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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

NATURAL GROCERS, CITIZENS FOR GMO LABELING, LABEL GMOS, RURAL VERMONT, GOOD EARTH NATURAL FOODS, PUGET CONSUMERS CO-OP, NATIONAL ORGANIC COALITION, AND CENTER FOR FOOD SAFETY *Plaintiffs,* v. SONNY PERDUE, Secretary of the United States Department of Agriculture; BRUCE SUMMERS, Administrator of the Agricultural Marketing Service; and the UNITED STATES DEPARTMENT OF AGRICULTURE, *Defendants.*	Case No. 20-5151-JD **FIRST AMENDED COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF**

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AMENDED COMPLAINT

Plaintiffs Natural Grocers, Citizens for GMO Labeling, Label GMOs, Rural Vermont, Good Earth Natural Foods, Puget Consumers Co-op, National Organic Coalition, and Center for Food Safety, on behalf of themselves and their members allege as follows:

INTRODUCTION AND NATURE OF ACTION

1. This case is about ensuring meaningful food product labeling, the public's right to know how their food is produced, and producers' and retailers' rights to provide it to them. Throughout U.S. history, government mandated food and ingredient information has always been the same: on packages and in language consumers could understand. This rulemaking is a significant departure from that standard.

2. Genetically engineered (GE) organisms have been a controversial topic in the public arena since their introduction into the food supply nearly three decades ago. Advocates, including plaintiffs, sought their labeling, like the labeling mandated by 64 other countries around the world. After several states passed labeling laws, Congress finally passed the Bioengineered Food Disclosure Act (Disclosure Act) in 2016.

3. The U.S. Department of Agriculture (USDA), charged with writing the implementing rules, finished them in 2019. Unfortunately, in its final decision the agency fell far short of fulfilling the promise of meaningful labeling of GE foods. In fact in many ways the result is in the direct or de facto concealment of these foods and avoidance of their labeling.

4. There are six claims in this action. First is the issue of how the disclosure is provided under the final rule: electronic or digital forms of labeling, also known as Quick Response code (QR code) or "smartphone" labeling. Congress

included this potential form of disclosure in the new law, but, recognizing its untested nature, made USDA undertake a study of its potential efficacy to eventually use it alone as a means of labeling. The study showed undeniably what opponents told the agency: (a) it was not realistic to have customers in a grocery store use their phone to scan barcodes for dozens of products, and (b) this form of disclosure would discriminate against major portions of the population—the poor, elderly, rural, and minorities—with lower percentages of smartphone ownership, digital expertise, or ability to afford data, or who live in areas in which grocery stores do not have internet bandwidth. Defendants' decision nonetheless to greenlight QR codes without other forms of labeling on products was arbitrary and capricious and contrary to law, in violation of the Disclosure Act and the Administrative Procedure Act (APA).

5. Second is the issue of what terminology is permitted. For 25 years, all aspects of the public dialog around GE foods—scientific, policy, market, legislative, consumer—have used either "genetically engineered" (GE) or "genetically modified" (GMO) to refer to genetically engineered foods.[1] Those are terms that all federal agencies, including USDA during this very rulemaking, used. They are what the public knows, understands, and expects, and what is currently used in the marketplace by producers. They are what other countries and U.S. trade partners use internationally. And, Congress used the new term "bioengineered" in the Act, at the same time, it instructed USDA to also include "any similar term" in its new standard. Despite that instruction and the overwhelming support from stakeholders to allow continued use of the far more well-known "GE"/ "GMO" terms, in its final rule USDA instead excluded "GE" and "GMO," prohibiting them from use in the on-package text or symbol labeling, only allowing use of the term bioengineered. That

[1] For clarity sake, we will use the term "GE" in this complaint to refer to genetically engineered foods.

decision was arbitrary and capricious, contrary to the Act's plain language and the APA and failed to fulfill the Act's fundamental purpose of informing consumers. It is antithetical to the Act's purpose because it will confuse and mislead consumers.

6. Third is the issue of what foods are covered (or not covered) under the scope. The vast majority of GE foods are not whole foods but rather highly processed foods with GE ingredients like sodas and oils, which by some estimates account for over 70% of all GE foods. The Act provided broad scope to USDA to cover all GE foods, and the legislative history shows that USDA and Congress made assurances that the majority of GE foods—those highly refined GE foods—would be covered. Yet in the final rulemaking, USDA decided to exclude highly refined GE foods, creating a new extra-statutory limitation. That decision was contrary to the Act and the APA, and again failed to fulfill the Act's core purpose of informing consumers.

7. Fourth is the right of improving on the limited and flawed disclosure the rules provide, particularly important given all the problems explained above. Manufacturers and retailers have a fundamental First Amendment Right to provide truthful commercial information to consumers, and consumers have a right to receive it. In this context, manufacturers and retailers have the right to label foods as produced through genetic engineering or as genetically engineered. Yet the final rule attempts to restrict that right in multiple ways, providing only limited and restricted voluntary labeling beyond its narrow scope. Those speech chilling restrictions violate the statute's text and purposes as well as the First Amendment's guarantees.

8. Fifth is the issue of states' rights in regulating seeds and their labeling under the broad preemption provisions in the Act. In general states and political subdivisions have a Tenth Amendment Right to regulate their own citizens in the absence of federal regulation. In this instance, states and political subdivisions have a right to directly and indirectly regulate genetically engineered seed labels,

because GE seeds are not included in the scope of the Act, nor are any federal standards for their labeling established in the Act or final rule. The Tenth Amendment prohibits the federal government from unlawfully "commandeering" state government actions. Yet the Act's overbroad preemption provision prohibits states from regulating GE seed labels, unlawfully commandeering state governments by ordering them not to pass any seed labeling laws directly or indirectly on this topic. It does this without providing any alternative federal regulatory scheme for GE seed labeling.

9. Sixth, and alternatively to the arguments raised above is the issue of providing sufficient notice to regulated entities and political jurisdictions regarding both permissible labeling terms and state/local laws under the new federal regulatory scheme. Regulated entities have a Fifth Amendment Right to clear, plain standards that provide sufficient notice regarding what is permissible to avoid USDA enforcement actions. In this context, the final rule contradicts itself and the Act with regards to permissible terminology to be used on food labels. Further, the Act and final rule also fail to set clear standards for what is permissible state and local GE seed labeling. These unclear standards are void for vagueness in violation of the Fifth Amendment.

JURISDICTION AND VENUE

10. This action arises under the U.S. Constitution and laws of the United States, including the Administrative Procedure Act (APA). Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§ 1331, 1343, & 1346.

11. Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. § 702.

12. This Court has authority to grant declaratory and equitable relief herein requested pursuant to 5 U.S.C. § 706(2) (setting aside agency action that is

arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law) and 28 U.S.C. §§ 2201–2202, and Rules 57 and 65 of the Federal Rules of Civil Procedure.

13. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

14. Venue is proper in the U.S. District Court for the Northern District of California pursuant to 28 U.S.C. § 1391(e).

THE PARTIES

Plaintiffs

15. Plaintiff **Center for Food Safety** (CFS) brings this action on behalf of itself and its members. CFS is a public interest, non-profit, membership organization that has offices in San Francisco, CA; Portland, OR; and Washington, D.C. CFS represents over 950,000 members, from every state in the country. The Disclosure Act and USDA's final rule implementing it adversely affect CFS and its members.

16. CFS's mission is to empower people, support farmers, and protect the environment from the harms of industrial agriculture. A large part of that mission is championing transparency in the food system and preserving informed consumer choice. For that reason a major CFS program area has always been improving food labeling and protecting the consumers' right to know what's in their food and what they feed their families.

17. For over two decades CFS has worked to ensure that GE organisms that could adversely affect public health, agriculture, and the environment are adequately labeled and properly regulated. CFS has a major program area specific to GE organism oversight, and numerous staff members—scientific, policy,

campaign, and legal—whose work encompasses the topic. CFS staff members are recognized experts in the field and are intimately familiar with the issue of GE foods, their inadequate oversight, their risks, and their adverse impacts.

18. As part of both of these missions and programs, CFS has long been committed to securing mandatory GE food labeling across the country. To that end CFS has worked closely with dozens of state legislatures and leaders in U.S. Congress on GE food issues and GE food labeling legislation. For example, in 2011, CFS drafted and filed a rulemaking petition with the Food and Drug Administration (FDA), on behalf of over 650 companies and organizations, calling on FDA to require the mandatory labeling of all GE foods, which garnered over 1.4 million individual public comments in support. In the void of federal leadership, in 2012-2016, several states stepped in to protect the public's right to know, and to that end, CFS also assisted in the successful passage of several state labeling laws, including the passage of state GE labeling laws in Vermont, Connecticut, and Maine.

19. CFS takes a multi-faceted approach in pursuing its mission, utilizing legal, political, and grassroots strategies, including public and policymaker education, outreach, and campaigning. For instance, CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the general public regarding the adverse effects of industrial food production—such as genetically engineered agricultural products and pesticides—on human health, the environment, and farmers and on the transparency of the food system. These educational and informational materials include, but are not limited to, news articles, videos, and other multimedia, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets. One example is the book *Your Right to Know: Genetic Engineering and the Secret Changes in Your Food* (Earth Aware Press, 2007).

20. Plaintiff **Rural Vermont** is a 501(c)(3) nonprofit organization founded in 1985 and based in Montpelier, Vermont. Rural Vermont is a grassroots membership organization that has worked for 35 years to bring the voices of the people who are affected by public policy decisions into the process of creating public policy. Its mission is to lead the resurgence of community-scale agriculture, through education, advocacy, and organizing.

21. From 2011 to 2016, Rural Vermont was a founder and leading member of the "Vermont Right to Know GMOs" Coalition. The Coalition led the grassroots effort that resulted in the successful passage of the first law in the United States that required the labeling of food produced through genetic engineering. That effort brought over 10,000 citizens into the legislative campaign as well as built a supporting coalition of scores of farms, food producers, restaurants, food co-ops, schools and other businesses and organizations who supported Vermonters' right to know how their food is produced.

22. Plaintiff **Citizens for GMO Labeling** is a nonprofit organization based in Connecticut with a mission of working across the country to pass state legislation to require the labeling of genetically engineered foods. In 2013 Connecticut passed one of the first GMO labeling laws. However, it required other states to pass similar laws prior to taking effect. From 2013-2016, Citizens for GMO Labeling provided support to over thirty state-based campaigns to label genetically engineered foods and helped pass similar labeling laws in other states.

23. While working to pass these laws, staff members were located in MA and RI and board members in CT, PA, MA, NJ, RI, and NY. The organization testified at state legislative hearings in NH, MA, and RI. In 2015 it hosted an advocate training for 80 GMO labeling advocates from states including, CT, MA, NJ, RI, PA, NH, VT, ME, NY, CA, ID, WA, AZ, FL, CO, HA, IA, MI, IL, NC, VA, DC, OR, NV, OH, DE, MD and GA. The organization's entire budget went toward

passing these state level GMO laws and protecting the laws that CT, VT, and ME passed.

24. The Disclosure Act preempted all current and future state labeling laws, and did so far beyond the scope and substance of what the law offered the public. In doing so it undid all the work the organization had undertaken prior to its passage and made it impossible to continue that work absent judicial review.

25. Plaintiff **Label GMOs** is a California-based nonprofit organization that spearheaded California Prop 37 (2012), a state ballot initiative to require the mandatory labeling of genetically engineered food. Prop 37 was the first major state-wide effort at GMO labeling, and was narrowly defeated (51%-49%) after opponents of disclosure broke the state record for spending in their opposition to it ($44 million). However Prop 37 galvanized a grassroots movement across the United States for the mandatory labeling of genetically engineered food, and inspired and sent off a chain of aligned future ballot initiatives in Washington (2013) and Oregon (2014) as well as state legislative efforts, including those that eventually passed into law in Vermont, Connecticut, and Maine. All of those disclosure laws and efforts were substantially identical. Label GMOs also worked to pass Senate Bill 1381 (2014) and other California legislative GMO labeling efforts prior to the preemption of those efforts by the 2016 Disclosure Act.

26. Plaintiff **Good Earth Natural Foods** is an independent natural and organic grocer based in Marin, California since 1969. Good Earth is committed to advocating for a healthier and more sustainable food system. Historically Good Earth was one of the original pioneers and creators of the organic farming standards and labeling, at the state level and then at the federal level, and has since that time worked to ensure the organic standard retains its original integrity. Later Good Earth helped start the Non-GMO project and its Non-GMO verified label. In 2011, Good Earth launched its own in-store labeling of products, including

locally produced and non-GMO verified. In 2012, Good Earth supported Prop 37, the California Right to Know GMO labeling initiative. Good Earth is committed to full transparency for its customers, including ensuring that foods produced with genetic engineering are labeled as such.

27. Plaintiff **Puget Consumers Co-op**, which operates stores under the tradename "PCC Community Markets," is the nation's largest community-owned food market based in Seattle, Washington. Founded in 1953 and with an active membership of just over 80,000 households, PCC operates 14 stores in the Puget Sound area and is a Certified Organic retailer.

28. PCC aims to create a cooperative, sustainable environment in which sustainable and organic supply chains thrive. A critical part of that work includes increasing transparency for consumers on how their food is grown and raised and what is in their food. To that end, PCC has been a dedicated advocate of GMO labeling and supporter of GMO absence certification programs, such as Certified USDA Organic and Non-GMO Project Verified.

29. As far back as in 2000, PCC members wrote over 12,000 letters to Congress in support of GMO transparency in foods. In 2012-2013, PCC led the effort for statewide GMO labeling as a steering committee member for I-522, the People's Right to Know Genetically Engineered Food Act. Although the ballot initiative was narrowly defeated by record spending, it helped build the momentum for labeling transparency nationwide and the successful passage of other state labeling laws. In 2011, PCC pledged to label all GMO items in its stores by 2018. In 2016-2018, PCC undertook substantial planning and actions to complete this pledge, including after the passage of the 2016 Disclosure Act. However, the final USDA rules forced PCC to shelve its store labeling plans because of the speech restrictions created by the disclosure scheme, legal uncertainty from its lack of clarity, and potential consumer confusion.

30. Plaintiff **Natural Grocers** is a Colorado-based specialty retailer of natural, organic groceries, body care products and dietary supplements since 1955, currently operating 157 stores in 20 states. Natural Grocers is committed to educating communities on nutrition and providing only natural and organic products that meet high standards for ecological sustainability. As part of these efforts, all Natural Grocers brand products are organic or non-GMO if organic is not available, and Natural Grocers sells only certified organic produce. Across all stores, Natural Grocers carries over 9,000 Non-GMO Project Verified products and over 10,000 organic grocery products.

31. Natural Grocers has long been a supporter of GMO labeling at both the state and federal level. In 2014, Natural Grocers supported the Right to Know Colorado Proposition 105 to label GMO foods and hosted Proposition 105 petition gatherers in all of its 34 Colorado stores. Natural Grocers is committed to providing transparency for its customers and consistently posts information on GMOs on its website to assist its customers in avoiding GMO products.

32. Plaintiff **National Organic Coalition (NOC)** is a national alliance of organizations representing farmers, seed producers and distributors, ranchers, environmentalists, consumers, retailers, and other companies involved in organic food production and the organic label. NOC seeks to advance organic food and agriculture and ensure a united voice for organic integrity, to maximize the multiple health, environmental, and economic benefits that only organic agriculture affords. Organic food production prohibits genetic engineering, and as part of its mission NOC advocates for transparent labeling of genetically engineered foods and seeds.

33. On behalf of NOC's members, including organic farmers, food producers, and retailers of all sizes, as well as consumers and environmental groups, NOC brings together diverse organic stakeholders to share information and create opportunities, offers government agencies and Congress innovative policy

solutions to challenging issues, and engages the wider organic community to advocate on its own behalf. NOC members testify at federal government hearings and agency meetings across the U.S. regarding organic issues and have participated in discussions regarding GE contamination of organic crops, prohibitions in organic for next-generation GMOs, and GMO labeling.

34. NOC has long sought to keep GMOs out of organic production and has advocated for strong enforceable regulations for a uniform national GE labeling standard. In 2018, NOC submitted public comments on the proposed GE labeling rule, urging the USDA to create a meaningful disclosure standard for GE foods. NOC member organizations unanimously oppose the final rule and remain committed to establishing a meaningful, fully transparent, and easily accessible food labeling system.

Defendants

35. Defendant **Sonny Perdue** is sued in his official capacity as USDA Secretary. As Secretary, Mr. Perdue has the ultimate responsibility for USDA's implementation of the Disclosure Act.

36. Defendant **Bruce Summers** is sued in his official capacity as Administrator of the Agricultural Marketing Service (AMS), an agency of the United States Department of Agriculture. The AMS administers programs at USDA related to the marketing of food and agricultural products. As Administrator, Mr. Summers has ultimate responsibility for AMS's implementation of the Disclosure Act.

37. Defendant **United States Department of Agriculture** is a federal agency of the U.S., which is charged with acquiring and providing to the people of the United States useful information on subjects connected with, among other things, agriculture and food labeling. As relevant here, USDA, including AMS, is

the Agency that Congress made responsible for the implementation of the Disclosure Act, including its implementing regulations.

LEGAL AUTHORITY

UNITED STATES CONSTITUTION

38. The First Amendment states that "Congress shall make no law . . . abridging the freedom of speech. . . ." U.S. Const., Amend. I.

39. The Tenth Amendment of the Constitution provides that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const., Amend. X.

40. The Fifth Amendment of the Constitution states that ". . . no person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. Const., Amend. V.

ADMINISTRATIVE PROCEDURE ACT

41. The Administrative Procedure Act (APA) provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

42. The definition of agency action within this statute "includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." *Id.* § 551(13).

43. The APA instructs that reviewing courts "shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . [or] contrary to constitutional right, power, privilege, or immunity." *Id.* § 706(2)(A).

44. Under the APA's standard of review, the Court evaluates whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An action is arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id*. at 43.

THE BIOENGINEERED FOOD DISCLOSURE ACT

45. The purpose of the Disclosure Act is to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered" within two years following its enactment. 7 U.S.C. § 1639b(a).

46. Bioengineering and any similar term is defined to be food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature." 7 U.S.C. § 1639(1).

47. While the Act generally uses the term, "bioengineered," it expressly includes "and any similar term" when it defines the "bioengineering" classification. 7 U.S.C. § 1639(1).

48. A food may "bear a disclosure that a food is bioengineered only in accordance" with the Act's implementing regulations. 7 U.S.C. § 1639b(b)(1).

49. The Act requires USDA to "establish such requirements and procedures as the Secretary determines necessary to carry out the standard." 7

U.S.C. § 1639b(a)(2). The Act mandates that USDA also "establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food" beyond those set out by the statute elsewhere in the agency's implementing regulations. 7 U.S.C. § 1639b.

50. While the Act permits the disclosure to be in the form of on-package text, symbol, or electronic or digital link, it required USDA to first study the efficacy of the electronic or digital disclosures, "to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." 7 U.S.C. § 1639b(c)(1).

51. The Act sets forth detailed factors USDA was required to analyze in the study: the availability of wireless Internet or cellular networks; the availability of landline telephones in stores; the challenges facing small retailer and rural retailers; efforts that retailers and other entities have taken to address potential technological and infrastructure challenges; and the costs and benefits of installing in retail stores stand-alone electronic or digital link scanners or other technology to provide disclosure information. 7 U.S.C. § 1639b(c)(3)(A)-(E).

52. The Act also requires that USDA "shall" solicit and consider public comments on the Study, underscoring its importance to the rulemaking process. 7 U.S.C. 1639b(c)(2).

53. The Act further specifies that any QR codes used for disclosure must be accompanied with the text "scan here for more food information" or similar language as well as include an accompanying phone number. 7 U.S.C. § 1639b(d)(1), (d)(4).QR codes must provide access "in a consistent and conspicuous manner, on the first product information page that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information." 7 U.S.C. 1639b(d)(2).

54. The Act prohibits USDA from requiring a food to be "considered a bioengineered food solely because the animal consumed feed from" a bioengineered source. 7 U.S.C. § 1639b(b)(2)(A). The Act further provides that USDA's regulations shall exclude "food served in a restaurant or similar retail establishment." 7 U.S.C. § 1639b(G)(i).

55. The Act includes an express admonition that it is not stripping FDA of any Federal Food, Drug and Cosmetic Act (FFDCA) authority or any party of any FFDCA obligation, meaning that the duty to not label in a false and misleading way still applies and there is no regulatory shield simply because a product is classified and labeled under the Act. 7 U.S.C. § 1639c(b)(1).

56. The statute provides that, if USDA determines in the study that "consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," then USDA "shall provide additional and comparable options" for accessing the disclosure for consumers. 7 U.S.C. § 1639b(c)(4).

57. The Act contains two preemption provisions. The first preemption provision expressly preempts States or any political subdivisions of States from establishing any labeling requirement different from that required by the Act. *Id.* § 1639b(e). The Act's second preemption provision is significantly broader and prohibits States and political subdivisions from "directly or indirectly" passing laws related to the "labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered" or "was developed or produced through genetic engineering, including any requirements for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering." *Id.* at 1639i(b).

58. The Act has a savings provision that requires that USDA "shall" apply the law "in a manner consistent with the United States obligations under international treaties." 7 U.S.C. § 1639c(a).

GENERAL FACTUAL BACKGROUND

I. Americans Have Long Asserted Their Right To Know Which Products Are Produced With Genetic Engineering, For a Multitude of Reasons

59. American consumers have called upon the U.S. government to label genetically engineered foods for many years, to secure access to the same information as residents of 64 other countries around the world.[2] Polls consistently show that nearly 90 percent of Americans want to know whether the foods they purchase were produced with genetic engineering.[3]

60. Consumers want those GE disclosures for numerous reasons: health, personal, economic, environmental, religious, and cultural. For example, on the health side, the public knows that the FDA, the Agency charged with ensuring the safety of most foods to eat, does not actually independently test the food safety of GE foods, or require them to be tested. That is, FDA does not "approve" GE foods for safety; instead, the Agency merely reviews the industry's own test results, and even this is not required, but rather proceeds on a confidential, voluntary basis, if the company chooses to consult with FDA.[4] Market entry for GE foods is based solely on confidential industry research.

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[2] *See, e.g., Genetically Engineered Food Labeling Laws*, https://www.centerforfoodsafety.org/ge-map/.

[3] *See, e.g., U.S. Polls on GE Food Labeling*, https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling.

[4] William Freese & David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 Biotech. & Genetic Eng'g Revs. 299, 303-04 (2004),

61. Moreover genetic engineering is very different than conventional breeding.[5] It is an imprecise technology that causes random and, in some cases, large-scale mutations in crop genomes,[6] and has a higher potential for generating unintended and potentially adverse human health effects than conventional breeding methods.[7] Scientific studies have shown that mixing plant, animal, bacterial, and viral genes through genetic engineering, in combinations that cannot occur in nature,[8] can and has caused unintended consequences: for instance, by making foods allergenic[9] or by introducing novel toxins.[10] Numerous scientific, health, and legislative bodies have concluded that GE foods have not been proven safe, that mandatory safety assessments are needed, and that they support labeling.[11]

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http://goo.gl/B9wSIa; *Consultation Programs on Food from New Plant Varieties*, U.S. Food & Drug Administration, https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties.

[5] Allison Snow, *Genetic Engineering: Unnatural Selection*, 424 Nature 619 (2003), http://goo.gl/Fn6hs3.

[6] Allison K. Wilson *et al.*, *Transformation-induced mutations in transgenic plants: Analysis and biosafety implications*, 23 Biotech. & Genetic Eng'g Rev. 209-234 (2006), http://goo.gl/JtDyk8.

[7] Inst. of Med. & Nat'l Research Counsel of the Nat'l Acads., *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 64, 65 n. 3 (2004), http://goo.gl/g9AuE1.

[8] Stanley N. Cohen *et al.*, *Construction of Biologically Functional Bacterial Plasmids in Vitro*, 70 Proc. Nat'l Acad. Sci. 3240-44 (1973), https://www.pnas.org/content/pnas/70/11/3240.full.pdf.

[9] J.A. Nordlee *et al.*, *Identification of a Brazil-nut allergen in transgenic soybeans*, 334(11) The New England Journal of Medicine 688-692 (1996).

[10] T. Inose & K. Murata, *Enhanced accumulation of toxic compound in yeast cells having high glycolytic activity: a case study on the safety of genetically engineered yeast*, 30 Int'l Journal of Food Science and Technology 141-146 (1995).

[11] Angelika Hilbeck *et al.*, *No scientific consensus on GMO safety,* 27:4 Envtl. Sci. Europe (2015), http://goo.gl/k2f4R6; Sheldon Krimsky, *An Illusory Consensus behind GMO Health Assessment*, Sci., Tech., and Human Values (August 7, 2015), https://www.centerforfoodsafety.org/files/an-illusory-consensus_82296.pdf.

62. Further, independent scientists are prohibited from conducting risk assessments of GE materials used in food products due to industry restrictions on research of those materials.[12] There are no long-term or epidemiological studies in the U.S. that have examined the safety of human consumption of GE foods, despite scientific recommendations for post-marketing surveillance. Without GE labeling, there is no accountability or traceability to link such foods to proliferating public health problems. Mandatory labeling of GE foods can provide a method for detecting, on a large epidemiological scale, the potential health effects of consuming such foods.[13] These facts rightly give consumers pause; thus disclosure through labeling allows them to make their own choices about whether to buy and consume GE foods.

63. Additionally, consumers want the ability to make purchase decisions that align with their values. On the environmental side, risks do not come from the unknown, but from the known and well established: GE crops are a key cog of inherently unsustainable industrial agriculture and cause significant adverse environmental impacts. With over 20 years of evidence to rely on, it is well established now that GE crops are at their heart a pesticide-promoting technology: The overwhelming majority of commercial GE crops are genetically engineered by pesticide companies, such as Monsanto (recently acquired by Bayer), Syngenta (acquired by ChemChina), and Corteva (the merged agricultural divisions of Dow and DuPont), to withstand application of herbicides they also sell.

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[12] Emily Waltz, *Under Wraps*, 27 Nature Biotech 880, 880-82 (2009); Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research*, N.Y. Times (Feb. 19, 2009), http://goo.gl/Nz7tWu.

[13] Philip J. Landrigan, M.D. & Charles Benbrook, Ph.D., *GMOs, Herbicides, and Public Health*, New England Journal of Medicine (2015), https://www.centerforfoodsafety.org/files/gmos-herbicides-and-public-health_82349.pdf.

64. Consequently, these GE crops have dramatically increased the overall pesticide output of American agriculture into our environment. Monsanto's genetically engineered "Roundup Ready" crops, which are resistant to glyphosate, have made glyphosate the most used pesticide in history, with roughly 280 million pounds applied annually in U.S. agriculture since 2012.[14] Newer GE crop varieties have increased the use of older pesticides such as dicamba and 2,4-D.[15] Reliance on these pesticide-promoting GE crop systems has caused a number of harms, including widespread pollution of our waterways and ecosystems,[16] injury to beneficial insects such as pollinators,[17] and harm to soil health.[18] Dicamba has caused massive herbicidal drift injury to sensitive crops, and also injures wild plants that many other organisms depend upon for food and/or habitat.[19]

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[14] Pesticide National Synthesis Project, *Pesticide Use Maps: Glyphosate*, U.S. Geological Survey (2012), http://goo.gl/hSFYL0; Charles M. Benbrook, *Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years*, 24 Envt. Sci. Eur. 1, 3 (2012), http://goo.gl/RaFkeM; R. J. Seidler, *Pesticide use on genetically engineered crops*, Ag/Mag Blog (Sept. 15, 2014), http://goo.gl/R7wocn.

[15] David Mortensen *et al.*, *Navigating a critical juncture for sustainable weed management*, 62 BioScience 75-84 (2012), http://goo.gl/RxZVM2; Brandon Keim, *New generation of GM crops put agriculture in a 'crisis situation,'* Wired (Sept. 25, 2014), http://goo.gl/ejbTLF.

[16] Feng-Chih Chang *et al.*, *Occurrence and Fate of the Herbicide Glyphosate and its Degradate Aminomethylphosphonic Acid in the Atmosphere,* 30 Envtl. Toxicology & Chemistry 548, 548-50 (2011), http://goo.gl/bZZTve; Richard H. Coupe *et al.*, *Fate and Transport of Glyphosate and Aminomethylphosphonic Acid in Surface Waters of Agricultural Basins*, 68 Pest. Mgmt. Sci. 16, 16-17 (2012), http://goo.gl/WSvHO2.

[17] Richard Coniff, *Tracking the causes of sharp decline of the monarch butterfly*, Yale Environment 360 (Apr. 1, 2013), http://goo.gl/EBCU33; J.M. Pleasants & K.S. Oberhauser, *Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population*, 6 Insect Conservation and Diversity, 135-144 (2013), http://home.cc.umanitoba.ca/~frist/PLNT4600/biodiversity/icad196.pdf.

[18] Robert J. Kremer, *Soil and environmental health after twenty years of intensive use of glyphosate*, 6 Adv. Plants Agric.Res 00224 (2017).

[19] Lekha Knuffman *et al., Drifting Toward Disaster: How dicamba herbicides are harming cultivated and wild landscapes,* National Wildlife Federation, Prairie Rivers Network, Xerces Society for Invertebrate Conservation (2020),

Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.[20] The well-established environmental impacts of GE crops (and their attendant pesticides) are widespread and dire. Many people reasonably want to align their food purchasing choices with their environmental values.

65. Further, protection of the environment and the protection of public health are intimately intertwined. In 2015, the World Health Organization's International Agency for Research on Cancer (IARC) concluded that glyphosate is probably carcinogenic to humans,[21] based in part on epidemiology studies showing increased risk of non-Hodgkin lymphoma (NHL) among farmers who used glyphosate formulations. In three lawsuits brought against Monsanto, juries ruled that use of Roundup and other glyphosate formulations contributed to the development of NHL in California users of these products. In June 2020, Monsanto's owner, Bayer, agreed to pay up to $10.9 billion to roughly 125,000 cancer victims who had filed similar lawsuits against the company.[22] The amount of glyphosate permitted in the food supply has increased dramatically since the 1980s, and a growing number of independent studies indicate that long-term glyphosate exposure poses risks to the liver, kidney and reproductive system.

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https://www.nwf.org/Educational-Resources/Reports/2020/08-05-20-Drifting-Toward-Disaster; Assoc. of Am. Pesticide Control Officials, *2005 Pesticide Drift Enforcement Survey Report*, https://www.centerforfoodsafety.org/files/aapco-2005_29712.pdf.

[20] Rick A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 Ecological Adaptions 1118, 1120-23 (2005), http://goo.gl/ZjYiHG.

[21] World Health Organization, *IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides* (March 20, 2015), http://goo.gl/KRhWNX.

[22] *Bayer to pay up to 10.9 billion to settle bulk of Roundup weedkiller cancer lawsuits*, Reuters (June 24, 2020), https://www.reuters.com/article/us-bayer-litigation-settlement/bayer-to-pay-up-to-10-9-billion-to-settle-bulk-of-roundup-weedkiller-cancer-lawsuits-idUSKBN23V2NP.

66. On the agricultural side, over the past two decades, the unintended mixing of genetically engineered DNA with conventional or organic crops and seeds, known as transgenic contamination,[23] has cost U.S. farmers billions of dollars in market losses.[24] For example, in 2017, farmers reached a $1.5 billion settlement with Syngenta for widespread GE corn contamination of corn set to be exported to China and other countries for which the GE corn was not approved, causing corn export markets to collapse.[25] Numerous foreign markets with restrictions on genetically engineered foods have restricted imports of U.S. crops due to concerns about such forms of production.[26] Some foreign markets are choosing to purchase agricultural products from countries other than the U.S. because GE crops are not identified in the U.S., which makes it impossible for buyers to determine whether products meet their national labeling laws or restrictions.

67. Further, the widespread adoption of crops engineered for pesticide resistance has proliferated an epidemic of resistant "superweeds" now covering at

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[23] Michelle Marvier & Rene C. Van Acker, *Can Crop Transgenes Be Kept on a Leash?*, 3 Frontiers Ecology & Env't 99, 100-01 (2005), https://www.centerforfoodsafety.org/files/can-crop-transgenes-be-kept-on-a-leash_82326.pdf.

[24] Andrew Harris, *Bayer Agrees to Pay $750 Million to End Lawsuits Over Gene-Modified Rice*, Bloomberg (July 2, 2011), http://goo.gl/ymErOa; K.L. Hewlett, *The Economic Impacts of GM Contamination Incidents on the Organic Sector* (2008), http://goo.gl/jf2F5E; Stuart Smyth *et al.*, *Liabilities & Economics of Transgenic Crops*, 20 Nature Biotech. 537 (2002), https://www.centerforfoodsafety.org/files/liabilities-and-economics-of-transgenic-crops_82369.pdf.

[25] Jef Feeley & Margaret Cronin Fisk, *Syngenta to pay $1.4 billion to settle Viptera claims*, Farm Futures (Sept. 26, 2017), https://www.farmprogress.com/business/syngenta-pay-14-billion-settle-viptera-claims.

[26] Tom Polansek, *China rejections of GMO U.S. corn cost up to $2.9 billion,* Reuters (Apr. 16, 2014), https://www.reuters.com/article/syngenta-corn-costs/china-rejections-of-gmo-u-s-corn-cost-up-to-2-9-bln-group-idUSL2N0N82DF20140416.

least 120 million acres of U.S. farmland.[27] These weeds have flourished, infesting farm fields and roadsides, complicating weed control for farmers, and forcing farmers to resort to more and increasingly toxic pesticides.[28] Many consumers do not want to support unsustainable agricultural practices that harm American farmers and instead want to make choices that align with their support of family farmers, not agrochemical companies. Again, proper labeling provides them this choice.

68. Juxtaposed against these facts, the U.S. public has discovered that the pesticide industry's hype about genetically engineered crops is false: Despite billions of dollars in research and nearly three decades of commercialization, no GE crops are commercially produced to increase yields, reduce world hunger, or mitigate climate change.[29] Rather, the commercial reality is that agrochemical companies have largely succeeded in engineering these crops to be resistant to the companies' own products—pesticides—in order to reap huge profits.

69. Further, studies show that, due to the prior lack of mandatory labeling, many American consumers are under an incorrect assumption as to whether the food they purchase is actually produced with genetic engineering, or not. Requiring meaningful and accurate disclosure of whether or not foods are genetically engineered reduces this consumer confusion and deception.

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[27] J. Pucci, *The war against weeds evolves in 2018*, CropLife (March 20, 2018), https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/.

[28] David Mortensen *et al.*, *Navigating a critical juncture for sustainable weed management*, 62 BioScience 75-84 (2012), http://goo.gl/RxZVM2; Scott Kilman, *Superweed outbreak triggers arms race*, Wall Street Journal (June 4, 2010), http://goo.gl/Fcolxd.

[29] Doug Gurian-Sherman, Union of Concerned Scientists, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops,* at 1-5 (April 2009), https://www.ucsusa.org/resources/failure-yield-evaluating-performance-genetically-engineered-crops; Jack A. Heinemann, *Reply to comment on sustainability and innovation in staple crop production in the US Midwest*, 12 Int'l J. of Ag. Sustainability 387-390 (2014), http://goo.gl/GruWvv.

70. Finally, consumers also want mandatory labeling for religious, cultural, ethical, moral, personal, or dietary reasons. Without mandatory disclosures, consumers of GE foods may unknowingly violate their beliefs or health restrictions. Labeling provides consumers with the information they need to make safe and informed decisions.

II. States Respond to Public Demand

71. Our country's history is one of states as the laboratories for democracy. A 2011 rulemaking petition by some plaintiffs requesting federal labeling resulted in 1.4 million public comments in support, but no federal agency action. So in the absence of federal action, public demand for GE labeling prompted state legislatures to draft and pass their own GE labeling laws. Between 2013 and 2015, more than 30 states introduced substantially similar GE food labeling bills. State labeling ballot initiatives were narrowly defeated in California (2012), Washington (2013), and Oregon (2014).

72. Connecticut and Maine passed labeling laws in 2013, albeit with clauses tying their effective dates to the passage of similar laws in other states. In May 2014, Vermont became the first state to pass a stand-alone labeling law, which went into effect in July 2016.

73. Further, states have been labeling and identifying GE seeds for years in a variety of ways. For example, Vermont has required GE information on seed labels since 2003, and Virginia since 2012. *See* Vt. Stat. Ann. tit. 6, § 644 (2003); Va. Code Ann. tit. 3.2, § 4008 (2012). Other states require "certification" of GE seeds, which results in labeling, tagging, or sealing. *See, e.g.*, Wash. Admin. Code § 16-302-170 (2010); Vt. Stat. Ann. tit. 6, § 611 (2015). Several additional states identify and regulate GE seeds through public notice requirements and permitting.

III. The Federal Disclosure Act

74. In July 2016, Congress enacted the Bioengineered Food Disclosure Act to "establish a national mandatory bioengineered food disclosure standard for bioengineered foods and foods that may be bioengineered" within two years following its enactment. 7 U.S.C. § 1639b(a).

CLAIMS

I. Claim 1: Electronic or Digital Disclosures

75. One of the most controversial aspects of the Disclosure Act was its unprecedented inclusion of novel "electronic or digital" disclosures, a first for government-mandated food product or food ingredient information. The form of such electronic disclosures are known as "Quick Response" codes or "QR Codes": a matrix barcode that requires a smart phone with a QR code scanner and broadband internet in order to access.[30]

76. The Act established three potential forms of the bioengineered disclosure: on-package text, a USDA-established on-package symbol, or an electronic or digital link. 7 U.S.C. § 1639b(b)(2)(D). Understanding the unprecedented nature of indirect electronic or digital disclosures and anticipating problems and unknowns, Congress required USDA to undertake a study to inform the rulemaking, identifying and analyzing: "the potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." 7 U.S.C. § 1639b(c)(1). The study was to be completed a full year before the regulations were to be finalized in order to give the agency sufficient time to apply the findings. 7 U.S.C. § 1639b(c)(1).

[30] These terms—electronic and digital disclosures or QR Codes—are used interchangeably here, as QR Codes are the only form of "electronic or digital disclosure" USDA discussed in the rulemaking.

77. The Act set forth detailed factors USDA had to analyze in the study: the availability of wireless Internet or cellular networks; the availability of landline telephones in stores; the challenges facing small retailer and rural retailers; efforts that retailers and other entities have taken to address potential technological and infrastructure challenges; and the costs and benefits of installing in retail stores stand-alone electronic or digital link scanners or other technology to provide disclosure information. 7 U.S.C. § 1639b(c)(3)(A)-(E).

78. If USDA then determined based on the study and the record that "consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," the Act required that USDA "shall provide additional and comparable options" for consumers for accessing the disclosure. 7 U.S.C. § 1639b(c)(4).

A. The QR Code Study

79. USDA publicly released its Study,[31] *A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure*, undertaken by a private contractor, Deloitte Consulting LLP,[32] on September 6, 2017, though it is dated July 2017. It was not supportive of the use of electronic or digital forms of the disclosure. Rather overall it concluded that "key technological challenges"—such as lack of technical knowledge, lack of association of digital links with food information, and lack of infrastructure—prevent consumers from obtaining the necessary information through the QR Code disclosure.[33]

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[31] *A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure* (July 2017), https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf.

[32] AMS, *Statement of Objectives Study of Electronic or Digital Link Disclosure National Bioengineered Food Disclosure Standard*, https://www.ams.usda.gov/sites/default/files/media/Statement%20of%20Objectives_for%20posting.pdf.

[33] USDA 2017 Study at 4.

80. Through direct observation of consumers, researchers determined that these myriad challenges "prevented nearly all participants from obtaining the information through electronic or digital disclosure methods."[34] Accordingly the Study recommended that "in order for the law to have intended outcomes for interested consumers, USDA and interested groups should address technological challenges."[35]

81. Among other relevant findings—all of which go to the factors specifically enumerated by Congress in the law set forth directly above—the Study concluded that:

- "Digital links are not inherently associated with additional food information, and consumers often assume they are for marketing and industry use."[36]
- "Consumers may not have equipment capable of scanning digital links on their own, and in most cases there is not a viable alternative provided by retailers."[37]
- Zero percent of the stores visited for the study were equipped with scanners capable of accessing information on a digital link.[38]
- "There are hundreds of scanning apps available in the market, many of which are not intuitive to use, causing consumer confusion and difficulty opening link results."[39]
- "85 percent of consumers struggled with complicated mobile software applications ("apps") regardless of their comfort using technology."[40]
- "Consumers may be unable to connect to broadband, or connect at speed that is so slow that they cannot load information."[41]

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[34] USDA 2017 Study at 4.
[35] *Id.* at 65.
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*

- "20 percent of retail stores do not currently have in-store WiFi, including 63 percent of small retailers."[42]
- Landlines "do not provide a viable means of accessing the digital disclosure due to limited availability of such phones for consumer use and restricted manufacturer call center hours."[43]
- As to the challenges facing small retailers and rural retailers: "Rural retailers are less likely to have broadband access, and small retailers will struggle to make costly investments in WiFi networks. As a result, consumer who shop at these stores will face difficulties accessing digital disclosures."[44]
- Installing scanners in retail stores "may prove cost prohibitive, particularly for small and rural retailers. In addition, there are limited benefits due to limited consumer knowledge around digital disclosure today."[45]
- Smart phone ownership rates: 77 percent of Americans, 67 percent of Americans in rural locations, 42 percent of Americans 65 or older, 64 percent of low income households.[46] The Deloitte study also cites a Pew study, which found that 58% of Americans over the age of 65, 36% of those earning less than 30,000 a year, and 33% of those living in rural areas do not own a smart phone.[47]
- "[S]martphone ownership is not necessarily a proxy for access, as some smartphones are not capable of scanning electronic or digital links. A device might be older, malfunctioning, or lack storage space, inhibiting one from scanning effectively."[48]
- "Scanning digital links is not an intuitive process for many consumers who lack technical knowledge on how to download and use scanner apps."[49]
- The Study identified multiple app design issues that frustrated consumers, sometimes to the point of abandoning attempts to obtain

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[42] USDA 2017 Study at 65.
[43] *Id.* at 5.
[44] *Id.*
[45] *Id.*
[46] *Id.* at 17.
[47] *Id.* at 48 (citing Pew Research Center, *Mobile Fact Sheet* (January 2017), http://www. pewinternet.org/fact-sheet/mobile/).
[48] *Id.* at 46.
[49] *Id.* at 40.

information. These include inadequate or unclear instructions, embedded and pop-up advertisements, delays in loading, special requirements for labels, and variance in display of results.[50]

- "According to the FCC, 34 million Americans (10 percent of the population) lack access to advanced broadband service. This is particularly true in rural and tribal areas, with 23 million Americans living in rural areas (39 percent) and 1.6 million living on tribal lands (41 percent) lacking access to advanced broadband."[51]

- "Based on the 10 Mbps standard, this study finds that 20.5 million people (6.4 percent of the US population) have inadequate broadband to load a basic electronic or digital link . . . . Moreover, while broadband may technically be available in a specific location, individual access is often dependent on the provider."[52]

- Though some grocery stores provide WiFi, "most only provide access for a limited period of time, sometimes as low as 30 minutes. The average time spent grocery shopping is 43 minutes. If consumers were to stop and scan digital links, that time would likely increase and may come up against WiFi time limits."[53]

- "[I]n a supercenter with free WiFi advertised around the store, it took 90 seconds to connect to a webpage after scanning a product, far beyond the two second wait time that most consumers expect . . . ."[54]

- "One year of WiFi in a retail store could cost $10,050 to cover 0 to 5,000 square feet of space . . . retailers see little return on this costly investment . . . ."[55]

- 100 percent of consumers polled did not recognize digital links were associated with food info.[56]

- "Only 15 percent of Americans scanned barcodes or QR codes to find information about a product's ingredients or nutrition information in the prior year; 29 percent had scanned these to find the price of a product or to check out at a store during the same period."[57]

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[50] USDA 2017 Study at 52.
[51] *Id.* at 55.
[52] *Id.* at 55.
[53] *Id.* at 59.
[54] *Id.*
[55] *Id.* at 67.
[56] *Id.* at 4.
[57] *Id.* at 43.

- Retailers are "also unaware that digital links include additional food information" and as such "consumers may receive inaccurate and inconsistent information from retailers—even if well intentioned—leading to further confusion."[58]

- "[B]oth retailers and consumers in the field tended to overlook guiding words surrounding the digital link . . . ."[59]

- "Consumers may recognize electronic or digital links, but do not know how to access information due to a lack of familiarity with scanning."[60]

82. As these non-exhaustive examples show, the Act's required study found multiple significant problems with the efficacy of digital and electronic disclosures; its analysis of every factor enumerated by Congress in 7 U.S.C. § 1639b(c)(3)(A)-(E) weighed against the sufficiency of such disclosures.

83. Congress also required that USDA "shall" solicit and consider public comments on the Study, underscoring its importance to the rulemaking process. 7 U.S.C. 1639b(c)(2). However USDA never held a public comment period on the Study or its findings. Nor, as discussed below, did USDA make any statutorily required sufficiency determination based on the Study until the final rule, after the close of public comment.

B. The Rulemaking as Related to Electronic and Digital Disclosures

84. In summer 2017, USDA put out for comment a scoping document, with "proposed rule questions under consideration."[61] Among the thirty questions presented, USDA addressed the QR code disclosure issue only in passing, and did not mention Congress's required study or its findings.[62]

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[58] USDA 2017 Study at 45.
[59] *Id.*
[60] *Id.* at 40.
[61] AMS, *Proposed Rule Questions under Consideration*, https://www.ams.usda.gov/rules-regulations/gmo-questions.
[62] *Id.* at Qt. 25 ("How should AMS ensure an electronic or digital disclosure can be easily and effectively scanned or read by a device? Context: AMS is aware that

1) Proposed Rule

85. In May of 2018, USDA issued the proposed rule (though referring to it as an actual proposal is misleading because the agency raised numerous possible alternatives for various issues it had to decide rather than actually proposing any). 83 Fed. Reg. 19,860 (May 4, 2018). As relevant to the QR Code disclosure, the proposed rule indicated that the regulations would include the text "scan here for more food information" or similar language, as required by the statute, as well as include an accompanying phone number, as also separately required by the statute. 83 Fed. Reg. at 19,875; *see* 7 U.S.C. § 1639b(d)(1), (d)(4). These provisions were later finalized and codified. *See* 7 C.F.R. § 66.106(a)(1)-(2).

86. The proposed rule also addressed the Deloitte Study, but did not meaningfully grapple with its findings or analysis. 83 Fed. Reg. at 19,875. The agency set forth the factors Congress required be studied, and that the agency had to make a post-Study determination regarding its sufficiency for consumers. *Id.* However, despite USDA having had the study since July 2017, at the time of the proposed rule in May 2018, the notice simply said that USDA "was still reviewing the study and its results to decide whether to make that determination." *Id.*

87. Nonetheless, USDA went on to presumptively float "an additional disclosure option," "should the Secretary determine that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital methods": a text message option, in which manufacturers could place instructions "text [number] for more food information" and provide an automated response. *Id.* at 19,876. USDA did not explain how this would comply with the Act's mandates, or solve the problem of having packages with only the insufficient QR Code disclosure on store shelves.

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electronic or digital disclosures need to be effective . . . ," but without mentioning the study or Act's requirements if they are found not to be).

2) QR Codes: Public Comments and Other Evidence

88. The Study echoed existing secondary sources on the lack of efficacy of these types of indirect electronic and digital disclosure for consumers. During the proposed rule comment period, commenters presented further evidence to the agency regarding their problems as opposed to on-package labeling.

89. Consumers Union cited 2018 research by the Pew Research Center, which determined that almost 58 million Americans do not own smart phones.[63] This percentage is higher among older Americans in rural areas. Only 46% of people over 65 years old own a smartphone, compared to 94% of those aged 18-29, and only 65% of people in rural areas own a smartphone, compared to 83% of those in urban areas and 78% of those in suburban areas.[64] Additionally, only 67% of people with an income of less than $30,000 own a smartphone, compared to 93% of those with an income of more than $75,000.[65] Studies show this income aspect will disproportionately affect minorities, due to the wage/wealth gap.[66]

90. The International Food Information Council further commented on strong consumer preferences for on-package text or symbols. Based on the organization's survey, 73% of consumers ranked symbols or visual representations 1st or 2nd (out of 6 options) on their list of preferences, while 63% of consumers ranked text on a food package 1st or 2nd.[67] In contrast, less than 20% ranked text

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[63] Consumers Union comment, at 19 (citing Pew Research Center, *Mobile Fact Sheet* (February 5, 2018), http://www.pewinternet.org/factsheet/mobile/).
[64] *Id.*
[65] Consumers Union comment, at 19 (citing Pew Research Center, *Mobile Fact Sheet* (February 5, 2018), http://www.pewinternet.org/factsheet/mobile/).
[66] Katherine Schaeffer, *6 facts about economic inequality in the U.S.* (Feb. 2020), https://www.pewresearch.org/fact-tank/2020/02/07/6-facts-about-economic-inequality-in-the-u-s/.
[67] International Food Information Council comment, at 6.

messages, internet websites, telephone numbers, and electronic or digital links as a 1st or 2nd preference.[68]

91. The Study results are consistent with a 2016 study conducted by the Annenberg Public Policy Center that found only 15 percent of Americans scanned barcodes or QR codes to search for ingredients and nutrition facts in 2015, while 29 percent scanned them to search for prices or to check out.[69]

92. Overall these existing studies show that digital and electronic labeling, like QR codes or websites, will not provide disclosure to a large portion of Americans, and that this portion is disproportionally minority, low-income, and elderly people. Half of low-income people do not own smartphones. Almost half of rural people do not own smart phones. Minorities are a disproportionate percentage of low-income and rural Americans. Two-thirds of the elderly do not own smart phones. In fact, USDA's study determined that only 77 percent of Americans own a smart phone.[70]

93. Even those who have the phones and service plans are not guaranteed consistent access to the internet.[71] Few people have ever used a QR code—only 16 percent have ever scanned a QR code, and only 3 percent of those people do it regularly.[72]

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[68] International Food Information Council comment, at 6.

[69] Annenberg Public Policy Center, *Will Consumers Use QR Codes to Learn About Genetically Modified Food?*, at 43, 62 (August 2016), http://www.annenbergpublicpolicycenter.org/will-consumers-use-qr-codes-to-learnwhether-food-is-genetically-modified/.

[70] USDA 2017 Study at 48.

[71] Charlie Osborne, *The state of LTE 4G networks worldwide in 2014 and the poor performance of the US,* ZDNet (Feb. 21, 2014), http://www.zdnet.com/article/the-state-of-lte-4g-networks-worldwide-in-2014-and-the-poor-performance-of-the-us/.

[72] The Mellman Group, *National Survey of Likely 2016 General Election Voters,* 20-21 (Nov. 2015), http://4bgr3aepis44c9bxt1ulxsyq.wpengine.netdna-cdn.com/wp-content/uploads/2016/02/15pre1123-d1-JLI-d9.pdf.

94. Moreover, smart phones and data plans are expensive, and nearly half of those who have smart phones have had to cancel or shut off their cell phone service for a period of time because the cost of maintaining that service was a financial hardship.[73]

95. As such, allowing labeling based on QR codes is discriminatory against the low-income, rural Americans, minorities, the elderly and other groups less likely to own a smart phone or know how it is used. Even for those who own smart phones, access to networks and/or internet while shopping is not guaranteed.

96. Smartphone ownership, access to a working phone, and access to reliable broadband is not all. Even among those who own smartphones, there are varying degrees of digital readiness. "Digital readiness" describes the extent of smartphone usage among individual owners. A study published by the Pew Research Center in 2016 looked into the varying degree of readiness among differing demographics.[74]

97. A user's digital readiness is based on their level of digital skills and their trust in the technological environment. There are several levels of readiness, including unprepared, traditional learner, reluctant, cautious clicker, and digitally ready. The unprepared are the least digitally ready and make up 14 percent of Americans. The reluctant make up 33 percent of owners, and while they have a slightly higher skill level, they have a low level of awareness of new technology and thus are infrequent technology users. Forming 5 percent of smartphone owners, the traditional learners choose not to engage digital tools to pursue their interests or

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[73] Aaron Smith, *U.S. Smartphone Use in 2015*, Pew Research Center: Internet & Tech. (Apr. 1, 2015), http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/.

[74] John B. Horrigan, *Digital Readiness Gaps*, Pew Research Center: Internet & Technology 3 (Sept. 20, 2016), http://www.pewinternet.org/2016/09/20/digital-readiness-gaps/.

inform themselves. The cautious clickers make up 31 percent of owners that have knowledge but do not use technology as frequently as the digitally ready, who make up 17 percent of owners and frequently use technology. The first three levels consist of owners who are less likely to use digital tools, such as QR codes, to inform themselves due to lack of technological knowledge or lack of trust in the technological environment. The last two groups consist of owners who are considered to be digitally prepared.

98. This shows that, due to lack of skill, knowledge, or trust, approximately 52 percent of smartphone owners would nonetheless still be unlikely to use QR codes, and would thus be left without an effective form of GE disclosure. The Pew study also further shows that such disclosure would be discriminatory. The completely unprepared group is disproportionately represented by the demographic characteristics of female users, ages 50+, lower income households, and lower levels of formal education. In contrast, the digitally prepared group is more likely to be represented by middle aged users, higher income households, and higher levels of formal education.

99. Even among the technologically enabled participants who participated in the online Deloitte survey, many participants noted challenges in accessing a working phone with the app needed to scan QR codes. While only six percent of participants did not own a smart phone, the percentage doubled for those that would still struggle to access QR codes due to malfunctioning phones, lack of storage space in the phone for a scanning app, and lack of scanners available in stores.

100. Even for users with space for a scanning app, no single app yet exists to scan for food information in a manner consistent with 7 U.S.C. 1639b(d)(2).[75] Currently, hundreds of free scanning apps are available, but these apps use

[75] USDA 2017 Study at 52-53.

advertisements to garner profit, which would violate the Act's mandate to "exclude marketing and promotional information" from the digital link.[76] Many scanning apps used by consumers in the Deloitte study led to inconsistent results, pop-up advertisements, and unexplained delays in loading, which caused user confusion and eventual abandonment.[77]

101. It is also the case that Americans simply do not associate QR codes with information about the contents of food products. This is unsurprising given the unprecedented form of this disclosure. Not only do very few Americans regularly use QR codes,[78] the majority of QR code scans came from magazines, websites, mail, billboards or signs, and emails, and not from packages.[79] Removing Americans who do not own smartphones (23 percent), and then cut that percentage down again for those that have ever scanned a QR code, and then again for those that have scanned a QR code to gain product information from a product label, the percentage of Americans that would actually have access to GE disclosure via QR codes is in the single digits.

102. In addition, electronic labeling disclosures put an undue burden on the shopper. Even if consumers had access and knowledge to use a QR Code, it is unrealistic for a shopper to scan all of the many items they are shopping for on any given shopping trip (which for a family of four could easily amount to more than 50 items). This would be an undue burden on the consumer and greatly impede access to information that is currently required for all other forms of food labeling.

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[76] USDA 2017 Study at 53.

[77] *Id.* at 52.

[78] The Mellman Group, *supra* note 46, at 21.

[79] Chadwick Martin Bailey, *9 Things to Know About Consumer Behavior and QR Codes*, CMB Consumer Pulse (2012), https://www.cmbinfo.com/cmb-cms/wp-content/uploads/2012/01/Consumer-Pulse-Template-QR-Codes-Final.pdf (finding that only 18 percent of those who reported scanning a QR code found them on packages and only 8-10 percent said they were highly interested in using a smartphone to scan a QR code).

103. Especially during the current COVID-19 pandemic, many Americans are visiting grocery stores less frequently to avoid exposure to the virus and purchasing more items during each visit.[80] Requiring a shopper to scan every single item he or she purchases would not only place an undue burden on the shopper, but would increase a shopper's exposure risk. Consumers cannot opt to purchase groceries online and research this information from home, as "The amended Act does not authorize AMS to require an independent website disclosure." 83 Fed. Reg. at 65,862. Such online disclosures are only voluntary.

104. For these reasons, numerous manufacturers and organizations oppose digital links as a disclosure option. Nature's Path, the largest certified organic breakfast cereal producer in North America, commented that digital links do not ensure fair and equal disclosure to all consumers because "high percentages of the population have barriers to access electronic presented information."[81] Similarly, Stonyfield, maker of the second leading brand of organic yogurt in North America, expressed concern that disclosure via QR code could create "technological hurdles" for consumers that lack technology to access the disclosure or because the technology fails to consistently work.[82]

105. Other companies opposed to digital disclosure include Straus,[83] Global Organics,[84] Next Foods,[85] Hain Celestial Group,[86] One Degree Organic Foods,[87]

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[80] Russell Redman, *How the coronavirus crisis is changing grocery shopping,* Supermarket News (April 3, 2020), https://www.supermarketnews.com/center-store/how-coronavirus-crisis-changing-grocery-shopping.
[81] Nature's Path comment, at 3.
[82] Stonyfield comment, at 4.
[83] Straus comment, at 9.
[84] Global Organics comment, at 2
[85] Next Foods comment, at 3.
[86] Hain Celestial Group comment, at 4.
[87] One Degree comment, at 3.

Organic Valley,[88] and Patagonia.[89] Numerous organizations also expressed disapproval of digital links as a disclosure option including the Institute for Agriculture and Trade Policy,[90] National Family Farm Coalition,[91] National Co-op Grocers,[92] National Sustainable Agriculture Coalition,[93] Consumers Federation of America,[94] and the Environmental Working Group.[95]

3) The Inadequacy of Text Message Disclosure

106. Commenters also pointed out that the Deloitte Study showed a text-messaging option would disadvantage the same population group as the QR code group. Many Americans in rural areas lack reliable cellphone service that would allow them to send or receive text messages.

107. Among those that do, the Study showed a lack of association between a phone number and food ingredient information. Neither consumers nor retailers associate "text here for more food information" messaging with basic food ingredient information (unsurprising and logical, given the unprecedented nature of presenting food ingredient information in such a manner). Consumers will not know what "food information" the message is referring to, as it is exceedingly vague. "Scan here for more food information" or "text here for more food information" does not give the consumer any idea that the information is about whether the food is produced with genetic engineering.

108. Many consumers polled in the Deloitte Study were concerned with their ability to receive information on their phones due to lack of reception.[96] Text

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[88] Organic Valley comment, at 5.
[89] Patagonia comment, at 5.
[90] Institute for Agriculture and Trade Policy comment, at 9.
[91] National Family Farm Coalition comment, at 1.
[92] National Co-op Grocers comment, at 6.
[93] National Sustainable Agriculture Coalition comment, at 8.
[94] Consumers Federation of America comment, at 5.
[95] Environmental Working Group comment, at 18.
[96] USDA 2017 study at 39, 54, 57.

messaging does not alleviate this problem: cell service is required to send and receive text messages. A grocery store having WiFi would not address the inability to text without reception, because text messages are not sent over WiFi.[97] For a QR code disclosure, consumers would need a charged smartphone with data, the QR scanning app, and good service in order to get the information. With text-messaging as the alternative, consumers would still need a charged cellphone with text messaging capabilities and good service to be able to receive the GE disclosure information. This alternative barely differs, including many of the same barriers, making the information inaccessible to the same people from either source.

109. Text messaging would disadvantage the same population groups as the QR code option: low income people, people who live in rural areas, and older people. Lower income people, less educated people, people of color, people in rural communities, and older citizens are less likely to own cellphones.[98] These groups overlap with those who viewed technological challenges as a setback to the QR code system.

110. The Study shows that lower income participants were more likely to be concerned with their ability to access QR code scanning tools.[99] The same setback would apply to a text message option. Lower income communities experience 15 percent less coverage from cell providers, be it because there are fewer telecom bases in low income areas or because the telecom bases are located closer to suburban areas.[100] Either way, low income communities get worse service and are therefore less able to send or receive text messages inside grocery stores. Without

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[97] SMS text messages may be sent via WiFi, but only though an SMS text app on a smartphone, creating the same issues with digital disclosure via QR code.

[98] Pew Research Center, *Mobile Fact Sheet*, Pew Research Center: Internet & Tech. (Feb. 5, 2018), http://www.pewinternet.org/fact-sheet/mobile/.

[99] USDA 2017 study at 48.

[100] Pantelis Koutroumpis & Aija Leiponen, *Crowdsourcing Mobile Coverage*, 40 Telecomm. Policy 532 (Jun. 2016).

service, text messaging for GE information is not a feasible alternative for these communities for the same reason QR codes are not a feasible option in the first place: lack of access to technology.

111. Inconsistency in cellular plans would also make this information more accessible to some than others. For example, not all Americans have unlimited texting.[101] For consumers who have pay-as-you-go texting, they would have to pay for each text they send to get information that could be listed directly on label. This scheme creates a barrier for low income consumers who cannot afford unlimited texting, making it harder for them to access the information.

112. Even when people have unlimited access to texting, this alternative still assumes that consumers will want to use texting for information at the grocery store as a practical matter. The average American adult only sends 10 text messages per day, and that number decreases as age increases.[102] This means that if someone 50 years old is in a grocery store and wants to access the GE disclosure information for just 5 items, they would have to text 5 different numbers to get information on these products, increasing the amount they texted that day by 50 percent.

113. Further just as with the QR code option, the burden of texting a number for every product greatly increases the amount of shopping time. The average grocery store visit lasts under an hour,[103] and even that amount of time is

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[101] Josh Zagorsky, *Almost 90% of Americans Have Unlimited Texting*, Instant Census Blog (Dec. 8, 2015), https://instantcensus.com/blog/almost-90-of-americans-have-unlimited-texting.

[102] Amanda Lenhart, *Cell Phones and American Adults,* Pew Research Center: Internet & Tech. (Sept. 20, 2010), http://www.pewinternet.org/2010/09/02/cell-phones-and-american-adults/.

[103] Jack Goodman, *Who Does the Grocery Shopping, and When Do They Do It?*, The Time Use Institute (Apr. 2016), http://www.timeuseinstitute.org/Grocery16paper.pdf.

probably too long for the busy family member doing the shopping.[104] Especially during the current COVID-19 pandemic, shoppers have been reducing grocery store visits and attempting to spend less time in stores to reduce their exposure risk. The logistics and practicability of having a family shopping in a grocery store send a text message and wait for a response for each of the 50 products the family purchases is unworkable in the real world.

114. Rather than electronic or digital disclosures or text messages, 89 percent of people who identified themselves as concerned about and wanting to know if food was produced through genetic engineering reported they made a decision about which food to buy by looking at the label.[105]

115. Further, putting a phone number on a package for consumers to text is not an "additional" option—the Act already required that the QR code disclosures also list a toll-free phone number from the outset, having nothing to do with the required Study, the agency's insufficiency determination, and its remedy. 7 U.S.C. § 1639b(d)(4).

116. Numerous manufacturers agree that text messaging does not provide an "additional" option for consumers. Patagonia commented that a text message option is not "additional" because "millions of Americans who live in rural areas may not have reliable cellphone service that would allow them to send or receive text messages."[106] Further, Straus commented that text message disclosure would

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[104] Jack Goodman, *Who Does the Grocery Shopping, and When Do They Do It?*, The Time Use Institute (Apr. 2016), http://www.timeuseinstitute.org/Grocery16paper.pdf.

[105] Cary Funk & Brian Kennedy, *The New Food Fights: U.S. Public Divides Over Food Science*, Pew Research Center (Dec. 1, 2016), http://www.pewinternet.org/2016/12/01/the-new-food-fights/.

[106] Patagonia comment, at 5.

pose an obstacle for consumers that must pay for text messages sent and received.[107]

117. Other companies and organizations opposed to text messaging as an "additional" option include Numi,[108] Next Foods,[109] Hain Celestial Group,[110] Puris,[111] Consumers Union,[112] Environmental Working Group,[113] International Food Information Council,[114] and National Co-op Grocers.[115]

4) Final Rule

118. In the Final Rule, USDA again discussed the electronic and digital disclosure method, and the Study on its efficacy or lack thereof. 83 Fed. Reg. 65,814, 65,828 (Dec. 21, 2018). After reciting the required study's factors, USDA finally made the finding Congress required:

> After reviewing the study and comments submitted to the [proposed rule] related to the study, the Secretary has determined that consumers would not have sufficient access to the bioengineering disclosure through only electronic or digital means under ordinary shopping conditions at this time.

83 Fed. Reg. at 65,828.

119. USDA acknowledged that "most consumers in the study experienced technical challenges in accessing the bioengineered food disclosure on their phones." *Id.* at 65,828; *id.* 83 Fed. Reg. at 65,855 ("AMS acknowledges that some consumers may lack access to technology required to utilize electronic or digital link disclosure.").

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[107] Straus comment, at 9.
[108] Numi comment, at 7.
[109] Next Foods comment, at 3.
[110] Hain Celestial Group comment, at 4.
[111] Puris comment, at 2.
[112] Consumers Union, at 20.
[113] Environmental Working Group comment, at 21.
[114] International Food Information Council comment, at 6.
[115] National Co-op Grocers comment, at 7.

120. The Act spoke to these exact circumstances: in the event USDA concluded that consumers "would not have sufficient access to the bioengineered disclosure through electronic or digital disclosure methods," then the Act required USDA to provide an "additional and comparable" means by which consumers could still access the information on the package. 7 U.S.C. § 1639b(c). USDA was required by the statute to remedy the sufficiency of QR code disclosures if its own study found it inadequate, and not let it be permitted on packages alone, where it would be meaningless to many consumers. Rather, Congress required USDA to only allow QR codes in that scenario if they were combined with another "additional" means of disclosure that consumers could access, such as on-package text or something "comparable" to it. 7 U.S.C. § 1639b(c)(4).

121. However despite the Secretary's findings that the QR code option alone fails to provide sufficient access for millions of Americans, and Congress's explicit instructions that USDA remedy that insufficient access, the final rule still allows QR code disclosure with no "additional" option on packages with QR codes for consumers that lack access and no "comparable" option to on-package text and symbols.

122. Instead, to "remedy" that failing, USDA then simply added its proposed text message option to the list of allowable disclosure methods that manufacturers could utilize. 83 Fed. Reg. at 65,828-29; *see* 7 C.F.R. § 66.108 (text message option); 7 C.F.R. § 66.100(b)(1)-(4) (adding text message (b)(4) to on package text (b)(1), on package symbol (b)(2), electronic or digital (b)(3)).

123. This did nothing to fix the problem that the Study found, and that Congress required to be remedied: namely manufacturers could still choose to use QR codes alone, with no other additional disclosure method required jointly. *See* 7 C.F.R. § 66.106 (electronic or digital disclosures).

124. The final rule acknowledges that many commenters opposed a text message option for the reasons explained above. In addition to leaving QR codes alone on a package as an option without any additional mandated form of disclosure that would actually work, USDA noted that comments pointed out the many problems with text messaging, even as its own stand-alone option: among them, the undue and unreasonable burden of requiring consumers in a grocery store to send a text message for every product they put in their cart in order to find out if it is genetically engineered or not; and that text messaging could result in additional charges or costs to consumers for individual text messages or additional costs for upgraded phone plans. 83 Fed. Reg. at 65,829 ("consumers may be subject to a text message fee charged through their wireless telephone carrier").

125. USDA rationalized its text message decision by stating that in its view the Act required it to set forth a "comparable option to access the BE disclosure, not that the option be comparable to on-package labeling." *Id.* at 65,856. The final rule does not explain how a comparable option to the inaccessible QR code option fulfills the Act's purpose of providing mandatory disclosure of GE information to consumers or brings meaning to Congress's mandatory Study.

C. Injuries

126. Plaintiffs and their members are injured by USDA's rulemaking decision to permit companies to use QR Codes alone for the bioengineered disclosure, despite the agency's own determination that such disclosure will be wholly insufficient for many Americans. These consumer and retailer members are injured by USDA's decision to nonetheless allow that QR Code "disclosure" for genetically engineered foods without any additional on-package disclosure also required, as mandated by Congress.

127. Many of Plaintiffs' members lack smart phones to access the bioengineered disclosure, or, even if they have smart phones, are not familiar with

the technology to be able to scan products. Other members live in areas in which broadband internet is not available in their normal grocery store, and retailers would need to start providing WiFi at their own expense. Other members would be unduly burdened by attempting to scan with a phone scanner dozens of food products to find out basic production information mandated by federal law during each trip to the grocery store. Retailers are not able to provide this information to their customers in a meaningful way, consistent with other clear forms of labeling.

128. These members who will not be able to access the information include a higher percentage of minorities, elderly, low-income, and rural residents. These members are injured by not having the same information provided to others as to whether their food is produced with genetic engineering, or not.

129. Plaintiffs and their members are also injured by USDA's decision to "remedy" the insufficiency of QR Codes by allowing companies the separate option of text message disclosures. The rule allows QR Code disclosures alone, without any additional disclosure, including text messages.

130. Even by themselves, text messages are not comparable to clear, on-package traditional labeling. For similar reasons as QR Codes, they injure members by not providing adequate access to the bioengineered disclosure. Members would be unduly burdened by attempting to text a 1-800 number for dozens of food products to find out basic food product information mandated by law. They would be charged increased fees for text messaging or have to purchase more expensive mobile phone plans.

131. These injuries would be remedied by a decision vacating the rulemaking.

FIRST CAUSE OF ACTION

Electronic and Digital Disclosures (Violation of the Disclosure Act and the APA)

132. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 131 of this Complaint as if fully set forth herein.

133. The Disclosure Act directed Defendants to study the "potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." 7 U.S.C. § 1639b(c)(1). The Act set forth detailed factors. 7 U.S.C. § 1639b(c)(3)(A)-(E).

134. If USDA determined, based on the statutorily required Study and the existing record that "consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," then the Act required that USDA "shall provide additional and comparable options" for consumers for accessing the disclosure. 7 U.S.C. § 1639b(c)(4). USDA's Study did formally determine that the electronic and digital disclosures would not provide consumers the information that Congress intended to be disseminated by passing the Act.

135. USDA nonetheless allowed manufacturers to still "disclose" that fact through QR Codes alone, without any "additional" disclosure means for consumers. By requiring USDA to mandate additional and comparable options in these circumstances, this was exactly the result Congress was intending to avoid. Defendants' interpretation of the "additional and comparable option" requirement as still allowing insufficient and inaccessible disclosure methods such as QR codes, despite the agency's own determinations, renders the Study and Congress's orders to apply it, meaningless.

136. By the plain language of the statute and Congress's intent, if a company wants to use a QR Code, it must also place on the food package an

additional and comparable disclosure method to on-package and symbol disclosure. Otherwise the purpose of the study and Congress's concerns about the accessibility of QR codes are circumvented. USDA's decision makes the Study and the directive to USDA to address problems it found both empty Congressional mandates.

137. That decision violated the Act, as well as was arbitrary and capricious agency action, contrary to law and the evidence in the record.

138. USDA's "remedy" for the insufficient QR Code disclosures was to add a fourth option for manufacturers: a text message option. Even assuming *arguendo* that text messages would be sufficient to comply with the statute—they are not, as explained below—but regardless, because QR Codes can still be used alone, that does nothing to address Congress's concerns about QR Codes and the Study's confirmatory findings on their inadequacies. Adding text messages elsewhere is adding nothing "additional" at all. Defendants failed to adequately consider or address how providing text messages as an "additional and comparable option" for manufacturers will ensure access for the millions of Americans determined by the Secretary to lack access to QR codes. As such it is arbitrary and capricious agency action, contrary to law and the record evidence.

139. Additionally, text messaging itself as a stand-alone disclosure method violates the Act and the APA. Text messaging suffers from some of the same problems as QR Codes. Defendants arbitrarily and capriciously failed to address the Study's findings and other record evidence that text messaging also is insufficient for many consumers due to lack of cell reception, consumers' failure to associate a phone number with GE disclosure information, and consumers' concerns about their ability to receive disclosure information via text message.

140. Text messaging is contrary to the Act because it is not "comparable" to on-package labeling or symbols. Nor is it even "additional" because the Act already requires that all labeling be accompanied by a telephone number to call.

141. The agency's decision to choose text messaging because it is "comparable" to QR Code labeling was also arbitrary and capricious, contrary to the APA and the Act. It vitiates Congress's intent to have the agency investigate a likely problem area, but then "remedy" it with a new measure that shares similar problems with what was held insufficient. The proper comparator is that which is sufficient to provide consumers the information intended (on-package disclosure), not what is already held insufficient. That result remedies the problem and makes the mandated Study meaningful. USDA's interpretation and application of "additional" and "comparable" options is arbitrary and capricious and contrary to law.

142. USDA's failure to comply with the Act and the APA by allowing QR codes and text messages in the manner it did harms Plaintiffs' and their members' interests.

II. Claim 2: USDA's Exclusion of Common, Similar Terms

143. Since the introduction of the technology nearly three decades ago, the common, well-established terminology surrounding these issues has been "genetically engineered" and/or "genetically modified." These are the terms that have been employed in the public space, the scientific literature, the policy dialogue, and the marketplace. For these reasons, these terms, as well as their shorthand, "GE foods" and "GMOs," are the terms with which consumers are familiar. Yet in the final rule USDA excluded their use from the standard. That decision was arbitrary and capricious.

A. The Statute

144. While the Act generally uses "bioengineered," it expressly includes "and any similar term" when it defines the "bioengineering" classification. 7 U.S.C. § 1639(1).

145. As to "bioengineered" itself, the definition goes on to define it as food that "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and for which modification could not otherwise be obtained through conventional breeding or found in nature." *Id.* This is the common definition of "genetic engineering" or "genetic modification," which USDA has approved in other programs as "GE"/ "GMO," and logically uses both "genetic material" and "modified" and "modification" in it. *Id.*

146. At other places, the statute uses the similar, commonly known terms of "GE" and "GMO." For example, Congress used and equated the known terminology as "similar" in directing that food products separately having USDA organic certification is sufficient to also label that product as "not bioengineered, non-GMO, or other similar claim" under the Act. 7 U.S.C. § 6524 (organic "certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as 'not bioengineered', 'non-GMO', or another similar claim").

147. In another clause, the savings clause, the Act similarly establishes that "a food may not be considered 'not bioengineered', 'non-GMO', or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subchapter." 7 U.S.C. § 1639c(c). Here again Congress grouped together "not bioengineered" and "non-GMO," and "any other similar claim, describing the absence of bioengineering."

B. The Rulemaking

148. In the summer 2017 scoping notice, USDA said it was determining what on-package text to include.[116] The agency noted that some food manufacturers were already using language compliant with the Vermont law to "identify their food

[116] AMS, *Proposed Rule Questions under Consideration*, at Qt. 12.

products as bioengineered, such as "Produced with Genetic Engineering."[117] As such the agency said that it was "considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard." It also said the agency was also considering "whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase."[118]

149. Documents received pursuant to the Freedom of Information Act (FOIA) show that in a follow up document from a May 2, 2017 USDA meeting titled "MPR Discussion on Bioengineered Food Disclosure Topics" the agency acknowledged that the agency "could view 'bioengineering' and the term 'genetic modification' and corresponding phrases 'bioengineered food' and 'genetically modified organism' or 'GMO' as similar" due to consumers' familiarity with these terms. The agency's only concern in doing so was that "GMO could have a negative connotation in the marketplace."

150. However in the 2018 proposed rule, USDA proposed only using the terms "bioengineered food" or "bioengineered food ingredient." The agency said it "considered using alternative phrases such as "genetically modified" or "genetically engineered," but said it was "not proposing any similar terms because we believe the statutory term, 'bioengineering,' adequately describes food products of the technology that Congress intended to be within the scope of the [Act]." 83 Fed. Reg. at 19,871.

C. Public Comments and Evidence

151. Numerous commenters presented evidence to the agency in opposition to its decision to limit the text to only bioengineered, and exclude the more commonly used terminology of "genetic engineering."[119] These comments

[117] *Id.*
[118] AMS, *Proposed Rule Questions under Consideration*, at Qt. 12.
[119] *See* National Co-op Grocers comment, at 5; Natural Products Association comment, at 16; Organic Valley comment, at 3; Stonyfield comment, at 3; Unilever

emphasized that "bioengineered" is not a term currently used by consumers, policymakers, food scientists, or companies in the marketplace.[120] Rather the much more well-known and common terminology of all of these relevant spaces are the similar terms of "genetic engineering" and "genetically modified."

152. The terms "genetically modified," "genetically engineered" and the acronyms "GMO," "GE," and "GM" are far more commonly used to designate food crops and foods subject to the Act's disclosure than "bioengineered." This is true of usage by the federal government itself, the scientific community, the political world, the food industry, and the general public.

D. Federal Agencies

153. Many federal agencies, including USDA in other capacities, favor the term "genetically engineered" in their regulatory and guidance materials, and have concluded that the term "genetically engineered" is interchangeable with "bioengineered."

154. The White House Office of Science and Technology Policy (OSTP) provides policy direction to regulators of agricultural biotechnology and uses "genetic engineering."[121]

155. The Government Accountability Office uses "genetically engineered."[122]

156. EPA uses "genetically engineered."[123]

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comment, at 6; Danone/Mars/Nestle/Unilever joint comment, at 2; Wawa comment, at 2; Whole Foods comment, at 3-4.

[120] *See* Mars comment, at 3; Schwan's comment, at 8.

[121] *See* Emerging Techs. Interagency Policy Coordination Comm., *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (2016).

[122] U.S. Government Accountability Office, *Genetically engineered crops: USDA needs to enhance oversight and better understand impacts of unintended mixing with other crops* (2016); U.S. Government Accountability Office, *Genetically engineered crops: Agencies are proposing changes to improve oversight, but could take additional steps to enhance coordination and monitoring* (2008).

[123] *See e.g.* EPA, *Registration of Dicamba for Use on Genetically Engineered Crops,* https://www.epa.gov/ingredients-used-pesticide-products/registration-dicamba-use-

157. Even for this rulemaking, USDA's own website and landing page called it the "GMO Disclosure" until, on information and belief, at least February of 2018.[124] Indeed, the URL still does, *see* https://www.ams.usda.gov/rules-regulations-terms/gmo-labeling-disclosure.

158. USDA also submitted to the U.S. Patents and Trademark office at least one proposed symbol for this forthcoming bioengineered disclosure that was "GMO" in a circle.

159. USDA in other contexts relies almost entirely on the term "genetic engineering" and "GE," both in its regulations and in materials that are directed to the public, for its regulation of GE plants under the Plant Protection Act. *See* 7 C.F.R. Part 340.[125]

160. USDA also currently has a Process Verified Program (PVP) for verifying companies' claims on the absence of "GE"/ "GMO" ingredients in products in which the agency continues to use the terms "GE" and "GMO" on labels. Beginning in 2015, the agency announced that, in response to pressures from industry, it would begin verifying companies' claims on the absence of "GE"/ "GMO" ingredients in products. This PVP allows companies to pay AMS to verify a claim, and if approved, to market their products with the USDA process verified label as "GE" or "GMO" free.

161. Through this PVP, USDA has repeatedly verified products as "GE" or "GMO" free from companies whose definitions of "GE"/"GMO" directly align with

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genetically-engineered-crops; *See also* EPA, *Overview of Plant Incorporated Protectants*, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants.

[124] *See, e.g.* https://web.archive.org/web/20170713175116/https://www.ams.usda.gov/rules-regulations-terms/gmo-labeling-disclosure.

[125] *See also* Biotechnology Regulatory Services, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.

the definition of bioengineered in the Disclosure Act. For example, USDA verifies 70 foods from one of the world's largest suppliers of fresh and prepared produce, Del Monte, as "non-GMO." Del Monte defines GMO's as "foods that have been derived from organisms whose genetic material (DNA) has been modified through the direct introduction of a gene from a different organism in a laboratory vs. traditional plant breeding methods."[126]

162. In its PVP, USDA not only allows the use of the terms "GE" and "GMO," but insisted on becoming the first U.S. agency to use these terms for labeling at the outset. Materials received via FOIA show emails from the senior advisor to the Secretary of USDA to AMS members working on a PVP for non-GE claims on packaging in 2015 that declared the use of "GMO"/ "GE" "the official approach and the policy approach of our Department as a whole" and emphasized the importance of remaining "firm and unified" in explaining the agency's rationale behind the use of the terms "GE"/ "GMO."

163. That rationale, explained in the agency's 2015 Discussion Points on "GE"/ "GMO" terminology, insisted that the term, "GMO," had "a rightful and undisputed place" in communicating with consumers to ensure public understanding of the claims on packaging. USDA described the term, "GMO," as "permeat[ing] American culture" and emphasized that "GE"/ "GMO" are "nearly universally utilized, understood and communicated by all American journalists, broadcasters, public officials, and throughout culture and the public at large as pertaining to products that have been derived in part through genetic engineering." USDA also noted that "GE"/ "GMO" are proper terms as they repeatedly appear on the agency's own website and other areas of USDA program work and pubic communication.

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[126] Del Monte, *Frequently Asked Questions*, https://www.delmonte.com/our-story.

164. Further, more materials received via FOIA from USDA show that USDA's 2015 policy considered the term, "GMO," as mandated by the Plain Writing Act of 2010, Executive Order 13563, and associated execute branch directives to ensure public recognition of the term. Specifically, the agency's Discussion Points quoted a 2011 federal directive from OIRA which states: "It is important to emphasize that agencies should communicate with the public in a way that is clear, simple, meaningful, and jargon-free. A lack of clarity may prevent people from becoming sufficiently aware of programs or services . . . ." The agency insisted that both "GE" and "GMO" were mandatory to ensure public recognition of the terminology of government materials.

165. Since the passing of the Disclosure Act, USDA has not removed this terminology for its PVP, and companies continue working with USDA to verify their non-GMO/non-GE claims.

166. USDA's sub-agency Food Safety Inspection Service (FSIS) also continues to use this terminology in labels. FSIS is the agency responsible for regulating meat, poultry, and egg products, pursuant to the Federal Meat Inspection Act (FMIA)[127], the Poultry Products Inspection Act (PPIA),[128] and the Egg Products Inspection Act (EPIA).[129] This authority includes the labeling of meat, poultry, and egg products, which must be approved by USDA before products can enter commerce.[130] Thus these are products that (in the main) do not fall under the scope of the Act,[131] and instead will remain regulated in labeling by FSIS.

167. Pursuant to these standards, FSIS has compliance guidance for companies seeking to make a label or labeling claims concerning GE absence

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[127] 21 U.S.C. §§ 601–695.
[128] 21 U.S.C. §§ 451–470.
[129] 21 U.S.C. §§ 1031–1056.
[130] *See* 21 U.S.C. § 607; 21 U.S.C. § 457; 21 U.S.C. § 1036.
[131] 7 U.S.C. § 1639a(c)(2).

labeling: the fact that (1) bioengineered or GE ingredients were not used in a meat, poultry, or egg product, or (2) how companies can make a labeling claim that a product was produced from livestock that were not fed GE grain or feed.[132]

168. FSIS allows the use of the terms "genetically modified organism" or "GMO" and equates them with bioengineered:

> At this time, FSIS approves negative claims that contain the terms "genetically modified organism" or "GMO" for meat, poultry and egg products that do not contain bioengineered ingredients and/or that are derived from livestock or poultry that do not consume bioengineered feed when substantiated with evidence of compliance with standards verified by a third-party certifying organization. FSIS does not define "bioengineered." Instead, FSIS relies on third-party certifiers to verify that products meet their standards for the absence of bioengineered or non-GMO material. The certifier can utilize either the AMS's definition of "bioengineering" in Pub. L. 114-216 or the U.S. Food and Drug Administration's (FDA's) definition of "modern biotechnology." FSIS also will continue to allow the use of synonymous terms such as "genetically engineered" or "GE."
>
> FSIS examples include:
>
> "Pasture raised beef fed a vegetarian diet with no bioengineered ingredients,"
> "Chicken raised on a diet containing no genetically engineered ingredients," or
> "Derived from beef fed no GMO feed."

Similarly, with respect to acceptable claim terminology for multi-ingredient products, examples of such claims FSIS will accept are:

> "Contains No GMO ingredients,"
> "No genetically modified ingredients,"
> "Ingredients used are not bioengineered,"
> "No genetically engineered ingredients through the use of modern

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[132] *See* USDA FSIS, *Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products,* https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement.

biotechnology."[133]

169. After the passage of the Disclosure Act, in August 2016, and again after the final rule in 2018, FSIS amended their compliance guide to revise it but re-affirmed the allowed "GE" or "GMO" terminology.[134]

170. Consumer information from FDA most often refers to genetically engineered and GE plants rather than bioengineered.[135] FDA equates and has approved of the accurate labeling use of these similar terms, concluding in two food product labeling guidance documents that "bioengineering" is interchangeable with the terms "modern biotechnology" and "genetic engineering."[136] "The term 'modern biotechnology' may alternatively be described as 'recombinant DNA (rDNA) technology,' 'genetic engineering,' or 'bioengineering.' " *Id.* FDA explained that

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[133] *See* USDA FSIS, *Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products,* https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement.

[134] *Id.*

[135] FDA, *Food from New Plant Varieties*, https://www.fda.gov/food/food-ingredients-packaging/food-new-plant-varieties ("The FDA regulates human and animal foods derived from plants including those that have been developed using genetic engineering or genome editing techniques, commonly referred to as 'GMOs' (Genetically Modified Organisms) or as 'bioengineered.'"); FDA, https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties (same).

[136] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been-derived; FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-labeling-indicating-whether-food-has-or-has-not-been-derived.

"[t]hese terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders. . . ."[137]

171. FDA guidance explains that manufacturers can voluntary label their food as not genetically engineered, so long as such information is truthful and not misleading. FDA gives several examples of potential accurate labeling statements, such as:

> "Not bioengineered."
> "Not genetically engineered."
> "Not genetically modified through the use of modern biotechnology."
> "We do not use ingredients that were produced using modern biotechnology."
> "This oil is made from soybeans that were not genetically engineered."
> "Our corn growers do not plant bioengineered seeds."[138]

172. In these labeling guidance documents, FDA and FSIS are applying their statutory mandates, under the Federal Food, Drug and Cosmetic Act (FFDCA), the FMIA, the PPIA, and the EPIA, that prohibit foods from being misbranded.[139] A food is misbranded if its labeling is "false or misleading in any particular."[140] These guidance statements are authoritative statements from FDA and USDA that using "GE" and "GMO" interchangeably with "bioengineering" is not false or misleading, and that producers may use them in order to avoid claims of misbranding.

173. The Disclosure Act includes an express admonition that it is not stripping FDA of any FFDCA authority or any party of any FFDCA obligation, meaning that the duty to not label in a false and misleading way still applies and

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[137] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, https://www.fda.gov/media/120958/download.
[138] *Id.* at 7.
[139] 21 U.S.C. § 331(a).
[140] 21 U.S.C. § 343(a)(1).

there is no regulatory shield simply because a product is classified and labeled under the Act. 7 U.S.C. § 1639c(b)(1).

E. Federal and State Legislation

174. Since the 98th Congress (1983-84) there have been 125 federal bills containing the phrase "genetically engineered" and 56 bills containing the phrase "genetically modified" in the context of GE foods. [141]

175. The use of the term "bioengineered" in past legislation all appears related to either defense (warfare) or medical contexts of biotechnology. A Westlaw search for the term "bioengineered" or "bioengineer[]" returns only 14 prior search results for the term appearing in federal statutes, four of which are in reference to the National Institute of Biomedical Imaging and Bioengineering, and two of which are notes to Federal Rules of Evidence, none in this context. The use of the term "bioengineered" shows up in federal regulations approximately seven times, none in this context.

176. At the state level, every state that enacted labeling laws (Vermont, Maine, and Connecticut) prior to the federal law's passage used the common "genetically engineered" terminology and not "bioengineered."

177. Every state that introduced labeling legislation (over 30) in the years prior used the same common language and not "bioengineered."[142]

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[141] Govtrack, Advanced Search, https://www.govtrack.us/congress/bills/browse#text=%22genetically+engineered%22+&congress=__ALL__. ; Govtrack, Advanced Search, https://www.govtrack.us/congress/bills/browse#text=%22genetically+modified%22+&congress=__ALL__.

[142] *GE Food Labeling: States Take Action* (June 10, 2014), https://centerforfoodsafety.org/issues/976/ge-food-labeling/fact-sheets/3067/ge-food-labeling-states-take-action.

F. International Use

178. Internationally, none of the top U.S. trade partners for U.S. food exports that require GE labeling use the term "bioengineered." For example, the European Union uses the terms, "GM" or "GMO," for labeling,[143] while China uses "GM."[144] On information and belief, all of them use some variation of "genetically engineered" or "genetically modified."[145]

1) Scientific Community

179. In the scientific community, Committees of the National Academy of Sciences have addressed genetically engineered foods in several book-length reports, and frequently use the term "genetically engineered (GE)" food or crop, but seldom or never use the term "bioengineered."

180. A search by CFS of PubMed publications on June 23, 2018 revealed that the scientific/medical community most often writes of genetically modified food(s) (96.3 percent of hits), less frequently of genetically engineered foods(s) (2.8 percent of hits), and hardly ever of bioengineered food(s) (just 0.8 percent of hits).

2) Bioengineered alone

181. Etymologically, the term means "engineering life," and thus has a broad array of meanings (discussed below) beyond the direct manipulation of genetic material conveyed by the more precise terms, "genetic-ally engineered" and "genetic-ally modified." The prefix "bio-" is widely understood to mean "life"–from high school and college biology courses, through the interchangeable use of biology and "life sciences," and via a plethora of other common terms with the bio- prefix.

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[143] European Commission, *Traceability and labeling*, https://ec.europa.eu/food/plant/gmo/traceability_labelling_en.

[144] Xiao Zhu, et.al, *Genetically Modified Food Labeling in China: In Pursuit of a Rational Path*, 71 Food Drug L.J. 30 (2016).

[145] *Genetically Engineered Food Labeling Laws*, https://www.centerforfoodsafety.org/ge-map/.

182. FDA found in focus group testing that consumers "tended to evaluate the terms" used to signify genetically modified foods "linguistically," thus the vagueness and breadth of "bioengineered" as "engineered life" would confuse many consumers.[146]

183. The term was coined in 1954 to mean the application of engineering principles to biological and medical sciences.[147] Ever since, bioengineering has been associated with either medical science and technology, or space exploration, not food production.

184. The first bioengineering program in U.S. higher education–established in 1966 at the University of California at San Diego–conducts research on tissue engineering, regenerative medicine, and four disease focus areas: cancer, cardiovascular disease, metabolic disorders, and neurodegenerative diseases.[148]

185. MIT's biological engineering program likewise has a strong biomedical focus, with research areas including biomaterials, biophysics, cell and tissue engineering, pharmacology, and toxicology. MIT refers to this program by the initials "BE," the same acronym that USDA proposed as a symbol for GE foods.[149]

186. The other major use relates to space exploration. The National Aeronautics and Space Administration has a Bioengineering Branch whose mission

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[146] Levy, A.S., Derby, B.M., *Report on Consumer Focus Groups on Biotechnology*, Consumer Studies Team, Center for Food Safety and Nutrition, FDA, Washington, D.C. (2000).

[147] Joe Buchanunn, *Professor Heinz Wolff, scientist and TV presenter, dies aged 89,* Brunel University, London (Dec. 16, 2017), https://www.brunel.ac.uk/news-and-events/news/articles/Professor-Heinz-Wolff-scientist-and-TV-presenter-dies-aged-89.

[148] University of California San Diego, *About Bioengineering*, http://bioengineering.ucsd.edu/about.

[149] MIT, *About Bioengineering*, https://be.mit.edu/about.

is "developing next generation technologies to enable humans to live beyond low Earth orbit for extended periods."[150]

G. The Marketplace and Current Food Product Labeling

187. In the marketplace, the food industry's use of GMO-free label claims for absence claims has accustomed consumers to "GMO" as the term of choice to designate genetically modified crop content (or its absence). The Non-GMO Project label, which reads "Non-GMO Project Verified," is found on more than 43,000 products. The market already uses "non-GMO" labels, like the Non-GMO Project Verified label, which is found on more than 43,000 products with sales exceeding $19.2 billion.[151]

188. The same is true for GE content: many companies are already out in the marketplace labeling with the text "produced with genetic engineering" or "may be produced with genetic engineering." These include Campbell Soup; General Mills; Mars, Inc.; Frito Lay; and Dannon, among others—all of which use terms like "produced with genetic engineering" or "partially produced with genetic engineering," while none use "bioengineered."

189. USDA has also contributed to consumers' familiarity by choosing the terms "GE" or "GMO" for use in its PVP. In addition to appearing on products from the major brand, Del Monte, USDA verified non-GMO claims currently appear on products from George's Inc., one of the top ten largest vertically integrated chicken producers in America, as well as Natural Products, Inc., a leading manufacturer of full fat soy ingredients, and several other companies.

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[150] NASA, *About Bioengineering*, https://www.nasa.gov/ames/research/space-biosciences/bioengineering-branch.

[151] Non-GMO Project, *Product Verification FAQs*, https://www.nongmoproject.org/product-verification/verification-faqs/. Other marketplace labels also use the term "Non-GMO," *see* Ken Roseboro, *New non-GMO certification programs emerging*, Organic and Non-GMO Report, http://non-gmoreport.com/articles/new-non-gmo-certification-programs-emerging/.

190. Strong consumer preference for terms like "GMO" have been confirmed through studies, including research done by Campbell Soup Company. As Katie Cleary, Campbell's senior manager of consumer insights stated, "Campbell has tested nine labels related to GE food ingredients in the past few months and found individuals viewed use of terms like 'bioengineered or genetically engineered' confusing . . . The feedback has been very consistent in our research that the preferred language is GMO." [152]

191. Mars, Inc., the maker of M&Ms, Snickers, and Milky Way, also requested to use the term "genetic engineering" because "the terms 'genetically engineered' or 'genetically modified' are seen as more consumer-friendly as compared to the term 'bioengineered,' as consumers have been exposed to such terms for a longer period of time."[153] Schwan's, maker of Red Baron, Freschetta, and Tony's frozen pizza, similarly stated the company's concern "that consumers will not understand the term 'bioengineered' or 'bioengineering' when used to disclose under the Standard."[154]

192. Numerous other major food manufacturers, trade groups, and grocers opposed the limiting of allowed text to "bioengineered" and explained to USDA that consumers need "GE"/ "GMO", including the National Co-op Grocers, Natural Products Association, Organic Valley, Stonyfield, Unilever, Danone, Nestle, Wawa, and Whole Foods.

193. As FOIA materials received from USDA show, USDA itself determined that the term, "GMO," "permeates American culture" and has "a rightful and

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[152] Pegg JR, *Campbell Soup finds consumers prefer clear GMO labeling*, Food Chemical News (Sept. 8, 2016), www.agra-net.com/agra/food-chemical-news/food-safety/packaging/campbell-soup-finds-consumersprefer-clear-gmo-labeling-526281.htm.

[153] Mars comment, at 3.

[154] Schwan's comment, at 8.

undisputed place" in ensuring consumers understand claims on packaging. An email from the senior advisor to the Secretary of USDA to AMS members regarding the PVP for non-GE claims on packaging in 2015 declared the use of "GE"/ "GMO" "the official approach and the policy approach of our Department as a whole" and emphasized the importance of remaining "firm and unified" in explaining the agency's rationale behind the use of the terms "GE"/ "GMO."

H. Public Awareness

194. Online search engines provide good measures of public awareness that corroborate the findings discussed above: namely, "bioengineered" is used primarily in medical or other non-food contexts, and the public is far more familiar with alternatives to "bioengineered food."

195. In Google searches conducted on June 20, 2018, only 6.5% of hits for the term "bioengineered" occurred in conjunction with "food" or "crop." In contrast, there were 2.4 times more hits for a subset of biomedical uses of the term.[155] Similarly, in U.S. books, only 1 in 20 occurrences of "bioengineered" is conjoined with food, in the term "bioengineered food" (Figure 1).

Figure 1: Search of U.S. Books for Use of "Bioengineered" With "Food", Source: Google Books Ngram Viewer (June 18, 2018).

[155] Namely: "bioengineered human OR skin OR tissue OR organ OR kidney OR pancreas OR heart OR liver OR graft OR hair."

196. Google Trends reports the relative frequency with which users employ various search terms over time, and so reflects familiarity with them among those interested in learning more about a subject. In every year from 2004 to 2019, the relative usage of three major search terms for GMOs was "genetically modified food" > "genetically engineered food" > "bioengineered food." Since 2009, the frequency of "bioengineered food" as a search term has been negligible (Figure 2). Averaged over the entire 16-year period, Americans used the former two search terms (combined) over 31 times more frequently than "bioengineered food" (Figure 2).

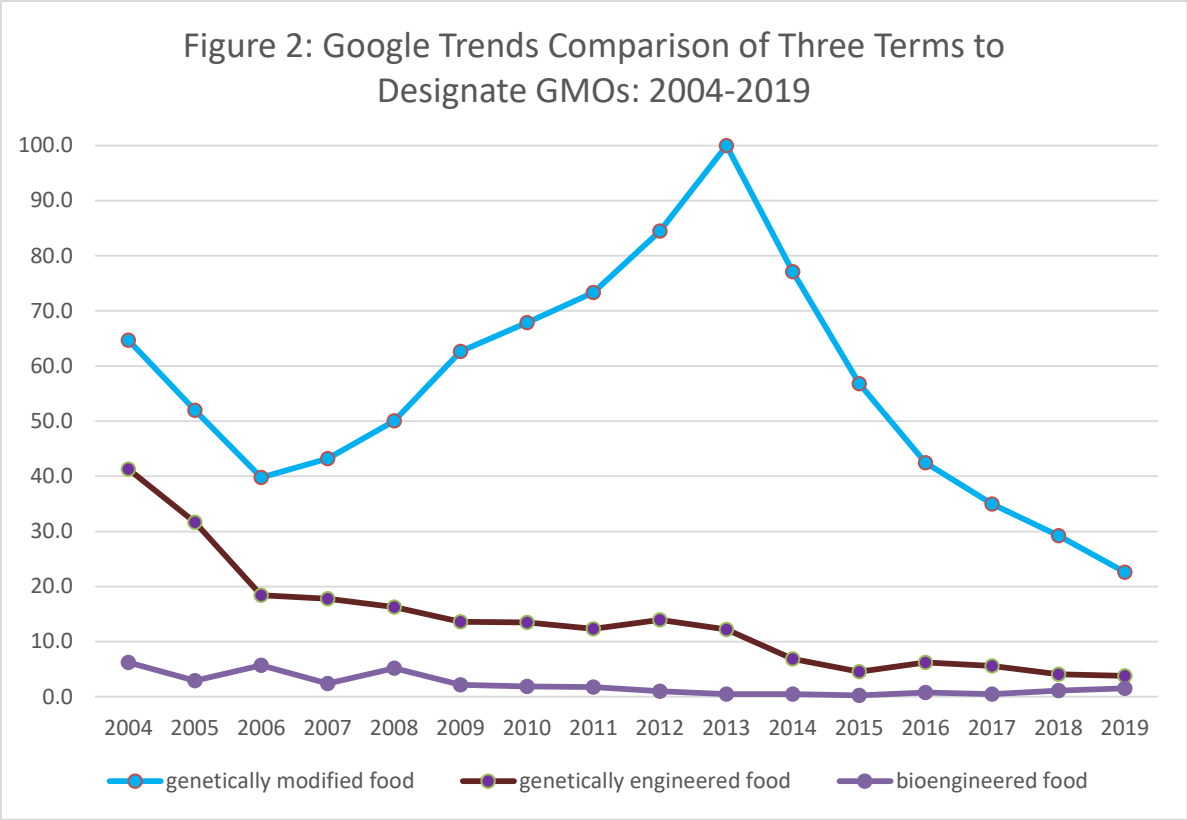

Figure 2. Based on Google Trends search (https://trends.google.com/trends/?geo=IT) of the three indicated terms (4/24/20). Monthly search frequency results averaged by year; results normalized with most intensive search term/year combination (genetically modified food in 2013) set to 100.

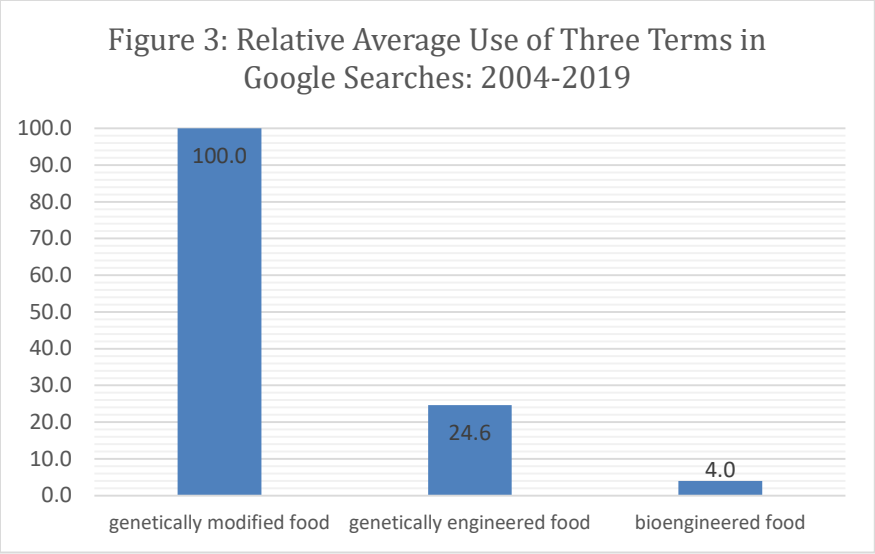

Figure 3: Based on Google Trends search (https://trends.google.com/trends/?geo=IT) of the three indicated terms (4/24/20). Monthly results for entire period summed; results normalized with the most used search term (genetically modified food) set to 100.

197. While "genetically modified food" is by far the most used full-text search term, even its search usage is dwarfed by that of the acronym "GMO." As shown in Figure 4, "GMO" has become the overwhelmingly predominant term in the U.S. since about 2010, and has been searched roughly 20 times more frequently than "genetically modified food" since 2016. The disparity between "GMO" and "bioengineered" food was too great to display graphically.

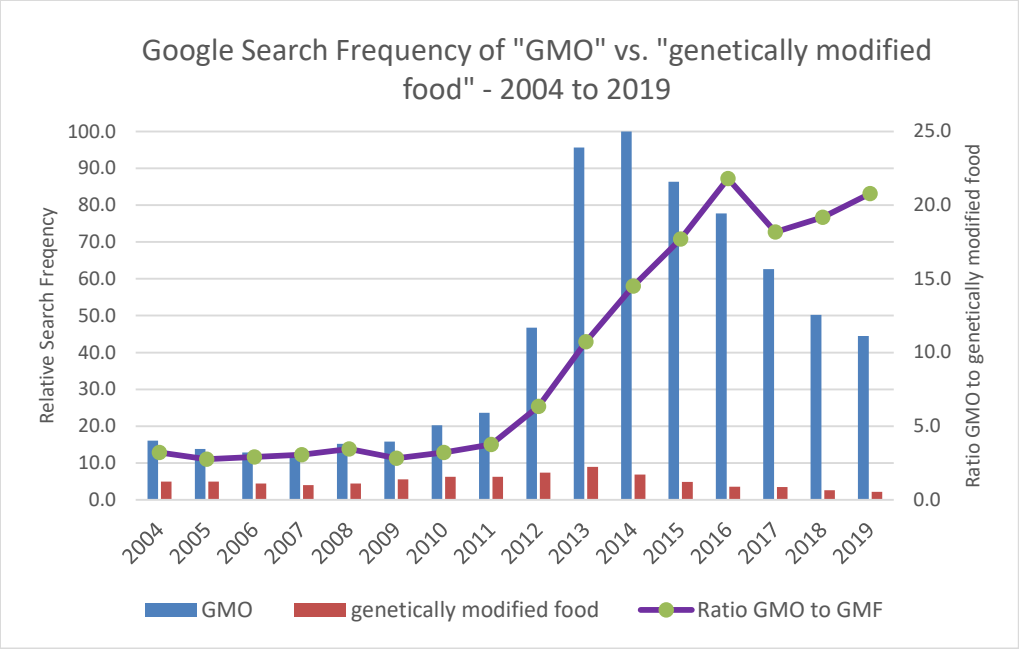

Figure 4: Based on Google Trends search (https://trends.google.com/trends/?geo=IT) of the two indicated terms (5/8/20). Monthly search frequency results averaged by year; results normalized with most intensive search term/year combination (GMO in 2014) set to 100.

I. The Final Rule

198. In the final rule, USDA mandated that on-package text be "bioengineered food," or, for multi-ingredient foods, "contains a bioengineered food ingredient." 83 Fed. Reg. at 65,827. See 7 C.F.R. § 66.102(a)(1)-(2).

199. In response to public comments presenting the above information to the agency on the problems with excluding the much more common and established similar terms "GE" and "GMO," and the concerns about consumers being confused, USDA said only that the agency believes the language "clearly and accurately describes the technology and provides consumers with the information they desire." 83 Fed. Reg. at 65,852.

200. In the final rule USDA made no effort to address the data on use and consumer confusion presented to it, let alone support its decision with the whole record.

201. In the final rule USDA gave no explanation of how it was compliant with the statute's use of "similar terms" to "bioengineered."

J. Injuries

202. Plaintiffs and their members are injured by USDA's decision to exclude the well-established and known similar terms of "genetically engineered" and "genetically modified" from permissible on-package labeling under the Act.

203. Because of USDA's decision, shoppers will be confused or misled by the disclosure and not receive or understand the information intended by Congress. Because of USDA's decision, many manufacturer and retailers are forced to change their current well-known terminology and are instead prohibited from labeling their products in the way that they wish and that they know would best inform consumers of the information. Retailers will bear the burden of having to educate their customers on this confusing terminology.

SECOND CAUSE OF ACTION

Limitations on Allowed On-Package Disclosure Language (Violation of Disclosure Act and APA)

204. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 203 of this Complaint as if fully set forth herein.

205. The Act specifically refers to "any similar term" to "bioengineered" as part of the classification. 7 U.S.C. § 1639(1). The Act also uses the similar terms of "GE" and "GMO" elsewhere, listing them as "similar" terms.

206. USDA's decision in the rulemaking to limit on-package disclosures to only bioengineered is contrary to the plain language of the statute and would

unlawfully turn the clause "similar terms" into surplusage, in violation of the Act and the APA.

207. USDA does not explain how it came to the arbitrary decision to limit the text to only "bioengineered," and exclude the more common, similar terms "GE" and "GMO," or support that decision with any rationale or data. That decision was arbitrary and capricious.

208. The record evidence overwhelmingly indicates that, because consumers are unfamiliar with "bioengineered," limiting the language to only this term fails to adequately inform consumers of the fact that foods are genetically engineered. "Bioengineering" is not a term currently used by consumers, regulators, manufacturers, or retailers involved with genetically engineered foods. The thirty-year history of the GE food labeling topic is virtually absent that term; instead "GE" and "GMO" are used and known to the public. This is shown through general public awareness; current marketplace labeling and standards; scientific uses; and international, legislative, regulatory, and policy applications. Based on this record evidence, USDA's determination that the term "bioengineered" alone fulfills the statutory goal of adequately informing consumers is arbitrary and capricious.

209. The Act also requires that USDA "shall" develop the disclosure standard "in a manner consistent with United States obligations under international agreements." 7 U.S.C. § 1639c(a). The final rule's exclusion of terms used commonly across the globe conflicts with the standards of numerous U.S. trading partners and the standards of the Codex Alimentarius, all of which use the terms GE and GMO.

210. USDA's decision creates a misleading and confusing labeling standard, violating the Act and the APA. Mandating the use of the bioengineered term alone is contrary to precedent, the Act, and Congressional intent, and is confusing and misleading to consumers.

III. Claim 3: Exclusion of "Highly Refined" Bioengineered Foods

211. Eighty-seven percent of food products containing GE ingredients contain "highly refined" GE ingredients, such as sodas and cooking oils made with genetically engineered ingredients.[156]

212. Consumers and retailers fully expected that producers would be required to disclose these ingredients under the Disclosure Act because without their labeling, the regulations establish a huge loophole that misses the vast majority of GE foods, contrary to the overarching purpose of the law.

213. During the Act's enactment, Congress, as well as the USDA's General Counsel, assured the public that these foods would be covered by the standard and require disclosure.[157] In fact, Congress assured the public that the Act would improve on the existing state labeling scope.[158]

214. However in the final rule USDA did the opposite and excluded "highly refined" GE foods from any required disclosure. That decision violated the Act and was arbitrary and capricious action in violation of the APA.

A. The Act

215. The first prong of the definition of bioengineering, upon which the disclosure classification mandate is based, explains that the classification includes any food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques." 7 U.S.C. § 1639(1)(A). That is, any food that "contains" any GE material is covered.

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[156] *EWG Analysis: Loophole Could Exempt Over 10,000 GMO Foods From Disclosure Law*, EWG Ag Mag (June 29, 2018), https://www.ewg.org/agmag/2018/06/ewg-analysis-loophole-could-exempt-10000gmo-foods-disclosure-law#.WzaZrxJKhTY.

[157] Letter from Jeffrey M. Prieto, General Counsel, USDA, to Debbie Stabenow, Senator, U.S. Senate (July 1, 2016), http://src.bna.com/gvy (assuring the Senator that the new law, if passed, provided authority to cover new GE techniques, such as gene editing, as well as GE foods made from highly refined oils, sugars, or high fructose corn syrup produced through genetic engineering).

[158] 162 Cong. Rec. S4906 (daily ed. July 7, 2016).

216. The Act further commands that USDA "shall" establish a nationwide standard for disclosure with respect to "any bioengineered food" but also "any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1).

217. The Act also includes a provision requiring USDA to, in its implementing rules, "establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food" beyond those set out by the statute elsewhere. 7 U.S.C. § 1639b.

218. The Act also requires that USDA "shall" develop the disclosure standard "in a manner consistent with United States obligations under international agreements." 7 U.S.C. § 1639c(a).

B. Legislative History

219. Congressional intent was explicitly to cover these types of ingredients under the scope of the Act.

220. Statements from ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow clarified that the Act's scope "does not prohibit the labeling of highly refined products derived from GMO crops including soybean oil made from GMO soybeans, high fructose corn syrup made from GMO corn, and sugar made from GMO sugar beets." 162 Cong. Rec. S4994 (daily ed. July 12, 2016).

221. In separate statements to the Senate, Senator Stabenow further clarified that the Disclosure Act "provides authority to the USDA to label refined sugars and other processed products." 162 Cong. Rec. S4783 (daily ed. July 6, 2016).

222. Senator Stabenow also stated that the Act would improve on the existing state labeling scope, 162 Cong. Rec. S4906 (daily ed. July 7, 2016), which would be impossible if the Act did not include highly refined GE ingredients like

sugar and oils in the scope of its mandatory disclosure standard, since all the state labeling laws included them.

223. USDA's General Counsel, Jeffrey Prieto, told Congress that it was the agency's interpretation of the Act that it is well within USDA's authority to interpret the definition of bioengineering as including highly refined GE foods. In a July 1, 2016 letter to answer Congressional questions on this point, Prieto confirmed that it was USDA's legal interpretation of the Act as giving the agency authority to include ingredients derived from "novel gene editing techniques such as CRISPR," and food products which contain "highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques." 162 Cong. Rec. S4994 (daily ed. July 12, 2016).

C. Marketplace

224. Approximately eighty-seven percent of foods containing genetically engineered ingredients on supermarket shelves are not whole foods (like genetically engineered squash), but contain highly refined GE ingredients (like sugar or corn or their derivatives).[159] By some estimates, that means approximately 70,000 foods contain a highly refined GE ingredient.[160] In its public comments on the proposed rule, Grocery Manufacturers Association estimated that excluding highly refined products would result in 78 percent fewer products labeled.[161] The massive public support for labeling that resulted in the passage of the Act was based on widespread understanding of this marketplace reality. American consumers expect foods containing highly refined products of GE ingredients to be labeled.

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[159] *EWG Analysis: Loophole Could Exempt Over 10,000 GMO Foods From Disclosure Law*, EWG Ag Mag (June 29, 2018), https://www.ewg.org/agmag/2018/06/ewg-analysis-loophole-could-exempt-10000gmo-foods-disclosure-law#.WzaZrxJKhTY.

[160] *Id.*

[161] Grocery Manufacturers Association comment, at 2.

225. A 2018 study by the University of Vermont found that labeling GE food reduced consumer distrust of GE food by almost 20 percent.[162] Omitting the vast majority of foods produced through genetic engineering from any disclosure requirement would be false and misleading to consumers.

226. Numerous major food companies, including Campbell Soup Company, Coca Cola, Danone, Mars, Nestle, and Unilever already disclose the presence of highly refined ingredients produced from GE crops, and strongly urged USDA to include highly refined products in the rule's classification.[163]

227. Numerous other major food companies such as Whole Foods, Schwan's, Wawa, and Happy Family that do not already label GMOs also voiced their preference for the right to label highly refined GE foods and that failure to do so would confuse consumers and not serve the purpose of the law.[164]

228. For example, Coca Cola commented that failing to label highly refined ingredients would result in a "disservice" to interested consumers because "It is critical to the spirit of this law that the final rule be based on the traceability of ingredients through the supply chain back to a plant, rather than being based on the presence of genetic material in the finished food."[165] Major food companies, Danone, Nestle, Mars, and Unilever, agreed in a joint comment letter that consumers expect disclosure of highly refined ingredients based on traceability to a

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[162] Jane Kolodinsky and Jayson L. Lusk, *Mandatory labels can improve attitudes toward genetically engineered food,* 4 SCI. ADV. 6 (June 27, 2018), http://advances.sciencemag.org/content/advances/4/6/eaaq1413.full.pdf.

[163] Campbell comments, at 6-7; Coca Cola comment, at 2; Danone/Mars/Nestle/Unilever comment, at 3.

[164] Hershey comment, at 2; Wawa comment, at 2; Unilever comment, at 4; Happy Family, at 2; American Bakers Association, at 1; Grocery Manufacturers Association, at 2; Organic Trade Association comment, at 12; Schwan's comment, at 4; Coca Cola comment, at 3; Whole Foods comment, at 1.

[165] Coca Cola comment, at 2.

GE plant source and would be misled otherwise.[166] Numerous companies requested mandatory disclosure of highly refined ingredients to avoid depriving consumers of the clarity and consistency they need to make informed choices about the products they purchase.[167]

229. Several companies further requested mandatory disclosure of highly refined GE foods to avoid the anticipated high costs of analytical testing, further rulemakings, and ongoing agency policy development required to exclude highly refined products from disclosure.[168] Unilever, the maker of Hellmann's mayonnaise, Ben & Jerry's ice cream, as well as over 400 other brands, pointed to the inconsistency between this standard and other established international standards of disclosure.[169]

230. The European Union and other countries have long required disclosure of highly refined products, and commented that the U.S. classification should require the same.[170]

D. Contains vs. Detectability

231. The statutory definition of bioengineering does not exempt foods that contain GE ingredients at levels "undetectable using common testing methods." 83 Fed. Reg. at 65,816. Simply because current testing methods do not detect material does not mean that the products do not "contain" genetically engineered DNA.

232. Commenters pointed out to USDA that DNA testing methods are rapidly becoming more sensitive. Foods from GE plants that just a few years ago had no detectable genetically engineered DNA are today found to contain it.

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[166] Danone, Mars, Nestle, Unilever joint comment, at 3.
[167] Hershey comment, at 2; Wawa comment, at 2; Unilever comment, at 4; Happy Family, at 2; American Bakers Association, at 2; Kraft comment, at 2; Grocery Manufacturers Association, at 2; Global Organics, at 1-2.
[168] Campbell comment, at 7; Hershey comment, at 2.
[169] Unilever comment, at 4.
[170] European Union comment, at 2.

233. For example, a limit of detection of 0.1 percent was once common for polymerase chain reaction (PCR)-based GMO detection tests, but today's methods are far more sensitive. German scientists recently developed a real-time PCR screening assay with a sensitivity over ten-fold greater: < 0.01 percent for several GM maize events in food and feed.[171]

234. More recently, a Japanese team developed a method that can detect rDNA from GE corn at a 0.005 percent limit of detection, or 20 times more sensitive than the previous standard, by increasing the amount of DNA template.[172]

235. A group of Chinese scientists reported a digital PCR (dPCR) detection method for screening GMOs with a limit of detection of 0.1 percent in 2015.[173] Two years later, the same team reported a high-throughput detection method based on multiplex enrichment quantitative PCR (ME-qPCR), with an absolute limit of detection of 0.001 percent, one hundred-fold lower than their dPCR method.[174]

236. Contrary to claims, oils from GE oilseed crops (e.g., soybeans, canola) do contain rDNA. The putative absence of rDNA in oils was a consequence of older, less sensitive testing methods.

237. Test method improvements have enabled detection of previously "undetectable" rDNA. A frequently cited paper on the absence of DNA in soybean

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[171] Huber et al., *Development and validation of duplex, triplex and pentaplex real-time PCR screening assays for the detection of genetically modified organisms in food and feed,* 61 Journal of Agricultural and Food Chemistry 10293-10301 (2013).
[172] Mano *et al.*, *Highly sensitive GMO detection using real-time PCR with a large amount of DNA template: single-laboratory validation,* 101(2) J. AOAC International 507-514 (2018).
[173] Fu *et al.*, *A highly sensitive and specific method for the screening detection of genetically modified organisms based on digital PCR without pretreatment*, 5 Scientific Reports 12715 (2015).
[174] Fu *et al.*, *Multiplex enrichment quantatitve PCR (ME-qPCR): a high-throughput, highly sensitive detection method for GMO identification,* 409 Anal. Bioanal. Chem. 2655-2664 (2017).

oil[175] was contradicted just two years later by the same Belgian research team.[176] (USDA cites the former but ignores the latter paper in the final rule (83 Fed. Reg. at 63,834)). Many other scientists have also detected DNA in refined oils: rDNA in soybean oils,[177] as well as DNA in commercial sunflower and maize oils.[178]

238. A simple PubMed search using the term "GMO detection" (without quotation marks) results in 287 hits. The number of papers has significantly increased over time from an average of 0.44 annually in the 1990s, to 10.2 in the 2000s, to 21.2 from 2010-2017. Many of these papers present new testing methods, or significant tweaks on existing methods. These include capillary electrophoresis (PCR-CGE), multiplex quantitative DNA array-based PCR (MQDA-PCR), nucleic acid-sequence-based PCR (NASBA)-implemented microarray analysis (NAIMA), digital PCR (dPCR), loop-mediated isothermal amplification (LAMP), DNA walking, nanopore sequencing, and next generation sequencing (NGS), among others.[179]

239. Sensitivity is continually increasing, and can arise from improvements in DNA extraction procedures, increased ability to amplify ever-shorter DNA

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[175] Gryson *et al.*, *Detection of DNA during the refining of soybean oil*, 79(2) JAOCS 171-174 (2002).

[176] Gryson *et al.*, *Influence of different oil-refining parameters and sampling size on the detection of genetically modified DNA in soybean oil*, 81(3) JAOCS 231-234 (2004) ("We have shown here that it is possible to detect DNA by PCR in oil phase after degumming if the DNA is extracted from a test portion with sufficiently high volume.").

[177] Bogani *et al., Transgenes monitoring in an industrial soybean processing chain by DNA-based conventional approaches and biosensors,* 113(2) Food Chemistry 658-664 (2009); Costa et al., *Detection of genetically modified soybean DNA in refined vegetable oils,* 230 European Food Research and Technology 915-923 (2010).

[178] Doveri & Lee, *Development of sensitive crop-specific polymerase chain reaction assays using 5S DNA: applications in food traceability*, 55(12) Journal of Agricultural and Food Chemistry 4640-44 (2007).

[179] Milavec *et al.*, *GMO quantification: valuable experience and insights for the future,* 406 Anal. Bioanal. Chem. 6485-97 (2014); Fraiture et al., *An integrated strategy combining DNA walking and NGS to detect GMOs*, 232 Food Chemistry 351-358 (2017); Fraiture *et al.*, *Nanopore sequencing technology: a new route for the fast detection of unauthorized GMO*, 8 Scientific Reports 7903 (2018).

fragments (especially important for DNA detection in highly processed foods), more advanced statistical procedures,[180] methods to minimize PCR inhibition,[181] and increasing the amount of DNA for PCR analysis, to name just a few innovations.

240. USDA has taken no account of this complexity. An agency guidance states that PCR "is the most widely used and commercially accepted test method,"[182] but fails to distinguish the plethora of different PCR-based methodologies that already exist, or their widely varying sensitivities (limits of detection), as alluded to above. Thus, the problem is not only that a "future test" will be developed, which detects rDNA that "current tests do not" (83 Fed. Reg. at 68,834), but rather also that the differing sensitivities of existing test methods, and the failure to prescribe a minimum sensitivity, virtually ensures inconsistent standards regarding mandatory BE disclosure, widespread confusion in the marketplace, and distrust of the Disclosure Act among consumers.[183]

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[180] Willems et al., S*tatistical framework for detection of genetically modified organisms based on Next Generation Sequencing*, 192 Food Chemistry 788-798 (2016).

[181] Doveri & Lee, *Development of sensitive crop-specific polymerase chain reaction assays using 5S DNA: applications in food traceability*, 55(12) Journal of Agricultural and Food Chemistry 4640-44 (2007).

[182] USDA, National Bioengineered Food Disclosure Standard: Draft Instructions on Testing Methods, at 2, https://www.ams.usda.gov/sites/default/files/media/NBFDSTestingMethodology.pdf.

[183] Regarding more sensitive future tests, USDA assures firms that they can safely ignore them. When technological progress increases test sensitivity such that formerly undetectable rDNA is detectable, such bioengineered foods may nevertheless continue to evade BE disclosure, indefinitely, based on refining processes validated on the less sensitive, outdated tests methods. *See* USDA, *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process*, at 3 (answer to Qt.13), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcessValidation.pdf.

E. FDA's Guidance on Testing Highly Refined Ingredients

241. FDA's established labeling standards[184] recognized the difficulty and variability of these tests, "particularly for highly processed foods such as oils" and confirmed that GE material may remain in foods at levels currently undetectable.[185]

242. In its guidance document for industry seeking to avoid misbranding in labeling GE foods, FDA endorsed the use of validated testing methods for confirming the presence of GE material in food while also advising that specific testing methodologies "likely will change" as new GE varieties are introduced into the marketplace.[186] FDA recognized the current difficulty in using tests for highly refined foods and concluded that it "may be more practical to substantiate a claim for such foods differently, such as documenting handling practices and procedures."[187]

243. FDA recognizes that just because a food or food ingredient may not contain detectable levels of genetic material from a GE source does not mean the food does not contain any such genetic material, and does not mean that the food is not GE; it only means that the genetic material is not detectable using present-day, readily available scientific methods.[188] In the context of gluten free labeling, FDA's solution for a lack of a single, valid scientific testing method for detecting gluten in fermented or hydrolyzed food is to require manufacturers to label based on the source of the food or ingredient until the agency decides on a precise testing method for the final product. 85 Fed. Reg. 49,240, 49,241 (Aug. 13, 2020). Instead of allowing manufacturers to use a variety of imprecise testing methods, FDA required

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[184] FDA *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, at 13, https://www.fda.gov/media/120958/download.

[185] *Id* (emphasis added).

[186] *Id.*

[187] *Id.*

[188] *Id.*

that manufacturers keep records proving that that the food or ingredients used in the food were "gluten-free" before fermentation or hydrolysis. *Id.* at 49,241. The agency acknowledged that testing methods for the detection of gluten fragments in fermented or hydrolyzed foods exist and have continued to advance, but currently no specific scientifically valid, consistent, and reliable test exists. *Id.* at 49,243. Until a scientifically valid method has been developed that can accurately detect and quantify gluten in fermented or hydrolyzed foods or ingredients, FDA's rule requires manufacturers to keep these records of sources. *Id.* at 49,241.

F. International Standards

244. Commenters pointed out that the inclusion of highly refined GE foods was required in order to be consistent with international genetically engineered food labeling standards and U.S. treaty obligations. This includes, among others, the *Codex Alimentarius* definition of modern biotechnology, which is internationally recognized by the World Trade Organization as the standard for settling trade disputes. *See* 83 Fed. Reg. at 65,835. Most countries that already label genetically engineered foods require that highly refined GE products be disclosed. *Id.* As such, excluding highly refined GE products could cause trade disruptions and confusion. *Id.*

G. Rulemaking

245. In the proposed rule, USDA put forth two "positions" for highly refined GE foods. 83 Fed. Reg. at 19,862-63. In the first, highly refined products would not require disclosure because, even though they contain GE ingredients and contain them in their original form, the ingredients are so highly processed that the final product allegedly does not "contain" that genetically engineered content. *Id.*

246. In the second, the GE classification would include all foods produced through bioengineering, including highly refined products. 83 Fed. Reg. at 19,863. These products contain genetically engineered material before they are processed.

Whether it is further detectable depends on the refinement process and testing method applied. And, even though a particular test may not detect the modified genetic material, this does not necessarily mean that there is no modified genetic material in the food. *Id.*

247. USDA invited comment on both positions. *Id.*

248. In the final rule, USDA adopted the first option and excluded highly refined GE foods from any required disclosure. 83 Fed. Reg. at 65,817.

249. The agency created a regulatory definition that "foods with undetectable modified genetic material are not bioengineered foods" and thus do not require disclosure. *Id. See* 7 C.F.R. § 66.1 (defining "bioengineered food," as, in relevant part, "a food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques," but "*provided that* such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.").

250. The agency referenced Section 66.9, which is the regulatory section setting forth how a manufacturer can "demonstrate that a food, including a refined food ingredient, does not contain detectable modified genetic material." 83 Fed. Reg. at 65,816.

251. The agency then concluded that "for refined foods that are derived from bioengineered crops, no disclosure is required if the food does not contain detectable modified genetic material." *Id.*

252. Section 66.9 of the rule sets up several ways for manufacturers to determine whether a food or ingredients contains GE material requiring disclosure. First, they can use their records to demonstrate that the food is sourced wholly from non-GE crop sources. 83 Fed. Reg. at 65,817; 7 C.F.R. 66.9(a)(1).

253. Second, manufacturers can use their records to show that the food has been through a refinement process validated to render the genetically engineered material undetectable. 83 Fed. Reg. at 65,817; 7 C.F.R. 66.9(a)(2).

254. Third, regulated entities can demonstrate that GE material is not detectable by maintaining certificates of analysis or other testing records which confirm the absence of the genetically engineered material pursuant to that test. 83 Fed. Reg. at 65,817; 7 C.F.R. 66.9(a)(3).

255. In the final rule's response to comments, USDA concluded that "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 disclosures because the conditions of processing serve effectively to degrade or eliminate the DNA that was initially present in the raw agricultural commodity." 83 Fed. Reg. at 65,835.

256. USDA rejected comments supporting inclusion of all GE foods, including highly refined ones, because "highly refined products have undergone processes that removed genetic material such that it cannot be detected using common testing methods," and thus the rule will not require disclosure. *Id.* ("With the adoption of Position 1, foods with undetectable modified genetic material are not bioengineered foods.").

257. In the response to comments, USDA acknowledged in part that, although its own General Counsel "seemingly advocated" for an interpretation "along the lines of Position 2" (that is, the inclusion of highly refined GE food), the agency had switched positions, and "will adopt Position 1." 83 Fed. Reg. at 65,835.

258. With regards to international standards aligned with requiring disclosure of highly refined GE foods, in the final rule, USDA said it had considered them but felt it was "bound by the plain language of the amended Act." The agency interpreted this plan language as requiring that "if a food does not contain

detectable modified genetic material, it is not a bioengineered food and does not require disclosure." 83 Fed. Reg. at 65,835-36.

259. With regards to the "other factors and conditions under which a food is considered a bioengineered food" provision of the Act, 7 U.S.C. § 1639b(b)(2)(B), USDA said it interpreted that provision as "one that limits the scope of the definition of 'bioengineered food,' thus potentially excluding certain bioengineered products from disclosure," rather than broadening it. 83 Fed. Reg. at 65,836.

260. With regards to all the highly refined GE products that would be excluded from the standard, USDA declared that the agency "does not have the authority to require BE disclosure for those foods regardless of the number of food products that may be affected." 83 Fed. Reg. at 65,836.

H. Post Final Rule USDA Guidance

261. In July 2020, USDA issued two guidance documents and two frequently asked question documents (FAQ) to assist manufacturers in their efforts to comply with the Disclosure Act.[189]

262. AMS's *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process* concedes that highly refined foods can contain currently undetectable genetic material from a GE source.[190] The FAQ explains that "a future test may detect modified genetic material in a highly refined food or ingredient that current tests do not."[191]

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[189] National Bioengineered Food Disclosure Standard; Guidance on Validation of a Refining Process and Selecting a Testing Method, 85 Fed. Reg. 40,867 (July 8, 2020).

[190] USDA, *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process* (July 2, 2020), at 3 (answer to Qt. 13), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcessValidation.pdf.

[191] *Id.* at 3 (answer to Qt. 13).

263. This same FAQ, however, assures stakeholders that they need not avail themselves of more sensitive future tests that would render previously undetectable rDNA detectable, and the food bioengineered. Rather, such bioengineered food may continue to evade BE disclosure requirements, indefinitely, based on a refining process validated by a less sensitive, outdated genetic test.[192]

I. Costs

264. Commenters pointed out that USDA's economic analysis concluded that excluding highly refined foods from the disclosure mandate would not save manufacturers any money.[193]

265. Rather, AMS's failure to require mandatory disclosure of highly refined foods creates a need to navigate the potentially high costs and complexities of analytical methods, sample sizes, process variability, and evolving limits of detection in order to obtain proper documentation, as demonstrated in these guidance documents.[194] Campbell's Soup Company commented that regulation of the processes that remove genetic material would be "impractical to implement for the agency and industry" due to complex and costly analytical testing methods with differing degrees of efficacy.[195] Several other companies similarly anticipate substantial costs of analytical testing for highly refined material and difficulty in enforcement.[196]

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[192] USDA, *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process* (July 2, 2020), at 3 (answer to Qt. 13), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcessValidation.pdf.

[193] USDA, *Overview of the National Bioengineered Food Disclosure Standard*, Webinar Transcript, at Slide 43, https://www.ams.usda.gov/sites/default/files/media/BEWebinarTranscript.pdf.

[194] Kraft comment, at 2; Hershey comment, at 2; Campbell's comment, at 5-6.

[195] Campbell's comment, at 5.

[196] Hershey comment, at 2; Kraft comment, at 2; Campbell's comment, at 5-6.

J. Injuries

266. Plaintiffs and their members are injured by USDA's decision to exclude "highly refined" GE foods, which encompass the vast majority of all GE foods, from the disclosure standard.

267. Because of USDA's exclusion decision in the final rule, these GE food products will remain undisclosed to consumers and retailers. The absence of this information—the same information provided to consumers in many other countries across the globe—injures consumers by leaving them in the dark as to the fact that these foods are actually made with GE ingredients, yet unlabeled.

268. The exclusion injures Plaintiffs and their members by depriving them of this information. It also injures them by causing confusion and misrepresentation. Consumers will see other products disclosed as GE, but not processed foods, and wrongly assume that these foods are not GE foods. As tests with differing sensitivities are adopted, a product made by one manufacturer will be exempt from BE labeling while a corresponding product with similar BE content will be subject to it, instigating consumer confusion and distrust in the disclosure standard. This increase in confusion and distrust will also injure retailers like Plaintiffs, who believe in providing meaningful transparency to their customers as part of their brand and business plan. Plaintiffs will be forced to educate their customers on these confusing claims.

269. The exclusion also injures retailers and manufacturers by increasing their costs in compliance with the standard and by requiring them to expend resources to discern which products are actually genetically engineered.

THIRD CAUSE OF ACTION

Exclusion of "Highly Refined" GE Foods
(Violation of the Disclosure Act and APA)

270. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 269 of this Complaint as if fully set forth herein.

271. The Act's definition of bioengineering, upon which the disclosure classification mandate is based, includes any food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques." 7 U.S.C. § 1639(1)(A). The Act also commands that USDA "shall" establish the food disclosure standard with respect to both "any bioengineered food and any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1).

272. The Act also includes a provision requiring USDA to, in its implementing rules, "establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food." 7 U.S.C. § 1639b.

273. USDA's determination to exclude the vast majority of GE foods from any disclosure was contrary to the plain text, the agency's own prior interpretation of it, and is arbitrary and capricious under the APA.

274. USDA's decision relied on its insertion of extra-statutory, ultra vires rationale to conclude that, if a food does not contain detectable modified genetic material based on the results of unspecified "common testing methods," it is not a GE food and does not require disclosure. The Act nowhere uses the term "detectable." Detectable does not mean contains. Nor does the word by itself have any meaning without specification of an analytical method with an associated limit of detection (numerical degree of sensitivity), which is nowhere specified in the rule. Thus, the mere fact that a currently-employed "common testing method" does not detect GE material in no way demonstrates that the food does not contain that GE

material. Two of the three methods for excluding refined foods from the standard (processing and testing, 7 C.F.R. 66.9(a)(2)-(3)) are extra-statutory and contrary to the record.

275. USDA's narrow classification and wholesale exclusion of thousands of GE food products is also contrary to broader provisions in the Act, establishing authority and ordering the agency to also establish disclosure for not just "any bioengineered food" but also foods that "may be bioengineered." 7 U.S.C. § 1639b(a)(1). The Act also required USDA to establish a process for "other factors and conditions under which a food is considered a bioengineered food." 7 U.S.C. § 1639b(b)(2)(B). USDA's determination in the final rule that it is restricted to classifying as GE only foods that have "detectable" modified genetic material in the final product is contrary to this statutory text and intent and is arbitrary and capricious.

276. USDA's failure to establish the "other factors and conditions" process in the rules also violates the Act, which stated that USDA "shall establish" that process. USDA's determination that the "other factors and conditions" process was exclusively to narrow the standard further, rather than provide the agency more discretion and breadth, was also contrary to the text and arbitrary and capricious.

277. The provision provides "other factors and conditions under which a food is considered a bioengineered food," 7 U.S.C. § 1639b(b)(2)(B), not "other factors and conditions under which a food is [not] considered a bioengineered food." The plain intent of including the petition process for addressing further "factors and conditions under which a food is considered a bioengineered food" was to broaden, not narrow, the classification's scope. 7 U.S.C. § 1639b.

278. USDA also acted contrary to law in looking only to the final end food product. Regardless of final product test results, USDA excluded foods that knowingly contain GE ingredients prior to that processing. Nothing in the statute

supports that limitation. Consumers care about the production method impacts and the chemicals associated with GE and their harms to the environment and farmworkers. By excluding highly processed GE foods, the final rule fails to accomplish the goals of the Act. By excluding those foods, the final rule is misleading and confusing to consumers, and permits products to be misbranded. That decision was contrary to international standards and consumer expectations and arbitrary and capricious, unsupported by the record.

279. The Act also requires that USDA "shall" develop the disclosure standard "in a manner consistent with United States obligations under international agreements." 7 U.S.C. § 1639c(a). The final rule's exclusion of the vast majority of GE foods, highly refined foods, conflicts with the standards of numerous U.S. trading partners, and the standards of the *Codex Alimentarius*, which includes these foods. USDA's conclusion that it was nonetheless constrained by the Act to require that in the final rule conflicts with these international standards and was contrary to the Act and arbitrary and capricious under the APA.

IV. Claim 4: First Amendment Freedom of Speech

280. The final rule, as interpreting and applying the Disclosure Act, also impermissibly impinges on the First Amendment's guarantee that free speech is to be protected because it prohibits commercial speech about foods produced through genetic engineering except in the narrow and inadequate forms approved by USDA in the final rule.

281. The rights at stake include both the rights of producers, retailers, importers, and other businesses to convey truthful and factual information concerning whether a food product or ingredient is genetically engineered, as well as consumers' rights to receive that information.

282. This prohibited speech is truthful and thus protected under the First Amendment because these foods would be produced with genetic engineering as a factual and scientific matter, whether or not USDA excluded them or disallowed those foods or that terminology from its exclusive bioengineered disclosure classification.

283. For example, with soda, a label that reads "produced with genetic engineering" would be truthful and factual if the soda was produced with ingredients that were genetically engineered, such as genetically engineered beet sugar and/or genetically engineered high fructose corn syrup.

284. Traditional and standard definitions of "genetic engineering" are also well-established in international standards, in existing and past federal guidance, and in state laws.

285. Many of these foods were already being labeled or were previously labeled as "produced with genetic engineering" in the marketplace. Both FDA and Defendant USDA have existing food labeling guidance that discusses and permits such truthful and factual labeling, as not false and misleading, as discussed *supra*. The absence of these same ingredients is also labeled in the marketplace, through Non-GMO labeling, which the USDA's regulatory scheme does not attempt to restrict.

A. Statute

286. The Act declares that it "shall apply to any claim in a disclosure that a food bears that indicates that the food is a bioengineered food." 7 U.S.C. § 1639a(a). Thus the law's "labeling" scope is broader than only on-package labels, and instead applies to "any claim" in any "disclosure."

287. The Act declares that "a food may bear a disclosure that the food is bioengineered *only in accordance with the regulations*" implementing it. 7 U.S.C. § 1639b(b)(1) (emphasis added). That is, the USDA's disclosure scheme is restrictive

and exclusive, and entities may not provide disclosure except in accordance with the new scheme.

288. The statute defines "bioengineering" of food as food "that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques . . . ." 7 U.S.C. § 1639(1)(A). This is the traditional definition for genetic engineering and genetically engineered foods.

289. The Act further provides that the rulemaking shall prohibit a food from being "considered a bioengineered food solely because the animal consumed fed from" a bioengineered source. 7 U.S.C. § 1639b(b)(2)(A).

290. The Act further provides that USDA's regulations shall exclude "food served in a restaurant or similar retail establishment." 7 U.S.C. § 1639b(G)(i).

291. The Act further provides that with regards to GE absence labeling, the statute prohibits a food from being considered "not bioengineered" or "non-GMO" or "any similar term" describing the absence of bioengineering "solely" because the food is not required to be disclosed as bioengineered under the Act. *Id.* § 1639c(c).

292. In a further showing of exclusivity, the Act expressly preempts States or any political subdivisions of States from establishing any labeling requirement different from that required by the Act. *Id.* § 1639b(e).

293. The Act also includes a second preemption provision, which again preempts States and political subdivisions from directly or indirectly establishing any labeling requirements. This provision is significantly broader than the prior provision, declaring that no other non-federal governmental entities are permitted to pass any laws related to "labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered" or "was developed or produced through genetic engineering, including any requirements for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering." *Id.* at 1639i(b). This provision is broader in

several ways: it includes the traditional terminology; it includes foods in restaurants and similar establishments; it includes seeds; and it includes claims not just for foods but any ingredients produced with genetic engineering.

B. Final Rule

294. The final rule defines "Bioengineered Food" to mean, *inter alia*, "food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques . . . ." 7 C.F.R. § 66.1. "Bioengineered substance" is defined the same. *Id.* This is the common definition for foods produced through genetic engineering.

295. The regulations define "labeling" to include not just the disclosure on the container but "all labels and other written, printed, or graphic matter: (1) Upon any article or any of its containers or wrappers; or (2) accompanying such article." 7 C.F.R. § 66.1. Thus retailer in-store disclosures, such as shelf tags or bin signs, would be covered as "labeling."

296. "Regulated entity" is defined to include "food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures." 7 C.F.R. § 66.1; 83 Fed. Reg. at 65,831 ("All food manufacturers, importers, and retailers who offer for retail sale foods on the List of Bioengineered Foods are considered regulated entities for purposes of the NBFDS insofar as they may be required to make BE food disclosures."). That is, any manufacturer or retailer that sells any foods listed as having bioengineered varieties is responsible for making bioengineered disclosures.

297. The regulations provide that "*except as provided in* § 66.116 for voluntary disclosure . . . a *label shall not bear a disclosure* that a food is a bioengineered food or contains a bioengineered ingredient . . . ." 7 C.F.R. § 66.3(a)(2) (emphases added). That is, the regulations prohibit voluntary disclosures except for

those explicitly permitted and detailed in the regulations. 83 Fed. Reg. at 65,830 ("Voluntary labeling is *only permitted* in these circumstances") (emphasis added).

298. The regulations declare that a food "derived from an animal *shall not be considered* a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance." *Id.* § 66.5(c) (emphasis added). 83 Fed. Reg. 65,824 ("The amended Act prohibits a food derived from an animal from being considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance."). That is, the rules prohibit the disclosure of meat or dairy even if the animal was fed genetically engineered feed.

299. The rules assign responsibility for primary labeling to both the manufacturer and retailer. For food packaged prior to receipt by the retailer, the manufacturer or importer "is responsible for ensuring that the food label bears a bioengineered food disclosure in accordance with this part." 7 C.F.R. § 66.100.

300. For bulk foods, like grains, fruits, and vegetables, "the retailer is responsible for ensuring the food bears a bioengineered disclosure in accordance with this part." 83 Fed. Reg. at 65,825 ("If a retailer packages a food or sells food in a bulk container and/or display, then the retailer is responsible for ensuring that the food bears a BE food disclosure in accordance with this part."); 83 Fed. Reg. at 65,831 ("AMS requires that retailers be held responsible for complying with the BE food disclosure of bulk food.").

301. The rules further establish that if a food is a bioengineered food it "must bear a bioengineered food disclosure" and that the disclosure "*must be* in one of the forms described" in the regulations. *Id.* § 66.100(b). Those forms would be electronic disclosure, text disclosure, symbol disclosure, or text message disclosure. *Id.*

302. For text disclosure, the only language permitted is "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient." *Id.* § 66.102. "A text disclosure *must bear the text as described in this section*." *Id.* (emphasis added). That is, labeling such foods as "genetically engineered" or "genetically modified" or "produced through genetic engineering" is not permitted.

303. Food sold in bulk containers (display case, bin, carton, or barrel), including seafood, is assigned to retailers, and such disclosures "*must use* one of the disclosure options described in 66.102 [bioengineered language], 66.104 [bioengineered symbol], 66.106 [QR code/electronic], 66.108 [text message]." *Id.* § 66.114 (emphasis added).

304. The voluntary disclosure section has two parts. 7 U.S.C. § 66.116. First, for "exempt entities," listed as "a very small food manufacturer, restaurant, or similar retail food establishment," they may voluntarily provide disclosure, but the disclosure "must be in one or more forms described," and listing 66.102 [bioengineered package text], 66.104 [bioengineered symbol], 66.106 [electronic QR codes], 66.108 [phone text message]. *Id.* § 66.116(a)(1)-(4); 83 Fed. Reg. at 65,830 (entities exempt from disclosure–"very small food manufacturers, restaurants and similar retail food establishments"–may only voluntarily disclose "in the same manner as those required to provide a BE disclosure."); 83 Fed. Reg. at 65,858 ("[A]ny methods to voluntarily disclose bioengineered food should match the disclosure methods available to regulated entities . . . ."). That is, if you are an exempt entity, you can only voluntarily label using the above, and cannot use "produced through genetic engineering," or similar commonplace language. 83 Fed. Reg. at 65,858 ("Therefore, an entity utilizing the voluntary disclosure provisions must comply with the disclosure requirements for text, symbol, digital or electronic link, or text message disclosure, as applicable.").

305. Second, the provision covers "foods derived from bioengineering." *Id.* § 66.116(b); *see* 83 Fed. Reg. at 65,830 ("This means that many refined products originating from bioengineered crops do not constitute bioengineered foods."). For foods that are excluded from mandatory disclosure because they are highly refined, regulated entities *may* disclose such foods, but only with one of the listed disclosures: text stating "derived from bioengineering" or "ingredients derived from a bioengineered source"; a symbol stating "derived from bioengineering"; QR code electronic disclosure pursuant to § 66.108; or text message disclosure pursuant to § 66.108. *Id.* Thus related entities that wish to disclose processed GE foods cannot use "produced through genetic engineering" or any other similar terms, and can only use the above methods.

306. This provision also excludes foods that are "not exempt from disclosure under § 66.5," meaning that foods excluded under that provision, like meat and dairy derived from livestock animals fed GE feed, are not covered by it and cannot even be labeled in the above manner. 7 C.F.R. § 66.116(b); 83 Fed. Reg. at 65,830 ("A food that is . . . exempted from disclosure under 66.5(c)-(e) is prohibited from voluntary disclosure under the NBFDS."); 83 Fed. Reg. at 65,858 ("[V]oluntary BE disclosure is available in limited circumstances and does not apply to any foods that the amended Act excludes . . . .").

307. Although the statute directs USDA to establish a disclosure standard "with respect to any bioengineered food and any food that *may be* bioengineered," 7 U.S.C. § 1639b(1) (emphasis added), in the final rule USDA refused to permit any "may be" labeling under the standard. 83 Fed. Reg. at 65,827 ("The 'may be bioengineered' disclosure cannot be used.").

308. Finally, despite the above multiple restrictions on speech and the stated exclusivity of the bioengineered standard, the regulations inexplicably state that "nothing in this subpart will prohibit regulated entities from making other

claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law." *Id.* § 66.118. Nowhere do the regulations explain this inconsistency, or what USDA means by "other claims" or believes is permissible.

309. The rules include a severability clause stating that "if any provision of this part is declared invalid . . . the validity of the remainder . . . shall not be affected." *Id.* § 66.11.

C. Injuries

310. Retailers, producers, and other would-be speakers are injured by Defendants' suppression of their speech rights regarding genetically engineered foods. Absent that prohibition, they could and would communicate to their customers the factual and truthful information about how these foods are produced.

311. These include retail and manufacturer "regulated entities," as defined by the regulations, as well as "exempted entities," as defined by the regulations, such as "retail food establishments" that wish to voluntarily disclose, depending on the situation.

312. These Plaintiffs' speech is unconstitutionally chilled by Defendants' exclusive and preemptive disclosure scheme. Absent prohibition by the new exclusive federal regulatory scheme, retailers could provide more meaningful transparency to customers in their stores. This would include the right to label using the traditional, consumer-known terminology of "genetically engineered" or "GMO," rather than "bioengineered"; disclosing highly refined products that are produced with genetically engineered ingredients; disclosing meat or dairy sourced from animals fed genetically engineered feed; disclosing food produced in in-store restaurants, bakeries, or delis; and disclosing other foods that only may be produced with genetic engineering. These labels could be applied through store shelf tags, hang tags, bulk bins, or other disclosure means, such as labeling their own store

varieties, if they are produced with genetically engineered ingredients. This chilling of their speech harms them economically as well as reputationally.

313. Defendants' actions place Plaintiffs at risk of non-compliance enforcement by USDA, if they are found to be violating the exclusive bioengineered standard. It also places them at risk of litigation from third parties, under state law actions or common law claims, who disagree with their disclosures and seek to enforce the limitations of the narrow federal scheme.

314. Consumers are also equally injured by the prohibition. The First Amendment protects listeners' rights, that is, the right of consumers to receive this information. Commercial speech is particularly protected under the First Amendment because of the value it provides consumers.

315. Because of Defendants' chilling of Plaintiffs' speech, consumers will not be able to receive information they expect and would otherwise greatly value having to do with whether foods are produced through genetic engineering. Grocery stores, retailers, and producers they rely on and trust are no longer permitted to provide them that information because of Defendants' prohibition on their speech. Even the disclosures consumers do receive will be rendered misleading, since most foods produced through genetic engineering will not be disclosed. Or, even if they are, they will only be disclosed through QR codes, or the unknown "bioengineered" terminology.

FOURTH CAUSE OF ACTION
***Prohibition on Speech* (Violation of the First Amendment)**

316. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 315 of this Complaint as if fully set forth herein.

317. The First Amendment guarantees the right to disclose truthful and non-misleading information on food labels. *See, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

318. The prohibited speech is truthful and thus First Amendment protected because the foods to be labeled are produced with genetic engineering as a factual and scientific matter, whether or not Defendants have excluded them from the bioengineered classification.

319. Existing federal law under the FDCA prohibits food from being misbranded, including if it is "false or misleading in any particular." 21 U.S.C. § 331(a). Yet, as detailed above, federal agencies have long-standing guidance permitting voluntary disclosures for both presence and absence of genetic engineering, showing that and how such disclosures are not false or misleading.

320. Many of these foods were already being labeled as "produced with genetic engineering" in the marketplace. Both FDA and USDA have guidance that discusses and allows such labeling, as not false and misleading, as discussed *supra*. Indeed, documents obtained from a Freedom of Information Act request indicate that USDA viewed the terms "GE" and "GMO" as mandatory to avoid misleading consumers.

321. In order to pass Constitutional muster, restrictions on speech must: (1) further a "substantial" governmental interest; (2) "directly advance" that interest; and (3) be "no more extensive than necessary," i.e., narrowly tailored, to serve that interest. *Central Hudson Gas & Electric Corp. v. Public Service Comm. Of N.Y.*, 447 U.S. 557, 567-68 (1980).

322. The final rule prohibits speech in at least four separate ways. First, the final rule prohibits entities from using the common and well-established terminology ("produced with genetic engineering" or "GMO") to label genetically engineered foods for any and all foods that it includes in its bioengineered classification. This applies to entities either already regulated or otherwise exempt but intending to label. Instead the only labeling permitted requires the use of the terms and methods otherwise established by the rule (bioengineered text or symbol, QR code, or text message) which, as explained above, fail to meaningful provide disclosure to consumers.

323. Second, as discussed, "highly refined" GE foods, the overwhelming majority of GE foods, are entirely excluded from mandatory disclosure requirements. The final rule allows voluntary labeling of these foods by entities (regulated or exempt) intending to label, but only narrowly using its own terminology of "derived from bioengineering." It again disallows and prohibits these entities from using the far more commonly known terms (produced with genetic engineering) for these GE products.

324. Third, numerous types of GE foods are excluded from the bioengineered classification and standard. This includes any meat or dairy from livestock fed genetically engineered feed. It also includes GE foods served in a restaurant or similar retail food establishment, such as in-store bakeries, delis, or restaurants. For these GE foods, the final rule prohibits any voluntary disclosure.

325. Fourth, despite the statute's instruction that the standard must also cover foods that only "may be" bioengineered, the final rule excludes any such labeling from the standard, and goes further, prohibiting any voluntary use of any such labeling. 83 Fed. Reg. at 65,827 (prohibiting "may be produced with genetic engineering").

326. Defendants' prohibitions on speech regarding genetically engineered foods lacks any governmental interest, let alone any substantial one.

327. In fact such chilling of further speech beyond the Act's narrow standard is directly contrary to the purpose of labeling and the Disclosure Act: to inform consumers. More, not less, related speech fulfills the Act's purposes.

328. Even assuming there was a cognizable governmental interest that was substantial, Defendants' prohibition on speech does not directly advance any such interest. The restriction is antithetical to the purpose of informing consumers that foods are produced through genetic engineering. More, not less speech would further the Act's purposes of informing consumers and providing transparency.

329. By omitting and not disclosing various GE foods and prohibiting them from the bioengineered standard, and then prohibiting their voluntary labeling as GE or otherwise, the agency misleads and confuses consumers, in direct contravention to the purposes of the Act.

330. Nor is the prohibition narrowly tailored, or no more extensive than necessary. Rather it restricts protected speech broadly, prohibiting speakers far beyond the disclosure standard the statute establishes. Far from being narrowly tailored, the final rule restricts speech beyond the contours of the disclosure classification it establishes, including speech related to restaurant and ready-made deli foods and speech related to seed labeling.

331. In the final rule, Defendants made no effort to show that its restrictions on speech are supported by governmental interests, let alone substantial ones, or to show that these interests are more than just general, abstract, or hypothetical.

332. The only plausible governmental interest here is in reducing consumer confusion and increasing consistent and honest communication with consumers. The final rule has the opposite effect. To limit speech as it does the rule must be

supported by a substantial government interest, but there is no cognizable governmental interest, let alone a substantial one, in prohibiting disclosures on genetically engineered foods beyond the bioengineered classification. Without justification, USDA created huge loopholes of foods that are not covered under the final rule, such as highly refined GE foods. USDA proscribed common, recognizable forms of labeling through prohibiting the use of the familiar terminology of "genetically engineered" and "genetically modified." USDA also allowed forms of labeling that will not meaningfully inform consumers, such as QR code disclosures and text message disclosures.

333. Plaintiffs request that the Court provide declaratory relief that entities' right to provide this truthful and factual information about genetically engineered foods is protected and cannot be restricted. Plaintiffs further seek that the Court declare these prohibitions and restrictions unlawful and severed from the rule.

V. Claim 5: Commandeering

334. The Tenth Amendment of the Constitution provides that: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

335. The preemption provision in 7 U.S.C. § 1639i(b) and the final rule's application of it violates the Tenth Amendment through impermissibly commandeering state governments to refrain from passing state laws labeling GE seeds without concurrently providing any federal regulatory scheme for labeling GE seeds. This broad preemption provision seeks only to impermissibly commandeer state governments and not to regulate private seed manufacturers, retailers, or importers when it comes to seed labeling or regulation. As such it violates the key foundational principle of federalism—that the federal government share power with

the states—by prohibiting any state regulation, without passing any federal regulation for private entities.

336. The Act consistently makes clear that disclosure requirements apply only to some but not all foods and definitely not to seeds; it is without any mention of seeds outside of the second, broader preemption provision, 7 U.S.C. § 1639i(b), which purports to preempt state regulation of not just "bioengineered" food, but GE food and GE seed labeling.

337. The Act's classification scope specifies that the Act applies "to any claim in a disclosure that a food bears that indicates that the food is a bioengineered food" without mention of seeds. 7 U.S.C. § 1639a(a). The fundamental term "bioengineering," as defined in the Act, includes only a definition "with respect to a food" and not with respect to seeds. *See* 7 U.S.C. 1639 (1). Under the Act, "A food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter." 7 U.S.C. § 1639b (b)(1).

338. In accordance with these mandates, USDA remained silent on standards for GE seed labeling in the final rule. "Regulated entities" subject to USDA's final rule included only food retailers, manufacturers, and importers, with no mention of seeds or those that produce or sell them. 7 C.F.R. § 66.1.

339. This unlawfully broad preemption provision with respect to state laws regulating seed labeling infringes on state governments' sovereign authority to "regulate their own citizens." *Reno v. Condon,* 528 U.S. 141, 151 (2000). Such a prohibition unlawfully commandeers states seeking to label seeds that are genetically engineered to protect biodiversity, ensure transparency in seed labeling, and regulate the GE seed industry in the interests of their citizens.

A. Existing state regulation on GE seed labels

340. In the absence of any federal regulation of GE seed labels and GE seed regulation in general, states have long stepped in to assert their authority in the regulation of GE seeds. Three states have established an advisory council on GMO seeds/biotechnology, including California, Minnesota, and Missouri. *See* Cal. Food & Ag. Code § 492; Minn. Stat. §§ 116C.92; Mo. Rev. Stat. § 620.1500. Several other states have preempted their local governments from regulating seeds, including GE seeds, such as New Jersey, Pennsylvania, Arizona, Iowa, Idaho, Oklahoma, Georgia, and Oregon. N.J. Stat. § 40:8C-2; Pa. Cons. Stat. Ann. tit. 3, § 7120 (2005); Ariz. Rev. Stat. Ann. § 3-243 (2007); Iowa Code Ann. tit. V, § 199.13A (2005); Ida. Code. Ann. § 22-413 (2007); Okla. Stat. tit. 2, § 8-26.1 (2007); Ga. Code Ann. § 2-11-35 (2005); O.R.S. § 633.738. These states, along with others, oversee GE seed regulation for purposes of transparency and environmental protection.

341. Numerous states have laws requiring the identification of GE seeds. These laws include direct GE seed labeling requirements; instruction requirements for GE seeds; certification requirements which result in tagging, sealing, or labeling; and public notice requirements.

342. Currently, both Vermont and Virginia have laws directly regulating the information on GE seed labels. *See* Vt. Stat. Ann. tit. 6, § 644 (2003); Va. Code Ann. tit. 3.2, § 4008 (2012). Vermont currently requires that all seeds containing GE material bear a label specifying the identity and relevant traits or characteristics of such seed as well as any requirements for their safe handling, storage, transport, and use. Vt. Stat. Ann. tit. 6, § 644 (2003). Similarly, Virginia requires that seed produced from transgenic (GE) plant material be labeled. Va. Code Ann. tit. 3.2, § 4008 (2012).

343. Although not directly requiring a GE seed label, Maine requires seed dealers selling GE seed to include instructions on labels on how to reduce the chances of contaminating non-GE crops. *See* Me. Rev. Stat. Ann. tit. 7, § 1052.

344. Several other states require the identification of GE seeds through a certification process, including Vermont and Washington. *See* Wash. Admin. Code § 16-302-170 (2010); Vt. Stat. Ann. tit. 6, § 611 (2015). These certification processes involve identifying GE seeds through tagging, labeling, or sealing. *See* Wash. Admin. Code § 16-302-110 (2010); Vt. Stat. Ann. tit. 6, § 614 (2015). Certification services in Vermont require "the identification of seeds that have been genetically engineered" in order "to help avoid adverse effects on the potential benefits of genetic engineering technologies and on the conservation and sustainable use of biological diversity through the use of such seeds." Vt. Stat. Ann. tit. 6, § 611 (2015). In Washington, GMO seeds are tagged, labeled, or sealed as part of their certification if they meet minimum trait standards as defined by the breeder or trait owner. Wash. Admin. Code § 16-302-170 (2010).

345. Several other states, including Virginia and Washington, require the identification of GE seeds through public notice. Va. Code §§ 2.2-5504; Wis. Stat. § 146.60. In Virginia, state law requires that public notice and a brief description of the proposed regulated introduction of genetically engineered seeds be issued within fifteen days after information is received. Va. Code §§ 2.2-5504. Similarly in Wisconsin, public notice must be released within five days of the receipt of required information on the release of GE seeds. Wis. Stat. § 146.60.

346. These state laws requiring identification of GE seeds fall far outside of the scope of the Disclosure Act, which provides only standards for GE food products.

B. The Disclosure Act

347. The Disclosure Act mandates that USDA "shall" establish a nationwide standard for disclosure with regards to "any bioengineered food" and "any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1). In accordance with the Disclosure Act, "A food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subtitle." 7 U.S.C.S. § 1639b.

348. The Act defines "food" as "a food (as defined in section 321 of Title 21) that is intended for human consumption" and provides no definition of "seeds." 7 U.S.C. § 1639(1). Section 321 of Title 21 of the Federal Food, Drug, and Cosmetic Act (FDCA) defines "food" as including "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C.A. § 321(f). The definition specifies that the Disclosure Act does not apply to the animal feed portion of this definition.

349. The Act includes two preemption provisions, the first of which expressly preempts States from enacting or continuing in effect any law that "directly or indirectly" relates to the labeling or disclosure of food that is subject to the national bioengineered food standard. 7 U.S.C. § 1639b(e). This preemption provision does not mention seeds.

350. The Act's second preemption provision includes a significantly broader range of products, encompassing not only bioengineered foods but also seeds. This second preemption provision prohibits States and political subdivisions from "directly or indirectly" establishing any labeling requirements related to "labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered" or "was developed or produced through genetic engineering, including any requirements for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering." *Id*. at §

1639i(b). This preemption provision also does not use "bioengineered," but instead the known term of "genetically engineered."

351. This preemption provision further provides a broader definition for "food," also referencing the 21 USC 321(f) definition of food, but not specifying "for human consumption." The preemption provision thus also includes "articles used for food or drink for . . . other animals" and prohibits state GE labeling laws for pet food. Hence the preemption provision attempts to preempt far broader and on far different topics than that which the federal labeling scheme establishes disclosures.

352. Nowhere does the Act mention seeds outside of this preemption provision, nor does the Act direct USDA to establish a federal regulatory scheme for seeds, nor does it in any way regulate private entities with regards to seeds. Rather the Act reiterates that disclosure standards apply to foods subject to labeling requirements under the FDCA and other federal laws. 7 U.S.C. § 1639a(c).

C. Final Rule

353. The final rule, in turn, defines a "regulated entity" under the scope of the Act, as "the food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures." 7 C.F.R. § 66.1. Importers regulated under this final rule include only those "who engage[ ] in the importation of food or food products labeled for retail sale into the United States," and retailers include only those "responsible for making bioengineered food disclosures." *Id*.

354. Nowhere does the final rule purport to regulate seed manufacturers, seed importers, or seed retailers. In fact, the final rule leaves seeds out of the codified section entirely. The only mention of seeds appears in the preamble section discussing 7 U.S.C. 1639i(b). 83 Fed. Reg. 65,814, 65,870-71 (Dec. 21, 2018).

355. Contrary to the broad preemption provision, the final rule reiterates the applicability of the Act to "bioengineered food," "intended for human consumption." 7 C.F.R. § 66.1. Applicable foods under the final rule include: (1)

foods subject to labeling requirements under the FDCA and (2) foods subject to other federal laws in which the most predominant ingredient would independently be subject to the labeling requirements under the FDCA or if 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. 7 C.F.R. § 66.3(b).

D. Injuries

356. Organic and conventional farmers, gardeners, certifiers, consumers, retailers, and other agriculture entities that rely on GE seed labeling are injured by Defendants' unconstitutional commandeering of state legislatures regarding GE seed labeling. Absent this preemption provision, current state laws directly and indirectly regulating GE seed labels would remain valid, and states could pass additional future state laws labeling GE seeds.

357. This provision unconstitutionally commandeers state governments to refrain from legislating without providing any federal regulatory scheme for GE seeds in return. Absent federal regulation on GE seed labeling, the preemption provision cannot be read as granting rights to private actors to label in accordance with the Disclosure Act. Instead this provision may only be read as unconstitutionally commandeering state legislatures to refrain from passing legislation without providing any federal alternative. The Act is not regulating private entities with regards to GE seed labeling; to the extent that preemption provision regulates that topic it is impermissibly overbroad.

358. Defendants' actions injure Plaintiffs, who will now be unable to avoid purchasing GE seeds based on mandatory state or federal GE seed labels. Farmer, seed grower, consumer, retailer, and other members of the Plaintiff organizations rely on existing state seed labeling laws. The elimination of state laws regarding GE seed labeling would injure these members economically should members purchase

unlabeled GE seeds and unknowingly contaminate their farming and gardening operations.

359. Because of Defendants' unconstitutional commandeering of state governments, consumers will not be able to receive information they expect and would otherwise greatly value having to do with whether seeds are GE. Farmers, gardeners, grocery stores, retailers, and producers they rely on GE seed labeling are injured because of the Defendants' preemption of state laws and failure to provide any federal GE seed labeling for seeds.

FIFTH CAUSE OF ACTION
***Commandeering* (Violation of the Tenth Amendment)**

360. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 359 of this Complaint as if fully set forth herein.

361. By attempting to prohibit state laws either directly or indirectly regulating GE seed labeling, defendants have encroached upon powers explicitly reserved to the states, pursuant to the Tenth Amendment.

362. The Tenth Amendment to the Constitution of the United States provides that the "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." The anticommandeering doctrine represents the recognition of this limitation through ensuring the preservation of the system of "dual sovereignty" established in the Constitution, under which the states are not meant to operate as instruments of the federal government, but as separate sovereigns in their own right. See *New York v. United States*, 505 U.S. 144, 175-177 (1992); *Printz v. United States*, 521 U.S. 898, 925-26 (1997).

363. 7 U.S.C. § 1639i(b) is unconstitutional under the anticommandeering doctrine because it sweeps far more broadly than the Disclosure Act and does not

regulate private entities. It commands that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any requirement relating to the labeling of whether a . . . . seed is genetically engineered . . . .or was developed or produced using genetic engineering."). *Id.* The Tenth Amendment prohibits the federal government from "requir[ing]" state and local governments "to govern according to Congress's instructions." *New York v. United States*, 505 U.S. 144, 162 (1992). This basic principle applies to Congressional orders "compelling a State to enact legislation" and orders "prohibiting a State from enacting new laws." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1467, (2018). 7 U.S.C. § 1639i impermissibly prohibits states from enacting GE seed laws.

364. Congress stays within the limits of the Tenth Amendment when it "confers on private entities . . . a federal right to engage in certain conduct subject only to certain (federal) constraints." *NCAA* at 1480.301. Yet 7 U.S.C. § 1639i(b) does the opposite by prohibiting state and local governments from engaging in GE seed labeling without conferring a federal right to private entities to label GE seeds only in accordance with a federal regulatory scheme. The Act entirely fails to mention seeds outside of the express preemption provision, provides no mandatory language in regard to requiring disclosure for seeds, and fails to direct USDA to enact any regulations in regard to labeling GE seeds. The result is a final rule which only regulates retailers, manufacturers, and importers labeling *foods*, not seeds.

365. Defendants' prohibitions on state laws regarding the labeling of genetically engineered seeds leaves seed growers, farmers, importers, retailers, or related entities without any federal standards for labeling seeds as GE/GMO. Such prohibitions fail to confer rights onto these individuals and instead impermissibly commandeer state governments.

366. This prohibition thus violates a core aspect of governing: states' sovereign authority to "regulate their own citizens." *Reno v. Condon,* 528 U.S. 141, 151 (2000). This provision is therefore unconstitutional as applied to GE seed labeling and cannot be validly enforced against current state laws regulating GE seed labels and or future such laws. As a direct and proximate result of these unconstitutional conditions, state governments and their citizens will be forced to accept a permanent regulatory void, in seed labeling for GE seeds and the elimination of existing legislation regulating GE seed labeling, to the detriment of their citizens.

367. Plaintiffs request that the Court provide declaratory relief that state governments' right to provide this truthful and factual information about genetically engineered seeds cannot be unconstitutionally commandeered and sever that portion of the statute. Plaintiffs further seek that the Court declare that this express preemption provision is unconstitutional.

VI. Claim 6: Void for Vagueness

368. Multiple provisions of the final rule discussed above also impinge on the Fifth Amendment's guarantee of due process because the rule limits First and Tenth Amendment Rights while failing to provide adequate notice to regulated entities and political jurisdictions on what terminology and laws are permissible. Thus in the alternative that Defendants claim the rule does not violate the First and Tenth Amendment in the manners alleged above in whole or in part, then it is also impermissibly vague in violation of the Fifth Amendment.

369. The federal regulatory scheme is vague in two ways. First, the final rule's provisions describing permissible terminology for labeling are inconsistent with the Act's plain language and other provisions of the final rule, thus providing vague standards. Second, the Act's preemption provision and final rule fail to

provide any standards for states and political subdivisions to use in determining which laws "indirectly . . . relat[e] to" the labeling of GE seeds.

370. As a result of these vague, inconsistent provisions, regulated entities and political jurisdictions could be subjected to arbitrary enforcement actions as they exercise their First Amendment Rights to provide truthful information to consumers and Tenth Amendment Rights to continue or enact state laws regulating GE seed labels.

371. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). The vagueness doctrine has two main objectives: (1) "to ensure fair notice to the citizenry" and (2) "to provide standards for enforcement [by officials]." *Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 551 (6th Cir. 2007). Statutes or regulations that limit constitutional rights and fail to do so are void for vagueness.

372. Under the first objective, "a statute which either forbids or requires the doing of an act in terms so vague that [regulated entities] of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law." *Id.* (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1925)). In regards to the second objective, ". . . if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to [officials] for resolution on an ad hoc and subjective basis.'" *Id.* (quoting *Grayned*, 408 U.S., at 108-09).

373. This requirement of clear language is especially important when First Amendment freedoms are invoked. If a statute "interferes with the right of free speech or of association, a more stringent vagueness test should apply." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982). Clarity

in the law is essential to avoid vagueness from preventing individuals from exercising their rights of speech. *Scull v. Va. ex rel. Comm. on Law Reform & Racial Activities*, 359 U.S. 344, 353 (1959).

A. The Disclosure Act

374. The Act mandates that USDA "shall" establish a nationwide standard for disclosure with regards to "any bioengineered food" and "any food that *may be* bioengineered." 7 U.S.C. § 1639b(a)(1) (emphasis added). Thus the Act's labeling scope encompasses bioengineered foods and "any foods" that "may be bioengineered."

375. While the Act generally uses the term, "bioengineered," it also expressly allows for "any similar term" in defining the "bioengineering" classification. 7 U.S.C. § 1639(1).

376. The Act's broad preemption provision prohibits states and political subdivisions from "directly or indirectly" establishing or continuing "any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered" or "was developed or produced through genetic engineering, including any requirements for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering." 7 U.S.C. § 1639i(b).

377. A food may "bear a disclosure that a food is bioengineered only in accordance" with the Act's implementing regulations. 7 U.S.C. § 1639b(b)(1).

B. The Final Rule

378. Although the statute directed USDA to establish a disclosure standard "with respect to any bioengineered food and any food that *may be* bioengineered," 7 U.S.C. § 1639b(1) (emphasis added), in the final rule USDA prohibited any "may be" labeling under the standard. 83 Fed. Reg. at 65,827 ("The 'may be bioengineered' disclosure cannot be used.").

379. Further USDA prohibited the use of "any similar terms," such as "GE" or "GMO" which are permitted in the statute. *See* 7 U.S.C. § 1639(1). The final rule states that if a food is a bioengineered food it "must bear a bioengineered food disclosure" and that the disclosure "*must be* in one of the forms described" in the regulations. *Id.* § 66.100(b) (emphasis added). Since text disclosures only allow "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" *Id.* § 66.102, "similar terms" such as "genetically engineered" or "genetically modified" are not permitted.

380. Despite the above clear prohibitions and limitations on speech, the final rule also inconsistently stated that "nothing in this subpart will prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law." 7 C.F.R. § 66.118. Nowhere do the regulations explain this inconsistency, or what USDA meant by "other claims" or believes is permissible.

381. Additionally, nowhere does the final rule provide any clear standards regarding which laws "indirectly . . . relat[e] to" whether a seed is GE or was produced with genetic engineering. The preemption provision is only mentioned in the preamble and completely overlooked in the codified section. *See* 83 Fed. Reg. 65,814, 65,870-71 (Dec. 21, 2018).

382. The final rule includes a severability clause stating that "if any provision of this part is declared invalid . . . the validity of the remainder . . . shall not be affected." 7 C.F.R. § 66.11.

C. Injuries

383. Assuming that the provisions discussed above are not set aside as violations of the First and Tenth Amendments, they injure Plaintiffs' Fifth Amendment rights as follows.

384. The final rule injures Plaintiffs through its vagueness and lack of clear instructions for regulated entities to use regarding terminology as they attempt to label GE foods.

385. Absent this vague, contradictory language in the new federal regulatory scheme, retailers, including Plaintiffs, would make "other claims . . . consistent with applicable Federal law" in their stores. This would include using the terminology of "genetically engineered" or "GMO," rather than "bioengineered" and the "may be" terminology permitted in the Act. Defendants' contradictions and vagueness prevent retailers from doing so, thus harming them economically as well as reputationally.

386. If Plaintiffs choose to make "other claims . . . consistent with federal law," such as using "may be" terminology and other "similar terms," Defendants' vagueness places Plaintiffs at risk of non-compliance enforcement by USDA, if Plaintiffs are found to be violating the exclusive bioengineered standard. It also places them at risk of litigation from third parties, under state law actions or common law claims, who disagree with their disclosures and seek to enforce the limitations of the narrow federal scheme.

387. Because of Defendants' vagueness, consumers, including members of Plaintiffs, will not be able to receive information they expect and would otherwise greatly value having to do with whether foods "may be" produced through genetic engineering or whether they are "GE" or "GMO." Grocery stores, retailers, and producers they rely on and trust will be uncertain as to which terminology is permitted and will refrain from providing that information to avoid enforcement actions.

388. Organic and conventional farmers, gardeners, certifiers, consumers, retailers, and other agriculture entities that rely on GE seed labeling are also injured by Defendants' vagueness regarding permissible indirect seed labeling at

the local and state level. Without this vague prohibition on any state or local law "indirectly . . . relating to" GE seed labeling, states and political subdivisions would keep current laws and continue to pass laws on which Plaintiffs rely to identify GE seeds.

389. Farmers, seed growers, and consumer members of Plaintiffs rely on state laws for seed labeling and certification, in order to avoid purchasing GE seeds unintentionally. Farmer and consumer members of Plaintiffs also rely on state laws requiring public notice, certifications, and instructions on GE seed labels to avoid GE seeds in farming and gardening. Any confusion regarding GE seeds would result in economic, property, vocational, reputational, and/or recreational injury to members who seek to avoid contaminating their farms or gardens with GE seeds.

390. Because of Defendants' unconstitutional vagueness, regulated entities will not be able to receive information they expect and would otherwise greatly value having to do with whether seeds are GE. Farmers, gardeners, grocery stores, retailers, and producers they rely on GE seed labeling are injured because of Defendants' vague prohibition on state laws that "indirectly" relate to whether seeds are GE.

SIXTH CAUSE OF ACTION
***Void for Vagueness* (In the Alternative Violation of the Fifth Amendment)**

391. Plaintiffs re-allege and incorporate by reference the allegations set forth in paragraphs 1 through 390 of this Complaint as if fully set forth herein.

392. The due process protection of the vagueness doctrine applies to constitutional rights and seeks to achieve two main objectives: (1) "to ensure fair notice to the citizenry" and (2) "to provide standards for enforcement [by officials]." *Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 551 (6th Cir.

2007). Statutes or regulations that limit constitutional rights and fail to do so are void for vagueness.

393. The Act and its implementing regulations violate Plaintiffs' First and Tenth Amendment rights as explained above. However in the alternative those same provisions also fail to provide sufficient notice to regulated entities and states as to what terminology and state/local laws are permissible under the Act. These provisions of the final rule are thus void for vagueness under the Fifth Amendment.

394. First, the final rule fails to adequately inform regulated entities about "other claims" they may make that are "consistent with applicable Federal law." The final rule purports to "provide for disclosure of foods that are or *may be* bioengineered to consumers." 85 Fed. Reg. at 65,815 (emphasis added). But the rule prohibits the labeling of foods that "may be bioengineered." 83 Fed. Reg. at 65,827. Further the final rule prohibits the use of "any similar terms," such as "GE" or "GMO" which are permitted in the statute.

395. The rule's vagueness is further intensified by the language stating that "nothing in this subpart will prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law." 7 C.F.R. § 66.118. In other words, the final rule simultaneously prohibits regulated entities from using the "may be" language mandated by the statute and the "similar terms" permitted by the statute, while also allowing these entities to make "other claims . . . consistent with applicable Federal law." In any alternative in which those prohibitions are not themselves violations of the First Amendment, then this contradiction creates unclear standards for regulated entities.

396. The lack of clear standards in the final rule provides insufficient notice to regulated entities regarding which "other claims . . . consistent with federal law" remain permissible to avoid enforcement actions. The absence of clear standards

creates a serious risk that these provisions will be enforced in an arbitrary manner. These provisions of the final rule are thus void for vagueness.

397. Second, the Act's preemption provision, 7 U.S.C. § 1639i(b)—in the alternative that it does not itself violate the Tenth Amendment under Claim 5—is then void for vagueness, because it does not make clear which state or local laws might subject a state or local jurisdiction to an enforcement action, rendering it impossible for jurisdictions to assess their current laws and make changes to avoid enforcement actions.

398. The statute prohibits states and political subdivisions from "directly or indirectly . . . establish[ing] under any authority or continu[ing] in effect as to . . . any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered . . . or was developed or produced using genetic engineering." 7 U.S.C. § 1639i(b). Yet the statute and the final rule fail to identify which state laws identifying GE seeds for purposes of environmental protection are "indirectly . . . relating to" the labeling of GE seeds or whether a food or seed was produced with genetic engineering.

399. Current state laws indirectly related to GE seed labeling could include those identifying GE seeds as part of a certification or public notice process. As described above, Virginia and Washington require the identification of GE seeds through public notice, *See* Va. Code §§ 2.2-5504; Wis. Stat. § 146.60; Vermont and Washington through certification processes which require tagging, labeling, or sealing, *See* Wash. Admin. Code § 16-302-110 (2010); Vt. Stat. Ann. tit. 6, § 614 (2015); and Maine through requiring instructions on labels. *See* Me. Rev. Stat. Ann. tit. 7, § 1052. It remains unclear whether these requirements fall into the Act's vague category of "indirect" regulation "relating to" the labeling of a GE seed.

400. This preemption provision thus provides insufficient notice to states and political subdivisions regarding which state laws and regulations states must

amend to avoid enforcement actions. The absence of clear standards creates a serious risk that this preemption provision will be enforced in an arbitrary manner.

401. The provisions in question are unconstitutional for the reasons stated in the above claims and should be struck in their entirety for the reasons stated in those claims. However, in the alternative, Plaintiffs here request that the Court provide declaratory relief that these provisions of the Act and the final rule are void for vagueness in violation of the Fifth Amendment and sever these portions of the statute and final rule.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court:

a. Adjudge and declare that USDA's final rule decision to allow the use of QR Code disclosure on packages without additional forms of disclosure is contrary to the Disclosure Act, not authorized by the Act, and constitutes a violation of the Act and the APA.

b. Adjudge and declare that USDA's final rule decision to prohibit the use of similar terms "genetically engineered" or "genetically modified" and instead limit any permitted on-package text to "bioengineered" is contrary to the Act and its purpose of informing consumers, and constitutes a violation of the Act and the APA.

c. Adjudge and declare that USDA's final rule decision to completely exclude all bioengineered foods that are highly refined from any disclosure is contrary to the Disclosure Act, not authorized by the Act, and constitutes a violation of the Act and the APA.

d. Adjudge and declare that USDA's restrictions on protected speech stemming from the final rule are contrary to the Disclosure Act, the First Amendment and fail to provide sufficient notice to regulated entities under the Fifth Amendment.

e. Adjudge and declare that the Act's preemption provision regarding GE seed labeling unconstitutionally commandeers state governments and political subdivisions in violation of the Tenth Amendment.

f. Adjudge and declare the Act's prohibitions on commercial speech and seed labeling laws fail to provide sufficient due process notice in violation of the Fifth Amendment.

g. Set aside or vacate the final rule based on Defendants' violations of the Act and APA.

h. Set aside any and all portions of the rule and the Act unlawfully restricting free speech in violation of the First Amendment.

i. Set aside any and all portions of the rule and Act unlawfully commandeering in violation of the Tenth Amendment

j. Set aside any and all portions of the rule impermissibly vague in violation of the Fifth Amendment.

k. Award Plaintiffs their fees, costs, expenses, and disbursements, including reasonable attorneys' fees, associated with this litigation under the Equal Access to Justice Act, 28 U.S.C. § 2412; and

l. Grant such further and additional relief as the Court may deem just and proper.

Respectfully submitted this 2nd Day of October, 2020.

/s/ Meredith Stevenson

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