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BIOENGINEERED FOOD

Three Sidley Austin attorneys discuss the long awaited proposal from the USDA as it moves toward a final rule regarding mandatory disclosures for “bioengineered food” and “food that may be bioengineered.”

INSIGHT: USDA’s Bioengineered Disclosure Standard a First Step But Questions Remain

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In early May 2018, the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) published its long-awaited proposed rule implementing the National Bioengineered Food Disclosure Standard (Disclosure Standard) (83 Fed. Reg. 19860 (May 4, 2018)). The Disclosure Standard amends the Agricultural Marketing Act (7 U.S.C. § 1621 et seq.) by, among other things, directing the USDA to establish a national mandatory disclosure standard for “bioengineered food” and “food that may be bioengineered.”

The rule, when finalized, could cover a broad scope of products, including fruits and vegetables, dairy products, processed foods and beverages, dietary supplements, as well as ingredients within these products.

The Disclosure Standard charges the AMS with establishing requirements and procedures necessary for a national mandatory bioengineered food disclosure standard within two years of the date of enactment (i.e., by

July 28, 2018). Comments on the proposed rule close on July 3, 2018, and the USDA has stated that it will not extend the deadline “[d]ue to the Congressionally mandated timeline for this rulemaking.” (USDA press release, *USDA Seeks Comments on Proposed Rule for National Bioengineered Food Disclosure Standard* (May 3, 2018), available [here](#)).

Despite its potential broad impact and delay in release, the proposal falls short in offering clarity with respect to a number of key issues, including the scope of products subject to mandatory disclosure, the rule’s applicability to new and emerging technologies (such as genome editing), and the availability of negative labeling (e.g., “Non-GMO”) claims. Further, AMS offers a list of products for which it will presume a disclosure is necessary, without fully clarifying how an entity can overcome this presumption. These, and other aspects of the proposal, are discussed in detail below.

Given the broad potential impact of the disclosure obligation, it is critical for stakeholders to carefully evalu-

ate the proposed rule, and AMS implementation efforts, and to monitor further AMS activity.

Proposed Rule Fails to Clarify Scope and Applicability of Disclosure Requirements

The proposed rule fails to clarify several significant points raised by the Disclosure Standard, including:

- the meaning of “bioengineered” foods;
- the threshold “amount of a bioengineered substance” in a food that would trigger disclosure; and
- whether the rule would cover highly refined foods or foods developed using gene-editing techniques such as CRISPR (clustered regulatory interspersed short palindromic repeats), ZFN (zinc finger nucleases), TAL-ENs (transcription activator-like effector nucleases), and RNAi (RNA interference).

Further, in a somewhat unusual move, AMS has adopted a burden-shifting approach that presumes mandatory disclosure for certain “commercially available” categories of bioengineered crops, as listed by AMS. While the list approach might appear to provide a straightforward method for determining applicability and compliance, it runs the risk of being overly simplistic, both under- and over-inclusive, and burdensome to maintain.

1. Meaning of “Bioengineering” Remains Unclear

The Disclosure Standard states that the term “bioengineering” refers to a 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.

Foods that meet this definition are subject to mandatory disclosure. If a food does not fall within the standard, no such disclosure is required. As such, the definition is the linchpin for mandatory disclosure.

Nevertheless, in its proposed rule, AMS offers no interpretation of this definition. The key term, “in vitro recombinant deoxyribonucleic acid (DNA) techniques,” remains ambiguous, leaving stakeholders to wonder whether this term should be narrowly interpreted to apply only to procedures used to join together DNA segments in a cell-free system and then introduce them into an organism, or broadly interpreted to apply to any modification to the genome, including gene editing.

Notably, there are existing definitions of recombinant DNA technology in other USDA-regulated contexts, which range from narrow in scope to very broad. For example, USDA’s Animal Plant Health Inspection Service (APHIS) has defined “recombinant DNA technology” narrowly to include only “procedures used to join together DNA segments in a cell-free system (e.g. in a test tube outside living cells or organisms).” (USDA, Agricultural Biotechnology Glossary, available here).

This definition was developed to identify those plants potentially subject to APHIS regulatory authority oversight under the Plant Protection Act (7 U.S.C. § 7701, et. seq.). In contrast, AMS, which manages the National Organic Program (NOP), defines recombinant DNA technology broadly to include “gene deletion, gene dou-

bling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology.” (USDA, Organic Production Glossary, available here).

The aim in the NOP context is to narrow the scope of plants identified as “organic” consistent with stakeholder input. It is unclear whether AMS would incorporate either of these definitions—or any other existing definition—in its application of the Disclosure Standard. Given the potential implication on scope, this is an issue worth monitoring.

The proposed rule also does not clarify what qualifies as “conventional breeding,” exempting a product from the disclosure requirement. AMS instead offers three possible interpretations of the term, each with a very different scope, and asks for stakeholder feedback. The three possible interpretations of “conventional breeding” offered by AMS are:

■ “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.” This is a definition that has been used by APHIS in its rule implementing the Plant Protection Act (82 Fed. Reg. at 7106 (2017)).

■ “Traditional methods of breeding or crossing plants, animals, or microbes with certain desired characteristics for the purpose of generating offspring that express those characteristics.” This is a definition that has been used by the National Research Council Committee in a 2004 report titled, “Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects.”

■ “[T]he creation of progeny through either: The union of gametes, i.e., syngamy brought together through processes such as pollination, including bridging crosses between plant and wide crosses, or vegetative reproduction.” This very narrow definition was included by the Environmental Protection Agency (EPA) in its regulations on Plant Incorporated Protectants (40 C.F.R. § 174.3).

Clearly, the choice of definition will have a significant impact for the scope of the available exemption. Unfortunately, AMS neglects to clarify how any entity would ultimately substantiate its view that a “modification could[] otherwise be obtained through conventional breeding.” It simply is not clear under the proposal whether there must be examples of an analogous modification obtained through conventional breeding or, alternatively, whether a stakeholder (or an expert) can simply assert the theoretical possibility that the modification could be obtained through the applicable definition of conventional breeding.

The proposed rule also lacks comprehensive discussion of the other exemption included in the definition of “bioengineering,” namely that for those foods that can otherwise be “found in nature.” Instead, AMS notes that in patent law, a series of recent cases have established that products of nature are not patentable subject matter under 35 U.S.C. § 101. Based on this limited insight, AMS goes on to suggest that it may therefore categorically exclude patented plants from the “found in nature” exemption. Even as it proposes this interpretation, AMS acknowledges that patent law is a poor stand-in for a more nuanced discussion, effectively leaving the scope of the “found in nature” exemption largely unresolved.

Finally, there is no explanation of what it means for a product to “contain” genetic material that has been modified through in vitro rDNA techniques, nor does AMS reach a decision on the appropriate threshold levels of a bioengineered substance that trigger disclosure. On this last point, AMS again delays a decision by offering three alternative thresholds, ranging from that which is “inadvertent or technically unavoidable” up to a level in the product of not greater than 0.9 percent or 5 percent of the total weight, and that which is intentional up to a level of not greater than 5 percent of the total weight.

Without further explanation of these key terms in a final rule, it could be challenging for industry to comply with the Disclosure Standard.

2. AMS Does Not Directly Address Whether Disclosure Standard Covers Products of Genome Editing

The proposal does not directly discuss genome editing or related technologies. The absence of such discussion is surprising particularly given the USDA Secretary’s March 28, 2018, statement on genome editing, which many thought could be a preview of AMS’ definition of “bioengineering.” (USDA press release, *Secretary Perdue Issues USDA Statement on Plant Breeding Innovation* (March 28, 2018), available here).

In the statement, Secretary of Agriculture Sonny Perdue suggested that genome editing is merely a more efficient means to develop plants that could “otherwise have been developed through traditional breeding techniques” and are “indistinguishable” from plants developed through such techniques.

AMS nonetheless appears to open the door to excluding certain new technologies from the definition of “bioengineering,” where the regulatory agencies involved in the Coordinated Framework for the Regulation of Biotechnology—i.e., the USDA, EPA, and the Food and Drug Administration (FDA)—make such a determination. However, this language is vague and subject to AMS consulting with these agencies “to understand if foods resulting from the new technologies would be consistent with the definition of ‘bioengineered food.’”

Accordingly, it is important to continue to monitor regulatory discussions of genome editing by the agencies involved in the Coordinated Framework and consider whether and how such discussions affect disclosure considerations.

3. The Proposal Does Not Expressly Discuss Negative (e.g., “non-GMO”) Labeling

The proposed rule does not directly discuss negative labeling (e.g., “non-GMO” or “non-bioengineered” or similar terms). Instead, it includes the following ambiguous statement: “regulated entities would be able to make other claims regarding bioengineered foods, provided that such claims are consistent with applicable federal law.”

It is worth noting that in an unrelated context, the USDA’s Food Safety and Inspection Service (FSIS) has issued guidance specifically discussing negative claims relating to bioengineering, and has stated that such labeling claims are permissible, as long as the claims are truthful and non-misleading. (FSIS Notice 54-16, *Volun-*

tary Labeling Statements That Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products (Aug. 19, 2016), available here; USDA, *Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products*, available here). The FSIS guidance applies specifically to meat, poultry and egg products, which generally are not subject to the Disclosure Standard.

It is unclear why AMS does not directly address negative labeling in its proposal, particularly in comparison to FSIS. Further, the proposed rule’s reference to consistency with “applicable federal law” is very broad and, therefore, creates substantial ambiguity regarding the scope of requirements for such claims.

4. AMS Presumes Disclosures for Certain Commercially Available Products But Questions Remain

In an effort to streamline the process of determining whether a disclosure is required, AMS proposes to publish and regularly update two lists of plant species that are presumptively “bioengineered” or “may be bioengineered” (e.g., canola, corn, soybean, sugar beet, papaya, potato). While the lists might appear to provide a straightforward approach, they run the risk of being overly simplistic, both under- and over-inclusive, and burdensome to maintain.

The lists rely on data reported by USDA’s Economic Research Services (ERS), data published by the International Service for the Acquisition of Agribiotech Applications (ISAAA), and FDA’s voluntary Consultation Program for Food Derived from Genetically Engineered Plant Varieties (Consultation Program).

Thus, plant varieties that have been considered by FDA (as part of its Consultation Program) at least once and meet AMS’ definition of “highly adopted” (tallied at >85% U.S. commercial market) are presumptively “bioengineered” and require such a disclosure. Plant species that have been considered by FDA at least once, and are “not highly adopted” (tallied at <85% U.S. commercial market), must presumptively bear a disclosure of “may be bioengineered.”

The lists create further ambiguity around the meaning of “bioengineering” by, among other things, relying in part on FDA’s Consultation Program as indicative that a food requires disclosure. While the plant varieties FDA has publicly evaluated to date include varieties modified via rDNA techniques, FDA’s Consultation Program is not limited to such varieties. In fact, as recently as January 2017, FDA stated that it could consider gene-edited plants under its program (82 Fed. Reg. 6564 (Jan. 19, 2017)).

Further, FDA’s program has not considered whether plant varieties could otherwise be obtained through “conventional breeding” or “found in nature,” which means that the program is not limited to plants that could fall within the “bioengineered” definition under the Disclosure Standard. In addition, FDA’s program does not consider non-plant substances, such as microorganisms.

AMS acknowledges that its proposed lists are incomplete, noting that the lists exclude certain products that are not yet commercialized (e.g., rice cultivars, pink-fleshed pineapple cultivars, and genetically engineered salmon). AMS also recognizes that the lists do not ad-

dress products such as “many enzymes, yeast, and a number of food produced in controlled environments,” and asks for comments on whether to add these to its lists.

A company can overcome a presumption of disclosure—and therefore not include the mandatory disclosure—if it documents that a listed product is not “bioengineered.” However, the necessary documentation and potential for AMS enforcement remains unclear. The proposed rule states merely that entities “must maintain records that include documented verification” that the food is not bioengineered or that it does not contain a bioengineered ingredient. In addition, for entities subject to disclosure, the proposal simply states that the entities “must maintain records that are customary or reasonable to demonstrate compliance,” and in “sufficient detail as to be readily understood and audited.”

The nature and extent of records demonstrating compliance or verification, is not, however, clear, which is perplexing, as this documentation is of utmost importance from an enforcement perspective.

5. AMS Proposes an Additional Process for Establishing Whether Food is Considered “Bioengineered”

AMS offers a second process for determining whether a food is “bioengineered” in an effort to implement the Disclosure Standard’s requirement that USDA “establish a process for requesting and granting a determination” by the agency “regarding other factors and conditions under which a food is considered” bioengineered. However, unlike USDA’s well-established “Am I Regulated” program, which allows stakeholders to request a case-specific determination regarding whether a genetically engineered product is regulated by APHIS (See APHIS, Am I Regulated Under 7 CFR part 340?, available here), AMS proposes a process that requires rulemaking, and offers little clarity on the “factors and conditions” considered in determining a food’s bioengineered status.

AMS states that it would evaluate the “request or petition” under three generally applicable standards:

(1) whether the requested factor or condition is within the scope of the statutory definition of “bioengineering”;

(2) the “difficulty” and “cost” of implementation and compliance; and

(3) other relevant information including “compatibility with the food labeling requirements of other Federal agencies or foreign governments” noting APHIS, EPA, and FDA in particular.

AMS’s consideration of “factors and conditions” therefore may be the primary mechanism for stakeholders to ask AMS to align its interpretation of “bioengineering” with other agency interpretations under the Coordinated Framework and in order to facilitate international trade. Indeed, AMS claims that the process is intended to limit the scope of bioengineered foods thereby “potentially excluding certain products from disclosure.”

Critically, the “request or petition” process, as proposed, is open to anyone, including parties that may wish to expand the definition of “bioengineering.” Thus, it may be possible for a third party to use this avenue to challenge a regulated entity’s determination of

its disclosure obligations under the Disclosure Standard, injecting a layer of uncertainty into such determinations.

6. Proposed Rule Appears to Exclude Incidental Additives and Undetectable Recombinant DNA

AMS proposes two factors and conditions relating to whether a food is considered bioengineered that, if adopted, would seem to narrow the scope of “bioengineered food.” Curiously, AMS addresses these while discussing its proposed process for requesting and granting a determination from the agency about whether a food is bioengineered. Nonetheless, the discussion is critical, particularly for foods produced using enzymes, dietary supplements, and highly refined foods.

First, AMS proposes that the use of incidental additives in a food—which are present in the food at insignificant levels, do not have any technical or functional effect, and therefore are exempt from ingredient labeling under FDA’s regulations, such as certain enzymes—would not trigger disclosure.

Second, AMS proposes that if regulated entities can demonstrate that the manufacturing process results in a final food product “where the modified genetic material cannot be detected and their records prove as such,” such foods “would no longer be considered a bioengineered food.”

Thus, if adopted, these “factors and conditions” could exclude a wide range of foods, including those that involve the use of incidental additives in the manufacturing process as well as highly refined foods, despite AMS’s otherwise broad definition of “bioengineering.”

7. Proposed Rule Offers Some Clarity Surrounding Certain Exemptions and Disclosure Options

The Disclosure Standard does offer some points of clarity, particularly surrounding certain exemptions and the mechanics of actual disclosure.

In addition to the thresholds discussed above, AMS proposes four other relatively straightforward, statutorily mandated exemptions that would not be subject to BE disclosure, including food certified under the National Organic Program (NOP); food served in a restaurant or similar retail food establishment; and very small food manufacturers, which AMS defines as any food manufacturer with annual receipts of less than \$2.5 million. Food from an animal also cannot be considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance.

Furthermore, AMS proposes several fairly unambiguous disclosure options in response to a Disclosure Standard requirement that “the form of a food disclosure . . . be a text, symbol, or electronic or digital link but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer” (7 U.S.C. § 1639b(b)(2)(D)).

Text Disclosure: AMS proposes that a bioengineered food that is a raw agricultural commodity or processed food containing only bioengineered ingredients (e.g., cornmeal) from the high adoption rate list bear the

statement “bioengineered food.” All of food products containing one or more bioengineered food ingredient from the high adoption list would bear the text “contains a bioengineered food ingredient.” For non-high adoption bioengineered foods, the proposed text disclosures include two additional options: “may be a bioengineered food” and “may contain a bioengineered food ingredient.”

According to AMS, “[t]he default presumption would be that any foods on the non-high adoption BE food list may be bioengineered,” and regulated entities would have discretion to use any of the textual disclosure options.

Symbol Disclosure: AMS proposes three alternative symbols with variations, “designed to communicate the bioengineered status of a food in a way that would not disparage biotechnology or suggest BE food is more or less safe than non-BE food.” Regulated entities “would be able to use each alternative symbol to designate BE food, food that contains a BE food ingredient, a food that may be a BE food, or a food that may contain a BE food ingredient.”

AMS’s adoption of a symbol will depend on feedback received on (1) perceptions, beliefs, or feelings in response to each of the proposed symbols; and (2) interpretation of the proposed symbols (i.e. what message a consumer would think each symbol is communicating). Notably, there is already some debate over whether the symbols proposed by AMS appropriately reflect the technology.

Electronic or Digital Link: Another disclosure option available for regulated entities to use is an electronic or digital link disclosure. The Disclosure Standard requires that the use of this method be accompanied by the statement “Scan here for more food information,” or equivalent language that reflects technological changes (7 U.S.C. § 1639b(d)(1)).

The AMS incorporates this disclosure method into the proposed rule and notes that current technologies such as quick response codes and digital watermark technology can be scanned on a food package using a smart phone or other device. To try to encompass these and other similar technologies, AMS proposes two examples of alternative statements that could appear above or below an electronic or digital link to direct consumers to the link for the BE food disclosure: “Scan anywhere on package for more food information” and “Scan icon for more food information.” According to AMS, each statement “would reflect changes in technology but still would provide consumers with the instruction necessary to access the disclosure.”

Text Message: AMS proposes a text message disclosure as another similar option, should the agency determine, after reviewing a statutorily mandated study it has commissioned, that consumers, while shopping, “would not have sufficient access to the bioengineeringBE disclosure through electronic or digital disclosure methods.” Here, the label would include the statement “Text [number] for more information.” The information in the response would include the text disclosures described above (e.g., “bioengineered food,” “contains a bioengineered food ingredient,” “may be a bioengineered food,” “may contain a bioengineered food ingredient”).

As required by the Disclosure Standard, AMS provides small food manufacturers with additional disclosure options (e.g., website address or telephone num-

ber) and includes alternative disclosure options for small and very small packages. Bulk foods including displays at seafood counters must use one of the disclosure options, but the disclosure would be required to appear on signage or other materials on or near the bulk item.

For non-bulk foods, AMS proposes to require the disclosure—whether disclosed via text, symbol, electronic or digital link, or text message—to appear on one of three places:

- (1) the information panel adjacent to the statement identifying the name and location of the manufacturer/distributor or similar information;
- (2) anywhere on the principal display panel; or
- (3) an alternate panel likely to be seen by a consumer under ordinary shopping conditions, if there is insufficient space to place the disclosure on the information panel or the principal display panel.

As the requirements are implemented, technical and other issues relating to disclosures, such as those permitted on internet webpages or via telephone seem likely to arise and therefore are worth monitoring.

Issues Relating to Compliance and Enforcement

Demonstrating compliance with the Disclosure Standard largely hinges on documentation and recordkeeping. AMS proposes that regulated entities subject to mandatory disclosure maintain records that are “customary or reasonable to demonstrate compliance” with the standard for at least two years after a food’s distribution for retail sale. Regulated entities containing ingredients on AMS lists of bioengineered foods that do not disclose that their products are bioengineered or contain bioengineered ingredients would be required to maintain documentation that verifies that the foods are not bioengineered, such as supply chain documents, purchase orders, supplier attestations, analytical testing results, or process certifications.

The failure to make a mandatory disclosure for a bioengineered food is prohibited under the Disclosure Standard (7 U.S.C. § 1639b(g)(1)). While AMS’s enforcement powers are limited under the law and do not include recall authority, the Disclosure Standard authorizes the agency to enforce compliance through records audits and examinations (7 U.S.C. § 1639b(g)(3)-(4)). Critically, the results of such an audit or examination could be made public.

In particular, AMS proposes that “any interested person who has knowledge of or information regarding a possible violation” of the Disclosure Standard “may file a written statement or complaint with the Administrator.” Thereafter, the Administrator may decide to audit or examine any records, and the entity subject to the audit or inspection has 30 days to object and request a hearing. AMS proposes that at the end of the process, it would make its summary findings available to the public.

Because the process, as proposed, is open to any interested person with knowledge of a possible violation, there is potential for manipulation or use of the process to impose unwarranted regulatory burdens or obstacles. This coupled with the unanswered questions regarding determining and documenting compliance creates regulatory uncertainty that, among other things, is

worth monitoring as AMS implements the requirements.

Conclusion

In summary, AMS proposal seems to raise more questions than it answers particularly with respect to key issues relating to the scope of coverage, new technologies, and demonstrating compliance. In light of the proposal's shortcomings, it is critical for stakeholders to participate in the rulemaking process as well as any subsequent guidance processes and to monitor developments under this highly evolving regulatory paradigm.

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