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Food & Beverage ADVISORY ■

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Bioengineered Foods in the Spotlight: Updating the BE Food List and a Challenge to the USDA's NBFDS Rule

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Request for Comments to Update List of Bioengineered Foods

On July 25, the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) published a request for comments on its recommendations to update the List of Bioengineered Foods to assist manufacturers, importers, and certain retailers in determining whether a bioengineered (BE) food disclosure is required under the National Bioengineered Food Disclosure Standard (NBFDS). Comments are due by **August 24, 2020** for: (1) adding BE sugarcane (insect-resistant) to the list; (2) adding the modifier "(virus resistant)" to the existing listing for summer squash; and (3) the current status of BE rice and BE cowpea.

As explained in our advisory on AMS's issuance of testing and validation guidance, if a regulated entity uses a food or ingredient produced from food that is on the List of Bioengineered Foods, the entity's records will determine whether the food must bear a BE food disclosure. Under the NBFDS regulations, AMS will consider revisions to the list annually through a *Federal Register* notice announcement, soliciting recommendations for updates to the list, and will consider supporting information and input from other agencies. AMS considers two criteria when identifying food to add to the list: (1) whether the food has been authorized for commercial production somewhere in the world; and (2) whether that food is currently in legal commercial production for human food somewhere in the world. If the list is revised through rulemaking, regulated entities will have 18 months to update their labels as needed, based on the addition of BE sugarcane and the modification to the summer squash listing. Because comments are due to AMS by the end of August, AMS would likely be able to finalize an update to the list by the end of 2020, and regulated entities would have until mid-2022 to change labels.

In its first proposed update to the list since finalizing the NBFDS rulemaking in December 2018, AMS has recommended that the list be updated to include "sugarcane (insect-resistant)," a BE variety developed using recombinant DNA technology to resist borer infestations. BE sugarbeet is already on the list. In the request for comments, AMS assessed the two criteria for adding a food to the BE list: (1) Brazil approved

BE sugarcane for commercial release in 2018; and (2) 4,000 hectares of BE sugarcane were planted in the 2018–2019 crop year. While adoption of this crop is not yet widespread, if BE sugarcane gets added to the list, regulated entities would need to look out for both BE sugarcane and BE sugarbeet in their supply chain to determine whether foods containing those ingredients require a BE food disclosure.

AMS also proposed to include the modifier "(virus resistant)" for the already-listed crop, "squash (summer)." This proposed modification is to reflect that the only BE summer squash currently available is virus resistant. The request for comments also seeks comment on both cowpea and rice, which AMS has indicated are at various stages of authorization but are not yet in legal production and therefore not yet eligible for inclusion on the list. AMS cites Nigeria's authorization of the commercial release of BE pod-borer-resistant cowpea and requests comment on whether the crop may be in legal commercial production when AMS initiates the rulemaking process. For rice, AMS cites the Philippines' approval of the safety of BE rice (golden rice), but notes BE rice is not yet authorized for commercial production and seeks comment on the current status of this rice.

NBFDS Under Attack

As the USDA moves forward on updates to the list and with its recent issuance of testing and validation guidance to determine whether a food or ingredient contains detectable modified genetic material, manufacturers and retailers have been working to review supply chain documents and update their labels in time for the mandatory January 1, 2022 compliance deadline. Many have already rolled out their BE labels on products based on the NBFDS final rule. Now, over 19 months since the NBFDS final rule was published, a coalition of nonprofit organizations and food retailers filed a lawsuit in the U.S. District Court for the Northern District of California (*Natural Grocers, et al. v. Sonny Perdue, Secretary of USDA, et al.*, No. 3:20-cv-05151) challenging key aspects of the NBFDS final rule for allegedly failing to abide by the NBFDS Act passed by Congress and Administrative Procedure Act (APA). The plaintiffs allege that the rulemaking is a significant departure from the NBFDS Act and a violation of the APA on the basis of four claims.

1. **AMS's decision to greenlight QR codes was arbitrary and capricious and contrary to the NBFDS Act.** The use of QR codes as a form of BE food disclosure has been a hot topic since before the passage of the NBFDS Act itself, with opponents arguing, as the plaintiffs have here, that the use of a QR code (or electronic/digital link disclosure) discriminates against those who do not have access to a smartphone or broadband to access the disclosure.

   The NBFDS Act requires the USDA to establish a regulation that requires the form of disclosure to "be a text, symbol, or electronic or digital link." Congress required that the USDA undertake a study to identify potential technological challenges with the use of electronic/digital link disclosure. If the USDA determined that consumers would not have sufficient access through an electronic/digital link disclosure, the USDA was to provide "additional and comparable options" to access the BE disclosure. The USDA ultimately determined that there would not be sufficient access and provided a text message disclosure as an additional option.

The plaintiffs challenge the USDA's decision to permit the electronic/digital link disclosure to appear alone when it should have been combined with "additional" means of disclosure on the same label. The plaintiffs contend the text message disclosure option was also inadequate because it raises the same concerns with access that the USDA already found with the electronic/digital link disclosure.

A plain reading of the NBFDS Act is likely to support the USDA's decision to retain the electronic/digital link disclosure as is. Congress prescribed specific requirements for electronic/digital link disclosure in the NBFDS Act, which the USDA followed in the regulations and provided a text message disclosure as an additional option when it determined that consumers would not have sufficient access through an electronic/digital link disclosure. However, should a court vacate this portion of the rule, regulated entities that have already invested time and money in developing electronic/digital link disclosures in accordance with the regulations will face significant costs.

2. **The USDA's exclusion of the terms "GE" and "GMO" in the standard was arbitrary and capricious, contrary to the NBFDS Act, and will confuse consumers.** Given the underlying name of the NBFDS Act, National *Bioengineered* Food Disclosure Standard, its continued reference to "bioengineering" and the authority provided to the USDA to choose "any similar term," the plaintiffs face an uphill battle in arguing that the USDA's use of the term "bioengineered food" was contrary to the NBFDS Act and arbitrary and capricious. While the USDA considered similar terms to bioengineering during the rulemaking, as explained in the preamble to the final rule, it justified its decision to only use "bioengineered" because using additional terms would "muddy the scope of disclosure." So long as an entity complies with the mandatory disclosure requirements, there is nothing in the requirements that prohibits regulated entities from using other terms or making other claims, such as "Non-GMO," on labels. Vacating this portion of the rule, as requested by the plaintiffs, would in effect vacate all disclosure options (text, symbol, electronic/digital link, text message) that use the term "bioengineered."

3. **The exclusion of highly refined foods was arbitrary and capricious and contrary to the NBFDS Act.** Unlike the other challenges to the form of disclosure used, this challenge goes to the heart of which foods actually require mandatory disclosure under the NBFDS. The plaintiffs allege that around 70% of foods using BE ingredients are highly processed foods that do not need to bear a BE disclosure under the final rule, making the NBFDS rule a toothless tiger. As acknowledged in the complaint, the USDA sought comment on whether highly refined foods should fall within the scope of mandatory disclosure. Ultimately, the USDA essentially created a detectability standard for refined ingredients, excluding food from mandatory disclosure that "does not contain modified genetic material if the genetic material is not detectable pursuant to [specific standards]" from the definition of BE food, and therefore from the scope of the NBFDS. The USDA also included a voluntary disclosure option for certain foods that do not meet the mandatory disclosure requirement but are "derived from" BE crops or foods on the list.

   To support their contention, the plaintiffs focus on (1) the change in the position from the USDA's former general counsel, who originally expressed support for requiring BE disclosure of highly refined foods; and (2) the evolving and improving ability to identify genetic material using testing methods

not addressed by the USDA. We expect the USDA will continue to argue that the plain language of the NBFDS Act supported its interpretation that "if a food does not contain detectable modified genetic material, it is not a bioengineered food and does not require disclosure." Given the number of highly refined ingredients sourced from BE crops on the market, regulated entities should closely follow the developments related to this challenge.

4. **The USDA's restriction on the use of industry's "right" to label foods produced through "genetic engineering" or as "genetically engineered" prohibits commercial speech in violation of the First Amendment.** The plaintiffs argue that the USDA's mandatory disclosure options, which require the word "bioengineered" and do not incorporate other terms, such as "produced with genetic engineering" or "GMO," unconstitutionally chill speech. While First Amendment challenges to FDA labeling and advertising restrictions have seen some success in federal courts, arguably nothing in the final NBFDS rule prohibits additional statements or other claims regarding these foods or ingredients on the product label, so long as they are made in accordance with other applicable law.

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