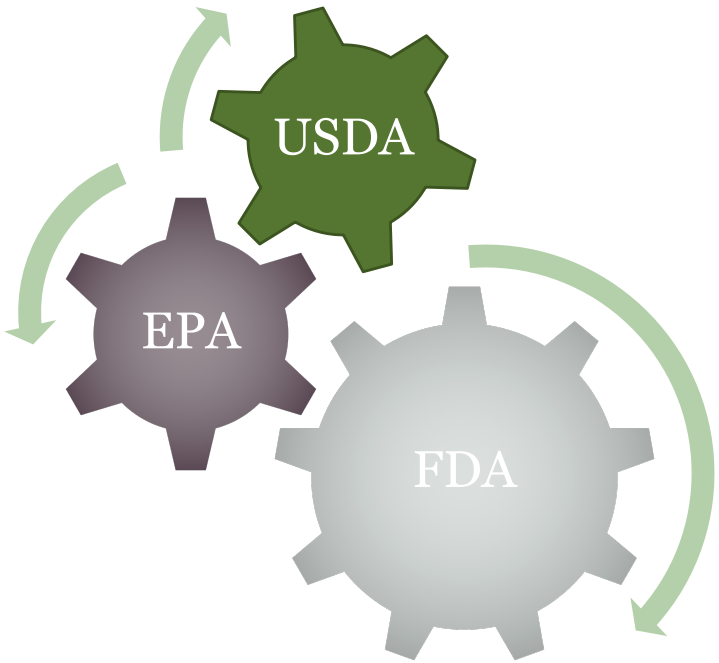
Hogan Lovells

Genetically Engineered Foods

Review of New Mandatory Disclosures

February 10, 2017

Current Federal GMO Regulatory Framework



- U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) share regulatory oversight over genetically engineered foods
- Depending on the genetic engineering process and the intended use, reviews by more than one agency may be required prior to market
- New law places USDA in charge of the disclosure requirements

Vermont GE Labeling Law

- Would require labeling of processed foods with statement such as “may b produced with genetic engineering”
- Prohibits “natural” claims on produc containing GE foods
- $1,000 per day penalty per uniquely marked product
- Holds manufacturer—not retailer—liable
- Contains exemptions

GMO Labeling: Help Has Arrived!

- Passed House of Representatives on July 14 (after Senate passed same language July 7)
- The bill:
  - Preempts state and local GE labeling laws
  - Provides a mandatory national disclosure standard for bioengineered foods, to be implemented by USDA
    - USDA must establish the mandatory disclosure standard within 2 years of the bill's enactment
    - Small businesses get an additional year after the implementation date for larger companies

Definition of "Bioengineered Food"

- 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.
- The law does not use the term "GMO"
- USDA must established definitions via rulemaking
  - USDA stated 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
  - USDA likely will address this issue in the final regulation

Scope

- A food derived from animals may not be considered bioengineered solely because the animal consumed bioengineered feed
  - Milk, meat, eggs would not be considered "bioengineered" solely because the cow, animal, or chicken consumed GE feed.
  - GE Salmon would be considered a bioengineered food

Scope

Law Covers

- Products subject to labeling requirements under the FFDCA
- Meat, poultry, and egg products subject to labeling requirements of the FMIA, PPIA, and EPIA **only if**:
  - the first ingredient would be subject to FFDCA; OR
  - if the first ingredient is broth, stock, water, or a similar solution, the second most predominant ingredient is subject to the FFDCA
- All other meat, poultry, and egg products are excluded
- Foods served in restaurants or other similar retail food establishments are exempt
- Very small businesses (not yet defined) are exempt

Scope

- Statute provides USDA with the flexibility and discretion to make many important decisions
  - What amount of a bioengineered substance may be present in food in order for the food to be considered a bioengineered food.?
  - What process should be established to create exemptions and what considerations apply?
- 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

Does this mean 3 categories of products?

1) GE
2) Non-GE
3) Others

Disclosure Options

- Disclosure Requirement Must Be:
  1. **A text**
  2. **Symbol, or**
  3. **An electronic or digital (can't use URL)**

  Small businesses (to be defined by USDA) get two more options:

  4. A telephone number and language, or
  5. A website
- USDA must provide reasonable alternative options for food contained in small or very small packages
- Food manufacturer gets to select the form of disclosure

Text: Bioengineered Food?
GMO? GE Food?

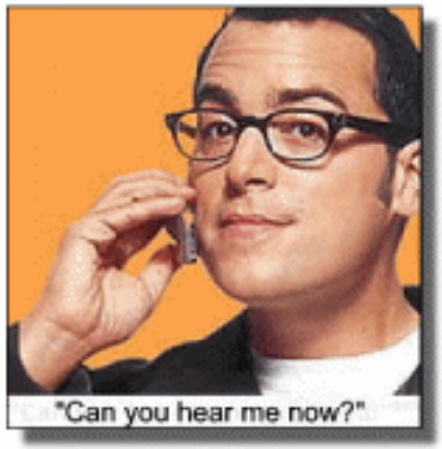
Symbol: bf? G? Something else?

Electronic Disclosure Requirements

- On-package language must accompany disclosure, limited to: "Scan here for more food information" *or equivalent language that only reflects technological changes*
- The electronic or digital link must provide the disclosure in a consistent and conspicuous manner on the first landing page, and it must exclude marketing and promotional material
- The electronic or digital link must also include a phone number that provides access to the disclosure
- Disclosure may not collected, analyze, or sell any personally identifiable information about the consumers or the devices of consumers
- Must be of sufficient size to be scanned and read by the device

Study of Electronic or Digital Link Disclosure

- USDA must conduct a study (and collect public comments) to identify potential technological challenges that could impede access to disclosures
  - WIFI/cellular network availability
  - Availability of landline telephones in stores
  - Challenges facing small and rural retailers
  - Efforts that retailers and others take to address these challenges
  - Costs and benefits of installing in-store scanner
- Must be conducted within 1 year of bill's enactment
- If USDA finds consumers would have insufficient access to disclosures while shopping, USDA must consult with retailers and manufacturers and provide "additional and comparable" access options



Consistency with Organic Standard

- USDA to consider establishing consistency between the disclosure standard and the Organic Foods Production Act of 1990
- Certified organic foods automatically eligible for a claim that the food is “non-GMO,” “not bioengineered,” or similar claims

Safety

- A bioengineered food that completes the pre-market Federal regulatory review process “shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.”

Enforcement

- Bill prohibits companies from:
  - Knowingly failing to disclose that a food is bioengineered as required by the standard and USDA's regulations
  - Declaring that a food is bioengineered except in compliance with the federal standard
- Companies must maintain and make available any records required under USDA regulations to establish compliance with the standard
- USDA authorized to conduct audits of records to demonstrate compliance with the standard
  - USDA must provide notice and an opportunity for a hearing on the results of the audit, after which USDA must make the results of the audit public
- USDA does not have recall authority based on compliance with disclosure standard

Preemption

- Preempts state and local laws that would impose requirements related to whether a food is bioengineered that are different from or in addition to the federal requirements
  - Preempted GE labeling requirements of Vermont Act 120, as well as CT and ME requirements
- Preemption took effect immediately
- States can adopt requirements identical to federal disclosure requirements and definition of bioengineering
- Preemption does not extend to "any remedy created by a State or Federal statutory or common law right."

Next Steps

- USDA to conduct study on access to disclosures (by July 2017)
- USDA sent advance notice of proposed rulemaking (ANPR) to OMB in early January…..and then retracted it after the Executive Order restricting new regulations
- USDA hopefully will be able to issue ANPR in Q1 or Q2 ’17
  - Must review comments
  - Issue a proposed rule
  - Review comments
  - Issue a final rule (Will EO require USDA to demonstrate no cost on industry and/or identify two regulations to repeal?)
- USDA would like to issue a final regulation by July 2018; but……

Label Harmonization?

- Nutrition label compliance July 2018
- Companies could be forced to undergo two significant label changes within 2 years
- Hopefully Trump Administration will be receptive to the burdens on industry

What Should Companies Do Now?

- Work with trade associations and urge the administration to postpone compliance date for NFP so there would be increased likelihood for a single change for NFP and Bioengineered Food labeling
- Be engaged in the rulemaking process
  - USDA has a lot of hard work to do
  - Identify ingredients that have GE inputs—ingredients and foods that raised challenges under Vermont's law—and make certain USDA addresses them
- Be patient

Questions?

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