SUMMARY OF USDA FINAL RULE

On July 29, 2016, Congress passed the National Bioengineered Food Disclosure Standard (Pub. L. 114-216), a law amending the Agricultural Marketing Act of 1946 to require the secretary of Agriculture to establish a mandatory, national disclosure standard for genetically engineered (GE) or GMO foods. On May 4, 2018, USDA's Agricultural Marketing Service (AMS) released its proposed rule. On Dec. 20, 2018, AMS released its final rule, to go into effect by Jan. 1, 2020, with a mandatory compliance date of Jan. 1, 2022.

Definition and scope

Scope of regulatory standard and exemptions

- **"Bioengineered food" or "BE foods"** – The final rule narrowly defines the term "bioengineered food" to only mean foods produced using rDNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature. In addition, a food is not considered to be bioengineered if it does not contain detectable levels of the modified genetic material, thereby excluding highly refined ingredients like sugars and oils.
    - In addition to excluding highly refined ingredients, the definition does not clearly require the disclosure of foods produced through all new GMO techniques, like CRISPR and RNAi.
    - In a letter dated July 1, 2016, then-USDA General Counsel Jeffrey Prieto wrote that the law provides USDA with the legal authority to include highly refined ingredients and products of new GMO techniques. USDA now says that such an interpretation is overly broad.
    - The vast majority of countries that label GMOs, require highly refined ingredients and products of modern forms of biotechnology to be labeled.
- **"Conventional Breeding"** – The final rule does not define the term.
- **"Found in Nature"** – The final rule does not define the term.
- **Threshold** – A product is exempt from the disclosure requirement if there is an inadvertent or technically unavoidable presence of a GMO substance of up to five percent in each ingredient. Intentional use of a GMO substance in the product will trigger the disclosure requirement even if below the 5 percent ingredient threshold. "*If a food manufacturer was producing a non-BE cracker, ran out of one non-BE ingredient, and decided to use a BE version of that ingredient, that would be considered an intentional use and would require a BE food disclosure."*
- **List of bioengineered foods** – USDA has created a central List of Bioengineered Foods to identify the GMO crops and foods that are commercially available around the world. The list provides food companies with an idea of which foods they must keep records for, and which foods may require a mandatory disclosure.
    - The list includes: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink-flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer) and sugarbeet.
    - A regulated entity must disclose that the food is bioengineered if it has that knowledge, even if a food is not on the list.
- **Organic** – Food certified under the National Organic Program is exempt.
- **Animal feed** – Food derived from an animal that is fed GMO feed but is not itself genetically engineered is exempt.

Recordkeeping, compliance and auditing

- The final rule includes a framework for recordkeeping, auditing and compliance with the list.
- A food company or retailer must maintain records about a food or ingredient if it uses a food, or an

ingredient produced from a food, on the list or if it has knowledge that the food or ingredient is GMO.

- A food company does not have to disclose if:
    - Records verify that the food is non-bioengineered.
    - Records verify that the food has been subject to a refinement process validated to make the modified genetic material in the food undetectable.
    - Certificates of analysis or other records of testing appropriate to the specific food confirm the absence of modified genetic material.
- The final rule establishes performance standards for detecting the presence of modified genetic materials in refined foods.
- Any person who suspects a possible violation may file a written statement or complaint to AMS. If AMS determines that further investigation of a complaint is warranted, an audit, investigation and public hearing may be conducted.

Disclosure standard

- Under USDA's final rule, if a food is required to bear a mandatory disclosure, companies will have four methods of disclosure (see below).
- For packaged food, the responsibility to disclose falls on the food manufacturer or importer.
- Retailers are responsible for GMO foods sold in bulk or packaged by the retailer.
- The final rule does not allow the use of "may be" or "may contain" statements.
- Disclosure must be prominent and conspicuous.

Method 1 – Text disclosure

- A text disclosure must bear this text, or the plural version, only:
    - "Bioengineered food" – for raw agricultural commodities or processed foods that contain only bioengineered food ingredients.
    - "Contains a bioengineered food ingredient" for multi-ingredient food that contains one or more bioengineered ingredients but isn't solely bioengineered.
- Food companies can only use those terms to describe GMO foods or ingredients.
- Food distributed solely in a U.S. territory can be labeled in the predominant language used in that territory.

Method 2 – Symbol

The final rule allows companies to comply with the disclosure requirement using the following symbol in color or in black and white:

Method 3 – Electronic or digital disclosure links

- Digital disclosure links must be accompanied by the following information on the food package:
    - Text that states "Scan here for more food information" or equivalent language reflecting technological changes (e.g., "Scan icon for more food information").
    - A phone number with the text "Call [number] for more food information."
- When a consumer scans a product, the product information page, which includes the bioengineered food disclosure, must be the first page the consumer sees.

- The disclosure can either be the text disclosure (Method 1) or symbol disclosure (Method 2).
- The rule prohibits digital disclosures from including marketing and promotional information, and from collecting, analyzing or selling any personally identifiable information about consumers or their devices.
- The accompanying telephone number must be close to the digital link and must provide the bioengineered disclosure to the consumer any time of day.
- The proposed rule does not stipulate:
    - QR code size – the law states that the electronic or digital link disclosure must be of sufficient size to be easily and effectively scanned or read by a digital device; however, the proposed rule does not stipulate any size requirements or provide any such guidance.
    - Design requirements specific to color, contrast, "quiet zone" or packaging material and shape, which can all impact how scannable an electronic or digital disclosure is.
    - Whether there can be multiple QR codes on a product.
    - What types of electronic or digital link disclosures are allowed.

Method 4 – Text message disclosure

- The final rule creates a fourth disclosure method, a text message disclosure, not required by law.
- The product label must include the statement "Text [command word] to [number] for bioengineered food information."
- The response must be a one-time response, and the only information in the response must either be the on-package text (Method 1) or the text allowed under voluntary disclosures (see below).
- Regulated entities are prohibited from charging text fees, including marketing info or collecting consumer data.

No "Comparable Options"

- The proposed rule does not provide for "comparable options," as required by the law, for consumers who may have trouble accessing the digital disclosures while shopping.
- Although the final rule allows for the use of a text message disclosure (one of the suggestions made in Deloitte's report to USDA), it does not stipulate that it is in addition to a digital disclosure. Therefore, companies would not be required to include the text message information on the package if they use the digital disclosure option, meaning it may not be used at all and therefore not comparable. In addition, many rural Americans do not have reliable cellular service that would allow them to send or receive text messages.

Small and very small food packages

- USDA defines "small food package" as having a total surface area of less than 40 square inches and "very small food package" as having less than 12 square inches.
- For small and very small food packages, companies would be allowed to shorten prompts as such: "Text for info"; "Scan for info"; or "Call for info".
- Companies that already include websites or telephone numbers on their small or very small food packages would be allowed to use those numbers as long as a consumer could get the disclosure.

Voluntary disclosure

- Entities like restaurants and very small manufacturers that are exempt from disclosure can still voluntarily disclose using the same forms of disclosure used by entities that must disclose.
- For foods or food ingredients that are derived from a food on the list of bioengineered foods but do not meet the definition of a GMO food under the rule, food companies can voluntarily disclose via:
    - The following on-package text:

        - "Derived from bioengineering."
        - "Ingredient(s) derived from a bioengineered source."
        - The term "Ingredients" may be replaced with the name of the crop or specific food, however it remains to be seen if companies will be permitted to voluntarily use terms like "genetically engineered" instead of bioengineered when making voluntary disclosures.
    - The following symbols:

    - An electronic or digital link that provides consumers the voluntary text or voluntary symbol.
    - A text message disclosure that provides consumers with the voluntary text or voluntary symbol.
    - Small manufacturers and small and very small packages can make disclosures in accordance with the small manufacturer and small and very small package options.
- Food companies are not prohibited from making other claims regarding bioengineered foods, like non-GMO claims, provided that such claims are consistent with applicable federal law.

Voluntary "bridge" labeling

- Companies may voluntarily label products that meet the requirements of Vermont's GMO labeling regulations until December 31, 2021.

Treatment of small and very small food manufacturers

In accordance with USDA's final rule, an estimated 86 percent of small and very small food manufacturers, producing 8 percent of products nationwide, will either be excluded from the disclosure requirement or will be afforded additional time to comply with less strict disclosure requirements.

Small food manufacturer – Small food manufacturers with annual receipts between $2.5 and $10 million get additional time to comply and have two additional disclosure options:

- "Call for more food information" with an accompanying telephone number that provides the text disclosure in audio form.
- "Visit [URL of the website] for more food information that provides the text disclosure or symbol disclosure."

Very small food manufacturer – Very small food manufacturers with annual receipts of less than $2.5 million are exempt from disclosure requirements but are allowed to disclose voluntarily.

Implementation dates

- Implementation date: January 1, 2020.
- Extended implementation date (for small food manufacturers): January 1, 2021.
- Voluntary "bridge label" date: Ends on December 31, 2021.
- Mandatory compliance date: January 1, 2022.