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Both Houses of Congress Pass S.764 Establishing the National Bioengineering Food Disclosure Standard, Which Would Immediately Preempt Key Parts of the Vermont GMO Labeling Law

July 15, 2016

Food, Drugs, and Devices

Yesterday, the United States House of Representatives passed Bill S.764 ("Joint Bill"), which will amend the Agricultural Marketing Act of 1946[1] to add Subtitle E: "National Bioengineered Food Disclosure Standard," and Subtitle F: "Labeling of Certain Food."[2] The United States Senate passed the same bill last week on July 7, 2016. The Joint Bill, if signed into law by President Obama,[3] will immediately preempt most provisions of Vermont's Act 120, "An Act Relating to the Labeling of Food Produced with Genetic Engineering" (Vermont Law), which requires that certain foods offered for retail sale in Vermont be labeled, "produced with genetic engineering" or with similar alternative statements depending on the specific circumstances.[4] The Vermont Law went into effect on July 1, 2016.

The Joint Bill represents a significant departure from the provisions in the Vermont Law and preempts not only key provisions of the Vermont Law, but also enactments by states and state political subdivisions relating to the labeling of genetically engineered foods. Importantly, however, the Joint Bill arguably does not preempt all provisions of the Vermont Law, and leaves intact any remedy created by a state or federal statutory or common law right. That means that the Vermont Attorney General can argue that the provisions of the Vermont Law relating to "natural" claims are still enforceable and consumers can still bring private actions regarding other label claims, such as natural claims, on genetically engineered foods based on common law and arguably under the Vermont Law as well.

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[1] 7 U.S.C. §§ 1621, *et seq*.

[2] The Joint Bill is available here.

[3] We understand that the White House has indicated the President is expected to sign the law.

[4] Vt. Stat. Ann. tit. 9, §§ 3041-3048 (2016); *see* April 30, 2015 Client Alert, "Court Allows Vermont's GMO Labeling Law to Go into Effect," available here.

The Scope of the Joint Bill

The Joint Bill applies only to foods subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act, and then only if:

- the most predominant ingredient of the food would independently be subject to the labeling requirements of the FDCA; or
- the most predominant ingredient of the food is broth, stock, water, or a similar solution; and
- the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA.[5]

The section of the Joint Bill that provides for required labeling defines "food" as those articles defined as "food" under FDCA Section 201 (21 U.S.C. § 321) that are intended for human consumption. The same section defines "bioengineering," when used with respect to a food, to describe food that contains genetic material with a modification to the genetic material attained through *in vitro* recombinant techniques and resulting in a modification that could not have been achieved through conventional breeding or found in nature.[6]

The Joint Bill directs the Secretary of Agriculture (Secretary) to establish by two years after enactment a national mandatory bioengineered food disclosure standard for bioengineered food and requirements and procedures to carry out that standard.[7] It also requires the Secretary to promulgate regulations, but does not set a date by which the regulations must be codified.[8] The regulations must require that, at the manufacturer's election, the form of the label disclosure be "a text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators [URLs] not embedded in the link."[9] If a manufacturer chooses the electronic or digital link labeling option, the link or address must be accompanied only by the words, "Scan here for more food information" or equivalent language reflecting only technological changes.[10] Small manufacturers alternatively could instead choose to provide 1) a telephone number accompanied by the statement, "Call for more food information"; or 2) an internet website address.[11] Manufacturers must maintain and make available to the Secretary records the

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[5] Sec. 292(c).

[6] Sec. 291.

[7] Sec. 293(a).

[8] Sec. 293(b).

[9] *Id*. By one year after enactment, the Secretary must conduct a study to identify potential technological challenges regarding the electronic or digital disclosure mechanisms. It that study determines consumers do not have sufficient access to the disclosure through these means while shopping, the Secretary will provide additional options. Sec. 293(c).

[10] Sec. 293(d)(1)(A).

[11] Sec. 293(b)(2)(F) and (d)(1)(B).

Secretary determines to be "customary and reasonable" in the food industry to establish compliance.[12]

The Joint Bill makes it a "prohibited act" to fail to make a required disclosure knowingly.[13] The Secretary can impose recordkeeping requirements through rulemaking and may examine records and audit the manufacturer for compliance with the requirements under the Joint Bill. After notice to the manufacturer and an opportunity for hearing, the Secretary shall make public the results of the audit.[14] The Joint Bill provides that the Secretary has no recall authority based on whether the food bears the required disclosure.[15]

The regulations, once established, will exclude food served in restaurants or other retail food establishments, and provide alternative disclosure options for food in small or very small packages.[16] The regulations will also exclude very small food manufacturers and allow small manufacturers at least an additional year to comply with the regulations.[17] The Secretary will determine what constitutes a very small and a small food manufacturer. The regulations will additionally prohibit an animal-derived food from being considered bioengineered solely because the animal consumed feed containing a bioengineered substance.[18]

The final provision of the Joint Bill provides that a certification under the national organic program is sufficient, but not the only basis, to allow the manufacturer to make a claim, such as "not bioengineered" or "non-GMO" regarding the absence of a bioengineered food.[19]

Preemption

The Joint Bill contains two different preemption provisions. The first, entitled "State Food Labeling Standards," says that for food in interstate commerce that is the subject of the national bioengineered food disclosure standard established by Section E of the Joint Bill, no state or state political subdivision may establish or continue in effect any requirement relating to labeling or disclosure of whether the food is bioengineered or developed or produced using bioengineering that is not identical to the Section E disclosure requirements.[20]

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[12] Sec. 293(g)(2).

[13] Sec. 293(g)(1),

[14] Sec. 293(g)(3).

[15] Sec. 293(g)(4).

[16] Sec. 293(b)(2)(E) and (G)(i).

[17] Sec. 293(b)(2)(F) and (G)(ii).

[18] Sec. 293(b)(2)(A).

[19] Sec. 296.

[20] Sec. 293(e).

Section F contains a separate preemption provision that begins by defining "food" more broadly than it is defined in Section E.[21] Section F defines food as it is defined in FDCA Section 201, but does not limit that definition to food intended for humans. Accordingly, the preemption in Section F is broad enough to encompass animal feed and pet food as well as human food. Section F then prohibits a state or state political subdivision from establishing or continuing in effect with respect to any food or seed in interstate commerce requirements regarding the labeling of whether the food or seed is "genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering."[22] The prohibition encompasses claims that a food or seed is or contains an ingredient developed or produced using genetic engineering and includes food served in a restaurant or similar establishment. Section 296 of the Joint Bill, however, states that neither the Joint Bill itself nor "any regulation, rule, or requirement promulgated in accordance with [the Joint Bill] shall be construed to preempt any remedy created by a State or Federal Statutory or common law right."

Key Considerations

The two main effects of the Joint Bill are to preempt the "produced with genetic engineering" labeling provisions of Vermont Act 120, which went into effect on July 1, and the enactment or enforcement of similar provisions in other states. Proponents of the Joint Bill hoped for its passage by both houses of Congress by early July specifically to address the effects of the Vermont law, although the regulations promulgated under that law created a six-month "safe harbor" for foods distributed before July 1, 2016, and offered for retail sale through December 31, 2016.[23] The Joint Bill is goes into effective upon enactment.

The Joint Bill's two preemption provisions respectively preempt "any requirement relating to labeling or disclosure of whether the food is bioengineered or developed or produced using bioengineering" and "labeling of whether the food or seed is 'genetically engineered (which shall include such other similar terms as determined by the Secretary) or was developed or produced using genetic engineering.'" The preemption provisions do not expressly preempt other labeling provisions relating to foods produced with genetic engineering or containing a genetically engineered ingredient. Therefore, the State of Vermont could argue that Section 3043(c) in its Act 120 is still enforceable, which provides:

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[21] Sec. 295.

[22] *Id*.

[23] Vermont Consumer Protection Rule 121.04(d). The Vermont Attorney General's Office had also announced in May 2016 that after January 1, 2017, its enforcement priorities would focus on willful violations such that it did not expect to bring enforcement cases based solely on a company's failure to remove improperly labeled products that were distributed before July 1, 2016. May 16, 2016 Vermont Attorney General Memorandum re "Updated AGO Enforcement Priorities for Act 120 (GE Food Labeling Law)," available here.

> Except as set forth under section 3044 of this title, a manufacturer of a food produced entirely or in part from genetic engineering shall not label the product on the package, in signage, or in advertising as "natural," "naturally made," "naturally grown," "all natural," or any words of similar import that would have a tendency to mislead a consumer.

Similarly, the Joint Bill's Section 296 specifically states that neither the Joint Bill nor any regulations preempt "any remedy created by a State or Federal Statutory or common law right." Therefore, the Joint Bill does not prevent consumer deception suits, including with respect to natural claims for foods produced with genetic engineering or containing a genetically engineered ingredient.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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