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ALERT

USDA Publishes Proposed Rule for National Bioengineered Food Disclosure Standard

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Today, the U.S. Department of Agriculture (USDA) published the long-awaited proposed rule to establish the National Bioengineered (BE) Food Disclosure Standard mandated by Congress in 2016. **Comments are due on July 3, a deadline that is unlikely to be extended.**

The proposal raises many questions and concerns. How USDA addresses them will have significant long-term impacts on the food industry. Comments will be critical both to help shape the final rule and to lay the groundwork for legal challenges, should the final rule impose requirements or obligations inconsistent with scientific facts, the relevant laws, or commercial realities.

You will soon receive notice of a Wiley Rein webinar that will provide an in-depth look at the proposed rule. In the meantime, below we summarize the rule and flag several key issues.

Proposed Rule Summary

Under the proposed rule, food companies would have three options for disclosing GMO ingredients: the use of on-package text, of three potential icons containing "BE", or of an electronic or digital disclosure (including text message option). Companies also would be required to retain records about a food's BE status and produce them within 5 business days of request to USDA's Agricultural Marketing Service (AMS).

The proposed rule would exclude meat, poultry, dairy, and egg products from animals that have eaten BE feed and products predominately made from them. Food service establishments and very small manufacturers also would be excluded from disclosure

Practice Areas

Environment & Product Regulation
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requirements.

The proposed compliance deadline is **January 1, 2020** for most manufacturers, or a year later for smaller companies. This would align with the compliance date for FDA's new Nutrition Facts Panel requirements, which was also finalized today. See final rule.

Key Issues of Significant Concern

With this proposal, USDA is addressing one of the most controversial areas of BE food labeling and manufacturing today. As a precursor to the proposed rule, USDA on June 28, 2017 released for stakeholder input a list of 30 questions. The proposed rule purports to reflect the responses USDA received to those questions, but in fact leaves many of the most contentious issues unanswered.

Definition of "Bioengineering" and "Bioengineered Food"

Unsurprisingly, USDA received conflicting views as to the appropriate definition of "bioengineered food." The definitions of highly refined foods and ingredients were of particular concern, since they control the key issue of which such products are subject to disclosure requirements.

USDA's task with this rule is to implement the National BE Food Disclosure Standard, which amended the Agricultural Marketing Act of 1946 to define "bioengineering" with respect to a food. It referred to food "(A) that 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." 7 U.S.C. 1639(1).

In the proposed rule, USDA ducked the issue of further clarifying this definition by proposing to incorporate the statutory definition into the regulation without further interpretation. But USDA also has requested public comment on what could be considered to constitute "bioengineering."

Definition of "Conventional Breeding"

The proposed rule also does not include a definition of the important term "conventional breeding," but instead asks whether there should be one and, if so, what it should be. The Agency notes three possible definitions, but comments of course could advocate others:

- "Traditional breeding techniques, including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion," or
- "Traditional methods of breeding or crossing plants, animals, or microbes with certain desired characteristics for the purpose of generating offspring that express those characteristics," or
- The definition of conventional breeding included in EPA's regulations governing plant-incorporated protectants, which appears at 40 C.F.R. §174.3: "the creation of progeny through either: The union of gametes, e.g., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include any of the

following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion."

USDA specifically asks for views as to whether a potential definition of "conventional breeding" under the rule should be limited to methods currently used to propagate or modify existing genetics.

Thresholds Triggering Disclosure

USDA is seeking comment on three different alternative thresholds that would trigger disclosure requirements. Whichever one is ultimately selected, USDA proposes verification with the regulated entity's customary and reasonable business records, rather than some new documentation:

- The first proposed alternative would exclude from disclosure requirements a food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more **than five percent (5%)** of the specific ingredient by weight, as long as no other trigger was met.
- The second alternative would exclude from disclosure such a food where the BE substance accounts for no more than **nine-tenths percent (0.9%)** of the specific ingredient by weight.
- The third alternative would allow the intentional inclusion of a food of BE ingredients without disclosure, as long as a specified threshold (such as 5% of the total weight of the product) was not met.

Comment Process

As noted above, USDA will be accepting comments through July 3, 2018. Comments may be submitted online through the Federal eRulemaking portal, www.regulations.gov. Comments may also be filed with the Docket Clerk, 1400 Independence Ave., SW, Room 4543-South, Washington, DC 20250; Fax: (202) 690-0338.

Wiley Rein attorneys Brian P. Sylvester (a former USDA lawyer) and Keith A. Matthews (former Director of EPA's Biopesticides Division) are particularly well-positioned to assist stakeholders with analyzing the nuances of the proposed rule's impact on their interests and preparing comments that will shape the final rule. Should you have any questions , please contact Keith A. Matthews (kmatthews@wiley.law).