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Contours of GMO Regulation and Labeling

Joanna K. Sax, JD PhD*

It is with pleasure that I provide a written memorialization of my remarks at the SMU Dedman School of Law 2016 Food Law Forum for the *SMU Science & Technology Law Review*. At the Food Law Forum, our panel focused on various aspects of food labeling and regulation, with a special emphasis on the labels “natural” and “GMO.” Specifically, my presentation addressed the need for changes to the regulation of genetically modified organisms (GMO) and the disconnect between consumer associations with various food labels and the scientific consensus. While this written record is lightly footnoted, it draws on decades of research by scientists and other scholars on genetically modified organisms and their calls for regulatory rules to match the scientific evidence.¹ An additional caveat is that my remarks center on food from crops only (not animals).

Perhaps one of the most surprising points to general audiences is that our entire food supply is genetically modified—either through conventional methods or the more precise genetic engineering techniques.² Put differently, we are not eating wild-type varieties; rather, we are eating domesticated crops. Conventional breeders employ a variety of techniques to obtain desired traits such as hybridization, UV radiation, and chemical mutagenesis.³ Through seed selection and commercial breeding practices, these techniques create food that is safe, contain desired traits, and include potentially hundreds to thousands of unknown and uncharacterized mutations.⁴ Let me be clear that the food in the commercial marketplace that is created through conventional breeding, while often produced through imprecise methods, is quite safe. Genetic engineering techniques can be used to obtain desired traits

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1. See, e.g., Gregory Conko et al., *A Risk-Based Approach to the Regulation of Genetically Engineered Organisms*, 34 NATURE BIOTECHNOLOGY 493, 493–503 (2016) (and references therein); Steven H. Strauss & Joanna K. Sax, *An End to Event-Based Regulation of GMO Crops*, 34 NATURE BIOTECHNOLOGY 474, 474–77 (2016) (and references therein).
2. David H. Freedman, *The Truth About Genetically Modified Food*, SCI. AM. at 5 (Sept. 1, 2013), <https://www.scientificamerican.com/article/the-truth-about-genetically-modified-food/>. (“The human race has been selectively breeding crops, thus altering plants’ genomes, for millennia. Ordinary wheat has long been strictly a human-engineered plant; it could not exist outside of farms, because its seeds do not scatter.”).
3. See, e.g., Conko, *supra* note 1.
4. See *id.* at 494.

in a much more precise way than conventional methods.⁵ Often, genetic engineering techniques are particularly critical to obtain a desired trait in a well-known and highly selected genetic background.⁶ Decades of research has shown that commercial crops produced by genetic engineering techniques are as safe as their conventional counterparts.⁷ This is so for a variety of reasons, including, but not limited to the precise nature of the techniques employed, the elastic genetic changes frequently occurring in plant genomes (meaning that one small change is not likely to lead to mass destabilization), and the highly selective commercialization process.⁸

Prior to market entry, foods produced from genetic engineering techniques are tightly regulated through a Coordinated Framework that includes the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).⁹ At the time the Coordinated Framework was instituted, a variety of concerns were expressed, including the potential for genetic engineering techniques to cause mass genome destabilization, expression of endogenous toxins at an unacceptable level, or other unknown deleterious consequences.¹⁰ While conventional food is technically subject to the same level of scrutiny as food produced through bioengineering, the reality is that it takes a genetically engineered product about thirteen years and \$136 million to move through the regulatory process, while conventional foods move to the marketplace without any pre-market regulatory review.¹¹ A number of scientists and their allies have called for regulatory change to align the regulatory process with the scientific evidence and to allow the public to enjoy the benefits of food produced through genetic engineering technology.

The regulation of genetically engineered food is highly complicated and cannot be fully explained or digested in my remarks, so the above is a simplified overview. But, with the above in mind, I will now turn to the labeling of genetically engineered food, colloquially known as “GMOs,” which has been used as a proxy, and candidly a red herring, for the public’s concerns about GMOs in the marketplace.

5. See Strauss & Sax, *supra* note 1, at 476; see also Conko, *supra* note 1, at 497–501.

6. Strauss & Sax, *supra* note 1, at 475.

7. See Conko, *supra* note 1, at 493.

8. See Strauss & Sax, *supra* note 1.

9. Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753–801 (Feb. 27, 1992).

10. *Statement of Policy – Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (May 29, 1992), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>.

11. See J.R. Prado et al., *Genetically Engineered Crops: From Idea to Product*, ANNUAL REVIEW OF PLANT BIOLOGY 65, 769–90 (2014).

Dozens of states have considered or enacted laws requiring that foods produced through genetic engineering techniques be labeled as GMO.¹² In July 2016, the federal government enacted the National Bioengineered Food Disclosure Standard (the subject of Professor Nathan Cortez's presentation at this conference), which pre-empts all state action and directs the USDA to promulgate rules regarding labeling of food created through genetic engineering.¹³ The stated purpose of some state labeling laws and the expressions of consumer advocacy groups calling for the labeling of genetically engineered food is so consumers know what is in their food, with a special emphasis on the health, safety, and environmental friendliness of the product.¹⁴ The problem with labeling food as "GMO" or "non-GMO" is that it does not really inform the consumer about the safety, health, or environmental friendliness of the food. The scientific consensus is that genetically engineered food is as safe, healthy, and environmentally friendly as other types of food.¹⁵ Or, at least, whether something is genetically engineered or not does not actually provide that information to consumers.

To understand whether consumers make associations of health, safety, and environmental friendliness with various labels, my colleague and I conducted a food labeling survey study.¹⁶ The details of the methods and results are published in the *Journal of Law, Medicine & Ethics*, so the below is simply an overview of our findings.¹⁷ Via survey, we asked subjects to rank how healthy, safe, or environmentally-friendly specific food types were with the following labels: organic, natural, non/low-fat, non-GMO, and GMO. Our results showed that the labels really mattered to the subjects. Respondents found all labels to be associated with healthier, safer, and more environmentally-friendly food compared to the GMO label. This finding was so even with the label "natural," which has no regulatory definition (and was the

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12. See, e.g., Joanna K. Sax & Neal Doran, *Food Labeling and Consumer Associations with Health, Safety and Environment*, 44 J.L. MED. & ETHICS 630, 630 (2016).
 13. National Bioengineered Food Disclosure Act, S 764, 114th Congress (2016) <http://www.agriculture.senate.gov/imo/media/doc/Mandatory%20Labeling%20Bill.pdf> (passed by Senate and House in July 2016 and amending The Agricultural Marketing Act of 1946, 7 U.S.C. 1621, *et seq.*).
 14. See, e.g., Sax & Doran, *supra* note 12.
 15. See, e.g., *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods*, AM. ASS'N FOR THE ADVANCEMENT OF SCI. (2012), http://www.aaas.org/sites/default/files/migrate/uploads/AAAS_GM_statement.pdf; see also *Genetically Engineered Crops: Experiences and Prospects*, NAT'L ACAD. OF SCI. (May 17, 2016), <http://www.nap.edu/catalog/23395/genetically-engineered-crops-experiences-and-prospects>.
 16. Sax & Doran, *supra* note 12.
 17. *Id.* at 630–37.

subject of Professor Diana Winters' thoughtful presentation).¹⁸ In other words, subjects associated food labeled as GMO to be less healthy, safe, and environmentally-friendly compared to other labels—an association not shared by experts.¹⁹

In this study, we also tested whether different food products might impact responses.²⁰ We included a multi-ingredient product (cereal), fruit (apple), and non-protein containing food (sugar). The reason for this decision is because if consumers are concerned about allergens or toxins in their food as a result of genetic engineering, then something like raw sugar—which has no protein—should not raise these concerns.²¹ We also tested fruit based on some evidence that organic produce is less safe than conventional produce, due to farming practices when handling manure fertilizer.²² In our survey, respondents did not differentiate by food product. Instead, it was the label that really mattered to them.²³

So, what does this mean? Some implications from our study suggest that respondents have a disconnect with the scientific consensus.²⁴ Also, interestingly, respondents have associations with the label “natural” even though the label “natural” really does not mean anything.²⁵ Our results also suggest that these labeling laws are not telling consumers the information that they say they want to know.²⁶ Our results could be used to help draft labeling laws

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18. *Id.* at 630 (citing *What is the Meaning of 'Natural' on the Label of Food?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm>).
 19. Sax & Doran, *supra* note 12, at 631, 633 (citing NAT'L ACAD. OF SCI., ENG'G, & MED., *GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS* (2016); C. Snell et al., *Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: A Literature Review*, 50 *FOOD & CHEMICAL TOXICOLOGY* 1134–48 (2012); AM. ASS'N FOR THE ADVANCEMENT OF SCI., *STATEMENT BY THE AAAS BOARD OF DIRECTORS ON LABELING OF GENETICALLY MODIFIED FOODS* (2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf).
 20. Sax & Doran, *supra* note 12, at 632.
 21. A. S. Bawa, & K. R. Anilakumar, *Genetically Modified Foods: Safety, Risks and Public Concerns-A Review*, 50 *J. FOOD SCI. TECH.* 1035, 1036 (2013).
 22. Avik Mukherjee et al., *Preharvest Evaluation of Coliforms, Escherichia coli, Salmonella, and Escherichia coli O157:H7 in Organic and Conventional Produce grown by Minnesota Farmers*, 67 *J. FOOD PROTECTION* 894, 894 (2004); Robert Wager et al., *Organics versus GMO: Why the Debate?*, GENETIC LITERACY PROJECT (Oct. 15, 2013), <http://www.geneticliteracyproject.org/2013/10/15/organics-versus-gmo-why-the-debate/>).
 23. Sax & Doran, *supra* note 12, at 633.
 24. *Id.* at 635.
 25. *Id.*
 26. *Id.* at 636.

that provide accurate information to consumers.²⁷ In other words, if consumers want to know what they are eating, then labeling laws should respond to that in a way that provides information for accurate associations.

Our article on the labeling survey, along with another forthcoming article of my own, discuss additional reasons for our results—specifically, processes in decision-making that might be at work.²⁸ Work done by us and others suggest that consumers are inappropriately assigning risk to foods produced by genetic engineering techniques. Important research in decision-making, including the theories of *affect* and *ambiguity*, may be contributing to consumer associations of high risk (and low benefit) to genetically engineered food.²⁹

Future directions should follow a number pathways. A robust scientific discussion should continue to address the contours of the application of genetically engineered food—e.g., safety, health, sustainability, innovation, and other related aspects. This is an on-going area of robust scientific research. The public policy discussion needs to change course and provide information to consumers in a way that assuages consumer concerns, provides accurate information, and allows consumers to appropriately assign risk. Consumer decision-making is a complicated process and there are likely multiple theories/justifications/reasons that are contributing all at the same time. Two theories that have been underutilized in policy implementation are affect and ambiguity. Affect refers to the “faint whisper of emotion” to guide decision-making.³⁰ Work by Paul Slovic and colleagues addresses how a person feels about something will impact their assignment of risk and benefit. Ambiguity refers to “a quality depending on the amount, type, reliability and ‘unanimity’ of information, and giving rise to one’s degree of ‘confidence’ in an estimate of relative likelihoods.”³¹ Work by Daniel Ellsberg and others suggests that when consumers are presented with ambiguous information, they may have trouble discerning which information is correct, which subsequently leads to an inappropriate assignment of risk to the particular subject matter.³² Future research that aims to understand the role of affect and ambiguity in consumer decision-making towards genetically engineered food, as

27. *Id.*

28. Joanna K. Sax, *Biotechnology and Consumer Decision-Making*, 47 SETON HALL L. REV. 433, 436–43 (2017).

29. *See, e.g., id.* The author thanks a colleague for the introduction to Paul Slovic’s work and the potential for its use in the debate surrounding GMOs (personal communication on file with author).

30. Paul Slovic & Ellen Peters, *Risk Perception and Affect*, 15 CURRENT DIRECTIONS IN PSYCHOLOGICAL SCI. 322, 322 (2006).

31. Daniel Ellsberg, *Risk, Ambiguity, and the Savage Axioms*, 75 Q.J. OF ECON., 643, 657 (1961).

32. *Id.*

well as other areas of controversial biotechnology, should provide great social value.³³

33. Sax, *supra* note 28.