Shook, Hardy & Bacon L.L.P.

ISSUE 366 | OCTOBER 1, 2010

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Senators Want FDA to Halt Review of GE Salmon

Led by U.S. Senator Mark Begich (D-Alaska), a group of legislators has asked the Food and Drug Administration (FDA) to halt its ongoing review of genetically engineered (GE) salmon, citing "serious concerns with the current approval process and many potential health and environmental risks that are associated with producing GE fish." FDA recently held public hearings to decide the fate of a new animal drug application (NADA) for AquAvantage® salmon, an Atlantic variety that uses genes from ocean pout and Chinook to increase the speed of maturation. Additional details about these hearings appear in Issue 365 of this *Update*.

In their September 28, 2010, letter to FDA Commissioner Margaret Hamburg, the Senators argue that the NADA process lacks transparency and does not adequately address the "creation of a new animal, especially one intended for human consumption." The signatories specifically point to reports that GE salmon "'have slightly higher levels of insulinlike growth factor…associated with greater cancer risk.'" They also highlight the potential for environmental damage from "escaped fish, fish waste, other pollutants, and infectious diseases," citing company data that suggests "5 percent of its eggs may not be sterile" and raising questions about interbreeding with wild fish, competition for habitat and food, and the abnormal behaviors of farmed fish.

According to the letter, the Senators are "finally…concerned about the dangerous precedent that this ruling could set, as companies will likely seek FDA approval for other genetically engineered products such as GE tilapia and GE trout." Begich further asserts that this call for FDA to stop the review "immediately" has already garnered support from "52 consumer and environmental groups, commercial and recreational fisheries associations, and food businesses and retailers," including the Alaska Marine Conservation Council, Bristol Bay Regional Seafood Development, and the Yukon River Drainage Fisheries Association. *See Senator Begich Press Release,* September 28, 2010.

Log Cabin Agrees to Reformulate Syrup Product After Congressional Alert to FDA

Pinnacle Foods Group LLC has reportedly agreed to reformulate its Log Cabin Syrup® after Vermont Representative Peter Welsh (D) called on the Food and Drug Administration (FDA) to investigate the company for selling a product in apparent

violation of agency regulations. Welsh's September 8, 2010, letter noted that the company's "All Natural Syrup" contains caramel color, among other ingredients. Welsh suggested that consumers outside the state "who have come to expect quality from natural Vermont products may be fooled by this misleading labeling." The product is apparently being sold in a beige plastic jug similar to real maple syrup packaging, raising the ire of maple syrup producers.

While FDA has not defined the term "natural," the agency allows it to be used if the claim is truthful and "the product does not contain added color, artificial flavors or synthetic substances," according to an agency spokesperson. Claiming that its product "provides consumers with a value-priced table syrup choice made from all natural ingredients," Pinnacle thanked the congressman and Vermont's agriculture secretary "for alerting us to the FDA's voluntary guidelines regarding the addition of color to a natural product, even if from a natural source." The company will remove the caramel color immediately. *See Product Liability Law 360*, September 27, 2010; *Congressman Peter Welsh Press Release*, September 28, 2010.

FDA Releases Draft of Five-Year Strategic Plan

The Food and Drug Administration (FDA) has released a draft strategic priorities document for fiscal years 2011-2015 that outlines four key cost-cutting strategic priorities and four strategic program goals designed to help FDA achieve its public health mission.

According to an October 1, 2010, *Federal Register* notice, the four cost-cutting priorities seek to (i) "advance regulatory science and innovation," (ii) strengthen the safety and integrity of the global supply chain," (iii) "strengthen compliance and enforcement activities," and (iv) "expand efforts to meet the needs of special populations." Among the program goals, FDA has highlighted intentions to establish effective tobacco regulation as well as advance food safety and nutrition by ensuring the safety of the food supply from farm to table and promoting healthy dietary practices and nutrition. FDA will accept comments until November 1, 2010.

FDA Meeting to Address Transmissible Spongiform Encephalopathies

The Food and Drug Administration (FDA) has announced a meeting of the Transmissible Spongiform Encephalopathies Advisory Committee, which reviews and evaluates available scientific data concerning the safety of products that might transmit spongiform encephalopathies such as Creutzfeldt-Jakob disease and the bovine variant commonly known as mad cow disease. Agenda items for the October 28-29, 2010, meeting in Gaithersburg, Maryland, include (i) "FDA's risk assessment for potential exposure to the variant Creutzfeldt-Jakob disease (vCJD) agent in U.S.-licensed plasma-derived Factor VIII" and (ii) "labeling of blood and blood components and plasma-derived products, including plasma-derived albumin and products containing plasma-derived albumin, to address the possible risk of transmission of vCJD." The committee will also discuss ways to reduce transmission risks and hear updates on the "development of devices to remove transmissible spongiform encephalopathy agents from blood components and chronic wasting disease." FDA requests written comments by October 21, 2010. *See Federal Register,* September 14, 2010.

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EPA to Regulate Rocket Fuel Ingredient Detected in Some Foods

The U.S. Environmental Protection Agency (EPA) has reportedly decided that it will regulate perchlorate, a man-made and naturally occurring chemical used in rocket fuel, explosives and fireworks. While it has not yet established an exposure limit, EPA's Office of Water sent the Office of Management & Budget a draft notice for its review, outlining EPA's decision to regulate the chemical by setting a maximum contaminant level under the Safe Drinking Water Act, said a news source.

The Food and Drug Administration has **found** perchlorate in a number of foods, most notably spinach, lettuce and tomatoes, and the Government Accountability Office (GAO) recently **reported** that it is widespread. GAO notes that the chemical "can disrupt the uptake of iodide in the thyroid, potentially interfering with thyroid function and negatively affecting fetal and infant brain development and growth."

According to a press report, EPA's decision could pose a challenge to chemical and aerospace companies that may be liable for a massive cleanup, as well as for water companies which may have to meet any standard set. The Department of Defense could also be affected. Because EPA must establish standards under the Safe Drinking Water Act low enough to offset exposures from other sources, such as food, some agency observers apparently expect that the maximum concentration level could be stricter than EPA's current cleanup target of 15 parts per billion. *See Inside EPA*, September 30, 2010.

EFSA Declines to Revise BPA Risk Assessment

The European Food Safety Authority's (EFSA's) panel on food contact materials, enzymes, flavorings, and processing aids has released its latest **risk assessment** for bisphenol A, concluding that there was not any "new evidence which would lead them to revise the current Tolerable Daily Intake [TDI] for BPA of 0.05 mg/kg body weight set… in its 2006 opinion and re-confirmed in its 2008 opinion." The CEF panel undertook the reassessment at the request of the European Commission, which directed scientists to (i) decide on the basis of recent literature whether to update the TDI; (ii) "assess a new study on possible neurodevelopmental effects"; and (iii) advise on a risk assessment made by the National Food Institute at the Technical University of Denmark.

Although one minority opinion evidently raised questions about "adverse health effects below the level used to determine the current TDI," panel members agreed on shortcomings in the animal studies suggesting "biochemical changes in the central nervous system, effects on the immune system and enhanced susceptibility to breast cancer." In addition, the panel noted some human epidemiological studies that link BPA exposure to coronary heart disease and reproductive disorders, but found "the design of these studies does not allow one to conclude whether BPA is the cause of these health effects." As the panel concluded, "At present the relevance of these findings for human health cannot be assessed, though should any new relevant data become available in the future, the Panel will reconsider this opinion."

In making its assessment, EFSA apparently conferred with European and international authorities, including the U.S. Food and Drug Administration, Health Canada and World Health Organization (WHO). It also plans to contribute to a November

2010 expert consultation sponsored by WHO and the Food and Agriculture Organization. Additional details about the consultation can be found in Issue 330 of this *Update. See EFSA News Story,* September 30, 2010.

In a related development, Japanese researchers have reportedly measured and reported BPA levels in the atmosphere. F. Pingqing and K. Kawamura, "Ubiquity of bisphenol A in the atmosphere," *Environmental Pollution,* October 2010. The study authors collected 260 air samples from "12 cities in India, China, Japan, New Zealand and the U.S.; two rural sites in China and Germany; eight marine areas in the Pacific Ocean, the Atlantic Ocean, the Indian Ocean, the Sea of Japan and the China Sea; and three polar regions in Canada and the Antarctic," according to a September 30, 2010, synopsis in *Environmental Health News*, which noted that densely populated regions of Asia and India showed 10,000 times the BPA levels found in remote polar regions.

"Researchers believe that BPA enters the air when plastics, electronics and other waste are burned, since the highest concentrations were measured near populated areas and coincided with high levels of other chemicals that are associated with burning plastics," states the news source. "Manufacturing processes for plastics and other consumer products containing BPA are also thought to be a major source of BPA in the air."

Embattled EFSA Chair Vows to Retain Post

European Food Safety Authority (EFSA) Chair Diana Banati has reportedly dismissed conflict-of-interest allegations arising from her involvement with the International Life Sciences Institute (ILSI), a public health nonprofit whose membership includes academic, government and industry scientists. According to Greens MEP José Bové, Banati failed to disclose her industry ties as an ILSI board member when installed at EFSA. "The commission should never have approved her appointment given her clear links to the food industry, which is completely at odds with the need for independence at the EFSA," Bové was quoted saying. "There can be no alternative but to replace Banati as chair of the EFSA."

Bové has purportedly raised the issue to cast doubt on EFSA's credibility as the European Commission looks to reform both the food safety body and the approval process for genetically modified organisms. A Banati spokesperson, however, has publicly denied the claims, noting that the chair's cooperation with ILSI was known at the time of her confirmation. "Banati does not have an active role in the institute and her appointment as EFSA chair has nothing to do with EFSA itself," stated her representative, adding that Banati will not resign over the protest. *See GM Watch, Le Monde* and *The Parliament,* September 30, 2010.

OEHHA Proposes Prop. 65 Rule Changes; Two Chemicals Added to Carcinogen List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) is seeking public comments on draft changes to those Proposition 65 (Prop. 65) regulatory provisions addressing no observable effect levels for listed chemicals. According to OEHHA, "[t]hese regulations set out the procedures and criteria for determining an exposure level where there would be no observable effect," and the

proposed changes would "clarify these procedures and criteria." Comments are requested by October 31, 2010.

Prop. 65 requires companies to provide warnings before exposing people to chemicals known to the state to cause cancer or reproductive toxicity. OEHHA is the lead agency implementing the law and maintains the Prop. 65 regulations.

The agency has **announced** the availability of updated hazard identification materials for two chemicals widely used in industry and also formed in certain foods during processing. According to the updated materials, 1,3-Dichloro-2-propanol (1,3-DCP) and 3-Monochloropropane-1,2-diol (3-MCPD), were added to the Prop. 65 list on September 21, 2010. 1,3-DCP is apparently found in foods such as soy and oyster sauces, malt products, sausage, minced beef, ham, and battered and fried fish. It may also be present in food-contact materials and some paper products. 3-MCPD has been found in the same foods as well as in anchovies packed in oil, some cheeses, roasted or toasted cereals, breads and biscuits, and instant coffee and roasted coffee beans. *See OEHHA News*, September 30, 2010.

Florida Considers Ban on Chocolate Milk, Sugary Drinks in Schools

The Florida Board of Education is reportedly considering a ban on chocolate milk and sugary beverages in the state's public schools. Board members evidently tabled the issue last spring in anticipation of federal government action, but recently decided to move forward to hear opinions from physicians and researchers on whether such a ban would improve children's health. Hearings will be held over the next two months, with possible legislation coming in December.

"When you think about it, we probably have a million overweight or obese children in our schools," board member John Padget was quoted as saying. "I think the clock is ticking in terms of personal health." Board member Susan Story reportedly wants the board to consider a possible ban on other foods sold in schools, including chips and ice cream. "To me, it's a bigger issue that needs to be looked at and not a chocolate milk-versus-white milk and soda," she said. "I would just want to make sure we look at everything and not just a piece. We might be fighting the wrong battle." *See Orlando Sentinel,* September 21, 2010.

States Set "Pure Honey" Standards; National Standard Sought

North Carolina has reportedly become the most recent state to adopt a definition for "pure honey" that beekeepers hope will get fake honey off the market. Because Americans consume some 350 million pounds of honey annually, but domestic producers produce just 150 million pounds, there is apparently a financial incentive for importers and others to sell honey cut with additives such as corn syrup. Other states that currently regulate honey include California, Florida and Wisconsin. While the Food and Drug Administration has undertaken efforts to stop the sale of chemically contaminated honey, the agency is also reportedly considering a petition seeking to establish a national standard. *See USA Today*, September 25, 2010.

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LITIGATION

Sixth Circuit Strikes Parts of Ohio Regulation Restricting Hormone-Free Labeling on Dairy Products

The Sixth Circuit Court of Appeals has determined that parts of an Ohio law regulating the use of labeling on dairy products from cows not treated with growth hormones violate the First Amendment. ***Int'l Dairy Foods Ass'n v. Boggs, Nos. 09-3515/3526 (6th Cir., decided September 30, 2010)***. The court also upheld other provisions and remanded parts of the rule relating to antibiotics and pesticides for further proceedings. Thus, the court overturned, in part, a district court determination that upheld most of the rule's provisions.

The Ohio Director of Agriculture adopted a rule in May 2008 that (i) prohibited dairy producers from claiming their milk was hormone free (a composition claim) and (ii) placed stringent restrictions on the use of the claim "this milk is from cows not supplemented with rbST [recombinant bovine somatotropin or recombinant bovine growth hormone (rbGH)]" (a production claim). Among other matters, the latter require verification, and contiguous labeling in a defined font, style, case, color, and size stating "The FDA has determined that no significant difference has been shown between milk derived" from hormone-supplemented and non-hormone-supplemented cows. Food and Drug Administration (FDA) guidelines do not allow the use of "rbGH-free" or "rbST-free" labeling and call for the use of an asterisk where production claims are made with the additional information, "[n]o significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."

Organizations representing both conventional and organic dairy producers filed challenges to the rule, and the district court upheld the rule on all but one of the claims. The court granted the state partial summary judgment as to the rule's restrictions on production claims due to an undeveloped factual record on whether the requirements were unduly burdensome as applied to small containers. The dairy producers filed an interlocutory appeal, limited to their First Amendment and Commerce Clause claims.

Citing evidence in the record which showed that the milk of treated and non-treated cows actually does differ in composition, the appeals court concluded that "composition claims like 'rbST free' are not inherently misleading." Because the state failed to prove that Ohio consumers have been misled by dairy-product labeling and that the rule was more extensive than necessary to serve the state's interest, the court determined that the state could not ban composition claims, but could require a disclaimer to inform consumers that rbST has yet to be detected in conventional milk.

As to the production-claim restrictions, the court found no error in the district court's determination that a disclosure requirement is reasonably related to the state's interest in thwarting the risk of consumer confusion, but found no rational basis for the contiguity requirement. According to the court, the use of an asterisk with the disclaimer information located elsewhere on the product packaging would suffice. The court was not persuaded that the rule violated

Commerce Clause precepts, finding any burdens or benefits placed equally on in-state and out-of-state producers.

Because the record was insufficiently developed on whether the rule appropriately banned composition claims related to antibiotics and pesticides, the court remanded that part of the case to the district court for additional proceedings. The court noted that the state failed to present any evidence on the testing procedures used to detect antibiotics and pesticides. "If the State's testing can detect these substances and prevent any amount of them from being present in conventional milk, then [the claims antibiotic- and pesticide-free] would be inherently misleading because they falsely imply that conventional milk contains antibiotics and pesticides when in fact the State tests to ensure that it does not." The court thus concluded that the state failed to show it was entitled to summary judgment on this part of the producers' challenge to the rule.

Plaintiffs Likely to Succeed on Merits of Challenge to APHIS GM Sugar Beet Permits

A federal court in California has determined that an agency decision to allow planting of genetically modified (GM) sugar beet stecklings (seedlings) without conducting an environmental assessment likely violated federal law and has ordered the parties to file briefs as to the appropriate remedy now that most of the stecklings authorized have been planted. ***Ctr. for Food Safety v. Vilsack*, No. 10-04038 (U.S. Dist. Ct., N.D. Cal., decided September 28, 2010)**. Additional information about the lawsuit's challenge to action taken by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) appear in Issue **363** of this *Update*.

The court first addressed whether seed companies could intervene in the matter and ruled that they could do so as to the remedies, but not as to the merits, that is, whether APHIS violated federal environmental laws including the National Environmental Policy Act (NEPA) by issuing the permits without conducting an environmental review. The companies were allowed to participate as *amici* in the merits proceeding. The court also addressed whether the plaintiffs had standing to seek a temporary restraining order against APHIS and determined they did, finding that they had demonstrated "that a government agency violated certain procedural rules and that these rules protect a plaintiff's concrete interests."

APHIS issued the permits less than three weeks after the same court in a different case ruled that the agency was required to conduct an environmental impact assessment (EIS) before deregulating GM sugar beets, which assessment could take several years. The agency justified its decision by claiming that the permits related to an act (planting) independent from the remainder of the sugar beet planting cycle and therefore did not require an EIS. The court rejected the "independent utility" argument, finding that the permits were issued for the sole purpose of allowing the production of seedlings "for transplant into basic seed (commercial) production trials in the winter of 2010-2011." While the seed companies argued that they had sought the permits for research and development, the court found no support in the record "that the permits had any utility other than enabling the seed companies to take the first step in a multi-step process related to the commercial production of genetically engineered sugar beets."

According to the court, "Plaintiffs have sufficiently demonstrated a likelihood of success on the merits, *i.e.*, that APHIS violated NEPA by considering the permits in isolation and segmenting them from the later cycles of genetically engineered sugar beet plantings and production." The court also rejected the agency's claim that its decision was warranted under a "categorical exclusion," finding it likely that reliance on the exclusion was unlawful and made "to avoid conducting any environmental review."

When the plaintiffs filed their petition for a temporary restraining order and preliminary injunction, they sought to enjoin any further permits and any plantings under the permits that had not already occurred. In later briefing, they sought an order requiring removal of the stecklings already planted. Because the court determined that APHIS "does not intend to issue any more permits of this nature" and "it appears as though the seed companies have already planted most, if not all, of the stecklings authorized by the permits at issue," the court asked the parties to file supplemental briefs addressing remedies and will hear the matter on October 22, 2010. The court concluded by requiring APHIS, under penalty of perjury, to provide information about "exactly when and where it made the information public that the permits had been granted" and "shall describe exactly what information was publicly disclosed."

Ben & Jerry's Agrees to Discontinue "All Natural" Claims; Litigation Ensues

Two days after the Center for Science in the Public Interest (CSPI) announced that Ben & Jerry's had agreed to phase out claims that its ice creams and frozen yogurts were "All Natural," when some product ingredients are processed, a putative class action was filed in a California federal court against the company seeking money damages for false advertising and an injunction to stop the company from making such claims. ***Astiana v. Ben & Jerry's Homemade, Inc.*, No. 10-4387 (U.S. Dist. Ct., N.D. Cal., filed September 29, 2010)**.

In August 2010, CSPI claimed that 48 of the company's products were mislabeled because they contained unnatural ingredients, and the watchdog threatened to bring its concerns to the Food and Drug Administration (FDA). More details about CPSI's action appear in Issue **360** of this *Update*. On September 27, CSPI praised the company for amicably resolving the dispute; the company's response indicated that it would remove the claims and "focus more strongly on our other core values," such as using milk from family farms that do not use growth hormones, certified fair trade ingredients and certified cage-free eggs, as well as "suppliers that work for social justice."

The lawsuit refers to CSPI 's action against Ben & Jerry's and cites FDA regulations that prohibit the "natural" claim to be made about a product containing "color, artificial flavors or synthetic substances." The plaintiff takes specific aim at the company's use of alkalized cocoa. She contends that "labeling of products as 'all natural' carry [sic] implicit health benefits to consumers—benefits that consumers are often willing to pay a premium over comparable products that are not 'all natural.'" Seeking to certify a statewide class of consumers, the plaintiff alleges unlawful and fraudulent business practices, false advertising and unjust enrichment. She requests restitution, an order enjoining misleading advertising, attorney's fees, costs, and "an accounting for, and imposition of a constructive trust upon, all monies received by B&J as a result of the unfair, misleading, fraudulent and unlawful conduct alleged."

WTO Rules Against U.S. Ban on Chinese Poultry

A World Trade Organization (WTO) panel has **determined** that the United States has violated its trade obligations by refusing to allow Chinese chicken parts into the U.S. market, an action that was apparently taken in a 2009 federal spending bill that denied the use of any U.S. Department of Agriculture funding to establish or implement any measure that would allow the importation. The law extended a five-year U.S. ban on Chinese chicken that was imposed during a bird flu outbreak. While the WTO can sanction countries that violate trade rules, this could take several years because the United States has the option to appeal the verdict. According to a news source, the Office of the U.S. Trade Representative has indicated that the restrictions were temporary and are due to expire soon. *See USA Today*, September 29, 2010.

OTHER DEVELOPMENTS

Drug-Positive Tour de France Champ Blames Steak Dinner

The New York Times reports that three-time Tour de France winner Alberto Contador is blaming a steak he ate on a rest day during the race for a drug test positive for clenbuterol. Experts have indicated that the small amount to which he could have been exposed would not have boosted his performance; the drug is apparently sometimes given to cattle illegally to speed up growth and increase muscle mass. The amount of clenbuterol found in Contador's samples was apparently very small, and the contaminated meat theory has been given considerable credence. Meanwhile, the Spanish cyclist has been provisionally suspended until race authorities determine whether he was using the drug. *See The New York Times*, September 30, 2010.

SCIENTIFIC/TECHNICAL ITEMS

Texas Students Link Sweetened Sport Drinks to Healthy Lifestyle, Says New Study

A new **study** reportedly claims that young people mistakenly view sugar-sweetened sports beverages as healthy alternatives to soft drinks. Nalini Ranjit, et al., "Dietary and Activity Correlates of Sugar-Sweetened Beverage Consumption Among Adolescents," *Pediatrics,* September 27, 2010.

University of Texas School of Public Health researchers surveyed 15,283 middle- and high-school students to determine the correlation between consumption of sugar-sweetened beverages and flavored and sports beverages (FSBs) to diet and physical activity.

According to the study, researchers discovered that more than 60 percent of boys and more than 50 percent of girls drank at least one soda, sports drink or other sweetened beverage like fruit punch each day, which could lead to yearly weight gain. Students active in sports and other physical activities consumed more sports drinks while those who led more sedentary lifestyles drank more soda. "The most likely explanation for these findings is that FSBs have been successfully marketed as beverages consistent with a healthy lifestyle, to set them apart from sodas," the study said. "Often, these

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beverages contain a minimal percentage of fruit juice or, more commonly, contain artificial fruit flavors, which conveys the impression that the drink is more healthful than it actually is."

Researchers also found that "vegetable and fruit consumption increased with the level of FSB consumption but decreased with the level of soda consumption." It concluded that "assessment and obesity-prevention efforts that target sugar-sweetened beverages need to distinguish between FSBs and sodas."

Red Meat Allegedly Linked to Metabolic Syndrome

A recent study has purportedly linked processed red meat consumption to metabolic syndrome (MetS), which includes health factors such as abdominal obesity and elevated triglycerides, LDL cholesterol, blood pressure, or fasting glucose, or reduced HDL cholesterol. N. Babio, et al., "Association between red meat consumption and metabolic syndrome in a Mediterranean population at high cardiovascular risk: Cross-sectional and 1-year follow-up assessment," *Nutrition, Metabolism and Cardiovascular Diseases,* September 26, 2010. Researchers evidently conducted cross-sectional analyses on a Mediterranean population at a high risk for cardiovascular disease, evaluating "a 137-item validated semi-quantitative food frequency questionnaire, anthropometric measurements, blood pressure, fasting plasma glucose and lipid profile" at baseline and after one year.

The study authors reported that among these individuals, "higher [red meat] consumption is associated with a significantly higher prevalence and incidence of MetS and central obesity." According to the researchers, the study is "the first that prospectively demonstrates a higher-incidence of MetS in those subjects consuming higher amounts of red meat. This is relevant because this condition has been considered an independent risk factor for cardiovascular disease."

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