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MEMORANDUM

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Re: **Congress Passes Mandatory GE Disclosure Legislation to Preempt Vermont Act 120**

The House of Representatives voted today to approve compromise legislation sponsored by Senate Agriculture Committee Chairman Pat Roberts (R-Kan.) and Ranking Member Debbie Stabenow (D-Mich.) that will preempt the Vermont and other state labeling laws relating to genetically engineered (GE) foods. 1/ The bill creates a national, uniform disclosure standard for GE foods that will consist of a text, symbol, or digital or electronic link. It now awaits President Obama's signature before becoming law. Passage of the law marks a major victory for industry, but the GE labeling issue will remain active for many years to come as the U.S. Department of Agriculture (USDA) works to implement the disclosure standard in the next two years. We expect that USDA will aim to issue its final rule by July 2018, with additional time for companies to come into compliance with that disclosure standard. This memorandum summarizes the key components of the disclosure standard and the bill's likely effect on state labeling laws.

Background

Vermont adopted Act 120 in May 2014, imposing labeling requirements for foods produced entirely or in part with genetic engineering and offered for retail sale in Vermont, and finalized its regulations implementing the law in April 2015. The law took effect July 1, 2016. Industry has sought to find a federal solution that would create national uniformity in the labeling of GE foods by preempting Vermont and other state labeling laws, such as those passed by Maine and Connecticut, which both have an effective date contingent upon additional states enacting similar laws.

In July 2015, the House approved a bill (H.R. 1599) sponsored by Representative Mike Pompeo (R-Kan.) that would have created a certification program for labeling GE and non-GE foods similar to the certification of organic foods under the National Organic Program (NOP). The Senate did not act upon this legislation. Instead, Senator Roberts proposed a bill earlier in the year that would have created a voluntary GE labeling standard, which would have become mandatory if after a period of time there was not substantial participation by industry in the program. That bill failed to garner the necessary support needed to pass a procedural vote in March 2016.

In June, Senators Roberts and Stabenow released their compromise bill to preempt Vermont and other state labeling laws while establishing a mandatory national disclosure standard. The Senate

1/ A copy of the legislation is available here: https://www.congress.gov/114/bills/s764/BILLS-114s764eas.pdf.

approved the bill on July 7. After having received the approval of the House, the bill now goes to President Obama to sign the bill into law. The President is not expected to veto the legislation.

Establishment of Standard for Bioengineered Foods

The bill requires USDA to establish a standard or definition for "bioengineered food" or food that may be bioengineered. The term "bioengineering" is defined to refer to a food that (A) contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature. In response to concerns raised by the U.S. Food and Drug Administration (FDA) that the definition of bioengineering could be interpreted to exclude many foods and ingredients commonly viewed as GE foods, USDA has explained that it interprets the legislation to authorize the agency to require disclosures for products containing highly refined oils, sugars, or high fructose corn syrup that have been processed or developed using bioengineering.

The bill states that a food derived from animals may not be considered bioengineered solely because the animal consumed bioengineered feed. For instance, milk would not be considered "bioengineered" solely because the cow consumed GE feed. In addition, the bill directs USDA to determine the amount of a bioengineered substance that may be present in food in order for the food to be considered a bioengineered food. USDA also must establish a process for requesting an agency determination regarding the additional factors and conditions under which a food would be considered bioengineered. Importantly, a food will not be considered "not bioengineered," "non-GMO," or any similar term simply because the food is not required to bear a bioengineering disclosure.

The bill applies to foods that are subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA). Products that are subject to the labeling requirements of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act are only subject to the disclosure standard if: (1) the most predominant ingredient would be subject to the labeling requirements of the FFDCA; or (2) the most predominant ingredient is broth, stock, water, or a similar solution, and the second most predominant ingredient would be subject to the labeling requirements of the FFDCA. All other meat, poultry, and egg products would be excluded.

Presumably, the focus on "subject to the labeling requirements" would provide the Secretary with the authority to exempt fresh produce, meat, and poultry when the products otherwise lawfully may be sold without a label.

USDA also is directed to exempt from the federal disclosure standard foods served in restaurants or other similar retail food establishments and to create an exemption for "very small businesses" – a term USDA will need to define.

Format of Disclosure

The bill directs USDA to establish a mandatory disclosure standard for bioengineered foods within two years of the bill's enactment. The form of the bioengineering disclosure must be a text, symbol, or electronic or digital link; and the manufacturer may choose among these options. This would include scannable technology such as the SmartLabel or a Quick Response (QR) Code. The bill would not allow Internet website URLs that are not embedded in the link to qualify for the disclosure (i.e., a company could not comply by posting the website URL on the package). Any electronic or digital link disclosure must be of sufficient size to be easily and effectively scanned or read by a digital device. In addition, USDA must provide reasonable alternative disclosure options for food contained in small or very small packages.

On-package language would be required to accompany electronic or digital link disclosures. The language would state, "Scan here for more food information," or similar language reflecting changes in the technology used to access the link (such as "take picture here" rather than "scan here"). The electronic or digital link must provide the bioengineering disclosure in a consistent and conspicuous manner on the first landing page that appears, and it must exclude marketing and promotional information. The on-pack electronic or digital link disclosures also must include a telephone number that provides access to the bioengineering disclosure, which must be accompanied by the statement "Call for more food information."

Small Businesses

The bill requires that small businesses (as defined by USDA) must be provided at least an additional year after the implementation date of the regulations issued under the law to comply with the standard. Small businesses also must be permitted to choose from among two disclosure options, in addition to the disclosure options available to all businesses: (1) a telephone number accompanied by language indicating that the number provides access to additional information (i.e., "Call for more food information"); or (2) an Internet website maintained by the small food manufacturer.

Study of Electronic or Digital Link Disclosure

Within a year of the bill's enactment, USDA must conduct a study and collect public comments to identify potential technological challenges that may affect whether consumers would have access to the disclosures through electronic or digital disclosure methods. The study must consider whether the following factors would affect consumer access to the bioengineering disclosure through electronic or digital disclosure methods:

- the availability of wireless Internet or cellular networks;
- the availability of landline telephones in stores;
- challenges facing small and rural retailers;
- efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and
- the costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technology that provide bioengineering disclosure information.

If after conducting the study USDA determines that consumers would not have sufficient access to bioengineering disclosures through electronic or digital disclosure methods while shopping, the agency must consult with food retailers and manufacturers and provide additional and comparable options to access the disclosure.

Preemption

The bill includes a strong preemption clause that preempts the GE labeling requirements of Vermont's Act 120 and any other state or local law that would impose labeling requirements related to whether a food (including foods served in restaurants or similar establishments) or seed is GE, that are different than or additional to the requirements established in the bill. The preemption provision will take effect immediately upon the bill being signed into law.

The scope of the preemption clause covers state statutory laws creating labeling standards for bioengineered or non-bioengineered foods, including any state common law and consumer protection laws to the extent that they would seek to impose different or additional requirements than those established in the bill. This will ensure that states cannot circumvent preemption by creating

laws imposing standards that are different than or in addition to the federal standard, nor can private citizens seek to impose such a standard through a private right of action.

States will be permitted, however, to adopt requirements relating to the labeling or disclosure of whether a food is bioengineered – as long as those requirements are *identical* to the mandatory disclosure requirements established under the bill. In addition, remedies established by state or federal statutory or common law rights are not preempted. This means that states could, for example, adopt laws to impose a civil penalty for companies failing to comply with the federal disclosure standard. In addition, in those states where such a cause of action exists under consumer protection laws, consumers could sue food companies, alleging that noncompliance with the federal disclosure standard is misleading or deceptive under state law.

The reach of the preemption clause will undoubtedly be the subject of future litigation. In Vermont, for example, the State may choose to litigate whether the preemption clause covers both the GE labeling requirements and the provision prohibiting the use of the term "natural" for foods that are produced entirely or in part with genetic engineering.

Consistency with Organic Standard

The bill directs USDA to consider establishing consistency between the bioengineering disclosure standard and the Organic Foods Production Act of 1990. In addition, certification of a food as organic under the NOP will be considered sufficient to make a claim that a food is "not bioengineered," "non-GMO," or a similar claim.

Enforcement

The bill prohibits companies from knowingly failing to disclose that a food is bioengineered as required by the federal disclosure standard and USDA's implementing regulations. In addition, companies will be prohibited from declaring that a food is bioengineered except in compliance with the federal standard. Companies subject to the disclosure standard must maintain and make available any records required by the Secretary's regulations to establish compliance with the standard.

USDA is authorized to conduct audits of any records required to demonstrate compliance with the standard. Following the audit, USDA must provide companies with notice and an opportunity for a hearing on the results of the audit, after which USDA must make the summary of the results of the audit public.

USDA will not have authority to recall food on the basis of whether the food complies with the disclosure standard.

Implications

Once signed into law, food manufacturers will no longer be required to comply with the GE labeling requirements of Vermont's Act 120, nor will they need to be concerned with the development of a patchwork of state labeling requirements. It will be important, however, to remain engaged on this issue. The bill leaves much of the details of the federal disclosure standard to USDA's discretion, and the industry will need to provide thoughtful input and feedback to USDA as the agency works to develop the regulations to implement the federal standard.

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Should you have any questions, or wish to discuss these issues further, please contact us.