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ALERT

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FDA Refusal to Define "Natural" Leaves Food Manufacturers at Risk for More and Costlier Class Action Litigation and Looking for Legislative Solutions

The U.S. Food and Drug Administration this month declined to weigh in on the issue of whether food products containing genetically modified ingredients can be labeled as "natural," refusing the request of three federal judges to provide clarification on companies' use of the term. The judges - two from California and one from New Jersey - had separately put class actions against food manufacturers on hold and referred the issue to the agency for an administrative determination. In a January 6, 2014, letter to the judges, FDA Assistant Commissioner for Policy Leslie Kux advised that the agency would not decide at this time "whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled 'natural.'" In addition, were the agency to consider making a determination on this issue in the future, noted the letter, it would do so through "regulation or formal guidance," rather than in the context of litigation between private parties. The FDA's refusal to issue a clear policy statement not only will likely pave the way for more class action litigation concerning the manufacturers' use of the terms "natural," "all natural" and "100% natural" on product labels, but may also make these suits costlier and more difficult to defend.

The Underlying Litigation

This past summer, two federal judges in California stayed suits against food manufacturers for a period of six months, pending an administrative decision from the FDA concerning whether a label using the term "natural" is appropriate for products containing genetically modified organisms (GMOs). The first case was a proposed class action suit against Gruma Corp. relating to its labeling of Mission brand tortilla chips as "All-Natural," when the chips allegedly contain corn grown from bioengineered, genetically modified seeds. The second action was against Campbell Soup in which plaintiffs claim that a product line is mislabeled as "100% Natural" because the soup may contain GMOs. More recently, a federal judge in New Jersey administratively terminated litigation alleging false advertising because Kix cereal labels say "All Natural Corn," even though the cereal is alleged to contain genetically modified corn.

In all three actions, the food manufacturer-defendants argued that the FDA had primary jurisdiction, and the judges agreed that the question of whether food products using GMOs can be labeled as "natural" is one best answered by the FDA.

The FDA Response

While the FDA has not formally defined "natural" in the context of food (and for the present will not do so), Kux reiterated the agency's stated policy regarding what the use of "natural" on food labeling means. Since 1993, the FDA's policy has been that "'natural' means that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." Citing the agency's "commitment to the principles of openness and transparency," Kux explained that, if the FDA were to "revoke, amend or add to" this longstanding policy - to address the specific issue of GMOs or otherwise - it "likely would embark on a public process, such as issuing a regulation or guidance document," in which it could "obtain data, information, and views" from all interested stakeholders. The letter also emphasizes that the agency has limited resources with which to address "priority food public health and safety issues," and that defining the term "natural" on food labels necessarily would involve other federal agencies, including the U.S. Department of Agriculture.

Looking for Other (Federal) Solutions

Manufacturers are also looking elsewhere for solutions: a key industry trade group, the Grocery Manufacturers Association (GMA), is currently working with federal legislators to propose a federal standard for use of GMO products in foods labeled "natural." A draft of the proposed legislation reflects three objectives: (1) to establish a process for the Food and Drug Administration (FDA) to conduct safety reviews of plant varieties proposed to be consumed as genetically engineered food; (2) to create a legal framework governing the use of labels disclosing the presence or absence of GMOs; and (3) to require the FDA to define the term "natural" for purposes of labeling. The federal GMO regulation would preempt state and local labeling requirements, including claims that products labeled in accordance with federal requirements are somehow false or misleading under state consumer protection laws.

State Regulation

If the GMA's proposed federal standard were adopted, food manufacturers would not need to worry about state labeling laws as they would be expressly preempted. Connecticut and Maine have passed labeling laws and a number of states may be considering such laws later this year, including Arizona, Colorado, Oregon, and Vermont. A patchwork of state laws with potentially conflicting requirements is not likely to benefit food manufacturers that market and sell on a national scale.

Implications for Food Manufacturers

The FDA's refusal to provide an administrative determination on this issue leaves food manufacturers that use "natural" and its various versions (all natural, 100 percent natural, made from all natural ingredients, etc.) at risk, not only for an increased number of lawsuits, but litigation that is both more costly and more difficult to defend. The FDA's position undercuts the manufacturer-defendants' preemption and primary jurisdiction arguments, which, if successful, generally result in an early dismissal of claims or suits. The agency's decision to absent itself from the discussion and the likelihood of increased litigation in this area will also lead to a patchwork of court decisions from across the country, as individual judges are left to decide whether the use of "natural" on a food product label that contains bioengineered, genetically modified ingredients is misleading to a reasonable consumer. In other words, food manufacturers cannot count on the FDA to save them from class action suits based on deceptive labeling and false advertising claims, and because the agency has given no indication for when - or if - it might establish a definitive food labeling policy, manufacturers will not be able to delay litigation in these suits pending formal guidance from the FDA.

Given this, food manufacturers' best option may be to continue to press for additional federal legislation. In the meantime, to cover the current ambiguity in the law, manufacturers that use the term "natural" on food labels also may want to consider disclosing that ingredients may have been grown from GMOs.

In the midst of all this uncertainty, one thing is clear: unless and until the federal government develops a comprehensive regulatory scheme for the labeling of GMO-containing food products, food manufacturers should expect to continue to be the target of class action lawsuits.

For more information about the content of this alert, please contact Michael Mallow, Livia Kiser and Mark Campbell.

For more information about Loeb & Loeb's Consumer Protection Department, please contact:

ROBERT M. ANDALMAN	RANDALMAN@LOEB.COM	312.464.3168
MARK D. CAMPBELL	MCAMPBELL@LOEB.COM	310.282.2273
CHRISTIAN D. CARBONE	CCARBONE@LOEB.COM	212.407.4852
TAMARA CARMICHAEL	TCARMICHAEL@LOEB.COM	212.407.4225
DARLENE M. CHO	DCHO@LOEB.COM	310.282.2168
ALBERT M. COHEN	ACOHEN@LOEB.COM	310.282.2228
AURELE A. DANOFF	ADANOFF@LOEB.COM	310.282.2398
PATRICK N. DOWNES	PDOWNES@LOEB.COM	310.282.2352
JESSICA M. HIGASHIYAMA	JHIGASHIYAMA@LOEB.COM	310.282.2072
JENNIFER A. JASON	JJASON@LOEB.COM	310.282.2195
THOMAS P. JIRGAL	TJIRGAL@LOEB.COM	312.464.3150
IEUAN JOLLY	IJOLLY@LOEB.COM	212.407.4810
BENJAMIN KING	BKING@LOEB.COM	310.282.2279
LIVIA M. KISER	LKISER@LOEB.COM	312.464.3170
EDWARD K. LEE	ELEE@LOEB.COM	310.282.2148
SCOTT S. LIEBMAN	SLIEBMAN@LOEB.COM	212.407.4838
RICHARD M. LORENZO	RLORENZO@LOEB.COM	212.407.4288
DAVID G. MALLEN	DMALLEN@LOEB.COM	212.407.4286
MICHAEL MALLOW	MMALLOW@LOEB.COM	310.282.2287
DOUGLAS N. MASTERS	DMASTERS@LOEB.COM	312.464.3144
NERISSA C. MCGINN	NMCGINN@LOEB.COM	312.464.3130
FIONA P. MCKEOWN	FMCKEOWN@LOEB.COM	310.282.2064
DANIEL G. MURPHY	DMURPHY@LOEB.COM	310.282.2215
JAY K. MUSOFF	JMUSOFF@LOEB.COM	212.407.4212
NATHAN J. MUYSKENS	NMUYSKENS@LOEB.COM	202.618.5010
JERRY S. PHILLIPS	JPHILLIPS@LOEB.COM	310.282.2177
RACHEL RAPPAPORT	RRAPPAPORT@LOEB.COM	310.282.2367
CHRISTINE M. REILLY	CREILLY@LOEB.COM	310.282.2361
AMANDA J. SHERMAN	ASHERMAN@LOEB.COM	310.282.2261
MICHAEL B. SHORTNACY	MSHORTNACY@LOEB.COM	310.282.2315
MEREDITH J. SILLER	MSILLER@LOEB.COM	310.282.2294
DENISE A. SMITH-MARS	DMARS@LOEB.COM	310.282.2028
WALTER STEIMEL, JR.	WSTEIMEL@LOEB.COM	202.618.5015
EMILY M. STONE	ESTONE@LOEB.COM	312.464.3126
MICHAEL A. THURMAN	MTHURMAN@LOEB.COM	310.282.2122
LAURA A. WYTSMA	LWYTSMA@LOEB.COM	310.282.2251
MICHAEL P. ZWEIG	MZWEIG@LOEB.COM	212.407.4960