FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 561 | APRIL 10, 2015

SHOOK HARDY & BACON

CONTENTS



## LEGISLATION, REGULATIONS AND STANDARDS

### Pathogens with Pandemic Potential Topic of Upcoming NSABB Meeting

The U.S. Department of Health and Human Services has **scheduled** a public meeting of the National Science Advisory Board for Biosecurity (NSABB) for May 5, 2015, in Bethesda, Maryland. Topics of discussion at the meeting will reportedly include (i) NSABB's **proposed framework** for guiding risk and benefit assessments of gain-of-function (GOF) studies involving pathogens and toxins deemed to have pandemic potential; (ii) the process of conducting the risk and benefit assessments; and (iii) the board's future deliberations on the GOF issue. Information about registration, webcast access and submitting comments is available on the National Institutes of Health **website**. *See Federal Register*, April 8, 2015.

### FDA Science Forum to Target Role of Scientific Research in Regulatory Decision Making

The U.S. Food and Drug Administration (FDA) will **host** a public workshop titled "FDA Science Forum 2015" on May 27-28 in Silver Spring, Maryland. The focus of the event will be highlighting science conducted at FDA, the role that research plays in informing regulatory decision making and providing a forum for collaborations with external organizations. The agency's eight Regulatory Science priority areas include (i) ensuring FDA's readiness to evaluate innovative emerging technologies, (ii) implementing a prevention-focused food safety system and (iii) strengthening social and behavioral science to help consumers and professionals make informed decisions about regulated products. Registration information is available on FDA's **website**. *See Federal Register*, April 9, 2015.

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## FTC Complaint Targets Fast-Food Ads in "Family-Friendly" YouTube Kids App

A coalition of consumer groups led by the Center for Digital Democracy, Campaign for a Commercial-Free Childhood (CCFC) and Center for Science in the Public Interest have filed a **complaint** with the Federal Trade Commission (FTC), alleging that Google's YouTube Kids application mixes "advertising and programming in ways that deceive young children, who, unlike adults, lack the cognitive ability to distinguish between the two." According to the April 7, 2015, press release, the groups also claim that the app promotes several "branded channels" for fast-food and toy companies, as well as "user-generated segments" "that feature toys, candy and other products without disclosing the business relationships that many of the producers of these videos have with the manufacturers of the products, a likely violation of the FTC's Endorsement Guidelines."

Filed on behalf of these consumer groups by Georgetown Law's Institute for Public Representation, the complaint asks FTC to investigate whether the YouTube Kids app violates Section 5 of the FTC Act. It also requests more information about how Google selects the "recommended" videos associated with delivered content. "It is unclear how the app determines which videos to recommend," opines the complaint. "Is Google tracking children's online viewing habits to make the recommendations? If so, has it given direct notice and obtained verifiable parental consent before tracking them as required by the COPPA [Children's Online Privacy Protection] Rule?"

In particular, the complaint singles out McDonald's Corp. for purportedly presenting promotional videos "styled as news reports on topics such as *What are McDonald's Chicken McNuggets Made of?,"* without identifying the content as advertising. As the coalition elaborates, "The McDonald's channel also features television commercials, such as the one for Smurfy Happy Meals. Branded channels, such as the McDonald's channel, take advantage of children because they do not understand that the entire channel is actually advertising."

"There is nothing 'child friendly' about an app that obliterates long-standing principles designed to protect kids from commercialism," said CCFC Associate Director Josh Golin. "YouTube Kids exploits children's developmental vulnerabilities by delivering a steady stream of

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advertising that masquerades as programming. Furthermore, YouTube Kids' advertising policy is incredibly deceptive. To cite just one example, Google claims it doesn't accept food and beverage ads but McDonald's actually has its own channel and the 'content' includes actual Happy Meal commercials."

## Environmental Advocacy Group Files Petition Seeking Protections for USDA Scientists

Public Employees for Environmental Responsibility (PEER) has filed a **petition** with the U.S. Department of Agriculture (USDA) arguing that the agency does not adhere to the goals of its Scientific Integrity Policy because the policy "fails to clearly prohibit political suppression and interference."

The policy was released in 2013 after President Barack Obama directed executive department heads to promote scientific integrity within each department, and PEER argues that USDA's policy does not protect its scientists to the extent that other agencies' policies protect theirs.

USDA's policy fails its scientists, PEER argues, because it does not (i) include political suppression and interference in its definition of misconduct; (ii) establish procedures for handling scientific integrity complaints; (iii) protect whistleblowers; or (iv) include "any process or mechanism for preventing politically motivated suppression or for challenging it once it occurs." PEER also argues that USDA has failed to adhere to its policy because it has not posted a website containing scientific integrity information. Further, the petition argues, the policy "actively *encourages* USDA to suppress scientific work for political reasons. The provision states that scientists 'should refrain from making statements that could be construed as being judgments of or recommendations on USDA or any other federal government policy, either intentionally or inadvertently.'"

PEER's petition cites examples of political interference in USDA scientists' work, including (i) directives to avoid publishing data on certain topics; (ii) orders to retract papers or remove sections of articles already accepted for publication; (iii) a demotion and reprimand for testifying before Congress; (iv) restrictions on topics for conference presentations; and (v) threats to damage the careers of scientists whose work triggers industry complaints. "Your words are changed, your papers are censored or edited or you are not allowed to submit them at all," one scientist anonymously told *Reuters*.

PEER argues that USDA should adopt various provisions appearing in other agencies' scientific integrity policies, including National Oceanic and Atmospheric Administration, the Departments of State and Commerce, Environmental Protection Agency, and Nuclear Regulatory Commission. "There is no reason why USDA scientists should labor under safeguards far inferior to those extended to their colleagues working inside other agencies," PEER Executive Jeff Ruch said in a press release. "To earn public credibility for its scientific work, USDA needs to spell out procedures by which political influences can be policed and scientists protected while allowing outside review of its handling of allegations and disagreements." *See Reuters,* March 28, 2015.

## LITIGATION

### Hain Celestial "All Natural" Beverage Suit to Continue

A California federal court has granted in part and dismissed in part a motion to dismiss a putative consumer class action against The Hain Celestial Group alleging that the company mislabels its Sunflower Dream Drink as "all natural" despite containing artificial or synthetic ingredients, including xanthan gum and folic acid. *Anderson v. The Hain Celestial Grp., Inc.*, No. 14-3895 (N.D. Cal., San Jose Div., order entered April 8, 2015).

Hain challenged the plaintiff's standing to sue for the alleged mislabeling of "substantially similar" products she did not personally purchase as well as standing for injunctive relief because she did not indicate that she would purchase Sunflower Dream Drink again. The court disagreed with the first argument, finding that the products the plaintiff did not purchase are substantially similar because they feature the same "all natural" representation and contain artificial, synthetic or extensively processed ingredients. Discussing the argument against standing for an injunction, the court acknowledged a split on the issue in other courts in similar cases and ultimately agreed with the courts that have denied requests for injunction without a showing of possible future purchases. Accordingly, the court dismissed the injunction request without leave to amend.

Hain also argued that the plaintiff failed to plead her arguments with particularity, but the court disagreed, finding that the plaintiff's complaint plausibly demonstrated why the challenged ingredients—

tricalcium phosphate, xanthan gum, vitamin A palmitate, folic acid, and vitamin D2—are unnatural. The court also dismissed Hain's argument that the "all natural" statement referred only to the sunflower seeds used to manufacture the product but not the product as a whole. "It cannot be confidently said, looking only at the label, that use of the word 'natural' in other less prominent locations renders 'it impossible for the plaintiff to prove that a reasonable consumer was likely to be deceived' by the 'All Natural' statement placed conspicuously on the front of the product, independent of any reference to sunflower seeds," the court said. "One does not have to suspend reality to understand what Plaintiff apparently concluded after examining the Sunflower Dream Drink: that a product bearing the unqualified statement 'All Natural' does not include any unnatural ingredients."

In a footnote, the court also dismissed Hain's argument that the U.S. Food and Drug Administration has not defined "natural" in the food context. "That argument is unpersuasive since the FDA's opinion on 'natural' is not a commentary on whether or not use of the word on food labels would mislead a reasonable consumer operating under a common understanding of its meaning," the court said.

Hain further argued that the label accurately listed each ingredient in the product, and the court admitted that the "argument has some attractiveness because, as a matter of common sense, consumers like Plaintiff who are seriously concerned about the presence of unnatural ingredients in food products are unlikely to rely solely on one cursory representation touting a product's attributes without reviewing the list of ingredients." Ultimately, however, the court rejected the argument because it could not "find as a matter of law that an accurate ingredient list excuses other allegedly misleading statements on a product's label" because the Ninth Circuit previously held "that a reasonable consumer is not 'expected to look beyond misleading misrepresentations on the front of the box to discover the truth from the ingredient list in small print on the side of the box.'" Accordingly, the court denied most of Hain's motion to dismiss but granted it in regards to the plaintiff's request for an injunction.

## Groups Challenge Change to Organic Law's Sunset Provision

Several policy groups, including Food & Water Watch and the Center for Food Safety, have filed a **lawsuit** challenging a U.S. Department of Agriculture (USDA) procedural change in how ingredients are removed

from the National List, a list of synthetics exempted from the Organic Foods Production Act (OFPA). *Ctr. for Food Safety v. Vilsack*, No. 15-1590 (N.D. Cal., filed April 7, 2015).

The National List catalogs synthetic and prohibited natural substances that may be used in organic farming despite not being inherently organic because the substances (i) have been determined by USDA not to harm human health or the environment, (ii) cannot be replaced with an organic alternative and (iii) are consistent with organic farming and handling.

The groups challenge a 2013 revision to the process for removing an exempted substance from the National List. OFPA created a sunset provision that removed substances from the list—thereby prohibiting their use in organic farming—after five years unless two-thirds of the National Organic Standards Board voted to keep them on the list. Under the revised rule, a substance stays on the National List unless two-thirds of the board votes to remove it. The groups argue that this change reversed the original default expiration standard to one of default retention. "We're now in the land of the midnight sun—the sun never sets," a co-founder of plaintiff Cornucopia Institute told *The New York Times*.

The lawsuit alleges that USDA violated the Administrative Procedure Act by failing to provide sufficient public notice and comment before the change took effect. The groups further allege that the rule creates inconsistent organic standards and violates OFPA, and they seek a court declaration in support of their arguments as well as an injunction barring implementation of the revised rule. *See The New York Times*, April 7, 2015.

## U.S. Government Sues Wholesome Soy Products over *Listeria* Outbreak

Attorneys in the U.S. Department of Justice and U.S. Department of Health and Human Services have filed a lawsuit against Wholesome Soy Products to permanently enjoin the company, its owner and manager from causing food to become adulterated under the Federal Food, Drug, and Cosmetic Act (FDCA) after government agencies allegedly linked the company's facilities to a 2014 outbreak of *Listeria* in Michigan and Illinois. *United States v. Wholesome Soy Prods., Inc.,* No. 15-2974 (N.D. Ill., filed April 3, 2015).

Wholesome Soy manufactured and sold mung bean and soybean sprouts until November 2014, when the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA) and state agencies allegedly traced incidents of *Listeria* infections observed in five people to the Wholesome Soy facility. An FDA laboratory allegedly found *Listeria* in 28 samples—including two from mung bean sprouts—taken during a September 2014 inspection of Wholesome Soy's plant and in nine samples from an October 2014 inspection.

The complaint further alleges that FDA inspections of the company's manufacturing facility in October 2014 revealed multiple insanitary conditions, including (i) inadequate cleaning practices; (ii) ineffective pest control measures; (iii) failure to properly maintain equipment, utensils and the sprout production environment; (iv) a building structure not constructed to allow for adequate floor and wall cleaning and maintenance; and (v) employee practices that allowed for potential contamination, including employees wearing boots and aprons that were not changed, cleaned or sanitized before reentering the production area.

FDA notified Wholesome Soy of its findings, the complaint says, and the owner allegedly told the agency that the company ceased production in August 2014 and retained a food safety consulting firm and an industrial cleaning and sanitizing chemical supplier. Wholesome Soy then resumed production less than a month later without adequately addressing its sanitation issues, the government argues, and FDA met with the owner in November 2014 to ensure that Wholesome Soy stopped production until it did so. "The facility is not currently producing or distributing food, but nothing prohibits Defendants from resuming production without adequate corrective actions," the complaint states. "Based on the foregoing, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will violate [the FDCA] again."

## Busch® Beer Not A "Product of U.S.A.," Suit Alleges

Two consumers have filed a putative class action against Anheuser-Busch in California state court alleging that the company misuses the "Product of U.S.A." claim on Busch® beer cans because the product is brewed with imported hops. *Nixon v. Anheuser-Busch Cos., LLC*, No. 15-544985 (Cal. Super. Ct., San Francisco Cnty., filed March 27, 2015). The complaint asserts that Anheuser-Busch charged premium prices for beer made in the United States despite using imported hops, or "a significant portion"

of the beer. The plaintiffs allege unfair competition and a violation of California's "Made in USA" law. They seek to represent a statewide class of purchasers and to receive damages and an injunction.

### Dutch Trader Jailed for Falsifying Documents in Horsemeat Scandal

A Dutchman has reportedly been sentenced to jail after authorities determined that his companies sold at least 336 metric tons of horsemeat labeled as beef in 2013. Willy Selten will serve 2.5 years for forging invoices, labels and declarations and using forged documents to sell meat. The court judgment apparently determined that Selten "contributed to a negative image for the Dutch meat industry and damaged the sector's interests" because he sold the horsemeat-beef mixture to foreign firms. During his trial, Selten admitted that he was negligent with his administration, but he argued that he is "not the big horsemeat swindler they're all looking for." Since 2013, Selten declared bankruptcy and faces damages claims of €11 million. Details about the sentencing of two U.K. men related to falsifying documents and failing to keep adequate records appear in issue **560** of this *Update*.

## OTHER DEVELOPMENTS

### EWG Launches Campaign Against Foods Containing Propylparaben

An Environmental Working Group (EWG) **investigation** has reportedly concluded that 49 processed snack foods contain propylparaben, a preservative commonly found in cosmetic products. In light of its findings and various studies allegedly linking exposure to the chemical to decreased fertility and other hormone-related issues, EWG is urging the U.S. Food and Drug Administration to reconsider the preservative's current "Generally Recognized as Safe" status as a food additive.

"It is of great concern to us that the use of an endocrine-disrupting chemical in our food is considered safe by our own government," Johanna Congleton, an EWG senior scientist was quoted as saying. "European Union regulators do not permit propyl paraben in food. So why do we?"

EWG is soliciting concerned consumers to sign an online petition to food companies that states: "Your company uses the endocrine-disrupting chemical propylparaben in your products! Parabens are being taken

out of some cosmetics and food products, but you continue to expose consumers to this chemical. As a supporter of EWG, I demand that you get hormone disruptors out of your food products!" *See EWG News Release*, April 8, 2015.

## FWW Report Examines "Controversial" Animal Drugs

Food & Water Watch (FWW) has released an April 2015 report alleging that the scientific research used by federal agencies to evaluate animal drug safety "is very heavily influenced by corporate drug companies." In particular, the report alleges that there were "virtually no independent, peer-reviewed" safety studies on one drug used as a growth promoter that was eventually withdrawn from the marketplace.

"Most of the available research examined commercial dimensions of Zilmax, such as the drug's impact on beef qualify, and more than three-quarters of the studies were authored and/or funded by industry groups, almost all of which were published in scientific journals sponsored and edited by industry groups," opines FWW in an April 8 press release. "Many academic journals have failed to establish or enforce rules requiring scientists to publicly disclose financial conflicts of interest, which has allowed deeply conflicted research to distort the scientific discourse."

Citing these issues, the consumer watchdog has urged Congress "to instruct the Food and Drug Administration (FDA) to dramatically revamp its animal drug approval process to be based primarily on independent science, instead of depending entirely on research furnished by drug sponsors." The report also calls on agricultural journals to disclose all funding sources and publish the full names, financial ties and affiliations of their authors and editors. *See Food & Water Watch News Release*, April 8, 2015.

### ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.