24, 2010, press release, the National Organic Standards Board (NOSB) in April 2010 called for amending the National List of Allowed and Prohibited Substances to permit the continued use of synthetic methionine, an amino acid essential for poultry health and development, because its prohibition would "cause substantial economic hardship" for producers. In addition, NOSB has recommended extending the allowance beyond October 1, 2012, to October 1, 2015, while decreasing "the maximum level of synthetic methionine permitted per ton of feed ration to the following levels: 2 pounds for laying and broiler chickens, and 3 pounds for turkeys and all other poultry." The board has also urged NOP to consider extensions beyond October 1, 2015, as part of its sunset review process rather than via petition.

NOP has indicated its intention to issue subsequent rulemaking on the above recommendations for the October 1, 2012, to October 1, 2015, period. It will

accept comments on the current interim rule until October 25, 2010. *See Federal Register,* August 24, 2010.

LITIGATION

Court Approves $50 Million Settlement of Claims Against Bankrupt Diacetyl Defendant

A New York bankruptcy court will reportedly allow Chemtura Corp. to resolve 90 percent of the respiratory disease claims pending against it for $50 million, or one-third of the $150 million sought by factory workers allegedly exposed to the popcorn-flavoring ingredient diacetyl. *In re: Chemtura Corp.*, No. 09-11233 (Bankr. S.D.N.Y., settlement approved August 23, 2010). Responding to claims by co-defendants that the settlement may not meet "good faith" requirements, the court reportedly indicated that it was "within the range of reasonableness."

The settlement will apparently resolve 15 lawsuits and 347 proofs of claim filed by individuals alleging personal injury from diacetyl exposure. The company has indicated that eight additional individual and five corporate diacetyl claims remain pending. According to a news source, the company has also reached an agreement with its insurers to cover half the cost of the settlement and provide up to a maximum of $10 million to indemnify any other diacetyl claim settled or litigated in the future.

The company apparently filed for bankruptcy in 2009, facing debts exceeding $10 billion, most of which involve government environmental claims. The U.S. Department of Justice reportedly announced on August 24, 2010, that the company has agreed to pay $26 million to clean up 17 contaminated sites in 14 states. The company is planning to emerge from bankruptcy by the end of September, after receiving permission from the court to incur about $1 billion in new debt as part of its Chapter 11 plan. *See Bloomberg*, August 9, 2010; *Product Liability Law 360*, August 23 and 26, 2010; *Reuters*, August 24, 2010.

Florida Consumers Bring Fraud Claims Against EVOO Companies

A putative class alleging that the extra virgin olive oil sold in the United States does not meet the "extra virgin" standard has filed consumer fraud claims against several of the largest importers of the product in a state court in Florida. *Nachio v. Am. Rice, Inc.*, No. 10-33154 (Cir. Ct., 17th Jud. Cir., Broward County, Fla., filed August 13, 2010). Like the plaintiffs in a class action filed in California, named plaintiff Joseph Nachio refers to the June 2010 extra virgin olive oil study conducted by University of California at Davis's Olive Oil Center researchers who concluded that the defendants' products are not "extra virgin" olive oil. Additional information about that litigation appears in **Issue 359** of this *Update*.

Nachio contends that the time-sensitive process required to produce extra virgin olive oil makes it impossible for defendants to sell the quantities they do, and that they sell true extra virgin olive oil solely in countries where "consumers have a longer history of consuming extra virgin olive oil and have a taste pallet

that commands only this true high quality product." Alleging that the products, which are actually "rancid or adulterated olive oil," are sold at a premium price, the plaintiff seeks to "recover the benefit of the bargain for himself and the class." He claims that the defendants "do not respect the American olive oil taste pallet as a whole and bank on the fact that Americans cannot discern between rancid or adulterated olive oil and true extra virgin olive oil."

The complaint lists a number of actions taken by government authorities around the world since 1993 after certain olive oils were found to be fake, including a Food and Drug Administration recall of olive oils found to be canola oil, and arrests and product confiscation in Italy after the discovery of a scheme to re-label oil from other countries as Italian. Seeking certification of a statewide class, the plaintiff alleges violations of the Florida Deceptive and Unfair Trade Practices Act and breach of express warranty. The complaint alleges individual damages less than $75,000 and contends that the action is not removable to federal court under the Class Action Fairness Act. The plaintiff seeks restitution, disgorgement, injunctive and declaratory relief, a corrective advertising campaign, attorney's fees, and costs.

Salmonella Litigants Close to Settling Claims Against Peanut Corp.

A magistrate judge has reportedly recommended that the trustee in bankruptcy for the Peanut Corp. of America (PCA), responsible for a *Salmonella* outbreak linked to nine deaths and hundreds of illnesses, distribute $12 million to resolve the tort claims of 120 individuals. The deal, which must be approved by a U.S. district court, involves insurance funds provided by Hartford Casualty Co. in 2009 and will apparently be supplemented by additional undisclosed funds from Kellogg Co. Virginia-based PCA recalled its peanut products and closed plants in Georgia and Texas following an outbreak that also led to a massive recall of processed foods containing the company's peanut paste, such as snack products, cookie dough, granola bars, and dog biscuits. *See Product Liability Law 360*, August 26, 2010.

Chinese Officials Arrest Dairy Personnel in New Melamine Contamination Scandal

After Chinese food safety authorities recently found milk powder laced with melamine, police have reportedly arrested three officials from the Dongyuan Dairy Factory in Qinghai province and three dairy suppliers from Hebei province. Another 41 suspects have apparently been detained. More than 225 tons of contaminated milk powder have been seized, and authorities believe it is left-over from the batches of melamine-tainted milk powder that should have been destroyed in 2008 when a massive contamination scandal sickened more than 300,000 children and was linked to the deaths of six infants. Producers added melamine to milk powder to increase its protein content, but the required protein level in dairy products has since been reduced to discourage the use of additives.

According to a press report, investigators are seeking evidence that local oversight authorities may have been derelict in their duties and will punish

those found responsible. Chinese consumers have reportedly lost confidence in domestic dairy products; imports have apparently skyrocketed despite increases in their cost. *See China Daily*, August 23, 2010.

OTHER DEVELOPMENTS

IOM Workshop to Target Legal Strategies for Preventing Childhood Obesity

The National Academies' Institute of Medicine Standing Committee on Childhood Obesity Prevention will convene a public **workshop** on October 21, 2010, in Washington, D.C., to "highlight the evidence on current and potential legal strategies and their outcomes" in the prevention of childhood obesity. The gathering of researchers, policy makers, legal scholars, industry representatives, and public health advocates will discuss (i) "current legal strategies in use at national, state, and local levels and their outcomes"; (ii) "other public health initiatives that have used legal strategies to elicit societal and industry changes"; (iii) "the challenges involved in implementation"; (iv) "when legal strategies are needed and effective"; and (v) "opportunities for coordination and sharing information on the success of existing and future legal strategies."

Sweetener's Ad Claims Could Mislead, Says Advertising Review Board

The National Advertising Review Board (NARB) has reportedly recommended that Heartland Sweeteners cease advertising its Ideal® sweetener as "more than 99 percent natural," after finding that the claim could be misleading to consumers. The board, an appellate arm of the advertising industry's self-regulatory system, apparently agreed with the National Advertising Division of the Council for Better Business Bureaus that the message conveyed by Heartland's advertising is that most of the product's sweetness comes from natural ingredients, when, in fact, the ingredient responsible for 80 percent of its sweetness is the artificial sweetener sucralose.

The company issued a statement indicating that it "respectfully disagrees with the NARB's decision and maintains that its 'more than 99 percent natural' claim is clear, truthful and not misleading." Less than 1 percent of the sweetener consists of sucralose. Still, the company has reportedly indicated that it is reviewing its advertising and packaging and will take the board's decision into account "because it supports advertising self-regulation." According to a news source, the advertisement review proceedings stemmed from a complaint submitted by Merisant Company, a Heartland rival. *See Foodnavigator-usa.com*, August 25, 2010.

GM Crops Provoke Passions in Italian Countryside

An Italian agronomist, frustrated by the government's refusal to approve the planting of genetically modified (GM) crops, has apparently engaged in an act of civil disobedience by planting two fields of GM corn and publicizing his action with a news conference and YouTube® video. Environmentalists report-

edly responded by descending on the fields near Vivaro, which had been seized by government officials; Greenpeace activists cut off the tassels in an effort to prevent the dissemination of pollen, and environmentalists with Ya Basta trampled the crop leaving signs stating "Danger—Contaminated—G.M.O."

According to a news source, while the European Union has approved the use of this particular seed, Italy requires farmers to submit any request to plant GM crops for government approval. To date, the Ministry of Agriculture has not apparently approved any GM crop for planting. The GM debate is particularly heated in Italy, where farmers are known for their specialized organic and heritage crops. They are reportedly concerned about cross contamination and the loss of their crops' organic designation and unique flavor. The rebellious agronomist, who may face a prison sentence or fine, has claimed that an army of Italian farmers is prepared to plant GM corn to force the government into addressing the corn borer problems plaguing conventional crops. Those who damaged the crop are also facing criminal penalties. *See The New York Times*, August 23, 2010.

SCIENTIFIC/TECHNICAL ITEMS

Researchers Allege BPA Linked to Increased Levels of Testosterone, Other Health Effects

Two recent studies have linked bisphenol A (BPA) to hormonal changes in men and genetic changes in female mice. Researchers in the first instance analyzed urine samples from 715 participants ages 20 to 74 enrolled in an Italian population study, measuring average daily exposure to BPA at approximately 5 micrograms. Tamara Galloway, et al., "Daily Bisphenol A Excretions and Associations with Sex Hormone Concentrations: Results from the InCHIANTI Adult Population," *Environmental Health Perspectives,* August 2010. Although these levels were in line with other surveys, the results also showed that "higher daily BPA excretion was associated with higher total testosterone concentrations in men." According to the authors, their findings are significant "because they provide a first report in a large-scale population of associations between elevated exposure to BPA and alterations in circulating hormone levels."

In addition, a second study has reportedly found evidence that low doses of BPA altered gene expression in fetal mouse ovaries. **Crystal Lawson, et al., "Gene Expression in the Fetal Mouse Ovary is Altered by Exposure to Low Doses of Bisphenol A," *Biology of Reproduction*, August 2010**. After dosing pregnant mice with BPA levels equivalent to those found in humans, researchers purportedly observed "modest but significant changes in gene expression in the fetal ovaries from exposed fetuses." They also noted that "the first changes were evident within 24 hours of exposure, and the most extensive changes correlated with the onset of meiosis," suggesting that later offspring produced by the grown fetus might be "chromosomally abnormal." *See e! Science News,* August 24, 2010.

Meanwhile, the Swedish Ministry of the Environment recently asked the Swedish National Food Administration and the Swedish Chemicals Agency to propose a national ban on BPA in baby bottles and other plastic products. As stated in a July

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 362 | AUGUST 27, 2010

29, 2010, press release, the government has decided to act in absence of a decision from the European Food Safety Authority, citing similar steps taken by Denmark and France. "A ban for the EU's 500 million inhabitants would of course have a greater impact than a ban for the 9 million people living in Sweden. But the process is too slow," Environment Minister Andreas Carlgren was quoted as saying. "It is unacceptable that young children are exposed to the risks that have been proven to be associated with bisphenol A, especially when changing to alternative materials is easy. This is why we are now making the first move by preparing a national ban."

Prenatal Pesticide Exposure Allegedly Tied to Attention Problems in Young Children

A recent study has alleged a relationship between prenatal exposure to certain widely used pesticides and an increased risk of attention problems in preschool-age kids. Brenda Eskenazi, et al., "PON1 and Neurodevelopment in Children from the CHAMACOS Study Exposed to Organophosphate Pesticides *in Utero*," *Environmental Health Perspectives*, August 19, 2010. Researchers at the University of California, Berkeley, School of Public Health collected urine samples twice during the pregnancies of more than 300 Mexican-American women in agricultural communities and later evaluated their children at ages 3½ and 5 for symptoms of attention disorders. They concluded that prenatal organophosphate metabolite levels were "significantly linked" to attention troubles by age 5, especially among boys.

"These studies provide a growing body of evidence that organophosphate pesticide exposure can impact human neurodevelopment, particularly among children," co-author Brenda Eskenazi said in a UC Berkeley press statement, adding that the results warrant precautionary measures when handling food exposed to pesticides. "I would recommend thoroughly washing fruits and vegetables before eating them, especially if you're pregnant," she said. *See UC Berkeley Press Release*, August 19, 2010.

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