Upcoming USDA Bioengineered Food Regulations

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Federal Disclosure Law: Background

- Law passed Senate and House in July 2016
- Authored by Senators Roberts (R-KS) and Stabenow (D-MI)
- Strong bipartisan votes
  - House 306-117
  - Senate 63-30
- Signed by President Obama July 29, 2016
- Senate Agriculture Committee Report, Dec. 9, 2016 (114-403)

Federal Disclosure Law: Background

- UNIFORMITY
  - Requires **Secretary of Agriculture** to establish a national, uniform **disclosure** standard for food intended for human consumption that is or may be “bioengineered”

- PREEMPTION
  - Prevents states and local governments from establishing or enforcing disclosure or labeling requirements except those that are identical to the national standard

Federal Disclosure Law: Background

BIOENGINEERING: "With respect to a food, refers to a food—

(A) that contains genetic material that has been modified through in vitro recombinant DNA techniques; AND
(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature"

Federal Disclosure Law: Background

- Preemption #1:
  "[No] State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard … that is not identical to the mandatory disclosure requirement under that standard." Subtitle E, Section 293(e).

Federal Disclosure Law: Background

- Preemption #2:

  "No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered…." Subtitle F, Section 295(b).

Federal Disclosure Law: Background

- Implementation by USDA under Agricultural Marketing Act
- USDA Rulemaking in 2 years (July 2018)
- Three options for disclosure by manufacturers:
  - Text on packaging
  - A symbol
  - An electronic or digital link (QR code)

Federal Disclosure Law: Background

- USDA State Preemption Letter
  - Preemption of Vermont law that took effect July 1, 2016 (and others not yet in effect)
  - State AG statement of non-enforcement
  - Challenge to Vermont law dismissed

Federal Disclosure Law: Background

- 30 “Proposed Rule Questions Under Consideration”
  - Issued June 26, 2017; comment period closed August 25, 2017;
  - Received over 112,000 responses
  - Submissions available on USDA’s website: https://goo.gl/R9jyw6

Federal Disclosure Law: Background

- Access/retailer Study (Sept. 6, 2017)
  - Conducted by Deloitte
  - Consumers will face challenges in using devices
    - Broadband availability
    - Apps – space/usability
    - Lack of awareness about the link
  - Lawsuit filed to enforce deadline; mooted by USDA action

Federal Disclosure Law: Background

- Proposed Rule:
  - Cleared USDA, received by OMB on December 27, 2017
  - Listed as “economically significant”
  - OMB had 90 days to review

FOOD AND DRUG LAW INSTITUTE

FDLI Food Advertising, Labeling, and Litigation Conference
26-27 September 2018

USDA's Proposed Bioengineered Food Disclosure Standard
Key Issues and Next Steps

Keith A. Matthews
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Introduction

I. Brief introduction:

II. Topic is complex, and USDA's proposed rule was woefully short on detail

    i. This is particularly true regarding threshold definitions critical to the rule

III. A very important point:

    i. Neither the statute, nor the proposed rule, nor the ultimate final rule have anything to do with food safety, or food purity, or healthy diets

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The Bioengineered Food Disclosure Standard Has No Significance Regarding Health or Safety

In this regard, nothing in the disclosure requirements set out in this proposed rule conveys information about the health, safety, or environmental attributes of BE food compared to non-BE counterparts. The regulatory oversight of USDA and other relevant Federal agencies ensures that food produced through bioengineering meets all relevant Federal health, safety, and environmental standards.

83 Fed. Reg. 19860/3 – 19861/1

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Definition of “Bioengineering” and “Bioengineered Food”

Statutory Definition:

The term “bioengineering” refers to a food:

> “(A) that contains genetic material that has been modified through in vitro recombinant DNA techniques; and
>
> (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.” 7 U.S.C. 1639(1).

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Definition of “Bioengineering” and “Bioengineered Food” (cont.)

AMS proposed to directly incorporate this statutory definition into the definition of “bioengineered food” without further interpretation of what “bioengineering” means, **but welcomes public comment on what could be considered to constitute “bioengineering”**.

83 Fed. Reg. 19862/2

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Definition of Bioengineered Food

(A) that contains genetic material that has been modified through *in vitro* recombinant DNA techniques;

Expressio Unius Est Exclusio Alterius

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Definition of Bioengineered Food (cont.)

(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.

This could significantly limit the scope of "bioengineered food"

and

exclude many transformations effected by gene editing techniques

what did USDA say about these terms?

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Conventional Breeding

As to the component terms of the definition of ‘‘bioengineering,’’ AMS seeks comment on whether the NBFDS should include a definition for ‘‘conventional breeding,’’ and if so, what it should be.

Possible definitions could be ‘‘traditional breeding techniques, including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion,’’ or ‘‘traditional methods of breeding or crossing plants, animals, or microbes with certain desired characteristics for the purpose of generating offspring that express those characteristics,’’ or EPA’s definition of conventional breeding in its regulations for plant-incorporated protectants in 40 CFR 174.3: ‘‘the creation of progeny through either: The union of gametes, *e.g.,* syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.’’

AMS seeks comment on whether a definition of ‘‘conventional breeding,’’ if included in the regulations implementing the NBFDS, should be limited to methods currently used to propagate or modify existing genetics.

83 Fed. Reg. 19863/2-3

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Found in Nature

AMS invites comment on [the] approach of using intellectual property protections as a method in determining whether a modification could not otherwise be found in nature, including specific comments on whether it should distinguish between the different categories of patents available under 35 U.S.C. 101. AMS also invites comment on other possible definitions or methods of determining whether a specific modification could not otherwise be found in nature.

83 Fed. Reg. 19864/1

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USDA General Counsel Response to Senator Stabenow

"(2) *Please explain whether the GMO Labeling Law provides authority to the USDA to require labeling of food products that contain genetically modified material, which result from gene editing techniques?*

Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products of certain gene editing techniques. This would include novel gene editing techniques such as CRISPR when they are used to produce plants or seeds with traits that could not be created with conventional breeding techniques.

In addition, the definition provides authority to include RNAi techniques that have been used on products such as the nonbrowning apple and potato."

Jeffrey M. Prieto, *General Counsel*

July 1, 2016

https://www.congress.gov/crec/2016/07/12/CREC-2016-07-12-pt1-PgS4994.pdf

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FDA/HHS Technical Assistance on Senate Agriculture Committee draft bioengineering legislation

“1. (2:10-15) The definition of "bioengineering" (new sec. 291) would result in a somewhat narrow scope of coverage. First, in subparagraph (A), the phrase “that contains genetic material” will likely mean that many foods from GE sources will not be subject to this bill. For instance, oil made from GE soy would not have any genetic material in it. Likewise, starches and purified proteins would not be covered.

Second, subparagraph (B) would limit coverage to foods where the genetic modification "could not otherwise be obtained through conventional breeding or found in nature.” It may be difficult to demonstrate that a particular modification could not be obtained through conventional breeding (or even that it could not occur in nature). In addition, it is unclear whether this refers to the effect of the rDNA construct or the location in the genome (i.e., the former could arguably be obtained via conventional breeding, whereas the latter cannot).”

http://www.centerforfoodsafety.org/files/fda-to-senate-ag-on-draft-legislation_29928.pdf

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Refined Foods

Position 1

One position adopted by respondents is that highly refined products do not ‘‘contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.’’ These commenters reasoned that those products have undergone processes that have removed genetic material such that it cannot be detected using common testing methods; therefore, highly refined products do not fall within the statutory definition of ‘‘bioengineering’’ and are exempt from the standard’s disclosure requirement.

83 Fed. Reg. 19862/3 – 19863/1

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Refined Foods (cont.)

Position 2

Another viewpoint contends that the scope of the definition of ‘‘bioengineering’’ includes all foods produced from bioengineering, such as highly refined products. One basis for this viewpoint is that highly refined products, for example, a sugar beet, contains modified genetic material before it is processed; therefore, one could suppose the resulting product (sugar) would contain at least some trace amount of genetic material from the BE sugar beet. Whether genetic material is detectable may depend on the characteristics of the refinement process, as well as the sample and the testing method applied.

83 Fed. Reg. 19863/1

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Undetectable Recombinant DNA

Several responses to the 30 questions requested that the NBFDS exclude food where the modified genetic material cannot be detected. Those responders cited research that found that refined sugar may not contain recombinant DNA. Should AMS ultimately decide to include highly refined ingredients within the definition of ‘‘bioengineered food,’’ this factor or condition, if adopted, would be a means to potentially exclude products where modified genetic material cannot be detected.

Were AMS to ultimately adopt ‘‘Position 2’’ as discussed above, AMS believes that this requested factor or condition would be consistent with the statutory definition of ‘‘bioengineering’’ in that the food product would be presumed to contain modified genetic material. Therefore, in applying the standards for consideration, this factor or condition would be within the scope of the definition of ‘‘bioengineering’’ in 7 U.S.C. 1639(1). This requested factor or condition may also satisfy the second standard as it could impact the cost of compliance. If regulated entities can demonstrate that the manufacturing process results in a final product where the modified genetic material cannot be detected and their records prove as such, food subjected to that process would no longer be considered a bioengineered food.

83 Fed. Reg. 19866/3

Treatment of Technologies

As to specific technologies, AMS recognizes that technologies continue to evolve, and that food produced through a specific technology may or may not meet the definition of BE food. The proposed process for establishing and amending the BE food lists would provide a vehicle by which AMS could evaluate whether a particular crop meets the definition of "bioengineering." As part of this process for amending the BE food lists, AMS would consult with the U.S. Government agencies responsible for oversight of the products of biotechnology—USDA–APHIS, EPA, FDA and appropriate similar successor members of the Coordinated Framework for the Regulation of Biotechnology—to understand if foods resulting from the new technologies would be consistent with the definition of "bioengineered food" and would be commercially available.

83 Fed. Reg. 19865/1

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Proposed Symbols

Color	Black and White	Color with “Bioengineered” text	Color with “May be” text
			
			
			

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Discussion of Comments

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Bioengineered Food Litigation: Will litigation be highly adopted?

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What We'll Discuss

- Existing food marketing class actions addressing National Bioengineered Food Disclosure Standard (NBFDS)
- Potential impact of NBFDS final rule on litigation

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Food Marketing Class Actions

- Continue to be an active and growing area of litigation
- Over 400 food marketing class action cases pending in federal courts in 2017
- Vast majority of cases filed in California (ND Cal) and New York

(Source: Institute for Legal Reform)

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Current GMO Claims Litigation

- Plaintiffs challenging “Non-GMO” labeling by claiming the presence – or suspected presence – of genetically engineered ingredients

- Plaintiffs challenging “natural” labeling claim on products allegedly containing GMO ingredients

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Recent GMO Cases Raising NBFDS

NBFDS raised as defenses

- Preemption
- Primary jurisdiction

NBFDS Preemption Provisions

Preemption 1: Express preemption of state and local bioengineered food (BE) labeling regulations:

“No State … may directly or indirectly establish … any requirement relating to the labeling or disclosure of whether a food is bioengineered … that is not identical to the mandatory disclosure requirement under that standard.”
7 U.S.C. § 1639b(e)

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NBFDS Preemption Provisions

Preemption 2: Express preemption of state and local **Genetic Engineering** labeling regulations:

"No State … may directly or indirectly establish … any requirement relating to the labeling of whether a food … or seed is genetically engineered … or contains an ingredient that was developed or produced using genetic engineering."
7 U.S.C. § 1639i(b)

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NBFDS Preemption Provisions

No Preemption of Any Remedy Created by Statutory or Common Law Rights

“[n]othing in this subchapter ... shall be construed to preempt any remedy created by a State or Federal statutory or common law right.”
7 U.S.C. § 1639j

Kao v. Abbott Labs., Inc., No. 17-cv-02790-JST, 2017 U.S. Dist. LEXIS 187379, 2017 WL 5257041 (N.D. Cal. Nov. 13, 2017)

- Plaintiff asserted Similac Advance Non-GMO baby formula is deceptively labeled because tests showed the presence of a genetically engineered version of soy developed to be herbicide tolerant

- Abbott Labs asserted preemption and primary jurisdiction defenses

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Kao v. Abbott Labs., Inc., No. 17-cv-02790-JST, 2017 U.S. Dist. LEXIS 187379, 2017 WL 5257041 (N.D. Cal. Nov. 13, 2017)

- Court: Preemption is an issue of 1st impression
  - Not premature to decide
  - Case not preempted

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Kao v. Abbott Labs., Inc., No. 17-cv-02790-JST, 2017 U.S. Dist. LEXIS 187379, 2017 WL 5257041 (N.D. Cal. Nov. 13, 2017)

- Court: Stay based on the Primary Jurisdiction Doctrine, which remains in place
  - United Stated Department of Agriculture (USDA) regulations will address the level of genetically modified ingredients that a product can contain while still being marketed as “non-GMO”
  - “If Abbott’s labeling complies with USDA rules, Plaintiffs would have great difficulty in proving their claims for unfair competition, false advertising or breach of warranty”

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Intersection with “Natural” Labeling

- Food and Drug Administration’s (FDA) rulemaking on “natural” soon?

- FDA Guidance: nothing artificial or synthetic (including all color additives) has been included in or added to, a food that would not normally be expected to be in that food

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NY District Court cases addressing NBFDS

In re KIND LLC "Healthy & All Nat." Litig.**,** 287 F. Supp. 3d 457, 460 (S.D.N.Y. 2018) – challenge to “non-GMO” and “natural” marketing

Holve v. McCormick & Co.**,** No. 16-CV-6702-FPG, 2018 U.S. Dist. LEXIS 137428, 2018 WL 3861406 (W.D.N.Y. Aug. 14, 2018) – challenge to “natural” claim on spices

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In re KIND LLC "Healthy & All Nat." Litig. & Holve v. McCormick & Co.

- Both courts declined to find preemption based on the NBFDS
- Both courts relied on 2016 FDA guidance on bioengineering
- Cases stayed based on primary jurisdiction for final NBFDS rule

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In re KIND LLC "Healthy & All Nat." Litig. – "Non-GMO" Stay

- SDNY: "But even if the USDA timely develops a standard, that determination will not have a dispositive effect on Plaintiffs' claims"
    - That said, USDA "guidance could explain whether ingredients derived from genetically modified crops could be considered non-GMO"

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In re KIND LLC "Healthy & All Nat." Litig. – "Non-GMO" Stay

- Plaintiffs moved to lift the stay in August 2018

- KIND opposed: "The issue of **whether highly processed foods should be considered bioengineered** is front and center in the Amended Class Action Complaint. . . .That means that the definition of bioengineered foods contained in the final regulations will likely provide the parties and the Court with relevant guidance on a specific aspect of plaintiffs' particular 'non-GMO' claims." (Dkt. 133)

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In re KIND LLC "Healthy & All Nat." Litig. – "Natural" Stay

- For natural, "Entering a stay seemed like the more prudent and appealing course of action. . .."
- Executive Order, 2018 FDA Bill
- Would consider lifting as to "natural" when NBFDS rule issued

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Recall NBFDS Goal

- “The intended goal [of the NBFDS] is national uniformity and avoiding the confusion and disputes that would arise if a jurisdiction could require disclosure relying on one or more other terms that might be used to refer in various ways to genetic engineering, biotechnology, or breeding techniques, now or in the future.” S. Rep. No. 114-403, at 6 (2016)

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GMO Feed

- 7 U.S.C.A. § 1639 (prohibiting “a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance”)

- Relied on in *Podpeskar v. Dannon Company, Inc.*, No. 16-cv-8478 (KBF), 2017 WL 6001845 (S.D.N.Y. Dec. 3, 2017), to dismiss claims against Dannon yogurt allegedly made from milk from cows who consumed BE feed

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Where Do We Go From Here?

- USDA aiming to publish final rule by December 1, 2018
- Timing already challenged - *Center for Food Safety et al v. Perdue et al.*, 4:18-cv-04633-HSG (N.D. Cal. 2018)

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Where Do We Go From Here?

- Key parts of NBFDS rule likely to impact litigation

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Potential Areas of Litigation Post-NBFDS Rule?

- Suits challenging voluntary claims
  - Natural
    - Numerous court cases stayed awaiting rule on “natural”
  - Non-GMO
- Suits challenging failure to make mandatory BE disclosures through state consumer statutes

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Potential Areas of Litigation Post-NBFDS Rule?

- Competitor lawsuits challenging disclosures

- Distributor/Retailer liability for BE unlikely
  - "[P]laintiff does not identify a single case in which a court permitted a false advertising claim to proceed against a distributor whose only alleged wrong was selling a mislabeled product." *Tortilla Factory, LLC v. Better Booch, LLC*, 2018 WL 4378700, at *11 (C.D. Cal. Sept. 13, 2018)

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Questions?

Thank you

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