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Implementing the National Bioengineered Food Disclosure Standard

Lesley K. McAllister*

Although controversial since their introduction in the 1990s, bioengineered foods are a major part of our food supply.¹ Bioengineered food (“GE Food” or “GMOs”) refers to plant and animal food products created with the use of genetic engineering (“GE”), wherein DNA from different species are combined to achieve desirable genetic characteristics in a way that would not occur naturally.² Over the past 15 years, GE crops in the US have increased from 3.6 to 173 million planted acres as of 2013.³ In 2012, 93% of all US soybean, 95% of all upland cotton, and 88% of all corn acres were planted with GE seed varieties.⁴ According to a recent survey conducted by the Grocery Manufacturers Associations, 70-80% of packaged foods contain GMOs, including soup, milk, cereal, soda, fruit juice, and baby food.⁵

For many years, environmentalists, consumer groups and others have argued that GE food should be labeled. In May 2014, Vermont passed Act 120, which made it the first state in the country to set a date mandating producers to label any genetically engineered food.⁶ Maine⁷ and Connecticut⁸ have also

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1. See Warren Leary, *F.D.A. Approves Altered Tomato That Will Remain Fresh Longer*, N. Y. TIMES (May 19, 1994), <http://www.nytimes.com/1994/05/19/us/fda-approves-altered-tomato-that-will-remain-fresh-longer.html>.

2. See THE NAT’L ACAD. OF SCIS., ENG’G., AND MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 58 USDA (2016), <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/>.

3. See Tadlock Cowan, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, CONG. RES. REP. RL-32809 (July 20, 2015).

4. *Id.* at 2.

5. See Richard Sexton & Steven Sexton, *Stand Up for GMO Foods by Labeling Them*, WALL ST. J. (Jun. 20, 2016), <http://www.wsj.com/articles/stand-up-for-gmo-foods-by-labeling-them-1466465085>.

6. See VT. CODE R. S121 (2016).

passed labeling laws while California, among other states, have widely debated the issue and proposed legislation⁹

The specter of a “patchwork” of different state labeling laws prompted the food industry to seek the passage of a federal GE labeling law. In July 2016, just after Vermont’s labeling law went into effect, Congress passed the National Bioengineered Food Disclosure Standard.¹⁰ It requires GE food to be labeled in a form chosen by the manufacturer which may be “a text, symbol, or electronic or digital link.”¹¹ Small manufacturers may instead use a telephone number while restaurants and very small manufacturers are exempt from the law altogether.¹² The new law immediately preempts all state GE food labeling initiatives and it gives the U.S. Department of Agriculture (“USDA”) two years to develop implementing regulations.¹³

This essay provides commentary and analysis of the law and suggestions for how it should be implemented by the Trump administration’s USDA. The law’s strengths and weaknesses are identified and discussed. The essay argues that the weaknesses can be largely remedied through clarifying regulations, but warns of the present risk of a “regulatory blockade” due to the law’s preemptive power.

7. Steve Mistler, *LePage Signs Bill to Label Genetically Modified Food*, THE PORTLAND PRESS (Jan. 9, 2014), http://www.pressherald.com/2014/01/09/lepage_signs_maine_gmo_labeling_bill/.

8. See Mark Pazniokas, *Vermont Prompts Fresh Look at Connecticut’s GMO Labeling*, THE CT MIRROR (Apr. 1, 2016), <http://ctmirror.org/2016/04/01/vermont-prompts-fresh-look-connecticuts-gmo-labeling/>.

9. Lynne Peeples, *Prop 37 GMO Labeling Law Defeated By Corporate Dollars and Deception*, *Proponents Say*, HUFFINGTON POST (Nov. 7, 2012), http://www.huffingtonpost.com/2012/11/07/proposition-37-gmo-labeling_n_2090112.html

10. See Dan Charles, *Senate Passes a GMO Labeling Bill That the Food Industry Likes*, NPR (July 8, 2016), <http://www.npr.org/sections/thesalt/2016/07/08/485145450/senate-passes-a-gmo-labeling-bill-that-the-food-industry-likes>; See Jenny Hopkinson, *The Next GMO-labeling Battleground: USDA*, (Jul. 20, 2016), <http://www.politico.com/story/2016/07/gmo-labeling-fight-heads-to-usda-225874>.

11. 7 U.S.C. § 1639(b)(2)(D) (2016).

12. 7 U.S.C. § 1639(b)(2)(F)-(G) (2016).

13. See Mary Clare Jalonick, *Senators Reach Deal on GMO Labeling*, ASSOCIATED PRESS (June 23, 2016), <http://bigstory.ap.org/article/88dde8b8f40a47b7b50f60ceff198849/senators-reach-deal-gmo-labeling>.

What's Right about the Law?

There are several issues the federal law got right. For one, given the interstate nature of our food system, a federal law is certainly appropriate. In addition, the legislation delegates the implementation of the law to USDA, which is also necessary. Finally, the new law will facilitate international trade, particularly in the countries that also require such labeling.

Federal Scope of Labeling

The passage of the federal law was motivated by the fact that several states had passed laws that required labeling. The federal law explicitly provides for preemption of these state laws.¹⁴ Assuming the federal agency takes action, this is both reasonable and appropriate as food labeling law should be national in scope. Our food easily travels across state boundaries and consumers throughout the country have a strong interest in knowing more about the food they purchase and consume. For consumers and producers alike, it is more efficient to have one labeling system for the whole country rather than different state labeling systems.

However, in the absence of a federal law requiring GM labeling, states had begun establishing their own labeling systems. Vermont's, passed in 2013, was the most complete. It required a label on any food sold in Vermont that is "entirely or partially produced with genetic engineering."¹⁵ Connecticut and Maine also passed laws mandating GMO labeling, but they included implementation criteria that were conditional on neighboring states passing similar legislation.¹⁶ In any event, these statutes and others¹⁷ are preempted by the new federal law.

14. See 7 U.S.C. § 1639(b)(2)(E) (2016).

15. VT. STAT. ANN. §§3041-3048.

16. *New Vermont GMO Labeling Law Fuels Debate*, KELLER AND HECKMAN LLP (July 15, 2014), <https://www.khlaw.com/New-Vermont-GMO-Labeling-Law-Fuels-Debate>.

17. Andrew Pollack, *Genetically Engineered Salmon Approved for Consumption*, N.Y. TIMES (Nov. 19, 2015), https://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html?_r=0.

Delegation to USDA

The federal law gives implementation authority to USDA to establish a system to disclose whether a food contains “genetic material that has been modified through bio-engineering.”¹⁸ USDA’s Agricultural Marketing Service (AMS) is tasked with writing regulations within two years.¹⁹ It is also required to conduct a study of the “technological concerns relating to using electronic means of disclosure” within a year.

Congress might have instead designated the Food and Drug Administration (FDA) as the implementing agency. Since the 1990s, the FDA has used its authority under the FDA to regulate GE food in multiple ways. For example, it conducted “consultations” for over 150 GE plants such as corn, soybeans, canola, and cantaloupe, which had been genetically engineered to have a variety of beneficial traits. Some of these traits include pest, virus, and herbicide resistance, increased fertility or protein content, and altered ripening color.²⁰ Further, in November 2015, FDA approved the first animal-based GE food, AquaBounty’s genetically-modified Atlantic salmon.²¹ That month, it also issued guidance for industry regarding the voluntary labeling of GE food.²²

The USDA, however, is arguably better equipped to design and implement a labeling regime for GE food. Most importantly, the USDA’s AMS has successfully administered the labeling system of the National Organics Program (NOP) for

18. 7 U.S.C. § 1639(1) (2016).

19. *Id.*

20. *Biotechnology Consultations on Food from GE Plant Varieties*, USDA (last updated Dec. 14, 2016),

http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search.

21. *Aqua Advantage Salmon*, USDA (last updated Apr. 7, 2016), <https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm>.

22. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, USDA (Nov. 2015),

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>.

nearly twenty years. Pursuant to the authority granted to the agency by the Organic Foods Production Act of 1990, it promulgated the regulations and published the guidance documents that have enabled the sector to grow more than three-fold, in excess of over \$40 billion in sales, in 2015.²³

Moreover, in the case of both organic and GE food, scientific research suggests they are safe and without negative impacts on human health. A recent report from the National Academy of Sciences, Engineering, and Medicine concluded that there was “no substantiated evidence of a difference in risks to human health between currently commercialized genetically engineered (GE) crops and conventionally bred crops. . .”²⁴ As such, GE food labeling—like organic food labeling—is not a matter of regulating food safety.

Even so, consumers still want to know how their food is produced. Americans overwhelmingly support the labeling of GE food. A Consumer Reports poll conducted in 2014 found that 92% of U.S. consumers believe that GE food should be labeled. Other polls conducted in the past decade reinforce the fact that Americans overwhelming support food labeling.²⁵ Further, political support for GE labeling is bipartisan as peoples’ reasons for backing the idea is wide-ranging, whether it concern environmental harm or the morality of genetic modification.

Labeling is an appropriate regulatory response for GE food. It simply confirms the presence of GMOs in a food product. What it does not do is present a judgment as to its nutritional benefit or lack thereof. Given USDA’s experience administering the NOP, it is arguably the most appropriate agency to

23. *U.S. Organic Sales Post New Record of \$43.3 Billion in 2015*, ORGANIC TRADE ORGANIZATION (May 19, 2016), <https://www.ota.com/news/press-releases/19031>.

24. *Distinction Between Genetic Engineering and Conventional Plant Breeding Becoming Less Clear, Says New Report on GE Crops*, NAT’L ACADEMIES OF SCIENCES, ENG’G, AND MEDICINE (May 17, 2016), <http://www.nationalacademies.org/onpinews/newsitem.aspx?RecordID=23395>.

25. *U.S. Polls on GE Food Labeling*, CENTER FOR FOOD SAFETY (last visited Feb. 28, 2017), <http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling>.

implement this law.

Conformity with other Countries

Passage of the NBFDS brings the US into greater conformity with GE labeling frameworks utilized around the world. Sixty-four countries including the member nations of the European Union, Russia, China, Brazil, Australia, Turkey and South Africa, require labeling of GE food.²⁶ Meanwhile, in the US, advocates have fought for decades for a labeling law.

The US's lack of labeling has caused problems in international trade. In June 2016, Brazil refused to import US grains that could not be ensured to be GMO-free.²⁷ Earlier that year, the Brazilian government fined Nestle and PepsiCo for concealing the presence of GMOs in their products.²⁸ With a mandatory labeling requirement in the US, international trade problems like these should become less common and it is likely international demand for US food exports would grow.

What's Wrong with the Law?

The NBFDS also has several notable weaknesses. Though a short law – barely 5 pages in length – the legislation was fast-tracked by Congress, thereby foregoing the usual Congressional hearings, testimony, recorded feedback from proponents and opponents, and amendments. In contrast, the GE labeling law passed by the state of Vermont held over 50 hearings and over 130 testimonies by witnesses were given.²⁹ Primary weaknesses of the federal law include uncertainty around the definition of

26. *Int'l Labeling Laws*, CENTER FOR FOOD SAFETY (last visited Feb. 28, 2017), <http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws>.

27. Tatiana Freitas, *GMO Concerns Stop Brazil Chicken Producers Buying U.S. Corn*, BLOOMBERG (June 8, 2016), <https://www.bloomberg.com/news/articles/2016-06-08/gmo-concerns-stop-brazil-chicken-producers-buying-u-s-corn>.

28. Lorraine Chow, *Nestle, Pepsi Fined for Concealing GMOs as Campbell Soup Announces Voluntary Label*, ECOWATCH (Jan. 8, 2016), <http://www.ecowatch.com/nestle-pepsi-fined-for-concealing-gmos-as-campbell-soup-announces-volu-1882146296.html>.

29. NAT'L SEA GRANT COLLEGE PROGRAM AMENDMENTS ACT OF 2015: HEARING ON S. 4850 114TH CONG. 2 (2016) (Stmt. of Sen. Patrick Leahy of Vermont).

“GE food,” lack of specificity in the form of labeling, and underdeveloped enforcement provisions.

Uncertainty in the Definition of GE Food

An all-important question in regulatory law is who is subject to the regulation and who is not. The answer is often found by considering the definitions presented in the law itself. In the NBFDS, Congress defined the term “bioengineered food” to be food that contains genetic material that has been modified through in-vitro recombinant DNA (rDNA) techniques and “for which modification could not otherwise be obtained through conventional breeding or found in nature.”³⁰ The question for the USDA – and eventually the courts – will be what food falls within the definition and which food does not.

While the Vermont law also defined genetic engineering in terms of the scientific process that produces the mutation, it not only includes just rDNA techniques but also the “fusion of cells.” As such, it might include foods not covered by the federal law. More significantly, the scope of the federal law may be limited by specifying that the modified genetic material must be “contained” in the food itself. In many European countries and China, a GM food is a food that consists of, contains, or is produced from genetically modified organisms.³¹ As raised by Senator Patrick Leahy in a statement released before the legislation was passed, “[t]his definition would exclude a wide variety of highly processed foods, from soybean oil to corn oil, corn syrup to sugar beets, and an array of other products that do not possess the actual genetic material after they have been processed.”³²

30. 7 U.S.C. § 1639(1)(b) (2016).

31. 2003 O.J. (L 268) 1 (China follows the definition of Europe); see Yu Zhuang & Wenxuan Yu, *Improving the Enforceability of Genetically Modified Food Labeling Law in China with Lessons for the European Union*, 14 VT. J. ENV'T L. 465 (2013).

32. Press Release, Full Statement Of Senator Patrick Leahy (D-Vt.) On The Senate’s Hasty Attempt To Preempt State Laws And Thwart A Consumer’s Right To Know (July 7, 2016) (on file at <https://www.leahy.senate.gov/press/full-statement-of-senator-patrick-leahy-d-vt-on-the-senates-hasty-attempt-to-preempt-state-laws-and-thwart-a-consumers-right-to-know>; see also Congress Passes Legislation Mandating a National Bioengineered Food Disclosure Standard: Five Things You Need to Know, SIDLEY (July 21, 2016), <http://www.sidley.com/news/07-21-2016-environmental-update> .

Lack of Specificity about the Form of Disclosure

The law does not determine the form in which the GE content of food will be disclosed. The form it takes is critical because if it is deemed confusing or unclear, the law's presumptive objective of informing consumers will be undermined. Unlike other national and subnational labeling laws, the federal law gives manufacturers three options: "a text, symbol, or electronic or digital link."³³

Because there are options, U.S. consumers will have to learn to recognize several types of labels rather than just one. The Vermont law, in contrast, requires one of three similar phrases to be stated on the package in "clear and conspicuous" text: "produced with genetic engineering," "partially produced with genetic engineering," or "may be produced with genetic engineering."³⁴ The EU labeling law similarly requires an on-package text label statement that reads: "This product contains genetically modified organisms [or the names of the organisms]."³⁵ Brazil requires a symbol, namely a black "T" within a black-bordered yellow-filled triangle (where the "T" stands for "transgenicos").³⁶

Moreover, the third option, which refers to what the industry calls a "Quick Response (QR) code" may equate to no disclosure at all for many consumers. To be read at the point of purchase, this option would require consumers have a scanning device and know how to use it. According to a survey conducted in July 2016, only four in ten Americans said that it is either somewhat or very likely that they would use their mobile phones or in-store scanners to learn whether a product contained

33. Nat'l Bioengineered Food Disclosure Standard Act, Publ. L. No. 114-216 § 293(b)(2)(d), 130 Stat. 834 (2016).

34. VT. STAT. ANN. TIT.9, § 3043(b)(1)-(3) (West 2016).

35. *Genetically Modified Organisms – Traceability and Labeling: Summary of Legislation*, EUR-LEX (Apr. 18, 2016), <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=celex:32003R1830>.

36. *Restrictions on Genetically Modified Organisms: Brazil*, LIBRARY OF CONGRESS (June 6, 2015), <http://www.loc.gov/law/help/restrictions-on-gmos/brazil.php>.

GE food.³⁷ Responding to critics of this option, Congress directed the USDA to conduct the aforementioned study of technological concerns year and authorized it to provide “additional and comparable options to access the bioengineering disclosure.”³⁸

Absence of an Enforcement Regime

The federal law does not create a strong enforcement mechanism for the new labeling scheme. In the few paragraphs of the law dedicated to enforcement, it provides that it is contrary to the law for a person to knowingly fail to make a disclosure required by the law. It further provides that manufacturers must maintain records that demonstrate compliance with the law.³⁹ Finally, the law sets forth the possibility of an audit to be conducted by USDA, which must include notice and a hearing on the results and, afterwards, that the summary of such audit be made public.⁴⁰

This enforcement approach falls far short of that used by the USDA in the NOP. For example, the Organic Foods Production Act of 1990 states that a person who misuses the label can be fined up to \$10,000 and that a false statement relating to the Act can incur criminal liability.⁴¹ Thus, while USDA may be authorized to audit companies, the law does not give the agency the authority to fine them or to pull noncompliant products from the shelves.⁴²

Further, the producers of food labeled as organic must hire a third-party certification firm accredited by the USDA to certify that the food is compliant with the organic label.⁴³ The

37. *Will Consumers Use QR Codes to Learn About Genetically Modified Food?*, ANNENBERG PUBLIC POLICY CENTER (Aug. 3, 2016), <http://www.annenbergpublicpolicycenter.org/will-consumers-use-qr-codes-to-learn-whether-food-is-genetically-modified/>.

38. 7 U.S.C. § 1639(b)-(c) (LexisNexis 2017).

39. *Id.* at (g).

40. *Id.*

41. 7 U.S.C. § 6519(c)(1) (LexisNexis 2016); *see also* 7 U.S.C. § 6519(c)(2); *see also* 18 U.S.C. § 1001 (LexisNexis 2011).

42. 7 U.S.C. § 1639(b)-(g) (LexisNexis 2017).

43. Lesley K. McAllister, *Harnessing Private Regulation*, 3 MICHIGAN J. OF

certifying agents conduct inspection as necessary to verify compliance with regulatory requirements and may suspend or revoke the organic certification of producers found to be out of compliance.⁴⁴ In contrast, it appears that GE labeling requires only a self-declaration by a company, without need for any third-party evaluation.

It is possible that other enforcement approaches may help fill this void. For example, the FDA may retain existing authority to regulate “truthful and misleading” claims on food labels.⁴⁵ Also, state consumer protection laws could potentially be applied by state enforcement authorities. Support is provided by the law’s statement that nothing in the law or its regulations “shall be construed to preempt any remedy created by a State or Federal Statutory or common law right.”

Looking Ahead to USDA Regulations

The law requires that implementing regulations be published within two years or by July of 2018.⁴⁶ The USDA has an opportunity to write regulations that resolve important uncertainties and strengthen the implementation of the law. First, the USDA must clarify the definition of “bioengineered food.” In doing so, the USDA should consider what it is consumers want to know. The USDA reportedly indicated, before the legislation was passed, that the agency interpreted the language of the bill to confer on the USDA broad authority to label GE food. Specifically, the agency would include “all traditional gene modification products which have come through the USDA approval process, such as GE corn, soybeans, sugar, and canola products on the market today, as well as products developed using gene editing techniques.” It seems likely that US consumers would prefer a broad interpretation over a narrow one.

ENVMT'L AND ADMIN. LAW, 291, 360 (2014).

44. *Id.*; 7 CFR § 205.403-205.406 (West 2012).

45. 21 U.S.C. § 343 (West 2012).

46. See generally Jay Sjerven, *Food Industry Considers President Trump's Regulation Freeze*, FOOD BUSINESS (Feb. 21, 2017), <http://www.foodbusinessnews.net/Opinion/JaySjerven?Food-industry-considers-president-trumps-regulation-freeze.aspx?CCK=/>.

The USDA also needs to develop regulations that further specify the form of disclosure. The USDA should ensure that the disclosure is clear and accessible to all consumers. In terms of enforcement, it is possible that the USDA could add a third-party verification system modeled after the NOP. While most existing third party verification systems have been created by law, others find their origin in federal regulations.⁴⁷

While not perfect, the law has some promise: it is a federal law; the USDA has expertise in establishing the consumer-tested NOP labeling program; and it brings US law into greater accord with the law of other countries on the issue of GE food labeling. Now it is critical that USDA write the regulations to clarify the law and set it up for effective implementation. The Disclosure Standard itself is required to be established within two years of the passage of the law. But as of early 2017, it was rumored that USDA still did not have the funding needed to undertake the study of technological concerns that is required within one year after the passage of the Act.⁴⁸ On the campaign trail in Iowa, Trump said he opposed efforts to require mandatory labeling of GE foods.⁴⁹

The present risk is regulatory blockade by preemption. The federal law was passed to preempt state laws like Vermont's. Now consumers throughout the national confront a regulatory blockade.⁵⁰ States cannot regulate because they are preempted, and signs point to potentially long delays from USDA. Citizens will eventually be able to sue the USDA for missing its statutory deadlines and the courts could force regulatory action, but under this scenario, implementing regulations are years away. Given the law's preemption of several hard-won state laws, the federal

47. See McAllister, *supra* note 43 at 329-30.

48. Marc Heller, *Budget Woes Delay GMO Law*, E&E News reporter (Jan. 9, 2017) <http://www.eenews.net/greenwire/2017/01/09/stories/1060048037>.

49. Glenn S. Kerner, *Food for Thought: The Federal GMO Labeling Law*, Food Safety Magazine (Feb. March, 2017) <http://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-for-thought-the-federal-gmo-labeling-law/>

50. Cf. John Upton, (Salon,) *Preemption nation: Trump, Congress could halt state action on climate*, (Jan. 11, 2017), http://www.salon.com/2017/01/11/preemption-nation-trump-congress-could-halt-state-action-on-climate_partner/

government now owes the public robust and prompt regulations that ensures that we know when we are purchasing and consuming genetically engineered food.