



July 3, 2018

United States Department of Agriculture
Agricultural Marketing Service
Docket Clerk
1400 Independence Avenue, SW
Room 4543-South
Washington, DC 20250

Submitted via Federal eRulemaking Portal (<http://www.regulations.gov>)

RE: Proposed Rule- National Bioengineered Food Disclosure Standard- Doc. No. AMS-TM-17-0050 83; Fed. Reg. 19860 (May 4, 2018)

Dear Sir or Madame:

The Biotechnology Innovation Organization (BIO) thanks the United States Department of Agriculture (USDA) Agricultural Marketing Service (USDA-AMS or the Agency) for the opportunity to provide comment on the proposed rule establishing a National Bioengineered Food Disclosure Standard (the Proposed Rule or Proposed NBFDS).

BIO is the world's largest bioscience innovation trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO represents the majority of agricultural biotechnology product developers in North America.

In the past few years, a number of states passed laws requiring or conditionally requiring on-package labeling of certain bioengineered food, setting up the potential for a patchwork of differing and conflicting national, state, and local requirements. Because this patchwork legislation could threaten the free movement of food throughout the United States and worsen stigmatization of technology, Congress passed The National Bioengineered Food Disclosure Law (the Law), which broadly preempts state and local laws while establishing a mandatory bioengineered food disclosure program with uniform national standards.

It is notable that responsibility for establishing and implementing the disclosure program rests with USDA, under the Agricultural Marketing Act, and not the United States Food and Drug Administration (FDA). This is because the disclosure program is designed solely for marketing purposes. The law creating the program has not changed the FDA's separate and distinct authority to require accurate labeling on all food, including bioengineered food, with respect to safety, nutrition, or material differences related to composition or certain properties of the food. That legal authority remains intact.

BIO supports the labeling laws and regulations as currently administered by the FDA and the principles underlying the USDA-AMS program that establishes a uniform national bioengineered food disclosure standard, including the scope of food subject to the standard.

BIO is a member of the Coalition for Safe Affordable Food (CFSAF), a broad-based coalition spanning the food supply chain—from seed producers, to growers, to food manufacturers and retailers—dedicated to increasing the public’s understanding about the science and safety of genetically engineered organisms. In addition to these comments, BIO directs USDA-AMS to CFSAF’s comments submitted July 3, 2018, to which BIO is a signatory.

While BIO is a signatory to CFSAF’s comments, BIO does not endorse CFSAF’s recommendation that BE food that would otherwise require disclosure (such as fresh BE papaya, summer squash, or fish), be exempt solely because of its unpackaged status. Raw fruits and vegetables sold in a bin or fish sold behind a fish counter are not products that Congress intended to be excluded from the disclosure. As such, BIO generally supports disclosure as laid out in proposed section 66.114(a). BIO agrees with CFSAF, however, that additional flexibility should be provided to retailers tasked with compliance. We also recommend that any unintentional commingling of BE produce with non-BE produce at the retail level not be considered a violation of the disclosure statute.

Additionally, BIO notes that it strongly supports the Agency’s proposal to incorporate the statutory definition of “bioengineering” into the definition of “bioengineered food.” Doing so complies with statutory mandate and provides consistency. BIO also supports clarifying “conventional breeding” and “found in nature,” as those terms are used in the definition of “bioengineered food.” BIO’s directs USDA-AMS to CFSAF’s comments for BIO’s suggested definitions for these terms. Though, as a threshold matter, BIO strongly recommends against the Agency’s proposal to use intellectual property protections as one method in determining whether a modification could not otherwise be “found in nature.” Whether a bioengineered trait is patentable (i.e., is a natural product but not a product of nature) is a completely separate question from whether the trait could be found in nature. That said, even if the tests were analogous, there is much uncertainty in the state of patent law and biotechnology such that guidance from the U.S. Patent and Trademark Office on the issue would be of little help.

We thank you for consideration of our comments, and we look forward to working with the Agency on implementing the National Bioengineered Food Disclosure Standard Law.

Sincerely,

A handwritten signature in black ink, appearing to read "D.O'Brien", followed by a period.

Dana O'Brien
Executive Vice President, Food and Agriculture
Biotechnology Innovation Organization