

ALERT

Ninth Circuit Upends USDA's Bioengineered Food Disclosure Requirements

November 11, 2025

In *Natural Grocers v. Rollins*, the U.S. Court of Appeals for the Ninth Circuit significantly upended certain parts of the U.S. Department of Agriculture's (USDA) National Bioengineered Food Disclosure Standard (BE Rule).

The 2018 BE Rule implemented the 2016 National Bioengineered Food Disclosure Standard amendments to the Agricultural Marketing Act, which require mandatory consumer-facing disclosure with respect to bioengineered food.

In an October 31, 2025 3-0 opinion, the court held that:

- The USDA BE Rule cannot exclude genetically modified food or food ingredients, subject to a refining process (e.g., highly refined foods) validated to render modified genetic material undetectable, from the definition of "bioengineered food" because of the USDA's legal error in determining that such refined foods do not "contain" modified genetic material.
- While the court rejected the BE Rule's existing "bioengineered food" definition as to the exclusion of refined foods, the opinion states that the USDA has the authority under a separate provision of the Act to set a threshold amount of genetically modified material necessary for a food to qualify as a "bioengineered food."
- The BE Rule's requirement to use the term "bioengineered food" in disclosures, rather than more familiar terms such as "genetically engineered" or "GMO," is lawful.
- The district court erred in not vacating aspects of the rule allowing electronic/digital link and text message disclosures to

Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Mary Beth Schultz
Partner
202.719.3471
mschultz@wiley.law

Lauren Petrin
Associate
202.719.3762
lpetrin@wiley.law

Practice Areas

Environment & Product Regulation
FDA and USDA Regulatory Compliance
Food & Drug

identify a food as bioengineered where the court found those methods did not provide consumers with meaningful access to the disclosure.

The Ninth Circuit returned the case to the district court, directing it to remand certain issues back to the USDA and to consider any appropriate steps to vacate or consider vacating portions of the BE Rule in accordance with the Ninth Circuit's opinion.

WHAT DOES THIS MEAN FOR FOOD MANUFACTURERS? The court's decision sends the case back to the district court to both seek arguments from the parties about the appropriate way to vacate certain sections of the BE Rule and to require the USDA to reconsider the regulatory definition of the phrase "bioengineered food."

For now, there is uncertainty about the methods, besides the labeled text or symbol options in the current BE Rule, that food manufacturers will be able to use to disclose that their products contain bioengineered material and what definition of "bioengineered food" will be in place until the amended BE Rule is in effect. While this will not be sorted out for a while, nothing will be required to change until the district court issues a ruling.

USDA will have to issue a new regulatory definition for "bioengineered food." The Ninth Circuit concluded that USDA has authority to set a threshold for relevant amounts of a bioengineered substance that would determine if a substance is a "bioengineered food" subject to the mandatory disclosure requirements under Section 293(b)(2)(B) of the Act. While USDA may choose to explore this option as a way to potentially move forward, the court's opinion does not appear to limit USDA from considering other potential options.

USDA will also have to amend the BE Rule regarding allowable methods for manufacturers to disclose that a food is bioengineered. As described more fully below, USDA is already working on a new rule on this issue.

BACKGROUND: The plaintiffs are a group of grocery retailers and public interest organizations challenging the BE Rule requirements. Three producer groups, the United States Beet Sugar Association, the American Sugarbeet Growers Association, and the American Farm Bureau Federation, intervened as additional defendants.

Plaintiffs asserted claims under the Administrative Procedure Act, arguing that the following provisions of the BE Rule were arbitrary and capricious and contrary to law:

1. Excluding from the definition of "bioengineered foods" those foods that include genetically modified ingredients but are so highly processed that the modified genetic material is "not detectable" in the final food product;
2. Mandatory use of the term "bioengineered" in required disclosures rather than the more familiar terms such as "genetically engineered" or "genetically modified organism (GMO)";
3. Allowance of QR codes and text messages to be adequate forms of disclosure that a food is bioengineered or contains bioengineered ingredients instead of disclosure on the food package with

statements or symbols.

Undetected Bioengineered Material Exemption

The Ninth Circuit concluded that USDA acted unlawfully in adopting a definition that exempted foods made from bioengineered ingredients from the disclosure standards if the modified genetic material is "undetectable" in the final food product. Under the current BE Rule, if the manufacturer can demonstrate "that the food has been subjected to a refinement process" that made the genetically modified material undetectable or has testing to "confirm the absence of modified genetic material," in the final product, the food is exempt from disclosure.

The panel rejected the USDA's conclusion that the non-detectability of genetically modified material in a final food product was legally equivalent to a finding that the food *does not contain* bioengineered material. The court noted that different detection methods vary in their "limits of detection," so the absence of modified genetic material based upon any particular method or test cannot establish that the food does not "contain" bioengineered materials. Since the regulations fail to define a "sufficiently sensitive detection method," the exclusion for foods with undetectable levels of genetically modified materials could not be upheld.

Although the exclusion for refined foods was found to be unlawful, the Ninth Circuit rejected plaintiffs' assertion that the USDA lacks any authority to establish threshold levels for the amount of bioengineered materials that may be present in food for it to be subject to the disclosure requirements. The court found that, under a separate provision of the Act (Section 293(b)(2)(B)), Congress explicitly granted USDA the authority to determine "the amounts of a bioengineered substance that may be present in food ... in order for the food to be a bioengineered food." This leaves open the possibility of USDA adopting a threshold amount of bioengineered substance that may be present in the food to subject it to the disclosure requirements.

The Ninth Circuit reversed the district court's summary judgment decision to defendants on this claim and remanded to the district court to grant summary judgment to the plaintiffs, remand the relevant regulations to the USDA for further consideration, and determine if, after receiving input from the parties, any parts of the BE Rule should be vacated.

Use of the Term "Bioengineered"

The Ninth Circuit rejected plaintiffs' assertion that USDA regulations mandating use of the term "bioengineered" in disclosures, rather than the more familiar terms such as "genetically engineered" or "GMO," was arbitrary and capricious. Plaintiffs argued that use of these well-known alternatives would increase consumer access to bioengineering disclosures in accordance with legislative intent to create uniform and robust standards of disclosure. The Ninth Circuit found that Congress authorized USDA to establish disclosure standards using the term "bioengineered" or "any similar term, as determined by [USDA]," which could conceivably include GMO or genetically engineered. However, the decision to adopt alternative terms was ultimately left for USDA, and it decided to require use of the term "bioengineered" to "ensure disclosure consistency and minimize marketplace confusion." For several reasons, including the fact that "bioengineered" is a narrower term than GMO and genetically engineered, the Ninth Circuit affirmed the district court's grant

of summary judgment for USDA, finding that USDA's decision was reasonable and within the agency's discretion.

Digital Methods of Disclosure

The Ninth Circuit vacated provisions of the BE Rule allowing electronic and text message disclosures, as these methods were shown to not provide consumers with meaningful access to the disclosure. While the district court originally found these provisions to be unlawful, it did not vacate the regulations due to the disruption it would cause to the food industry. The Ninth Circuit acknowledged that vacatur would cause disruptions but concluded that the disruptive concern could be "fully addressed by ordering only a prospective vacatur of the two challenged provisions."

The Ninth Circuit remanded this claim to the district court with instructions to prospectively vacate the regulations associated with electronic and text message disclosures – 7 C.F.R. §§ 66.106 and 66.108 – after receiving input from the parties. While we do not know how the prospective vacatur will be implemented, the Ninth Circuit provided examples of appropriate remedies including delaying the effective date of vacatur or establishing a timeline for selling already-labeled products. USDA has been in the process of amending the electronic and text message disclosure regulations since the district court initially found them to be unlawful. The agency issued a request for information in April 2024 for public input on amendments to the electronic disclosure options. The proposed rule is expected to be published in December 2025, which may provide clarity on USDA's current thinking on the methods of disclosure available to food manufacturers to be in compliance with the law.

Wiley will continue to provide ongoing analysis regarding regulatory activities related to the BE Rule. We have a team of experienced, cross-disciplinary attorneys who are prepared to address client issues arising from this ruling. Please reach out to the authors of this alert for additional information.

Emma Howard, a Law Clerk at Wiley Rein LLP, contributed to this alert.