BIOENGINEERED FOOD DISCLOSURE COMPLIANCE: PRACTITIONERS' PERSPECTIVE ON WHAT LIES AHEAD

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ABSTRACT

For the first time at the federal level, foods labeled for U.S. retail sale will soon need to comply with mandatory bioengineered food disclosure requirements under USDA's National Bioengineered Food Disclosure Standard (NBFDS). In this Essay, food and beverage industry attorneys Samuel D. Jockel and Rachel E. K. Lowe explore the requirements under the NBFDS and provide insights on what lies ahead, including the regulatory enforcement and litigation landscape following the January 1, 2022 mandatory compliance deadline.

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I. INTRODUCTION

It is the year 2022 and four different packaged peanut butter products are being sold at the same United States retailer. In no particular order of predominance, each of the products contain: (1) a refined corn ingredient, such as high fructose corn syrup or fructose corn syrup; (2) a blend of vegetable oils, including soybean oil; (3) salt; and (4) roasted peanuts. Should the label for each of these products carry a bioengineered food disclosure? The answer lies in the National Bioengineered Food Disclosure Standard (NBFDS) and its implementing regulations.

On January 1, 2022, for the first time at the federal level, manufacturers, importers, and certain retailers will be required to disclose the presence of bioengineered (BE) food or food that contains BE food ingredients on products labeled for United States retail sale under the United States Department of Agriculture's (USDA) Agricultural Marketing Service's (AMS) NBFDS.[1] The enabling statute, Public Law No. 114-216, was enacted by President Obama on July 29, 2016 and required the Secretary of Agriculture to promulgate regulations establishing a mandatory standard for the disclosure of BE food.[2]

Through its mandatory disclosure requirement for BE foods, the NBFDS was the federal government's response to a patchwork of various state efforts to establish requirements for the labeling of genetically engineered foods.[3] Most notably, Vermont's Act 120 established a mandatory labeling standard for food offered for retail sale in Vermont that was produced entirely or in part from genetic engineering.[4] Act 120 went into effect on July 1, 2016 and required certain manufacturers to label food sold in Vermont that was produced entirely or partially with genetic engineering, depending on its composition, as follows: (1) "produced with genetic engineering;" (2) "partially produced with genetic engineering;" or (3) "may be produced with genetic engineering."[5] The Vermont law also included

1. Sam Jockel & Rachel Lowe, *The Approaching Bioengineered Food Disclosure Deadline: Enforcement and Litigation Landscape After January 1, 2022*, FOOD & DRUG L. INST. (Mar. 23, 2021, 9:42 AM), https://www.fdli.org/2021/03/the-approaching-bioengineered-food-disclosure-deadline-enforcement-and-litigation-landscape-after-january-1-2022/ [https://perma.cc/G59K-RWRM].

2. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified as amended at 7 U.S.C. §§ 1639, 6524).

3. *See* Jockel & Lowe, *supra* note 1.

4. VT. STAT. ANN. tit. 9, § 3043(a) (2021).

5. *Id.* at § 3043(b)(2)-(3).

a private right of action and penalties of up to $1,000 per day per SKU for violations.[6]

If individual states are left to their own devices, the most restrictive genetic engineering state labeling standard may create a *de facto* national labeling standard or, more likely, there may be myriad inconsistent state standards for manufacturers and consumers to navigate, and courts to address through litigation.[7] In describing the preemptive effect of the FDA's Federal Food, Drug, and Cosmetic Act (FDCA), Judge Richard Posner of the Seventh Circuit Court of Appeals explained, for example,

> [i]t is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy.[8]

The same rationale could apply to any food labeling requirement.

Not surprisingly, at a Congressional hearing on February 11, 2016, then United States Secretary of Agriculture Tom Vilsack explained that, if the federal government did not address the impending implementation of the Vermont genetic engineering labeling law, "you're going to create multiple standards and multiple responses which is going to create further confusion," as well as increased costs to food companies, which will ultimately trickle down to consumers.[9] On a bipartisan basis, both the United States House of Representatives and the United States Senate passed Senate Bill 764 in July 2016, officially titled "An Act [t]o reauthorize and amend the National Sea Grant College Program Act, and for other purposes," which contained the NBFDS.[10] As a result, Vermont's law was never enforced.[11] Other similar state legislative efforts related to the labeling of

6. *Id.* at § 3048(a).

7. Jockel & Lowe*, supra* note 1.

8. Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

9. *Rep. Robert Aderholt Holds a Hearing on the USDA Office of the Secretary Budget for F.Y. 2017,* Bloomberg Government 15 (Feb. 11, 2016) (statement of Tom Vilsack, Sec'y, USDA).

10. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified as amended at (7 U.S.C. §§ 1639, 6524).

11. *GE Food Labeling Rule*, OFF. VT. ATT'Y GEN. (March 18, 2021, 6:32 PM), https://ago.vermont.gov/ge-food-labeling-rule/ [https://perma.cc/5L6X-JMMM] ("Following President Obama's signing of S.764, which establishes a 'National Bioengineered Food Disclosure Standard,' the Vermont Attorney General will no longer be enforcing Act 120,

genetically engineered foods did not move forward because the NBFDS law immediately preempted any state or local requirement: (1) relating to the labeling or disclosure of whether food is BE or produced using bioengineering that is not identical to the mandatory disclosure requirement under the NBFDS; and (2) relating to the labeling of whether food is genetically engineered or produced using genetic engineering.[12]

On May 4, 2018, almost two years after the federal statute was passed, AMS, which was delegated authority by the Secretary of Agriculture to establish and administer the NBFDS, published its proposed rule implementing the NBFDS.[13] AMS received over 14,000 comments in response to its proposed rule during a 60 day comment period, which reflected divergent views within industry and consumer groups alike regarding what should be disclosed and how it should be disclosed.[14] In contrast, FDA received just over 1,000 comments during its seven month comment period requesting input on the use of the term "healthy."[15] AMS published the final NBFDS rule on December 21, 2018 (the USDA implementing regulations are referred herein as the "NBFDS regulations").[16]

Now, just months away from the January 1, 2022 mandatory compliance deadline, manufacturers, importers, and retailers must navigate the complex regulatory requirements under the NBFDS.[17] As a result of many factors—including flexibilities under the NBFDS, the role a regulated entity's records play in determining whether food is BE, and the perceived risk associated with the regulatory enforcement and litigation landscape that lies ahead—separate manufacturers for each of the four peanut butter products referenced at the outset of this Essay could disclose the product's BE food status on the label through at least four different ways: (1) a mandatory BE food disclosure under the NBFDS (disclosing via text, symbol, text message, or electronic/digital link); (2) a

Vermont's first-in-the-nation law requiring the labeling of food produced with genetic engineering (GE).").

12. 7 U.S.C. §§ 1639b(e), 1639i(b).

13. *See generally* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19,860 (May 4, 2018) (to be codified at 7 C.F.R. pt. 66).

14. *Establishing the National Bioengineered Food Disclosure Standard*, USDA (Dec. 20, 2018), https://www.usda.gov/media/press-releases/2018/12/20/establishing-national-bioengineered-food-disclosure-standard [https://perma.cc/UDN4-KLQS].

15. *Use of the Term "Healthy" in the Labeling of Human Food Products*, REGULATIONS.GOV (Apr. 18, 2021, 2:29 PM), https://www.regulations.gov/docket/FDA-2016-D-2335 [https://perma.cc/T3GU-BNBH].

16. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,833 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

17. *Id.* at 65,832.

voluntary "derived from" BE food disclosure under the NBFDS (disclosing via text, symbol, text message, or electronic/digital link); (3) the use of an absence claim (*i.e.*, Non-BE or Non-GMO); or (4) no disclosure about the presence or absence of BE content.[18]

To explore how peanut butter products containing the same ingredients can be labeled multiple ways under one federal regulatory labeling scheme and the associated regulatory and enforcement landscape that lies ahead, Part II provides an overview of the requirements under the NBFDS; Part III forecasts the regulatory enforcement landscape following January 1, 2022; Part IV examines the potential litigation landscape following January 1, 2022; and Part V discusses the ongoing litigation challenge to the NBFDS rulemaking.

II. OVERVIEW OF THE REQUIREMENTS UNDER THE NBFDS

A. Applicability: Who and What is Subject to the Disclosure Requirements Under the NBFDS?

The NBFDS disclosure requirement extends to food manufacturers and importers of food labeled for retail sale in the United States that package food prior to receipt by retailers, as well as retailers that package food or sell food in a bulk container and/or display.[19] Ultimate responsibility for whether food should carry a mandatory BE food disclosure falls on those "regulated entities," as they are referenced throughout the NBFDS regulations.[20]

While the NBFDS will be enforced by the USDA's AMS, the vast majority of food subject to the NBFDS will be regulated by the United States Food and Drug Administration (FDA).[21] Specifically, the NBFDS limits the definition of "food" to food under the FDCA at 21 U.S.C. § 321 that is intended for *human* consumption.[22] Therefore, food not intended for human consumption—such as pet food or animal food—is not subject to the NBFDS. For FDA-regulated food products, the NBFDS's mandatory BE food disclosure requirement applies to all food subject to the labeling requirements under the FDCA.[23]

18. *Id.*
19. 7 C.F.R. § 66.100(a) (2021).
20. *See* 7 C.F.R. § 66.1 (2021).
21. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65,815.
22. 7 C.F.R. § 66.1.
23. 7 C.F.R. § 66.3(b)(1) (2021).

In contrast to food regulated by the FDA, the NBFDS's applicability to food under statutes enforced by the USDA is quite limited.[24] Food subject to the labeling requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is subject to BE food disclosure if:

> (i) the most predominant ingredient of the food would independently be subject to labeling requirements under the FDCA; or (ii) the most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA.[25]

For example, in the preamble to the final rule, the AMS explains a soup with the following ingredient list (by order of predominance)—broth, carrots, chicken, etc.—will be subject to the mandatory disclosure requirement under the NBFDS (though, ultimately, may not require disclosure depending on the ingredients used and associated records).[26]

Genetically modified organisms (GMO) is only referred to twice in the NBFDS law, both times in relation to absence claims (*i.e.*, labeling a food product as "non-GMO").[27] Instead, the NBFDS statute defines "bioengineering," and refers to bioengineering or "bioengineered food" over 30 times.[28] With this established nomenclature, the NBFDS regulations incorporate the statutory definition of bioengineering into the definition of bioengineered food, with an important modification:

> A food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; *provided that [s]uch a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9*.[29]

The effect of the italicized language is to exclude foods from the definition of bioengineered food—and therefore from the scope of the NBFDS—where modified genetic material is not detectable. As detailed below, this is a critical distinction for many packaged food manufacturers who use corn syrup, oils, and

24. *See id.* at (b).

25. *Id.* at (b)(2).

26. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65,816.

27. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834, 838-39 (2016) (codified as amended at 7 U.S.C. §§ 1639c, 6524).

28. *See generally* National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified as amended at 7 U.S.C. §§ 1639, 6524).

29. 7 C.F.R. § 66.1 (2021) (emphasis added).

other refined products that may not contain any detectable modified genetic material.

Further, the definition of bioengineered food is also subject to one articulated "factor and condition" (*i.e.*, incidental additives as described in the FDA's regulations at 21 CFR § 101.100(a)(3)), which are excluded from the definition of bioengineered food, and therefore not subject to the mandatory disclosure requirement.[30]

To aid regulated entities considering whether food is BE and subject to disclosure, the NBFDS includes a List of BE Foods.[31] The List of BE Foods identifies the crops or foods that are both (1) authorized for commercial production somewhere in the world and (2) reported to be in legal commercial production for human food somewhere in the world.[32] Through a Federal Register notice announcement, AMS will consider revisions to the List of BE Foods on an annual basis, soliciting recommendations on updates to the List of BE Foods, and will consider supporting information and input from other agencies.[33] Following its review, AMS will determine whether to initiate rulemaking to amend the List of BE Foods, and regulated entities will have 18 months to make updates to their labels as needed if the List of BE Foods is revised.[34]

Ultimately, the List of BE Foods provides a good first reference point for regulated entities that must make a determination whether food is BE and therefore, may require disclosure under the NBFDS. Under the regulations, if a regulated entity uses food or an ingredient produced from food that is on the List of BE Foods, its records—such as supplier documentation of the BE food status of an ingredient—will determine whether the food must bear a BE food disclosure.[35] On July 24, 2020, AMS published a request for comments on its recommendations to update the List of BE Foods that would add BE sugarcane (insect-resistant) to the list and add the modifier (virus resistant) to the existing summer squash list, and as of this writing, AMS has not yet issued an update to incorporate these

30. *See id.*; *see infra* Part III (discussing factors and conditions).

31. 7 C.F.R. § 66.6 (2021) ("The list of Bioengineered Foods consists of the following: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugar beet.").

32. 7 CFR § 66.7(a)(4) (2021).

33. *Id.* at (a).

34. *Id.* at (a)(5), (b).

35. *See* 7 C.F.R. § 66.102(a) (2021) ("If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered . . . .").

recommendations on the list.[36] The list is not exhaustive, so entities will still be required to disclose BE foods if they have actual knowledge that the food is BE.[37]

Importantly, even if a food or ingredient is on the List of BE Foods, such as sugar beets, disclosure is not necessary if a processed or refined food derived from a BE ingredient does not contain any detectable modified genetic material that could be considered BE.[38] Under 7 C.F.R. § 66.9(a), to demonstrate that a food's genetic material is not detectable, the entity must maintain records that either: (1) verify the food is sourced from a non-BE crop or source; (2) verify "the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable" (a "validated refining process" is defined further in the regulations under 7 C.F.R. § 66.9(b)); or (3) provide for testing records "appropriate to the specific food that confirm the absence of modified genetic material."[39] The regulations also set out general standards of performance that must be followed if using analytical testing, including that the testing method used is fit for the purpose and testing validity ensures consistent accurate analytical performance.[40]

Despite the detectability standard under 7 C.F.R. § 66.9, in the preamble to the final rule, AMS concedes that refined ingredients are unlikely to require BE food disclosure:

> Based on the available scientific evidence, refined beet and cane sugar, high fructose corn syrup, degummed refined vegetable oils and various other refined ingredients are unlikely to require BE food disclosure because the conditions of processing serve effectively to degrade or eliminate the DNA that was initially present in the raw agricultural commodity.[41]

Despite AMS's stance that it is unlikely these ingredients will require disclosure, it is ultimately up to regulated entities to ensure adequate records demonstrate that modified genetic material is in fact not detectable in the refined or processed food or ingredient.[42]

36. National Bioengineered Food Disclosure Standard, 85 Fed. Reg. 44,791, 44,792 (July 24, 2020) (to be codified at 7 C.F.R. pt. 66).

37. 7 C.F.R. § 66.109 (2021).

38. 7 C.F.R. § 66.9 (2021); *see* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,833 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

39. 7 C.F.R. § 66.9(a); *see id.* at (b).

40. *Id.* at (c).

41. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65,834.

42. *See* 7 C.F.R. § 66.9.

To that end, AMS has released two guidance documents concerning validation and testing for entities wishing to confirm whether a food or ingredient does not contain detectable modified genetic material.[43] The validation guidance outlines general steps to validate a refinement process, including identifying the key step in the process that renders modified genetic material undetectable.[44] Importantly, in the guidance, AMS acknowledges that validation refers to the process, not the facility where the process occurs.[45] Therefore, once a process has been validated, another manufacturer does not need to revalidate that process if completed in a different facility.[46] AMS's detectability guidance also provides basic instructions to address various aspects of detectability testing, including, for example, ensuring that a test method be appropriate (validated) for the product/commodity being tested.[47] Taken together, compliance with the guidance documents is important because regulated entities may rely on testing records, or records involving a validated refinement process from ingredient suppliers, as a means of demonstrating a particular ingredient or finished product is not required to bear a BE food disclosure under the NBFDS.[48]

Ultimately, the determination as to whether a food or ingredient is BE is a function of a regulated entity's records.[49] The ability to secure records to demonstrate that a food does not contain modified genetic material—and is therefore outside the scope of the mandatory BE food disclosure—will vary significantly from regulated entity to regulated entity. This, in turn, will create a system where one regulated entity could determine a particular ingredient is a BE food, while another regulated entity could determine the same or similar ingredient is not BE. For example, the presence of an ingredient on the List of BE Foods, or

43. *See generally* USDA, NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD GUIDANCE ON TESTING METHODS (March 18, 2021, 6:29 PM), https://www.ams.usda.gov/sites/default/files/media/NBFDS_testingMethodology.pdf [https://perma.cc/LVU7-ZTSR]; USDA, NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD GUIDANCE TO ENSURE ACCEPTABLE VALIDATION OF A REFINING PROCESS (Mar. 18, 2021, 6:30 PM), https://www.ams.usda.gov/sites/default/files/media/NBFDS_ValidationGuidance.pdf [https://perma.cc/4MFU-MGMG].

44. *See generally* NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD GUIDANCE TO ENSURE ACCEPTABLE VALIDATION OF A REFINING PROCESS, *supra* note 43.

45. *See generally id.*

46. *Id.* at 1.

47. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD GUIDANCE ON TESTING METHODS, *supra* note 43, at 1.

48. *Id.*

49. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD GUIDANCE TO ENSURE ACCEPTABLE VALIDATION OF A REFINING PROCESS, *supra* note 43, at 3-4.

an ingredient produced from a food or crop on the list, such as sugar, high fructose corn syrup, or soybean oil in a peanut butter product, automatically triggers the BE food disclosure requirement unless the regulated entity has records to demonstrate those components do not meet the definition of bioengineered food or another exemption is applicable.[50]

Aside from demonstrating modified genetic material is not detectable in a food, there are several express exemptions to the disclosure requirement in the regulations, including: "(a) [f]ood served in a restaurant or similar retail food establishment; (b) [v]ery small food manufacturers;" (c) a threshold for inadvertent or technically unavoidable presence of BE substances of up to 5% for each ingredient (intentional use of a food or ingredient that contains a BE substance would not qualify under the exemption); and "(e) [f]ood certified under AMS's National Organic Program (NOP)."[51] Further, under the NBFDS, "food derived from an animal shall not be considered [BE] . . . solely because the animal consumed feed produced from, containing, or consisting of a [BE] substance."[52]

B. Disclosure Options and Considerations

The NBFDS creates a mandatory affirmative disclosure scheme.[53] Under the NBFDS enabling statute and implementing regulations, absence claims (e.g., non-GMO) are only referenced with regards to foods certified under NOP, where that NOP certification will be considered sufficient to make an absence claim.[54] Importantly, the NBFDS requirements therefore pertain to mandatory disclosures of the presence of BE food and voluntary disclosures for food derived from bioengineering.

Once a food is determined to be BE and requires labeling under the NBFDS, those responsible for disclosing its presence can choose between one of four options (text, symbol, electronic/digital link, or text message), each with its own specific requirements.[55] AMS has chosen to use the term BE in the disclosure options instead of adopting other similar terms, explaining this terminology

50. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,826 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66) ("If a food or food ingredient is on the List of Bioengineered Foods, and the regulated entity's records show that the food is a bioengineered food or does not indicate whether or not the food is bioengineered, the food must bear a [bioengineered] disclosure.").

51. 7 C.F.R. § 66.5 (2021).

52. *Id.* at (d).

53. 7 U.S.C. § 1639b(a).

54. *Id.* at (f); *see also* 7 C.F.R. § 66.5(e).

55. 7 C.F.R. §§ 66.102-.108 (2021).

accurately reflects the scope of disclosure and the use of other terms, such as genetic engineering or genetically modified organisms, "may create inconsistencies with the preemption provisions or muddy the scope of disclosure."[56] Even before the NBFDS enabling statute was passed, the electronic/digital link option (*e.g.*, a QR code) has been of particular interest as, unlike the other options, the BE disclosure will not be immediately consumer-facing on the label.[57] Specifically, under the electronic/digital link option, consumers must first access the electronic/digital link (*e.g.*, scanning a QR code) before viewing the BE food disclosure.[58] The regulations also require the electronic/digital link provide the BE food disclosure on the first product information page accessed through the link, without any marketing or promotional material.[59] Ultimately, this is the first time a mandatory food labeling element has been permitted via electronic/digital disclosure in the United States.

As for the appearance of the disclosure, the NBFDS requires the disclosure to "be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions."[60] The disclosure must be placed either on:

> (1) the information panel directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer, or any statement disclosing similar information[;]
>
> (2) . . . the principal display panel[; or]
>
> (3) . . . an alternate panel . . . if there is insufficient space to place the disclosure on the information panel or the principal display panel.[61]

The regulations also provide additional disclosure options for small food manufacturers (use of a telephone number or internet website) and modified disclosure options for small and very small packages.[62] For foods sold in bulk

56. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,837 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

57. *See, e.g.*, Letter from Rev. Jesse Jackson, President & Founder, Rainbow PUSH Coal., to President Obama, President, U.S. (July 14, 2016), http://www.centerforfoodsafety.org/files/jesse-jackson-letter-to-obama_12626.pdf [https://perma.cc/MAP6-LNSG].

58. 7 C.F.R. § 66.106(b)(1) (2021).

59. *Id.*

60. 7 C.F.R. § 66.100(c) (2021).

61. *Id.* at (d).

62. 7 C.F.R. §§ 66.110, 66.112 (2021).

containers at retail, the disclosure must appear on signage on or near the bulk item.[63]

The NBFDS also allows entities to voluntarily disclose the presence of BE foods, including certain foods that do not meet the definition of BE food but are derived from BE crops or food on the List of BE Foods.[64] In the preamble to the final rule, AMS explained this option will provide flexibility by allowing voluntary labeling for refined products originating from BE crops that do not constitute BE foods.[65] The voluntary disclosure would communicate to consumers that a refined food originates from a BE food.[66] However, to take advantage of voluntary disclosure, regulated entities will still need to demonstrate the food does not meet the definition of bioengineered food (*i.e.*, it does not contain detectable modified genetic material).[67] Ultimately, while the voluntary disclosure option allows additional flexibility for regulated entities, the use of this option could create increased confusion in the marketplace. For example, the same peanut butter product with identical ingredients and associated records could either carry a voluntary disclosure indicating the food is "derived from bioengineered" or it could include no disclosure at all, should its manufacturer be able to demonstrate the product is not subject to mandatory disclosure.

C. Recordkeeping

The key to compliance under the NBFDS is the maintenance of records, which, as described above, ultimately drives the decision as to whether a food is BE. Regulated entities must maintain records "for at least two years beyond the date the food or food product is sold or distributed for retail sale."[68] The regulations require records must be kept if an entity's food or ingredient is on the List of BE Foods or the entity has actual knowledge the food is BE.[69] The regulations provide

63. 7 C.F.R. § 66.114(b) (2021).

64. 7 C.F.R. § 66.116 (2021) (noting that under the "derived" voluntary disclosure option, for foods that do not meet the definition of bioengineered food (i.e., that do not contain modified genetic material), to qualify for voluntary disclosure, the food cannot be an incidental additive, nor can it qualify for the other exemptions under 7 C.F.R. § 66.5. Further, if food is on the List of Bioengineered Foods, entities that are otherwise exempt from the requirements of the NBFDS (*e.g.,* very small food manufacturers and restaurants and similar retail food establishments) can also voluntarily disclose.).

65. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,830 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

66. *Id.*

67. 7 C.F.R. § 66.116(b) (2021).

68. 7 C.F.R. § 66.302(a)(3) (2021).

69. 7 C.F.R. § 66.109 (2021).

examples of what types of records can be used (*e.g.*, supply chain records, bills of lading, invoices), but as indicated in the preamble to the final rule, AMS explains regulated entities are free to determine for themselves which of their customary business records will demonstrate compliance and should be maintained.[70]

Taking the peanut butter product as an illustration, the use of the same ingredients—even from different ingredient suppliers—could result in different BE food disclosure labels depending on the regulated entity's associated records and interpretation of those records. Suppose peanut butter manufacturer A has records demonstrating that all the ingredients, some of which are on the List of BE Foods or produced from a food or a crop on the list, are not BE. Based on the regulations and associated AMS guidance on testing and validation, manufacturer A is comfortable in relying on those records to conclude the food is not BE. In this scenario, manufacturer A can either not provide a BE disclosure, or, assuming full compliance with the voluntary derived from bioengineering disclosure requirements, could voluntarily disclose the food is derived from bioengineering because those ingredients were derived from a food on the List of BE Foods. Peanut butter manufacturer B may have similar or the same records that manufacturer A has for the same ingredients. However, manufacturer B is not satisfied with the level of assurances provided by the supplier (because, for example, the records have not been recently updated) and therefore chooses not to rely on those records to conclude the food is not BE. In that scenario, manufacturer B chooses to disclose the food is BE. Beyond a review of records, decisions whether the disclosure is required or voluntary will also be informed by (1) perceptions of the regulatory enforcement and litigation risk that lies ahead and (2) business concerns, such as customer insights and competitor disclosures.[71]

III. REGULATORY ENFORCEMENT LANDSCAPE

When compared to the regulatory enforcement authority underlying other mandatory labeling requirements, the USDA's enforcement authority over regulated entities' failures to disclose BE foods according to the requirements under the NBFDS is quite limited.[72] For example, the FDA has the ability to recall, seize, or take other action against FDA-regulated food products not in

70. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,834 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66); 7 C.F.R. § 66.302(a)(4).

71. SAGE, ENSURING COMPLIANCE WITH THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD 4 (2020), https://www.sage.com/en-us/-/media/files/sagedotcom/us/documents/pdf/industry/food%20and%20bev/manufacturingguide_gmolabeling_whitepaper_1029980.pdf?la=en-us [perma.cc/683Y-7YTV].

72. *See* 21 U.S.C. § 334(b); 21 U.S.C. § 353(b)(3).

conformance with prescribed labeling elements, such as nutrition information or allergen labeling.[73] Though it does not have mandatory recall authority over products under its jurisdiction, the USDA also has myriad enforcement tools at its disposal to address violative product labeling, including authority to detain and seize products and the ability to seek civil penalties or criminal prosecution.[74]

Under the NBFDS, the USDA lacks the authority to recall products, seize products, or issue monetary damages for a prohibited act, which is defined as a failure to make a BE food disclosure as required.[75] The NBFDS allows any interested person with information regarding a possible violation to file a written statement or complaint with the Administrator of AMS.[76] Should AMS determine that further grounds exist to investigate a complaint, its investigations will include auditing an entity's records.[77] Beyond conducting investigations, the USDA's enforcement authority is limited to making public the summary of the audit results or the summary of the final investigation results at the conclusion of the hearing for a noncompliant entity.[78]

As outlined in Part II, the NBFDS sets requirements for what foods should be disclosed and the way disclosures should appear on the food label. AMS could view the prohibited act—failure to make a BE food disclosure as required—as extending to failures to make a BE food disclosure *when* required or failures to make a BE food disclosure *as* required by the technical disclosure provisions in the regulations.[79] While regulated entities should expect the filing of written complaints by competitors and consumer groups, interested stakeholders should closely monitor how the USDA uses its enforcement discretion and whether mere technical violations of the regulations will be the subject of investigations.

The regulatory enforcement landscape may also shift due to changes in the scope of what foods are BE under the NBFDS. As described in Part II, as of this writing, AMS's request for comments to update the List of BE Foods to add BE

73. *See* 21 U.S.C. § 334(a) (granting FDA authority to seize any food that is adulterated or misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce); 21 U.S.C. § 353 (b)(3) (granting FDA mandatory recall authority with respect to all FDA regulated foods other than infant formula).

74. *See* 21 U.S.C. § 673 (granting USDA authority to seize meat and meat food products); 21 U.S.C. § 676 (outlining the fines and imprisonment sanctions for violations of the Federal Meat Inspection Act).

75. 7 C.F.R. § 66.400 (2021).

76. 7 C.F.R. § 66.402(a) (2021).

77. *See id.* at (b).

78. 7 C.F.R. § 66.406 (2021).

79. *See* 7 C.F.R. § 66.400; *see supra* Part II.A.

sugarcane (insect-resistant) remains outstanding.[80] As the revisions to the List of BE Foods will be iterative moving forward, the scope of what is BE under the NBFDS will shift based on revisions to the list.

Further, the scope of BE food disclosure may also shift as part of the "factors and conditions" process. Specifically, the regulations include a process to consider "other factors and conditions under which a food is considered a bioengineered food."[81] The regulatory definition of bioengineered food is subject to factors and conditions, one of which AMS has already adopted (*i.e.*, incidental additives), as described in Part II.[82] AMS's process for considering other factors and conditions includes consideration of requests or petitions in light of specific standards for consideration.[83] If AMS determines the request satisfies the standards for consideration, AMS will initiate a rulemaking to amend the definition of bioengineered food.[84] Ultimately, as was done with incidental additives in the final rule, AMS has explained that "the impact of adopting the proposed factors or conditions . . . would be to limit the scope of the definition of 'bioengineered food,' thus potentially excluding certain products from disclosure."[85] Interested stakeholders should monitor whether the petition process is used to further refine the definition of bioengineered food—and therefore the scope of the disclosure.

Outside of the USDA's enforcement authority, individual states may adopt their own BE food disclosure law with identical requirements to the NBFDS and remedies additional to those imposed by the NBFDS.[86]

While the NBFDS lacks a private right of action, it expressly does not preempt states from adopting identical bioengineered food disclosure requirements that impose remedies for violations of their standards that go beyond the enforcement tools provided by the USDA, such as injunctive relief or monetary damages. As of this writing, no state has adopted an identical bioengineered food disclosure standard.[87]

80. National Bioengineered Food Disclosure Standard, 85 Fed. Reg. 44,791, 44,791 (July 24, 2020) (to be codified at 7 C.F.R. pt. 66).

81. 7 U.S.C. § 1639b(b)(2)(C).

82. 7 C.F.R. § 66.1(1) (2021).

83. 7 C.F.R. § 66.202 (2021).

84. 7 C.F.R. § 66.200(c) (2021).

85. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,834 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66).

86. Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

87. Jockel & Lowe, *supra* note 1.

Additionally, the NBFDS does not preempt any remedy created by a state or federal statutory or common law right.[88] Alternatively, as previously indicated, the NBFDS law does preempt non-identical state requirements "relating to the labeling or disclosure of whether a food is bioengineered" and preempts states from establishing laws concerning *genetically engineered* food ingredients.[89]

IV. LANDSCAPE AND LITIGATION

The risk of costly litigation is often a key factor in labeling decisions.[90] This is no surprise given that, in recent years, hundreds of consumer class action lawsuits have been filed in state and federal courts against food manufacturers challenging nearly every labeling claim, slack fill, third party certifications, and more.[91] In fact, in the United States District Court for the Northern District of California alone, also known as the "food court," over 50 putative class actions were filed against food manufacturers in 2019 and 2020.[92] And, unlike other consumer disputes that can be compelled to arbitration, the parties are often forced to invest years and money necessary to litigate food labeling cases through to class certification or summary judgment.[93] Sometimes defendants win early. Yet, other cases settle on an individual or class basis for a variety of reasons. In 2020, litigants reached various class settlements, sometimes providing up to eight figures of relief

88. 7 U.S.C. § 1639j.

89. 7 U.S.C. § 1639b(e); 7 U.S.C. § 1639i(b).

90. *See The Food Court: Trends in Food and Beverage Class Action Litigation*, U.S. CHAMBER: INST. FOR LEGAL REFORM (Feb. 24, 2017), https://instituteforlegalreform.com/research/the-food-court-trends-in-food-and-beverage-class-action-litigation/ [https://perma.cc/AMS2-YHGY].

91. *See id.*

92. Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT U.L. REV. 329, 332-33 (2014); Jones v. ConAgra Foods, Inc., No. C 12-01633 CRB, 2014 WL 27027226, at *1 (N.D. Cal. June 13, 2014) (noting that as early as 2014, one judge in the Northern District of California explained "[t]his district has seen a flood of such cases, in which plaintiffs have challenged, with varying degrees of success, marketing claims on everything from iced tea to nutrition bars.").

93. *See The Food Court: Trends in Food and Beverage Class Action Litigation*, *supra* note 90.

to the settlement class.[94] Very rarely are these cases tried to a jury following class certification.[95]

Given USDA's limited regulatory enforcement authority, potential litigation risk from both consumers and competitors is likely to drive NBFDS compliance.[96] While the NBFDS statute lacks a private right of action, it does not preempt any remedy created by a state or federal statutory or common law right.[97] In effect, as with challenges to other labeling statements and claims, unfair competition and state consumer protection statutes that prohibit false or deceptive trade practices are likely to serve as the basis for challenges to BE food disclosure labeling.[98] States cannot, however, impose labeling requirements that are not identical to the NBFDSs requirements.[99] As compliance with the NBFDS is not mandatory until January 1, 2022, the NBFDS has not been the subject of much litigation and is referenced in less than 10 cases in a search of nationwide case law. With that said, the NBFDS has already been raised defensively by litigants in consumer false advertising cases involving non-GMO or "natural" claims on food product labels.[100] At least one court has concluded a suit challenging a non-GMO label was not preempted by the NBFDS.[101] A different court dismissed a suit challenging a

94. *See* Order Preliminarily Approving Class Action Settlement and Certifying the Settlement Class at 1, Ferron v. Kraft Heinz Foods Co., No. 0:20-cv-62136-RAR, (S.D. Fla. Dec. 9, 2020) (explaining the plaintiff challenged whether Maxwell House and Yuban coffee products would yield as many servings as advertised and the parties settled their dispute. The settlement provides for a maximum settlement fund of $16 million, with up to $3.9 million in attorney fees); *see also* Order Denying Without Prejudice Motion for Preliminary Approval at 8, Hadley v. Kellogg Sales Co., No. 16-cv-04955-LHK (N.D. Cal. Feb. 20, 2020) (noting the court denied settlement approval for a variety of reasons where the proposed class relief included a $12 million cash component and an $8,250,000 "voucher component" for the class).

95. Nationwide Biweekly Admin., Inc. v. Superior Ct. of Alameda Cty., 462 P.3d 461, 473 (Cal. 2020) (this is especially the case in California, where the majority of food and beverage labeling class actions are filed, because there is no jury trial right for a violation of California's Unfair Competition Law).

96. Jockel & Lowe, *supra* note 1.

97. 7 U.S.C. § 1639j.

98. Jockel & Lowe, *supra* note 1.

99. *Id.*

100. *See In re* KIND LLC "Healthy & All Nat." Litig., 287 F. Supp. 3d 457, 460 (S.D.N.Y. 2018); Holve v. McCormick & Co., 334 F. Supp. 3d 535, 555 (W.D.N.Y. 2018); Inst. for Fisheries Res. v. Hahn, 424 F. Supp. 3d 740, 745 (N.D. Cal. 2019) (explaining that the NBFDS was also referenced tangentially in a case involving salmon whose rDNA was manipulated to grow faster).

101. *KIND LLC "Healthy & All Nat." Litig*., 287 F. Supp. 3d at 464.

natural labeling claim on a peanut butter product.[102] There, the plaintiff claimed that because the product contained sugar and sugar beets are allegedly ubiquitous and likely to be genetically engineered, the labeling was deceptive.[103] Relying on the NBFDS, the court determined the label would not plausibly mislead the reasonable consumer and California's statutory safe harbor was satisfied because the

> [agency] has determined that sugar derived from GMO sugar beets does not have to be disclosed on labels as it is discretionary. Because Defendant complies with [the agency on] labeling regulations, it cannot be [prohibited from using the term 'natural' nor can it] be liable under state consumer law for failing to inform consumers that the item they purchased potentially contains sugar derived from GMO beets.[104]

As we look ahead, there are several categories of product labeling that are likely to face scrutiny, albeit potentially unjustified, from plaintiffs' counsel, including (1) products containing ingredients on or produced from a food on the List of [BE] Foods with labels that include absence claims (e.g., non-GMO) or natural claims[;] . . . (2) products with labels that allegedly fail to disclose the presence of [BE] food despite being required to[;] . . . and (3) [products with labels that] do not disclose [BE food] in accordance with the specific disclosure requirements under the NBFDS.[105] Various defenses may apply to such claims, such as preemption of any case directly seeking to enforce compliance with the NBFDS.[106]

Further, the impact of the NBFDS in the marketplace remains to be seen. "Competitors may also seek to use the Lanham Act or the Better Business Bureau's National Advertising Division as a means of challenging each other's marketing claims in this space."[107] For example, what happens when manufacturer A labels its peanut butter product consistent with the requirements of the NBFDS, but manufacturer B's product does not bear a disclosure and testing reveals the product contains modified rDNA? The testing and investment to make that determination will be cost prohibitive for many entities, and the risk of opening one's own portfolio to scrutiny may create a détente amongst competitors regarding NBFDS compliance. On the other hand, if the comments to the NBFDS rulemaking are any

102. Forsher v. J.M. Smucker Co., No. 5:19CV00194, 2020 WL 1531160, 31-32 (N.D. Ohio Mar. 31, 2020).

103. *Id.* at 2.

104. *Id.* at 31.

105. Jockel & Lowe, *supra* note 1.

106. *Id.*

107. *Id.*

indication, stakeholders in the industry take diverse positions regarding both the spirit of the rule and of BE and genetically modified foods generally.

V. WILL THE NBFDS FINAL RULE SURVIVE?

The NBFDS's rulemaking is already the subject of past and ongoing litigation. The NBFDS's rulemaking was first challenged on August 25, 2017 when the Center for Food Safety sued the USDA, the Secretary of the USDA, and the Administrator of AMS in the United States District Court for the Northern District of California.[108] The complaint alleged the defendants failed to meet the deadline under the NBFDS statute to release a study aimed at identifying potential technological challenges that could impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods.[109] The Center for Food Safety agreed to a voluntary dismissal of the lawsuit after the USDA released the mandated study on September 6, 2017.[110] Subsequently, on August 1, 2018 in the same jurisdiction, the Center for Food Safety and the Center for Environmental Health sued the USDA, the Secretary of the USDA, and the Administrator of AMS for failing to issue the final regulations by the statutory deadline of July 29, 2018, thus constituting an "unlawfully withheld" agency action under the Administrative Procedure Act (APA).[111] The lawsuit was voluntarily dismissed with prejudice on January 7, 2019 after the USDA had complied with the NBFDS by releasing a study on digital disclosure.[112]

In the latest attack, a coalition of nonprofit organizations and food retailers, including, again, the Center for Food Safety, filed a lawsuit against the USDA, the Secretary of the USDA, and the Administrator of AMS, challenging several aspects of the NBFDS final rule for allegedly failing to abide by the NBFDS law passed by Congress under the APA.[113] Plaintiffs filed suit in the Northern District of California in 2020, over 19 months after the NBFDS final rule was published.[114]

108. Complaint for Declaratory and Injunctive Relief at 1, Ctr. for Food Safety v. Perdue, No. 3:17-cv-04967-EDL (N.D. Cal. Aug. 25, 2017).

109. *Id.* at 2.

110. Notice of Voluntary Dismissal with Prejudice at 1, Ctr. for Food Safety v. Perdue, No. 4:17-cv-04967-JSW (N.D. Cal. Nov. 11, 2017).

111. Complaint for Declaratory and Equitable Relief at 2, Ctr. for Food Safety v. Perdue, No. 4:18-cv-40633-HSG (N.D. Cal. Aug. 1, 2018).

112. Order Granting Plaintiffs' Motion for Voluntary Dismissal at 1, Ctr. for Food Safety v. Perdue, No. 4:18-cv-04633-HSG, (N.D. Cal. Jan. 7, 2019).

113. Complaint for Declaratory and Equitable Relief at 3, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020).

114. *Id.*

In their complaint, the plaintiffs alleged the rulemaking for the NBFDS final rule was a "significant departure from the NBFDS [statute] and a violation of the APA . . . ."[115] They asserted—at length—that:

> (1) AMS's decision to greenlight QR codes [that are] allegedly "inaccessible" by some was arbitrary and capricious and contrary to the NBFDS law;[116] (2) USDA's exclusion of the terms [genetically engineered (GE)] and 'GMO' in the standard was arbitrary and capricious, contrary to the NBFDS [statute], and confusing to consumers;[117] (3) the exclusion of highly refined foods was arbitrary and capricious and contrary to the NBFDS law;[118] and (4) 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.[119]

The USDA denied that the plaintiffs were entitled to any relief "asserting the agency complied with all applicable laws."[120] In response to challenges (1), (2), and (4) above—each of which pertains to the appearance of the BE food disclosure—the NBFDS law and the USDA's rulemaking process are likely to provide strong support at summary judgment for the "USDA's decisions to retain the electronic/digital link disclosure as a separate disclosure option, as well as its decision to only make use of the term 'bioengineered food' under the mandatory disclosure requirement."[121] However, challenge (3) above—the treatment of highly refined foods—"could potentially have the most [significant impact as] it goes to the heart of which foods are considered [BE] and [would] require mandatory disclosure under the NBFDS. As an indication of the lawsuit's [significance], three industry associations have already moved to intervene in the case," and, as of this

115. *Id.* (citing Complaint for Declaratory and Equitable Relief at 3, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020)).

116. *Id.* (citing Complaint for Declaratory and Equitable Relief at 4, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020)) (challenging several aspects of the USDA's decision to permit the electronic/digital link disclosure to appear on a package without any other bioengineered food disclosure. They argue, among other things, that the electronic disclosure should have been combined with "additional" means of disclosure on the same label.).

117. *Id.* (citing Complaint for Declaratory and Equitable Relief at 44, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020)).

118. *Id.* (citing Complaint for Declaratory and Equitable Relief at 65, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020)).

119. *Id.* (citing Complaint for Declaratory and Equitable Relief at 82, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. Jul. 27, 2020)).

120. Defendants' Answer to Plaintiffs' Complaint for Declaratory and Equitable Relief at 60, Nat. Grocers v. Perdue, No. 3:20-cv-05151-JD (N.D. Cal. Oct. 2, 2020).

121. Jockel & Lowe, *supra* note 1.

writing, there are "no public indications the USDA has changed its positions on the rulemaking in light of the new administration."[122]

VI. CONCLUSION

While compliance remains mandatory until January 1, 2022, it is up to those entities subject to the NBFDS "to develop a compliance strategy that takes into account both the flexibilities provided under the NBFDS and the potential enforcement and litigation risk that lies ahead" should the regulations survive the current legal challenges.[123]

For the manufacturers of the peanut butter products in our example—and any other regulated entity that is subject to the NBFDS—the following questions may guide evaluations of a product's BE food status: (1) Are existing records sufficient, or is additional information needed from your suppliers to determine the BE status of an ingredient or food? (2) If you are relying on testing records or records involving a validated refinement process to demonstrate that a product is not BE, what testing or validation was completed, and was it performed in accordance with AMS guidance? Is any additional testing or validation needed to support a determination about the product's BE status? (3) Once a determination is made that a food requires a BE food disclosure, what disclosure option (text, symbol, electronic/digital link, or text) will be used? Who owns the brand and has ultimate decision-making authority over this issue? If mandatory disclosure is not required, is the "derived from bioengineering" voluntary disclosure applicable? How will disclosure affect the placement of other claims on product labels? Are there any potential inconsistencies between BE food disclosure and other claims on the label? (4) And is a recordkeeping system in place to ensure continued compliance with the NBFDS? Who will be responsible for monitoring the List of BE Foods? Who will be responsible for monitoring changed formulations and supply relationships?

The answers to each of these questions will be unique to each regulated entity and each product subject to the NBFDS.

Given the significant flexibilities under the NBFDS and the expected variability in compliance, from a practitioner's perspective, at least initially, implementation of the NBFDS is likely to be driven by competitive concerns. While the NBFDS prevented an unworkable patchwork of competing state laws

122. *Id.*; Parties, Nat. Grocers v. Perdue, No. 3:20-cv-05151 (N.D. Cal. initially filed Jul. 27, 2020).

123. Jockel & Lowe, *supra* note 1.

for labeling genetically engineered foods, it remains to be seen whether the industry and consumers alike will embrace the new disclosure system.