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King & Spalding is pleased to provide this edition of the *International Food Law Gazette*, a publication of our Food & Beverage Group with lawyers in the U.S. and in the EU. The articles in this publication cover various issues and developments in the U.S. and EU that are of particular interest to the food and beverage industry: from FDA's approval of the first genetically modified food-producing animal to leading cases before the Court of Justice of the European Union, foreign supplier verification programs and customs compliance, trademark developments, "natural" labeling, and the food sector as an EPA enforcement target. We hope you enjoy the articles in this edition!

Smitha G. Stansbury (Washington, D.C.), Ulf H. Grundmann (Frankfurt a. M.), Co-Editors

FEATURED ARTICLES

FDA Approves First Genetically Modified Food-Producing Animal

Frederick H. Degnan – Washington, D.C.

On November 19, 2015, the United States Food and Drug Administration (FDA) approved a new animal drug application (NADA) that authorizes the marketing of the AquAdvantage Salmon, a genetically modified Atlantic salmon. In approving the NADA, FDA concluded, among other things, that the AquAdvantage Salmon is as safe to eat as any non-genetically modified Atlantic salmon. The approval is controversial. Consumer and environmental groups have made no secret of their distrust of the technology, and of the agency. More »

Foreign Supplier Verification Programs and Customs Compliance: Three Key Facts Companies Need To Know

Shannon Doyle Barna, Smitha G. Stansbury, and J. Michael Taylor – Washington, D.C.

On November 27, 2015, the Food and Drug Administration (FDA) published the final rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals under the FDA Food Safety Modernization Act (FSMA) (Final Rule). While the Final Rule has a number of far-reaching implications for companies that import foods for human and animal consumption into the U.S., there are certain provisions that will be of particular interest to personnel with the day-to-day responsibility of working with U.S. Customs and Border Protection (CBP). More »

Court of Justice of the European Union: Ruling on Package Design of Foodstuffs (Teekanne Felix)

Ulf H. Grundmann and Elisabeth Kohoutek – Frankfurt a. M.

By judgment of June 4, 2014, Case C-195/14, the Court of Justice of the European Union (ECJ) ruled that it is unlawful to use a package design for a fruit tea that gives the impression that an ingredient is present, when it is not in fact present, and this is apparent solely from the list of ingredients on the fruit tea's packaging. The listing of ingredients in compliance with food labeling requirements may, even though correct and comprehensive, be incapable of sufficiently correcting a consumer's erroneous impression that stems from the overall package design. More »

2015 U.S. Trademark Developments Every Food and Beverage Lawyer Should Know *Kathleen E. McCarthy – New York*

In 2015, U.S. courts provided trademark practitioners with several issues to discuss and debate. Identified and summarized below are the top five most discussed issues. **More** »

Do the Restrictions on Advertising with Nutrition and Health Claims also Apply to Communications Addressed Exclusively to Health Care Professionals?—Interpretation of Regulation (EC) No 1924/2006 on Nutrition and Health Claims Made on Foods Ulf H. Grundmann and Elisabeth Kohoutek – Frankfurt a. M.

The Court of Justice of the European Union (ECJ) will soon decide on the issue of whether the restrictions on promoting foodstuffs with nutrition and health claims also apply to communications addressed exclusively to health care professionals (HCPs). **More** »

A Sea Change on the Horizon for California's Food Court? FDA Calls for Comment on Use of the Term "Natural" for Food Products

Bradley W. Pratt – Atlanta

There have been hundreds of class action lawsuits filed (primarily in the federal courts in California, sometimes referred to as the "Food Court") over the last few years against food and beverage manufacturers whose products use the term "natural" in their marketing and labeling. These lawsuits allege that the term "natural" is often false and misleading because many products contain ingredients, or are produced using methods, that consumers would not consider "natural" at all. This litigation explosion was made possible, in part, by FDA's long regulatory silence regarding permissible uses for the term. More »

Food-Processing Sector May Be the U.S. EPA's Next Enforcement Target *Ilana Saltzbart – Washington, D.C.*

Every three years, the United States Environmental Protection Agency (EPA) sets national enforcement initiatives to focus its civil and criminal enforcement resources on specific environmental issues. On September 15, 2015, EPA issued a public notice regarding its proposed national enforcement initiatives for fiscal years (FY) 2017-2019. Of particular note, EPA has proposed to adopt a new enforcement initiative targeting wastewater discharges from the food-processing sector. This proposal marks the first time EPA has identified food processors for a national enforcement initiative. More »

Co-Editors: <u>Ulf H. Grundmann</u> and <u>Smitha G. Stansbury</u>

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