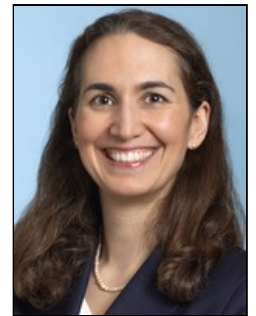


## Food Companies Are Hedging Their Bets With GMO Labeling

Law360, New York (April 18, 2016, 11:02 AM ET) -- The past year has seen a significant amount of frantic activity around whether to establish mandatory labeling for foods containing or produced with genetically modified organisms or, more specifically, foods produced through the use of genetic engineering (GE) techniques. This may seem odd since genetically engineered foods were first introduced into the U.S. food supply over 25 years ago,[1] plus there is no scientific evidence that GE ingredients pose any sort of health or safety risk. But the sudden urgency surrounding the GE labeling issue needs to be viewed in the context of some critical recent events, including the following:



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1. Regardless of the scientific data that support the safety of GE-derived ingredients, public support for across-the-board GMO and GE labeling has been growing and is putting pressure on the federal and state governments to develop appropriate legislation. [2] We say "across-the-board" because there are numerous options available to consumers who wish to avoid GE ingredients, including organic products and those labeled with voluntary third-party certifications like the "Non-GMO Project Verified Seal."



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2. In 2014, Vermont passed Act 120, a law that requires food manufacturers to label all products regulated by the U.S. Food and Drug Administration if they are produced in whole or in part through genetic engineering. The law also prohibits such foods as being labeled as "natural." [3] Act 120 is set to take effect on July 1, 2016, and a number of other states are poised to follow Vermont's lead.

3. Federal legislation to establish a national standard for GE food labeling stalled last month, after the Senate failed to pass companion legislation to H.R. 1599, the Safe and Accurate Food Labeling Act of 2015 (known to GE labeling supporters as the "Deny Americans the Right to Know," or DARK, Act). [4]

4. The FDA strongly reasserted its regulatory jurisdiction over the labeling of food products, both plant and animal-derived, produced with genetic engineering at the close of 2015 by: (a) issuing final guidance that affirms a voluntary GE labeling system for food manufacturers; [5] (b) approving the first GE animal as safe for human consumption and for use in human food; [6] and (c) releasing a draft guidance that describes a similar voluntary labeling standard for food products that contain the aforementioned approved GE animal (an Atlantic salmon engineered to reach market size more quickly through inclusion of a gene from Chinook salmon). [7]

### Update on the Status of State and Federal Legislation

Although Vermont is acting as the bellwether for imposing strict labeling requirements on manufacturers of food products that contain GE ingredients, other states have taken up the issue as well. Notably, Connecticut and Maine have enacted GE labeling legislation; however, the laws contain delayed implementation clauses and will only take effect once a “sufficient number” of neighboring states adopt GE labeling laws.[8] In addition, legislatures in fourteen other states, including Arizona, Illinois, Massachusetts and New York, have proposed legislation that would require food manufacturers to label GE food products.[9] These states are likely awaiting the results of a legal challenge to Vermont’s Act 120 brought by food businesses through their trade associations. While the U.S. Court of Appeals for the Second Circuit is currently considering the plaintiffs’ arguments for a preliminary injunction,[10] which would prevent the law from going into effect, the parties are also gearing up for a trial on the First Amendment issues related to Act 120 to be held at the U.S. District Court for the District of Vermont.[11]

At the federal level, the Republican Party-controlled House of Representatives pushed forward a national GE labeling standard last year, with Rep. Mike Pompeo, R-Kan., leading the charge with his sponsorship of H.R. 1599, the Safe and Accurate Food Labeling Act of 2015.[12] The bill, which sets forth a framework for mandatory FDA review and approval of GE food products as safe (a process that currently exists but is mostly optional) along with a voluntary standard for labeling such products, passed the House and was referred to the Senate in July 2015.[13]

The efforts towards national legislation stalled, however, when a divided Senate failed to approve the companion bill, S.2609, during a vote on March 16, 2016.[14] Although similar legislation was reintroduced in the House on March 25, 2016, Senator Chuck Grassley, R-Iowa, is “not optimistic” that Congress can pass legislation on a national labeling standard — which would be intended to preempt similar state requirements — before Vermont’s Act 120 goes into effect on July 1, 2016.[15] As of mid-April, when the biotechnology industry organized its national “fly-in” to meet with members of Congress, the sponsor of the Senate bill was still reportedly working to advance the legislation through some sort of compromise with Democrats.

Nonetheless, even if such a federal law is enacted, it seems all but certain that states, as well as environmental and consumer groups, would challenge it if the final standard does not require manufacturers to label food produced through genetic engineering. And even if such law includes explicit language preempting conflicting state laws, it is unclear whether a voluntary national standard would effectively preempt mandatory state requirements, and we would expect that to be another legal issue that would get lobbed to the courts. Which means that the long-simmering GE labeling debate likely won’t be over when (or if) Congress finally steps in.

## **Tensions Between Current Federal and State Requirements**

Putting aside the possibility of congressional action in the next two months, food manufacturers are currently faced with two distinct and opposing standards for GE labeling that will exist beginning on July 1, 2016 — one at the federal level and one at the state level — and the situation is causing unnecessary confusion for food manufacturers and consumers alike.

On the one hand, the FDA reasserted its stance on food labeling in two guidance documents issued in November 2015. The final guidance pertaining to foods derived from GE plants[16] and the draft guidance pertaining to foods that contain GE Atlantic salmon[17] both assert the agency’s authority over the labeling of GE food products and describe applicable labeling standards. Importantly, however, the FDA does not require manufacturers to include such label statements on products when there is no material difference between the GE and non-GE versions of a particular ingredient. These recently released guidance

documents are consistent with FDA policy that has been in place since 1992 and states that manufacturers may, but are not required to, label GE-derived foods.[18] Without a statutory amendment that tells it otherwise, the FDA is unlikely to give any ground on this long-standing policy and its interpretation of the Food, Drug and Cosmetic Act, which requires that food labeling not be false or misleading.[19]

On the other hand, Vermont's Act 120 sets forth mandatory language that must appear on labeling of GE food products and prohibits the use of other language (i.e., any word derived from "nature").[20] Vermont's mandatory standard only applies to food products regulated by the FDA, which sets Act 120 in direct opposition to the FDA's voluntary standard, and also creates the potential for consumer confusion. For instance, food manufacturers cite the fact that Act 120 would require Campbell Soup Co.'s regular SpaghettiOs (regulated by the FDA) to be labeled as GE but would not cover SpaghettiOs with meatballs, which are regulated by the U.S. Department of Agriculture.[21] Moreover, large food businesses and their trade associations, including the Grocery Manufacturers Association, the Coalition for Safe and Affordable Food and the Vermont Retail and Grocers Association, oppose patchwork state legislation and support creation of a preemptive national standard in order to avoid an inconsistent morass of differing standards.[22] Confusion like that which will result in the SpaghettiOs example likely would be multiplied if other states create different, and potentially conflicting, labeling standards.

It is also worth noting that, without a scientific basis for requiring food producers to label GE foods, state mandatory labeling laws are vulnerable to First Amendment challenges that they compel commercial speech. In fact, Vermont's Act 120 is presently the subject of such a challenge in the U.S. District Court for the District of Vermont.[23] The issue presented in that case, Grocery Manufacturers Association v. Sorrell, is similar to the issue raised in International Dairy Foods Association vs. Amestoy, a Second Circuit case from 1996 concerning whether Vermont could require milk produced using recombinant bovine growth hormone ("rBGH" — also known as "rBST") to bear special labeling.[24] In that case, the court imposed a preliminary injunction on the labeling law taking effect, based on a finding that IDFA's challenge on First Amendment grounds would likely prevail at trial.[25] Similar to the situation today for GE foods, the FDA had released a report on the safety of milk from cows treated with rBGH[26] and the National Institutes of Health had determined that "meat and milk from rBST-treated cows are as safe as those from untreated cows." [27] In other words, there was no compelling reason for the mandatory labeling requirement, although farmers and companies remained free to craft nonmisleading statements to alert shoppers about their nonuse of rBGH (and 20 years later, we are certainly all familiar with those rBGH/rBST label claims).

## **National Food Companies Have Begun to act in Response to the Vermont Deadline**

So, in short, food manufacturers in America right now are facing intense and competing pressures on this issue. First, consumer opinion is heavily skewed in favor of including GMO and GE notices on food labeling.[28] Second, the integrated nature of the U.S. food supply system makes developing differential labeling systems difficult and costly and, therefore, individual states, even small ones like Vermont, can have a huge impact on food companies' national operations.[29]

The uncertainty in the food industry finally reached a tipping point in March after the Senate Agriculture Committee's labeling bill didn't make it through a floor vote. Large food manufacturers, such as Campbell, Con Agra Foods Inc., General Mills Inc., Kellogg Co. and Mars Inc., publicly announced their intentions to include GMO and GE statements on food product labels. In these statements, all of them cited public pressure, Vermont's Act 120 and Congress's failure to pass a national standard as providing impetus for their decisions. [30] On the one hand, the decision positions these and other companies as being responsive to overall consumer demand, as well as responsible corporate and community citizens

because they're seeking to comply with the Vermont mandate (which comes with significant per day penalties for noncompliance) rather than pull their products from Vermont. On the other hand, however, the food industry argues that mandatory labeling raises the cost of food production, has the potential to cause consumer confusion — both from inconsistent labeling for different types of products and also effects of overinformation or “overwarning” (especially when there are no safety issues about which consumers are being “warned”) — and sets an undesirable precedent whereby future advancements in food production methods would need to be disclosed on direct packaging.

Indeed, food manufacturers claims that state GE labeling laws — especially if we end up with an inconsistent patchwork across the country — will raise costs of food production whether companies decide to comply with state labeling laws or, instead, to switch to non-GE ingredients to avoid the need for compliance. Supporters of a national labeling standard often cite a study from the Corn Refiners Association stating that enactment of mandatory GE labeling laws will cause food costs to rise by \$1050 per family per year.[31] However, other studies have found more modest increases, such as a 2014 Cornell University study finding that food costs in New York State would rise by \$500 per family if companies substitute non-GE ingredients in their products.[32]

Increased costs resulting from mandatory labeling laws have already affected food-producing businesses in Vermont, and they may potentially alter consumers' available choices in the marketplace. For example, Vermont Fresh Pasta switched from canola oil, which is produced from GE plants, to non-GE olive oil in its production process.[33] The company reports that production costs increased by 10 percent, but the change has not led to increased purchasing or greater profits. And Blue Valley Gourmet has stated that if Act 120 applies to its fruit spreads sold in Vermont, the company is likely to discontinue flavors that contain GE ingredients rather than source new ingredients and reformulate those products.[34]

## **Conclusion**

Now that large food manufacturers are conceding to public demands to declare the presence of GE ingredients, regardless of what happens between now and July 1 (or what may happen afterward in the courts), it is going to be difficult to put the genie back in the bottle. Attempts to backtrack on recent announcements of “full disclosure” likely would become a PR disaster for those companies and have lasting effects on consumers' perception of their brands. So in practical effect, we're entering a whole new world of food labels where “may be partially produced with genetic engineering” is a commonly seen phrase. What that means for the industry's bottom line and consumer preferences will certainly be interesting to watch.

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[1] FDA's Regulatory Program for Genetically Engineered (GE) Food, Testimony of Michael M. Landa before the Subcomm. on Health of the U.S. House of Representatives Committee on Energy and Commerce (2014); Daren Bakst, A Q&A on the Mandatory Labeling of Genetically Engineered Foods, The Heritage Foundation (July 22, 2015).

[2] See, e.g., D. Charles & A. Aubrey, *How Little Vermont Got Big Food Companies to Label GMOs*, NPR.org (March 27, 2016); Christopher Doering, *Companies Begin Embracing GMO Labeling*, The Des Moines Register (Apr. 2, 2016).

[3] Vt. Stat. Ann. tit. 9, ch. 82A, §§ 3041-3048 (2014) (effective July 1, 2016).

[4] P. Kollipara, *Opposition Stalls U.S. Senate Bill Aimed at Blocking GMO Food Labels*, Sciencemag.org (March 17, 2016); Philip Brasher, *GMO Labeling Bill Stalls in Senate*, Agri-Pulse.com (March 16, 2016).

[5] U.S. Food & Drug Admin., *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (2015) (hereinafter *GE Plant Guidance*).

[6] FDA Has Determined That the AquAdvantage Salmon Is as Safe to Eat as Non-GE Salmon, FDA.gov (Nov. 19, 2015). Although beyond the scope of this article, a comprehensive national GE labeling standard arguably is also necessary to quell the political and legal turmoil created as a result of FDA's decision to approve this GE salmon for commercial sale. Environmental and consumer associations opposed to the sale of GE salmon recently filed a lawsuit against FDA, claiming, among other things, that the Agency acted beyond its statutory authority to approve the salmon. In Alaska, a major source for wild salmon, opposition to FDA's policy of voluntary labeling has been strong. Alaska Senator Lisa Murkowski even threatened to block a vote on the nomination of Dr. Robert Califf as FDA Commissioner until the Agency reversed its guidance on voluntary labeling of GE salmon (which, however, did not happen prior to Dr. Califf's confirmation in March 2016).

[7] U.S. Food & Drug Admin., *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon* (2015) (hereinafter *GE Atlantic Salmon Draft Guidance*).

[8] E.C. Pelonis & A.D. Jijon, *GMO Disclosure Debate Divides the Food Industry*, Law360 (Jan. 29, 2016); M. Quinn, *Federal GMO Labeling Bill Would Trump State Laws, Governing* (March 10, 2016).

[9] 2016 State Labeling Legislation Map, Ctr. For Food Safety.

[10] Joe Van Acker, *States Rally to Defend Vermont GMO Label Law in 2nd Circ.*, Law360 (Sept. 1, 2015).

[11] L. Murphy & B. Smith, *Vermont Law Top 10 Environmental Watch List 2016: #3 Vermont Act 120: A Light in the DARK for GMO Food Labeling*.

[12] *Safe and Accurate Food Labeling Act of 2015*, H.R. 1599, 114th Congress.

[13] *Id.*

[14] Kollipara, *supra* note 4.

[15] Doering, *supra* note 2.

[16] *GE Plant Guidance*, *supra* note 5.

[17] *GE Atlantic Salmon Draft Guidance*, *supra* note 7.

[18] U.S. Food & Drug Admin., *Statement of Policy – Food Derived from New Plant Varieties*

(1992).

[19] 21 U.S.C. § 343(a)(1) (2012). The Agency has interpreted the statute to mean that special labeling for foods is not required unless the absence of such labeling may “(1) pose special health risks . . . (2) mislead the consumer in light of other statements on the labeling . . . or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic (e.g., taste, smell, or texture), or functional characteristics of the food it resembles when in fact it does not.”

[20] Vt. Stat. Ann. tit. 9, ch. 82A, §§ 3041-3048 (2014) (effective July 1, 2016).

[21] A. Gasparro & J. Bunge, *GMO Labeling Law Roils Food Companies*, Wall Street J. (March 20, 2016).

[22] B. Kennedy, *New SmartLabel Initiative Gives Consumers Easy Access to Detailed Product Ingredient Information*, GMA Newsroom (Dec. 2, 2015); *Coalition for Safe and Affordable Food*; Alex Apple, *WCAX: Win in Washington for Vermont’s GMO Labeling Law, Rural Vermont* (March 16, 2016).

[23] S. Sundar, *Food Cos., Vt. Want GMO Law Trial to Wait for 2nd Circ. Input*, Law360 (Feb. 25, 2016).

[24] 92 F.3d 67 (2d Cir. 1996).

[25] *Id.* at 71.

[26] U.S. Food & Drug Admin. *Report on the Food and Drug Administration’s Review of the Safety of a Recombinant Bovine Somatotropin* (revised Apr. 23, 2009).

[27] Presentation of W.P. Hobgood, V.P. Animal Sci. Div., Agricultural Grp. of Monsanto Co., *Veterinary Med. Advisory Comm.*, (March 31, 1993).

[28] A. Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times (July 27, 2013).

[29] Gasparro & Bunge, *supra* note 21.

[30] Doering, *supra* note 2.

[31] *Cost Impact of Vermont’s GMO Labeling Law on Consumers Nationwide*, Corn Refiners Ass’n (Feb. 21, 2016).

[32] W. Lesser & S.E. Lynch, *Costs of Labeling Genetically Modified Food Products in N.Y. State* (2014).

[33] Gasparro & Bunge, *supra* note 21.

[34] *Id.*