**National Bioengineered Food Disclosure Standard**

**Highlights of the Final Rule**

**On December 21, 2018, USDA’s Agricultural Marketing Service (AMS) published a** [**final rule**](https://www.federalregister.gov/documents/2018/12/21/2018-27283/national-bioengineered-food-disclosure-standard) **to implement the National Bioengineered (BE) Food Disclosure Standard.** The rule requires disclosure of BE ingredients in foods, and implements a law passed by Congress to pre-empt similar state labeling requirements. The requirements for disclosure are now codified at 7 CFR Part 66.

**Who is regulated by the disclosure rule?**

In general, regulated entities are food manufacturers and importers of food. However, exemptions include foods served in restaurants or similar establishments, very small food manufacturers (less than $2.5 million annual sales), and certified organic food. (The National Organic Program already prohibits the use of BE ingredients.)

**What other exemptions apply?**

Foods with no bioengineered substances are exempt, even if they contain up to 5% BE “presence.” Importantly, this presence must be “inadvertent or technically unavoidable,” so normal ingredients or additives (including enzymes) are *not* exempted by the 5% allowance.

In addition, animal foods are not considered BE merely because the animal consumed BE feed.

**Does this mean that animal foods are non-BE or “non-GMO”?**

Not necessarily. In fact, the law provides that being exempt from disclosure is not sufficient, on its own, to make this kind of “absence claim.” Absence claims are under the jurisdiction of the Food and Drug Administration (FDA) and the Federal Trade Commission, not AMS.

**Would foods *containing* animal products ever be subject to disclosure?**

Yes, potentially. If animal products are ingredients of a food that is FDA-regulated, then disclosure requirements would apply if the food contains BE ingredients.

If animal products are ingredients of a food that is USDA-regulated, disclosure requirements apply *only* if (1) the first listed ingredient in the product is itself BE, *or* (2) the second-listed ingredient is BE and the first ingredient is water, broth or stock.

In other words, the mere presence of an animal product as an ingredient does not automatically exempt the entire product from disclosure. The animal product itself does not trigger disclosure requirements, but another ingredient might.

**Are refined ingredients considered BE?**

No, unless they actually contain detectable modified genetic material. As a result of the refining processes to which they are subject, foods like refined beet sugar, high-fructose corn syrup and soybean oil are generally exempt from disclosure under the final rule. Regulated entities do have to be able to demonstrate these foods’ lack of modified genetic material, and can do so by (1) verifying that they are sourced from non-BE crops; (2) showing that the refining process has been validated to render modified genetic material undetectable; or (3) conducting analytical testing to confirm the absence of modified genetic material.

The treatment of highly refined substances is the result of AMS’s final definition of “bioengineered foods,” which is quite similar to the corresponding definition in the law. One of the key phrases in the definition is that a BE food “contains genetic material that has been modified …” If genetic material is destroyed in the refining process, AMS is considering the resulting food not to “contain” the material and therefore not to be BE for purposes of disclosure.

Another result of this definition is that new gene editing techniques like CRISPR-Cas9 would probably *not* trigger disclosure requirements. The definition requires that the “genetic material … has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques …” Gene editing typically deletes genes rather than introducing genes of a different species, as in traditional bioengineering.

**What if companies want to disclose highly refined ingredients?**

Companies are allowed to voluntarily disclose ingredients that are “derived from” a BE food. The food must be on AMS’s List of Bioengineered Foods. (Corn, soybeans and sugarbeets are on this list.) Among the disclosure options is a specific symbol that is different from the symbols used for mandatory BE disclosure (*see below*).

**How can companies disclose BE ingredients?**

The options are (1) a text disclosure on the package, (2) use of a symbol provided by AMS, (3) an on-label electronic or digital link, or (4) a text message that can be requested by the consumer. In the final rule, AMS specifies, in some detail, the required content and appearance of each option.

**When must companies comply with the final rule?**

The rule has implementation dates and compliance dates. The implementation dates are January 1, 2020, for all regulated entities other than small food manufacturers, whose implementation date is January 1, 2021. The more important date is the compliance date, which is January 1, 2022, for all regulated entities. The compliance date is when FDA will begin taking actions to enforce the rule.

Because the compliance date is a year later than in the proposed rule, FDA is not allowing the use of existing inventories without the disclosure label after the compliance date. This is a change from the proposed rule.