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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

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.

TOM VILSACK, 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

PLAINTIFFS' MOTION AND MEMORANDUM FOR SUMMARY JUDGMENT

Date: April 21, 2022
Time: 10 a.m.
Courtroom: 11, 19th Floor
Hon. James Donato

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on April 21, 2022, or as soon thereafter as counsel can be heard, 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, will move this Court for summary judgment on all issues raised in their October 2, 2020 Amended Complaint, Dkt. 19.

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GLOSSARY OF ACRONYMS

AMS	Agricultural Marketing Service
APA	Administrative Procedure Act
FDA	Food & Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
GE	Genetically Engineered
GMO	Genetically Modified Organism
PCR	Polymerase Chain Reaction
PPIA	Poultry Products Inspection Act
QR Code	Quick-Response Code
USDA	United States Department of Agriculture

INTRODUCTION

This case is about the public's right to know what they eat and feed their families, and about retailers' rights to provide them that information in a meaningful way. For more than three decades, advocates, including Plaintiffs, fought for the right to know whether the foods on grocery market shelves were produced with genetically engineered (GE) ingredients. These advocates only sought the same transparency already required by sixty-four other countries around the world, including all of the U.S.'s major trading partners. After several states passed GE food labeling laws, Congress finally enacted the National Bioengineered Food Disclosure Act (Disclosure Act or Act) in 2016, creating a national standard. Defendant United States Department of Agriculture (USDA or Agency), charged with implementing the Act, issued the final regulations setting out the National Bioengineered Food Disclosure Standard (Disclosure Standard) in December 2018, with an effective date of next year.[1]

Unfortunately, USDA's Disclosure Standard falls far short of fulfilling the promise of meaningful GE food labeling. Instead, the Disclosure Standard excludes most GE foods from mandatory disclosure, limits the applicable labeling terminology to the obscure "bioengineered," and allows disclosure in a form never before approved in a federal label—electronic Quick Response (QR) codes—that the Agency itself determined would conceal the disclosures from many Americans. If that were not enough, the Disclosure Standard forbids retailers from doing better than the feeble standard USDA set, restricting their constitutional rights to speak clearly and plainly to their own customers about GE foods using familiar means and terms.

The Disclosure Standard's lack of transparency not only erases the past efforts of states but also prevents any future efforts. The Act preempts state laws "directly or indirectly … relating to" whether a food or seed is bioengineered, replacing them with the rules set by the Act and Disclosure Standard. 7 U.S.C. § 1639i(b). Since the Disclosure Act contains no GE seed labeling standards, the Act simply eliminates them. And for GE food labeling, it replaces transparent, on-

[1] Specifically, the Agricultural Marketing Service (AMS), a subset of USDA, issued the Disclosure Standard. Plaintiffs will use USDA or Defendants for clarity throughout.

package labeling of all GE foods with a disclosure standard suffering from so many flaws and loopholes, it is rendered meaningless.

The Disclosure Standard violates the Disclosure Act, the Administrative Procedure Act (APA), and the Constitution in multiple respects. First, the Disclosure Standard is contrary to the text, purpose, structure, and history of the Disclosure Act, rendering it arbitrary and capricious under the APA. Second, the Disclosure Standard violates regulated entities' First Amendment rights to provide disclosure to consumers. Third, the Disclosure Act commandeers regulatory powers reserved to States through overbroadly prohibiting state laws related to GE seed labeling without providing any corresponding federal GE seed labeling standards whatsoever. And fourth, the Disclosure Standard and Act are contrary to the Fifth Amendment because their vague and contradictory language fails to provide notice to regulated entities and states as to what remains permissible, allowing for arbitrary enforcement. Plaintiffs ask this Court to grant summary judgment in their favor, declare the Disclosure Standard invalid, and vacate and remand the rule. Plaintiffs also ask this Court to sever constitutionally infirm provisions of the Disclosure Act and declare them invalid.

RELEVANT STATUTORY BACKGROUND

I. THE NATIONAL BIOENGINEERED FOOD DISCLOSURE ACT.

The Disclosure Act is the first federal law to establish a nationwide system requiring disclosure of GE foods. The Act's purpose is to avoid "misinformation and confusion for consumers," H.R. Rep. No. 114-208, pt.1, at 11 (2015), by setting a nationwide "bioengineered," or GE, food disclosure standard. This mandatory disclosure standard preserves the public's right to know what is in their food and how it is produced. *Id.* at 61 ("Consumers have the right to know what is in their food and how it is grown."); *see also* AR259331[2] (USDA stating the Act's purpose is consumers' right to know).

[2] USDA produced the original Administrative Record with Bates numbering 00000001 to 00445056. *See* ECF No. 44. USDA produced additional documents on August 13, 2021, following Plaintiffs' request, numbered 00445085-108. Citations to those documents are preceded by "AR"

To achieve this purpose of a mandatory labeling standard, Congress directed USDA to "establish such requirements and procedures as the Secretary determines necessary to carry out the standard." 7 U.S.C. § 1639b(a)(2). Once these broad standards for "any bioengineered food and any food that may be bioengineered," *Id.* § 1639b(a)(1), are established, a food may "bear a disclosure that the food is bioengineered *only* in accordance" with the Act's implementing regulations. *Id.* § 1639b(b)(1) (emphasis added).

In passing the Disclosure Act, Congress sought to create a uniform national law, 7 U.S.C. § 1639b(a)(1), "consistent with United States obligations under international agreements." *Id.* § 1639c(a). Congress intended for the Disclosure Act to cover at least as broad of a scope as the existing state labeling laws, 162 Cong. Rec. S4906 (daily ed. July 7, 2016), including specifically for it to cover highly refined foods. 162 Cong. Rec. S4783 (daily ed. July 6, 2016); *see also* 162 Cong. Rec. S4994 (daily ed. July 12, 2016). Congress worried that some state laws would only label some GE products, not others, resulting in a misleading labeling standard. 162 Cong. Rec. S4782 (explaining inconsistencies in state labeling laws). To ensure a broad scope of disclosure, Congress broadly defined "bioengineering" as "a food … that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C. § 1639(1)(A).

The Act further ensures this broad scope by also requiring that USDA establish a process for "other factors and conditions under which a food is considered a bioengineered food." *Id.* § 1639b(b)(2)(C). In contrast the Act only limits the disclosure scope in several express ways: exempting "food served in a restaurant or similar retail establishment" from mandatory disclosure, *id.* § 1639b(b)(2)(G)(i); with regards to meat products, prohibiting a food to be "considered a bioengineered food solely because the animal consumed feed from" a bioengineered source, *id.* §

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followed by the corresponding number. The parties will file a Joint Appendix within two weeks following the completion of briefing.

1639b(b)(2)(A), that is, meat from livestock fed GE grains; as well as prohibiting disclosures for meat from some future GE animals themselves.[3] *Id.* § 1639a(c).

The Act provides three potential disclosure forms: text, symbol, or electronic link. 7 U.S.C. § 1639b(b)(2)(D). But Congress recognized that the unprecedented and controversial electronic "QR" code labeling might not work, so Congress required further research on its efficacy and impacts on consumers and retailers, to analyze, among other things, the "potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." *Id.* § 1639b(c)(1). And if USDA determined in the study that "consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," then Congress required that USDA "*shall* provide additional and comparable options" for accessing the disclosure. *Id.* § 1639b(c)(4) (emphasis added).

The Disclosure Act uses the terms "genetically engineered" and "bioengineered" interchangeably and directs USDA to use "any similar terms" to bioengineered in the implementing regulations. The definition of "bioengineering" includes both "[t]he term 'bioengineering', *and* any similar term as determined by the Secretary." *Id.* § 1639(1) (emphasis added). Elsewhere, Congress requires use of a "similar term" to "genetically engineered." *Id.* § 1639i(b) (preempting state laws labeling foods and seeds as "genetically engineered … which *shall* include such other similar terms as determined by the Secretary of Agriculture," such as "bioengineered") (emphasis added).

Finally, the Act also broadly prohibits States and their political subdivisions from "directly or indirectly" passing laws related to the "labeling of whether a food … or *seed* is genetically

[3] The Disclosure Act also prohibits labeling if the meat product is regulated by Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA) unless the most predominant ingredient of the food would independently be subject to the labeling requirements under the Food, Drug, and Cosmetic Act (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. *See* 7 U.S.C. § 1639a(c)(2).

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.* (emphases added).

FACTUAL AND PROCEDURAL BACKGROUND

I. THE PUBLIC'S CALL FOR GE FOOD LABELING.

Sixty-four countries, including all of the European Union, Japan, South Korea, China, Australia, New Zealand, Russia, India, and other key U.S. trading partners, already have laws mandating GE food labeling. 162 Cong. Red. H4937 (daily ed. July 14, 2016). Although the U.S. approved the first GE crops in the 1990s, AR243917-42, it did not require their labeling. Instead, for over two decades, U.S. consumers demanded their labeling, first in the marketplace, then states, and then in Washington, D.C.[4] Mandatory labeling is necessary to ensure consumers are fully and reliably informed about the food they buy and eat. Labels provide informed consent and prevent consumer deception or misleading labeling by omission. At a time when American unanimity is rare, polls have consistently shown that over 90% of Americans support the mandatory labeling of GE foods. AR101709; AR253122.

Consumers want to know if foods and seeds are produced using genetic engineering for numerous reasons: health, personal, economic, environmental, religious, and cultural.[5] For example, on the health side, many consumers know that the FDA does not independently test the safety of GE foods or require them to be tested.[6] AR243927-30; AR258450; *see also* AR253999; Woodcock Decl. ¶ 4; Witherspoon Decl. ¶ 5; Freese Decl. ¶ 6. That is, FDA does not "approve" GE foods for safety; instead, the FDA merely reviews the industry's test results, and even this is not required, but rather proceeds on a confidential, voluntary basis, if the company chooses to consult with FDA. AR243927-30. Market entry for GE foods is thus based solely on confidential industry research. *Id.* This rightly gives some consumers pause.

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[4] For more detailed background treatment, sections of the Amendment Complaint are also herein cited. *See* Am. Compl. ¶¶ 59-73, ECF No. 19.

[5] Am. Compl. ¶¶ 60-70.

[6] Am. Compl. ¶¶ 60-62.

On the environmental side, Americans now have decades of proof showing that GE crops are at their heart a pesticide-promoting technology: The overwhelming majority of commercial GE crops are genetically engineered by pesticide companies to withstand application of herbicides they also sell.[7] AR252972; AR252998; AR252936-7; Freese Decl. ¶ 8; Woodcock Decl. ¶ 5; Witherspoon Decl. ¶ 4. Consequently, these GE crops have dramatically increased American agriculture's overall pesticide output into our environment, leading to widespread pollution of our waterways and ecosystems, injury to beneficial insects such as pollinators, and harm to soil health.[8] AR174095; AR174110-15; AR252956. Further, the widespread adoption of crops engineered for pesticide resistance has proliferated an epidemic of resistant "superweeds" now covering at least 120 million acres of U.S. farmland.[9] AR252942-44; AR169139. Many people reasonably want to align their food choices with their environmental values.

Juxtaposed against these facts, the U.S. public has peeled back the pesticide industry's false hype about GE crops: Despite billions of dollars in research and nearly three decades of commercialization, no GE crops are commercially produced to increase yields, reduce world hunger, AR253002-6, or mitigate climate change.[10] AR252989-91. Rather, agrochemical companies have largely succeeded in engineering these crops to be resistant to the companies' own products—pesticides—to reap huge profits. AR252974-75; AR253015-18. Overall, GE crops are a pillar of a consolidated, patented industrial agriculture system that has hurt American farmers.[11]

Finally, 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 produced with genetic engineering, or not. AR258452. Requiring meaningful and accurate disclosure of whether foods are genetically engineered reduces this consumer confusion and deception.

[7] Am. Compl. ¶ 63.
[8] Am. Compl. ¶¶ 63-67.
[9] Am. Compl. ¶ 67.
[10] Am. Compl. ¶ 68.
[11] Am. Compl. ¶¶ 63-67.

These myriad concerns spurred calls for GE food labeling decades ago. As far back as in 2000, some of Plaintiffs' members submitted thousands of letters to Congress. Simpson Decl. ¶ 6. In 2007, without any federal or state action, some Plaintiffs helped start the "non-GMO Project" private GE absence label. Squire Decl. ¶ 3. On the GE presence disclosure side, in 2011, a rulemaking petition by some Plaintiffs calling for mandatory federal labeling garnered 1.4 million comments in support, but again spurred no federal agency action.[12] Spector Decl. ¶ 11.

In the absence of federal action, public demand prompted states to fulfill their role as the "laborator[ies]" of our democracy[13] and introduce their own GE food labeling laws.[14] AR248901-2. Between 2013 and 2015, more than thirty states introduced bills. AR260301; AR243453. Connecticut and Maine passed laws in 2013, albeit with clauses tying their effective dates to the passage of other state laws. AR258470-73. In 2014, Vermont became the first state to pass a stand-alone law. AR258440-48; *see also* AR258468-69.

These labeling laws set high standards for transparency: Each required the well-known, longstanding terminology, GE/GMO; required the labeling all GE foods, including highly refined products; and required on-package text labeling. *See* AR258435-73. In response, numerous major food companies, including Campbell Soup Company, AR254456, Coca Cola, AR181584-86, Danone, AR180964-69, AR254457, Mars, AR180759-63, and Unilever, AR178649-57, began labeling their foods produced with GE ingredients.

This labeling movement did not only include foods: State legislatures also passed laws identifying GE seeds in the absence of federal regulation.[15] *E.g.*, Vt. Stat. Ann. tit. 6, § 644 (Vermont seed labeling 2003); Va. Code Ann. tit. 3.2, § 4008 (Virginia seed labeling 2012). Other states require GE seed certification, which results in labeling, tagging, or sealing. *E.g.*, Wash.

[12] Am. Compl. ¶ 71.
[13] *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).
[14] Am. Compl. ¶¶ 71-72.
[15] Am. Compl. ¶¶ 340-46.

Admin. Code § 16-302-170 (2010); Vt. Stat. Ann. tit. 6, § 611 (2015). Still other states identify and regulate GE seeds through public notice requirements and permitting.[16]

II. USDA'S FINAL RULE.

In enacting the Disclosure Standard, USDA ignored the transparent GE labeling requirements of hard-fought state laws. Instead, USDA promulgated a final rule that mirrored the proposed draft rule's most controversial provisions,[17] despite broad opposition.[18] 83 Fed. Reg. 65,814 (Dec. 21, 2018).

First, regarding QR code disclosures, USDA had no choice based on its own study but to conclude that QR codes would not disclose information in a meaningful way. The QR code study confirmed what Congress suspected: QR codes are *not* a feasible option to ensure disclosure for all Americans. *See* AR250043-250118. The study concluded that "key technological challenges"—such as lack of technical knowledge, lack of association of digital links with food information, and lack of infrastructure— "prevented *nearly all participants* from obtaining the information through electronic or digital disclosure methods." AR250046 (emphasis added). Among other critical findings, the study found that all consumers failed to associate QR codes with food information, AR250046; no stores were equipped with scanners for those without smart phones, AR250091; 85 percent of consumers struggled with software apps, AR250046; the majority of small retailers did not provide in-store Wi-Fi, *id.*; and nearly one quarter of Americans lacked a smart phone.

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[16] Am. Compl. ¶¶ 344-45.

[17] These controversial provisions included standalone QR code disclosures, 83 Fed. Reg. 19,860, 19,875 (May 4, 2018); Am. Compl. ¶¶ 84-87, terminology limited to only "bioengineered food" or "bioengineered food ingredient," 83 Fed. Reg. at 19,871; Am. Compl. ¶¶ 148-150, and two "positions" for highly refined GE foods, one in which disclosure is mandatory and one in which it is not. 83 Fed. Reg. at 19,862-63; *see also* Am. Compl. ¶¶ 245-260.

[18] Numerous major food companies commented that they prefer using the familiar terms, GE/GMO, to ensure consumer understanding. Am. Compl. ¶¶ 151, 190-92; AR181220; AR180761. Numerous major companies disagreed with QR code disclosures, *id.* ¶¶ 104-105; AR227418-19; AR178908-9; AR227418-19; AR178933, and phone text message disclosures. *Id.* ¶¶ 116-17; AR229328; AR233590; AR183566. Many also opposed excluding highly refined foods due to cost of testing, *id.* ¶¶ 229, 265; AR234545-6; AR183323-4; AR174742-43, and consumer expectation. *Id.* ¶¶ 226-28; AR17672; AR181585; AR180966.

AR250053. As a result, USDA reached the well-supported conclusion 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.

But USDA nonetheless still allowed QR codes alone, with no additional disclosure method required on the same package. *See* 7 C.F.R. § 66.106 (electronic disclosures). Instead, to "remedy" the failings found by the study, USDA allowed for phone text message disclosures as a *separate* option. 83 Fed. Reg. at 65,828-29; *see* 7 C.F.R. § 66.108 (phone text message option); § 66.100(b)(1)-(4) (adding phone text message option to other options of on-package text, on-package symbol, and electronic or digital). That is, companies can still use QR codes *alone*. USDA did not explain how this fixes the problems its study found, and that Congress required to be remedied. USDA's sole stated rationale is that the Act required a "comparable option to access the BE disclosure, not that the option be comparable to on-package labeling." 83 Fed. Reg. at 65,856.

Similarly, despite again widespread opposition during the comment period, the Disclosure Standard also restricts the acceptable labeling terminology to "bioengineered food," or, for multi-ingredient foods, "contains a bioengineered food ingredient." *Id.* at 65,827; 7 C.F.R. § 66.102(a)(1)-(2). It prohibits the widely used terms, GE and GMO, allowing only the new term entirely foreign to shoppers and stakeholders. 7 C.F.R. § 66.102 ("A text disclosure *must bear the text as described in this section*.") (emphases added); *id.* (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as permissible disclosure options).

USDA's sole prohibition rationale is its "belief" that bioengineered "clearly and accurately describes the technology and provides consumers with the information they desire." 83 Fed. Reg. at 65,852. USDA made no effort to address the data on use and consumer confusion presented to it, nor offered any explanation of how the restriction complies with the Act's requirement that the definition of "bioengineering" apply to both "bioengineered" *and* "similar terms." 7 U.S.C. § 1639(1).

The final rule also prohibits any "may be" labeling, despite the Act's mandate that USDA establish a disclosure standard "with respect to any bioengineered food and any food that *may be*

bioengineered," 7 U.S.C. § 1639b(a)(1) (emphasis added); *compare* 83 Fed. Reg. at 65,827 ("The 'may be bioengineered' disclosure cannot be used.").

Not only did USDA restrict *how* consumers can access the information, it also simply cut out most GE foods from the *scope* of required disclosure by removing all "highly refined" GE foods. The final rule claims, with no basis in the text and contrary to the law's legislative history, that the Agency "does not have the authority to require BE disclosure for [highly refined] foods regardless of the number of food products that may be affected." 83 Fed. Reg. at 65,836. USDA asserts that foods knowingly produced with GE ingredients no longer "contain" GE material after the refining process because certain unspecified testing methods do not "detect" it. *Id.* at 65,816. USDA thus created a regulatory definition that "foods with undetectable modified genetic material are not bioengineered foods" and do not require disclosure. 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 grafting on "*provided that* such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.") (emphases added).

USDA provided no explanation for how it arrived at its conclusion that foods that "contain" GE material must also contain *detectable* GE material. USDA also did not square its narrow classification and wholesale exclusion of thousands of GE foods with the Act's mandate that the Disclosure Standard encompass not just "any bioengineered food" but also foods that "may be bioengineered." 7 U.S.C. § 1639b(a)(1). USDA failed to even provide a set testing method to determine if foods contain detectable GE material. While the Disclosure Standard allows for regulated entities to use testing records to prove the absence of detectable GE material, the Agency failed to acknowledge the myriad testing methods available, each with varying degrees of sensitivity to detect GE material, 83 Fed. Reg. at 65,817; 7 C.F.R. § 66.9(a)(3), resulting in the potential for companies to use less sensitive tests and an inconsistent labeling standard.

The Disclosure Standard also places prohibitions and restrictions on voluntary GE food disclosures beyond the limited scope of USDA's new standard. 83 Fed. Reg. at 65,830; 7 C.F.R.

§ 66.3(a)(2). The section has two parts. *See* 7 C.F.R. § 66.116. First, "exempt entities," such as restaurants and small manufacturers, may voluntarily disclose using only the same standards for regulated entities, meaning BE text, symbol, QR code, or phone text message. *Id.* § 66.116(a)(1)-(4); 83 Fed. Reg. at 65,830, 65,858. Second, regulated entities, including retailers and grocers, can voluntarily label highly refined foods or certain other exempted foods, *see* 7 C.F.R. § 66.116(b), but only using the text, "derived from bioengineering" or "ingredients derived from a bioengineered source"; a symbol stating "derived from bioengineering"; a QR code electronic disclosure; or a phone text message disclosure. *Id.* § 66.116(b)(1)-(4). The Disclosure Standard also excludes from any labeling otherwise exempted foods, like meat and dairy derived from livestock fed GE feed. *Id.* § 66.116(b); 83 Fed. Reg. at 65,830, 65,858.

The Disclosure Standard does not mention GE seed labeling. Seed manufacturers, importers, and retailers do not fit in USDA's definition of "regulated entities" as "the *food* manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures." 7 C.F.R. § 66.1 (emphasis added). Nowhere does the codified section mention seeds.[19]

Despite all the above restrictions on speech and the Act's requirement that GE foods must "bear a disclosure that a food is bioengineered *only* in accordance" with the Act's implementing regulations, 7 U.S.C. § 1639b(b)(1) (emphasis added), the Disclosure Standard inexplicably states that "[n]othing 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 does USDA explain this inconsistency, or what it means by "other claims."

STANDARD OF REVIEW

Summary judgment is appropriate if there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). This challenge is reviewed under the APA standards of judicial review for agency actions, pursuant to which courts are to "hold unlawful and set aside"

[19] The only seed mention is in the preamble quoting the preemption provision. 83 Fed. Reg. at 65,870-71.

decisions that are, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or adopted "without observance of procedure required by law." 5 U.S.C. § 706(2). In determining whether an action is "arbitrary and capricious," courts evaluate 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 v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168 (1962)). An agency 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.*

"When the Government restricts speech, the Government bears the burden of proving the constitutionality of its actions." *U.S. v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 816 (2000); *Phila. Newspapers, Inc. v. Hepps*, 475 U.S. 767, 777 (1986) ("[I]t has long been established that the government cannot limit speech protected by the First Amendment without bearing the burden of showing that its restriction is justified.").

ARGUMENT

I. THE DISCLOSURE STANDARD RESTRICTS ACCESS TO GE FOOD DISCLOSURES IN VIOLATION OF THE DISCLOSURE ACT AND THE ADMINISTRATIVE PROCEDURE ACT.

USDA's final rule ignores virtually all the Disclosure Act's statutory provisions designed to ensure disclosure of all GE foods for all Americans. Instead, USDA's Disclosure Standard strips away the hard-fought labeling requirements of States—requirements Congress sought to encompass—replacing them with inaccessible digital disclosures, unfamiliar terminology, and an

extra-statutory definition of "bioengineered food." USDA's flawed rationales for doing so violate the plain language of the Disclosure Act and are arbitrary and capricious under the APA.[20]

A. The Rule's QR Code Disclosure Option Violates the Plain Language of the Disclosure Act and Is Arbitrary and Capricious.

The Agency's decisions to choose phone text messaging as its "additional and comparable" option, and to still allow standalone QR Code labeling, were arbitrary and capricious, contrary to the APA and the Act. Congress mandated "additional and comparable options" to QR codes for the purpose of "access[ing] the bioengineered disclosure" if the Secretary finds "that consumers, while shopping, would not have sufficient access." 7 U.S.C. § 1639b(c)(4). In doing so, Congress plainly required USDA to provide "additional and comparable options" to *remedy* the issue of inaccessible QR codes. USDA's interpretation that Congress intended only for another inaccessible phone text message option—separate and apart from the standalone QR code option the Agency itself found insufficient—not only defies logic but violates the Act's plain language.

First, standalone phone text messages do not provide an "additional" option because the Disclosure Standard does not require them *in addition to* QR codes *on the same package*. Read in context, Congress plainly requires "additional" options to QR codes for the purpose of "*access[ing]* the disclosure" if the Secretary finds QR codes inadequate. *Id.* (emphasis added). To interpret "additional" as still allowing USDA's standalone QR code option would improperly render both the requirement of "additional and comparable options," and the study requirement itself as surplusage. *See* A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 174 (2012) ("[E]very word and every provision is to be given effect" and "[n]one should needlessly be given an interpretation that causes it … to have no consequence.").

[20] Plaintiff member organizations and their members have standing because their members' economic, health, and environmental interests and rights to receive the disclosure information are injured, and will continue to be injured, by USDA's Disclosure Standard. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 342-43 (1977); *see* Youngblood Decl.; Gordon Decl.; Larry Decl.; Cook-Littman Decl.; Spector Decl.; Witherspoon Decl.; Glover Decl.; Woodcock Decl.; Freese Decl.; Buxton Decl.; Allen Decl. (filed concurrently).

But even if "additional" were ambiguous, USDA's interpretation of "additional" as "in addition to" standalone QR codes constitutes quintessential arbitrary and capricious rulemaking. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. The interpretation blatantly ignores the findings of USDA's own study, AR250043-250118, as well as other evidence revealing the inaccessibility of QR codes, especially for poor and minority communities, which more frequently have cut off service, AR250785, and run out of data.[21] AR250786.

USDA understood these issues. It explicitly "determined that consumers would *not* have sufficient access to the bioengineering disclosure through *only* electronic or digital means." 83 Fed. Reg. at 65,828 (emphases added). USDA should have then prohibited standalone QR codes and required an "additional" option *on the same package* as QR codes. Only this remedy would give voice to Congress's mandatory study, its requirement for an "additional" option, 7 U.S.C. § 1639b(c)(4), and the Secretary's determination. Phone text messages cannot fulfill this requirement, however, because the Disclosure Act *already* requires that all QR codes be accompanied by a telephone number, rendering them not "additional." 7 U.S.C. § 1639b(d)(4).

Second, USDA's interpretation that Congress did not require an option "comparable" to on-package labeling, 83 Fed. Reg. at 65,856, violates the Act. Again, the Act requires "comparable options" for purposes of "*access[ing] the disclosure*." *Id.* § 1639b(c)(4). It would defy logic for Congress to commission this study on QR code accessibility, require the Secretary to base a finding on it, then "remedy" it with another option "comparable" to insufficient QR codes. The proper comparator is that which *is sufficient* to provide consumers the information intended (on-package disclosure). That result remedies the problem and makes the mandated study meaningful.

And the record shows that phone text messaging is *not* comparable to on-package disclosures: It suffers from many of the same flaws as QR codes. Phone text messaging disadvantages the same population groups as the QR code option: poor people, people who live in rural areas, and older people.[22] AR250228-33. With text-messaging, consumers still need a charged

[21] *See* Am. Compl. ¶¶ 79-83, 88-105.
[22] Am. Compl. ¶ 109

cellphone with text messaging capabilities and good service.[23] AR250081; AR250096; AR250099. But poor people, minorities, rural communities, and older citizens are less likely to own cellphones, AR250229-30, more likely to have cellular service cut off, AR250785, and less likely to have reliable cellular service.[24] AR250096; AR250047, 250100. Without service for these communities, text messaging for GE information is not a feasible alternative for the same reason QR codes are not a feasible option in the first place: lack of technological access. Moreover, as with QR code scanning, the undue burden of texting for each and every product during the limited time most people have to go food shopping is well-established in the record. AR250080-1; AR445093; Glover Decl. ¶ 8; Woodcock Decl. ¶¶ 6-7. It vitiates Congress's intent for USDA to "remedy" a known problem with a new measure that shares similar problems with what was found insufficient. Rather, what gives meaning to Congress's study and "additional and comparable options" mandate is additional disclosure for QR code-labeled products comparable to the other accessible disclosure options provided by statute: on-package text and symbol disclosures.

Accordingly, USDA's "solution" to the problem it admits is neither "additional," nor "comparable," and is thus arbitrary and capricious, contrary to the APA and the Act.

B. USDA's Prohibition of Terms Other Than "Bioengineering" Ignores Disclosure Act Commands.

As with its duty to provide "additional and comparable" disclosure options, USDA further ignores Congress's plain language requirement to use both "bioengineered" *and* similar terms in the Disclosure Standard. It is true, of course, that Congress mandated the term "bioengineered" in creating the Disclosure Standard. But in so doing, Congress also made plain that the Disclosure Standard must include *both* the terminology "bioengineered" *and* "any similar term, as determined by the Secretary" to refer to "a 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."

[23] Am. Compl. ¶ 108.
[24] Am. Compl. ¶ 110.

7 U.S.C. § 1639(1). The use of "and" makes plain that the Disclosure Standard must include both. *See* Scalia & Garner at 116 (the conjunctive canon: "*And* joins a conjunctive list").

Yet nowhere in the Disclosure Standard does USDA allow for "bioengineered" *and* "any similar term." Instead, USDA *prohibits* the use of similar terms, without so much as mentioning this requirement. 7 C.F.R. § 66.100(b) ("If a food must bear a bioengineered food disclosure under this part, the disclosure must be in one of the forms described in this paragraph."); *id.* § 66.102 ("A text disclosure must bear the text as described in this section."); *id.* (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as permissible disclosure options). That is, labeling such foods with the similar terms "genetically engineered" or "genetically modified" or "produced through genetic engineering" is not permitted. In doing so, USDA yet again improperly rendered an Act command mere surplusage.

USDA's prohibition on the similar terms, GE and GMO, is contrary to law and arbitrary and capricious for numerous reasons. First, the prohibition ignores the "similar terms," GE and GMO, provided in the Act itself. Congress repeatedly used the terms genetically engineered and GMO throughout the statute interchangeably with "bioengineered." *See* 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"); *accord* 7 U.S.C. § 1639c(c) (grouping together "'not bioengineered', 'non-GMO', or any other similar claim"); *see supra* at 4. The very definition of "bioengineered" also makes plain Congress's stance: food that "contains *genetic* material that has been *modified* through in vitro recombinant deoxyribonucleic acid (DNA) techniques." *Id.* (emphases added). But USDA still refuses to recognize "GE" and "GMO" as "similar terms."

Second, USDA's current prohibition starkly departs from its past policy. Just three years prior, USDA declared that "using 'GMO/GE' is the official approach and the policy approach of our Department as a whole." AR238654. USDA firmly required the use of GE and GMO in its Process Verified Program (PVP) for verifying companies' claims on the absence of GE ingredients because only these terms would ensure public recognition, as required by the Plain Writing Act of

2010, Executive Order 13563, and associated execute branch directives. AR238656-57. USDA described the term GMO as "permeat[ing] American culture" and "nearly universally utilized, understood and communicated by all American journalists, broadcasters, public officials, and throughout culture and the public at large." AR238657.

USDA also continues to use GE/GMO elsewhere. For example, USDA's subagency FSIS uses the terms, bioengineered, GE, and GMO, interchangeably in its guidance for labeling claims under meat labeling laws. AR445096-97. USDA also uses GE in its GE plant regulation under the Plant Protection Act. *See* 7 C.F.R. Part 340. Even in this very rulemaking, USDA used GMO on its website *until at least July of 2017* and submitted to the U.S. Patents and Trademark office at least one disclosure symbol that was "GMO" in a circle. *See* Stevenson Decl. ¶ 3, Ex. A; AR238739-40. In May 2017, USDA admitted it "could view" GMO as "similar" due to consumers' familiarity and the "longstanding" use of GMO by the government and scientific community. AR242955.

When an agency changes its position, it must (1) "display[ ] awareness that it is changing position," (2) show "the new policy is permissible under the statute," (3) "believe[ ]" the new policy is better, and (4) provide "good reasons" for the new policy. *Organized Vill. of Kake v. USDA*, 795 F.3d 956, 966 (9th Cir. 2015) (quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)). When the new policy "rests upon factual findings that contradict those which underlay its prior policy," an agency must provide "a reasoned explanation … for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Fox*, 556 U.S. at 515-16.

USDA's 180-degree reversal fails all four factors enumerated under *Kake* and *Fox*. USDA's only explanation is its newfound "belie[f]" that "bioengineered" "clearly and accurately describes the technology and provides consumers with the information they desire." 83 Fed. Reg. at 65,852. But USDA fails to even explain how this new term—never before used in food labels—will "clearly" provide information to consumers, let alone provide any "good reasons" for its reversal of policy or any reason "bioengineered" is better. *Kake*, 795 F.3d at 966; *Fox*, 556 U.S. at 515-16. Instead, USDA contradicts its own assertion that bioengineered communicates "clearly" by admitting it will need to "engage in outreach and education to provide information about the new disclosure

term." 83 Fed. Reg. at 65,852. This brief explanation fails to show any awareness that its prohibition on GE/GMO represents a change in position, or, as discussed *supra*, how prohibiting GE/GMO fulfills the statute's mandate to provide "similar terms." *Kake*, 795 F.3d at 966.

Third, USDA's explanation not only reverses its prior policy, but cuts against the weight of evidence. The record makes plain that GE/GMO has served as the prominent terminology used by federal agencies, scientists, the marketplace, and states over the past two-plus decades.[25] *E.g.* AR258435-39, AR258440-48, AR258470-73 (state laws and bills). The scientific community, similarly, uses GE/GMO in the context of food, with the Committees of the National Academy of Sciences seldom or never using "bioengineered." AR243582-243835; AR251980-252586. FDA, like USDA itself elsewhere, *equates* the terms "genetic engineering" and "bioengineering" to both describe "modern biotechnology," AR25541-22, and encourages the use of not just "not bioengineered," but also "not genetically engineered," and "not genetically modified through the use of modern biotechnology." AR255424. Manufacturers, too, have only labeled foods using the terminology GE/GMO,[26] and many seek to continue.[27] AR180760-61; AR181220.

In sharp contrast, numerous record studies, research, and comments confirm that consumers do not recognize the term, bioengineered. AR233475-77. For example, 2017-2018 research showed an average of over six hundred thousand searches for GMO, fewer than eighty thousand for "bioengineered," and *none* for "bioengineered food" or "BE food." AR229213-16. Unsurprisingly, then, Campbell Soup Company determined after testing nine labels that consumers understand GMO, while terms like "bioengineered" confuse consumers. AR254518-19. The vast majority of consumer comments agreed that GE and GMO plainly communicate the disclosure, while bioengineered misleads and confuses them.[28] AR254476-77; AR95879-80; AR17667; 178749-50; Glover Decl. ¶ 13; Woodcock Decl. ¶ 10; Buxton Decl. ¶ 13. USDA's decision to nevertheless prohibit GE/GMO and its failure to grapple with the public's lack of

[25] *See* Am. Compl. ¶¶ 153-197 (describing widespread use of GE and GMO).
[26] Am. Compl. ¶ 188.
[27] Am Compl. ¶¶ 194-97.
[28] Am. Compl. ¶¶ 191-92.

understanding of bioengineered constitutes arbitrary and capricious agency action in violation of the APA. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

C. The Rule's Exemption for Highly Refined Foods Is Contrary to the Disclosure Act Because the Act Requires Disclosure of "Any Bioengineered Food."

USDA's Disclosure Standard is also contrary to law because USDA unlawfully cabins its authority over "any bioengineered food *and* any food that may be bioengineered," 7 U.S.C. § 1639b(a)(1) (emphasis added), by exempting highly refined foods from disclosure. The Disclosure Act contains two express disclosure exemptions, for "food served in a restaurant or similar retail establishment," *id.* § 1639b(2)(G)(i), and for animals that "consumed feed produced from" a bioengineered source. *Id.* § 1639b(b)(2)(A). Yet, even though the Act nowhere mentions "highly refined" foods, USDA exempts them as well. 83 Fed. Reg. at 65,816. In so doing, USDA created a purportedly meaningful disclosure standard for a class of foods while *exempting nearly seventy percent* of those foods from any disclosure.[29] AR233209; AR233464. Its refusal to require labeling of all GE foods is contrary to law and arbitrary and capricious.

First, the Disclosure Act makes plain that USDA "shall" develop a disclosure standard for "any bioengineered food *and* any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1) (emphasis added); Scalia & Garner at 116 ("*And* joins a conjunctive list"). Specifically, "bioengineered food" includes food "that *contains* genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C. § 1639(1)(A) (emphasis added). Read together, 7 U.S.C. § 1639b(a)(1) and § 1639(1)(A) mandate that USDA develop a disclosure standard for *both* food that "contains" GE material and food that *may* "contain" GE material. Scalia & Garner at 167 (whole-text canon). To make this broad intended scope even more plain, the Act also mandates that USDA expand which foods may be considered "bioengineered" through establishing a process for "other factors and conditions under which a food is considered a bioengineered food." 7 U.S.C. § 1639b(b)(2)(C).

[29] Am. Compl. ¶¶ 211, 224.

But again, USDA refused to abide by the textual instructions Congress included in the Act. Instead, USDA claims, with no textual basis, that the Agency "does not have the authority to require BE disclosure for [highly refined] foods," 83 Fed. Reg. at 65,836, and that Congress's mandate to establish "other factors and conditions" perversely requires USDA to "*limit[ ]* the scope" of disclosure. *Id.* at 65,836 (emphasis added). Neither interpretation can stand. The Disclosure Act mandates the labeling of *any* food that "contains" GE material, 7 U.S.C. § 1639(1)(A), and food that even "may" contain GE material. 7 U.S.C. § 1639b(a)(1). And USDA must broaden this scope further by establishing "other factors and conditions under which a food *is* considered a bioengineered food," 7 U.S.C. § 1639b(b)(2)(C) (emphasis added), not "other factors and conditions under which a food is [*not*] considered a bioengineered food." Combined, these provisions plainly require that USDA include GE foods that contain and even may contain highly refined GE ingredients.

USDA supports its extra-statutory exemption through its rationale that highly refined foods do not contain "detectable" GE material based on unspecified "common testing methods." 83 Fed. Reg. at 65,834. *But the Act nowhere uses the term "detectable."* Instead, the Act mandates disclosure for *any* food that "contains" GE material or *may* "contain" GE material. The mere fact that a current "common testing method" does not detect GE material in no way demonstrates that the food does not actually *contain* that GE material.

USDA's exclusion of highly refined foods also runs counter to its own prior interpretation and the Act's legislative history. On July 1, 2016, USDA's General Counsel, Jeffrey Prieto, sent a letter to Congress interpreting the Act as granting authority to include 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). And Congress agreed, explicitly stating that the Disclosure Act provides authority to USDA to cover refined sugars and other processed products. 162 Cong. Rec. S4783 (daily ed. July 6, 2016) (Disclosure Act "provides authority to the USDA to label refined sugars and other processed products."); 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (Act's scope "does not prohibit the

labeling of highly refined products"). Congress knew full well most GE food products were these highly refined processed foods and that covering them was vital. Sponsors of the bill explicitly reassured other Congressional members that "[T]his bill gives USDA broad authority to label GE products," including those referenced in USDA's July 1, 2016, letter, such as highly refined foods. 162 Cong. Rec. S4906, S4845 (daily ed. July 7, 2016).

Second, even if the plain text was ambiguous, USDA's exclusion of highly refined foods from mandatory disclosure is contradicted both by its own assertions and the weight of evidence. USDA's own guidance admits that highly refined foods nonetheless *still* "contain" GE material.[30] Specifically, USDA's guidance[31] concedes that highly refined foods *can* contain currently undetectable GE material and explains that "a future test may detect modified genetic material in a highly refined food or ingredient that current tests do not."[32] Thus even if the scope was limited by "contain"—as discussed above, it is not, but rather includes "may contain" and other factors that USDA could set—what is "contained" is not synonymous with what is "detected" by a common test. A house may contain mold, whether or not it is detected by the eyes of the homeowner.

The record leaves no doubt that many highly refined foods "contain" GE material, even when not detectable. Numerous studies demonstrate newer, more sensitive methods that detect GE material in previously "undetectable" highly refined foods.[33] For example, a frequently cited paper on the absence of DNA in soybean oil, AR243380-84, was contradicted just two years later by the same research team. AR243385-89.[34] Many other scientists have also detected DNA in

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[30] Am. Compl. ¶¶ 261-63.

[31] In July 2020, USDA issued a guidance to assist manufacturers, the 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), and a Frequently Asked Questions document to answer the public's questions about these processes. *Guidance to Ensure Acceptable Validation of a Refining Process*. *See* USDA, *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process* (July 2, 2020), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcessValidation.pdf.

[32] *Id.*

[33] *See* Am. Compl. ¶¶ 231-240.

[34] USDA cites the former but ignores the latter paper in the final rule. *See* 83 Fed. Reg. at 65,834.

refined oils like soybean oils, AR244044-50, and commercial sunflower and maize oils. AR243943-47. Sensitivity is continually increasing. *E.g.*, AR243883-93; AR243943-47.

This wide testing sensitivity range creates a major loophole.[35] By avoiding newer, more sensitive technologies, regulated entities could evade disclosure indefinitely. A manufacturer could, for example, detect GE material using one polymerase chain reaction (PCR)-based detection method, then try different methods until finding one that does not detect GE material. Surely this is not what Congress intended in requiring disclosures for any foods that "contain" GE material *and* those that "may contain" it. Such a loophole violates the Act's purpose of providing information to consumers.

The record also belies USDA's explanation that only a "future test" may detect GE material that "current tests do not," 83 Fed. Reg. at 68,834, and only *then* may disclosures become necessary. Rather, differing sensitivities of *existing* methods virtually ensure that GE material will be detected and labeled in some products but not in other comparable products, depending only on the respective testing methods, as soon as the Disclosure Standard takes effect. For example, USDA's guidance states that PCR "is the most widely used and commercially accepted test method,"[36] but fails to distinguish the plethora of different PCR-based tests that already exist, some which detect GE material at levels that others cannot.[37] This broad detection range creates an arbitrarily shifting disclosure standard.

Third and finally, the record overwhelmingly indicates that what matters to people—the reason they demanded labeling for decades—is the broader impacts on farmers and the

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[35] *See* Am. Compl. ¶¶ 231-240.

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

[37] For example, while a limit of detection of 0.1 percent was once common, AR244007-16, scientists recently developed a real-time PCR screening with a sensitivity over ten-fold greater: < 0.01 percent for several GE corn products. AR243232-40. Current methods have limits of detection all the way down to 0.005 percent, or 20 times more sensitive than many PCR tests not long ago. AR243461-69.

environment of GE crop systems.[38] *E.g.*, AR260341; AR251209; AR234589; AR248831. They want to know if foods are produced using pesticide-promoting, GE crop systems, not whether a test can detect transgenic DNA in the final product. *Id.*; *see also* Glover Decl. ¶ 6; Woodcock Decl. ¶ 5; Freese Decl. ¶¶ 7-9. They demand labeling to give them a choice against an agricultural system they deem harmful,[39] just as other food system information—like organic, fair trade, or animal welfare labels—enables consumers to choose between agricultural production systems.

USDA acted contrary to law in looking only to the testing results of end food products and ignoring how they were created. Regardless of final product test results, USDA excluded foods that knowingly contain GE ingredients. Nothing in the statute or record supports that limitation.

II. THE DISCLOSURE ACT AND DISCLOSURE STANDARD ARE CONSTITUTIONALLY INFIRM.

A. Under the First Amendment, USDA May Not Prohibit Plaintiffs' Truthful, Non-Misleading Commercial Speech.

The Disclosure Act and Disclosure Standard also unconstitutionally ban Plaintiffs' protected commercial speech.[40] Defendants must justify any such prohibitions under the Supreme Court's *Central Hudson* test, but Defendants make virtually no attempt to do so, nor can they.

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[38] Am. Compl. ¶¶ 63-67.

[39] Though because the bioengineered label itself is (or is supposed to be) entirely neutral, it also enables anyone to support GE food production systems.

[40] Plaintiff retailers have standing to challenge speech restrictions under the First Amendment because they intend to engage in speech prohibited under the Disclosure Standard. *Culinary Workers Union, Local 226 v. Del Papa*, 200 F.3d 614, 618 (9th Cir. 1999) (All a plaintiff must do to demonstrate injury-in-fact in a First Amendment case is "allege that [it has] been 'threatened with prosecution, that a prosecution is likely, or even that a prosecution is remotely possible.'"); *LSO, Ltd. v. Stroh*, 205 F.3d1146, 1154–55 (9th Circ. 2000) (It is "sufficient for standing purposes that the plaintiff intends to engage in 'a course of conduct arguably affected with a constitutional interest' and that there is a credible threat that the challenged provision will be invoked against the plaintiff."); *Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1094 (9th Cir. 2003) ("[I]n the First Amendment-protected speech context, the Supreme Court has dispensed with rigid standing requirements."); *see* Squire Decl.; Lewis Decl.; Simpson Decl. Customers of Plaintiff retailers have standing because when there is a right to disseminate commercial information, their customers have a reciprocal "listeners'" right to receive the information. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976); *Thunder Studios, Inc. v. Kazal*, 13 F.4th 736, 743 (9th Cir. 2021); *see* Bragman Decl. ¶ 4; Bialic Decl. ¶ 3.

1. The Disclosure Standard Restricts Commercial Speech and Is Subject to Review Under *Central Hudson*.

The Disclosure Act and Standard restrict Plaintiff retailers, who, but for the limitations explained above, intend to improve on the overly narrow and misleading standard USDA set for their customers. For products *within* the narrow scope, USDA flat out prohibits the well-established terminology—"produced with genetic engineering," "genetically engineered," and "GMO"—that Plaintiffs seek to use in their stores. 7 C.F.R. § 66.102; 7 U.S.C. § 1639b(b)(1). This prohibition extends to Plaintiffs' shelf tags, in-store displays, and bin signs "accompanying" food products, 7 C.F.R. § 66.1, which Plaintiffs have used and seek to use to inform customers about GE foods. Plaintiff PCC Natural Markets, for example, had detailed plans six years in the making to label all GE foods in its stores that it had to freeze because of the new federal scheme. Simpson Decl. ¶¶ 7, 12, 14-16. Plaintiff Good Earth provided shelf tags labeling products in the store as "genetically engineered" since 2011 and would like to continue. Squire Decl. ¶ 4, 17-18.

The speech prohibition also runs to the products USDA has *refused to include* in the mandatory standard, extending to voluntary disclosures of "highly refined" foods as well as foods prepared in Plaintiffs' bakeries, cafés, and delis. 7 C.F.R. § 66.116(b) (limiting voluntary disclosures of highly refined foods to "derived from bioengineering"); *Id.* § 66.116(b)(1)-(4) (limiting all other voluntary text disclosures to "bioengineered"). If a bottle of Coke is so "highly refined" that the GE sugar used to produce it cannot be detected with a certain test, Plaintiff retailers know their customers still want to know that it was produced with genetic engineering. Squire Decl. ¶ 14; Simpson Decl. ¶ 18; Lewis Decl. ¶ 17. And Plaintiff Good Earth would like to voluntarily disclose the GE ingredients in bakery and café items if necessary. Squire Decl. ¶ 9. Yet again, the standard chills their speech.

The Disclosure Standard even attempts to prohibit a phrase expressly mandated in the statute, which several Plaintiffs sought to use: "may be bioengineered." 83 Fed. Reg. at 65,827 ("The 'may be bioengineered' disclosure cannot be used."); *see* 7 U.S.C. § 1639b(a)(1) (mandating disclosures for "any … food that may be bioengineered"); Squire Decl. ¶ 16; Simpson Decl. ¶ 19; Lewis Decl. ¶ 22. This prohibition prevents Natural Grocers from providing in-store displays for a

limited number of GE items to inform customers using "may be bioengineered" or "may be genetically engineered." Lewis Decl. ¶ 22. Finally, the Act prohibits disclosure, even voluntary, of any meat or dairy from livestock fed GE feed that Plaintiffs would like to provide for their customers. 7 U.S.C. § 1639b(b)(2)(A); 7 C.F.R. § 66.5(d); Lewis Decl. ¶ 24; Simpson Decl. ¶ 13.

The prohibited disclosures qualify as core commercial speech, *e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995), and, as such, Defendants' prohibitions on them must pass muster under *Central Hudson*. They cannot.

2. The Disclosure Standard Fails *Central Hudson* Scrutiny.

Because the Disclosure Standard restricts commercial speech, Defendants bear the burden of demonstrating it satisfies *Central Hudson* scrutiny, a test that asks four questions: (1) whether the speech "concern[s] lawful activity and [is] not … misleading"; (2) "whether the asserted governmental interest" justifying the restriction "is substantial"; (3) "whether the [restriction] directly advances the governmental interest asserted"; and (4) whether the restriction "is not more extensive than is necessary to serve that interest." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Defendants fail every step.

First, there is no question that the first prong of *Central Hudson* is satisfied. In no way is the terminology "genetically engineered" or "genetically modified organism" false or misleading because the foods to be labeled *are* produced with genetic engineering as a factual and scientific matter. The Act's very definition of "bioengineering" is food "(A) that contains *genetic* material that has been *modified* through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C. § 1639(1) (emphasis added). Congress itself used this terminology interchangeably in the Act. *See supra* at 4. USDA just three years before issuing the Disclosure Standard believed the opposite: that any terminology *other* than GE and GMO would mislead consumers. AR238656-58. If GE or GMO were misleading, existing federal law under the FDCA prohibiting "misbrand[ing]," 21 U.S.C. § 331(a), would have prevented numerous agencies' long-standing guidance permitting voluntary disclosures. *See, e.g.* AR255419-33; AR445096-97; *Grocery Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583, 594 n.1, 628 n.33 (D. Vt. 2015) (GE is not misleading).

Second, the government must show a "substantial" governmental interest that is "directly" advanced by its speech prohibition. *Central Hudson,* 447 U.S. at 566. The Act itself fails provide any rationale, let alone a substantial one, in limiting disclosures to only those in line with the Disclosure Standard. 7 U.S.C. § 1639b(b)(1). And only a single sentence with no explanation provides USDA's record support: Prohibiting GE and GMO will "ensur[e] disclosure consistency and minimiz[e] marketplace confusion." 83 Fed. Reg. at 65,851. Assuming this is Defendants' purported substantial governmental interest and that the single sentence is enough to make it more than mere *post hoc* argument,[41] while stopping consumer confusion serves in some instances, *see Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985), here USDA utterly fails to show that its restriction "'directly and materially' advances" this interest. Indeed, far from showing direct and material advancement as required, the record shows that USDA's restriction—resulting in regulated entities using only QR codes or unknown terminology, and only on certain GE foods—will have the *opposite* effect: increased confusion.

Namely, USDA created huge loopholes with its testing methods to allow *inconsistent* disclosures of highly refined foods. *See supra* at 21-22. USDA banned common, recognizable forms of labeling through prohibiting the use of the familiar terminology, GE/GMO, in favor of obscure terminology it *admits* will confuse consumers and require "outreach and education." 83 Fed. Reg. at 65,851; *see supra* at 17-18. And USDA allowed novel forms of labeling it determined will not

[41] No matter what interest the government asserts, the court must still "test the consistency between ... the specific interests asserted by the government during litigation ... and the legislative purposes ... as made explicit in the statute's text or evidenced by its history or design." *Retail Digit. Network, LLC, v. Appelsmith*, 810 F.3d 638, 648 (9th Cir. 2016). Nowhere in the legislative history does Congress discuss restricting terminology to serve any of these interests. In fact, much of the legislative history primarily uses the terms, GE and GMO. H.R. Rep. No. 114-208, pt. 1 (2015) (only using the term, "bioengineered," twice and using "genetically engineered numerous times); 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (using "genetically modified" more than "bioengineered"); 162 Cong. Rec. S4783 (daily ed. July 6, 2016) (using both terms nearly equally); 162 Cong. Rec. S4906 (daily ed. July 7, 2016) (using GE/GMO more than twice as many times as "bioengineered"). As such, any "[p]ost hoc rationalizations for a restriction on commercial speech may not be used to sustain its constitutionality." *Retail Digit. Network, LLC,* 810 F.3d at 648.

meaningfully inform consumers at all, such as QR code disclosures and phone text message disclosures, that will create further confusion. *See supra* at 8-9. Far from directly and materially advancing any substantial interest in avoiding consumer confusion, Defendants' prohibition on retailers' speech will undermine that interest and cause widespread confusion.

Third, USDA's speech restriction—banning retailers from providing better information to customers than the Agency's miserly and confusing new standard—is not narrowly tailored, that is "no more extensive than is necessary." *Central Hudson*, 447 U.S. at 566. In commercial-speech cases like this "the preferred remedy is more disclosure, rather than less." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977). Indeed, the Disclosure Standard restricts speech far beyond the contours of the Act. It fails to include "similar terms"; prohibits the use of "may be bioengineered," as mandated by the Act; and permits only limited, voluntary disclosures on highly refined foods through its extra-statutory exemption. It is irreconcilable with the First Amendment.

3. The Disclosure Standard Is Unconstitutionally Vague.

In addition, and alternatively, the Disclosure Standard violates the Fifth Amendment because it is impermissibly vague. Namely, its "prohibitions are not clearly defined," *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972), because it contradicts the Act while assuring regulated entities that "Nothing in this subpart will prohibit regulated entities from making other claims regarding bioengineered foods … consistent with applicable Federal law." 7 C.F.R. § 66.118. Several "other claims" Plaintiffs would like to make are *permitted* by the Disclosure Act but *prohibited* by Defendants in the Disclosure Standard. First, Plaintiffs would like to disclose foods that "may be bioengineered" as mandated by the Act, Squire Decl. ¶ 16; Simpson Decl. ¶ 19; Lewis Decl. ¶ 22, but the rule prohibits this label. 83 Fed. Reg. at 65,827. Second, Plaintiffs would like to use "similar terms," like GE or GMO which are again permitted in the statute but prohibited by USDA. 7 C.F.R. § 66.102. If "nothing" in the Disclosure Standard prohibits regulated entities from making this statutorily mandated claim, it remains unclear which standard they should follow: the Disclosure Standard or the Act. The only criteria informing USDA's findings of which other claims are "consistent with federal law" but prohibited by the final rule is

their own *ad hoc* judgment. This does not pass constitutional muster. *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18 (2010) (law violates due process if it is "so standardless that it authorizes or encourages seriously discriminatory enforcement") (internal quotation marks omitted).

B. The GE Seed Labeling Prohibition Violates the Tenth Amendment.

Finally, the Disclosure Standard also is contrary to the Tenth Amendment because it attempts to commandeer state and local governments by prohibiting them from "directly or indirectly establish[ing] under any authority… any requirement relating to the labeling of whether a … seed is genetically engineered." 7 U.S.C. § 1639i(b).[42] The Tenth Amendment's anticommandeering doctrine prohibits the federal government from "requir[ing]" state and local governments "to govern according to Congress's instructions." *New York v. U.S.*, 505 U.S. 144, 162 (1992). This limitation exists to ensure 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. *Id.* at 175-177; *Printz v. U.S.*, 521 U.S. 898, 925-26 (1997). The doctrine applies to Congressional orders "compelling a State to enact legislation" *and* orders such as 7 U.S.C. § 1639i(b), "prohibiting a State from enacting new laws." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1478 (2018).

Congress only 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." *Murphy*, 138 S. Ct. at 1480. But the Disclosure Act's seed preemption provision does the *opposite*. It prohibits States and political subdivisions from "directly or indirectly establish[ing]" any labeling requirements related to "labeling of whether a … seed is genetically engineered" but without conferring a federal right to private entities to label GE seeds only in accordance with a federal regulatory scheme. The Act only creates a disclosure standard for bioengineered *foods*, not seeds, 7 U.S.C. § 1639b(a)(1), and USDA rightfully omits GE seeds from the Disclosure Standard.

[42] Plaintiffs have standing because the invalidation of Vermont's state labeling law has caused economic injury and deprived consumers of their right to know, sufficient to satisfy Article III's standing requirements. *Bond v. U.S.*, 564 U.S. 211 (2011); Allen Decl. ¶¶ 13-14; Buxton Decl. ¶ 14; Youngblood Decl. ¶ 11; Gordon Decl. ¶ 20.

Nowhere does the Act even mention seeds outside of state seed laws, let alone lend itself to be "best read" as regulating private entities' GE seed labels. *Murphy*, 138 S. Ct. at 1479. The result is a violation of the Tenth Amendment and core principles of federalism: commandeering state regulation decisions without passing any federal regulation.

Additionally, or alternatively, the Act's vague seed prohibition violates the Fifth Amendment's due process requirements. Defendants provide no clues which laws may "indirectly" establish any labeling requirements "relating to" GE seed labeling. Numerous current state laws "indirectly" relate to GE seed labeling, such as those identifying GE seeds as part of a certification or public notice process.[43] It remains unclear which requirements count as "indirect" regulation, falling far short of providing sufficient constitutional notice to states and political subdivisions regarding which state laws and regulations states must amend or eliminate.

III. THIS COURT SHOULD VACATE THE DISCLOSURE STANDARD AND SEVER AND DECLARE INVALID THE ACT'S UNCONSITUTIONAL PROVISIONS.

To remedy these constitutional violations and USDA's arbitrary rulemaking, this Court should vacate the Disclosure Standard and remand it to the Agency; declare invalid the Disclosure Standard's restrictions on speech under the First Amendment; and sever and declare invalid constitutionally infirm provisions of the Disclosure Act.

First, for Plaintiffs' statutory claims, a reviewing court "*shall* … hold unlawful and set aside agency" actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2) (emphasis added). As such, vacatur and remand is the textual, default remedy for agency action held unlawful, and thus Defendants, not Plaintiffs, carry the burden to show why another result, such as remand without vacatur, is appropriate instead. *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018). Although "rare circumstances" exist which do not warrant vacatur, such circumstances do not exist here. *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010). The "seriousness of the agency's errors" weighs heavily in favor of vacatur because they cut to the core purposes of the Disclosure

[43] Am. Compl. ¶¶ 341-45.

Act and gut meaningful labeling for GE foods. *Pollinator Stewardship Council v. U.S. EPA*, 806 F.3d 520, 532 (9th Cir. 2015). And any alleged economic harm or disruption to regulated entities alone would be insufficient to warrant remand without vacatur when "balance[ing] the [Agency's] errors against the consequences of such a remedy.'" *Cal. Cmtys. Against Toxics v. U.S. EPA*, 688 F.3d 989, 993 (9th Cir. 2012); *see Ctr. for Env't Health v. Vilsack*, No. 15-cv-01690-JSC, 2016 WL 3383954, at *12-13 (N.D. Cal. June 20, 2016) (holding that disruption to industry alone insufficient).

Second, this Court should hold unlawful and set aside the Disclosure Standard as "contrary to constitutional right" under the First Amendment for its restrictions on Plaintiffs' speech. 5 U.S.C. § 706(2)(B). Alternatively, this Court should hold unlawful and set aside the Disclosure Standard's speech restrictions as void for vagueness under the Fifth Amendment.

Third, for Plaintiffs' constitutional claims under the Disclosure Act, this Court should declare invalid and sever 7 U.S.C. § 1639b(b)(1), limiting disclosures to only the Disclosure Standard, in violation of the First Amendment. *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 549 (2001). Additionally, the Court should also sever and invalidate 7 U.S.C. § 1639b(b)(2)(A) under the First Amendment and 7 U.S.C. § 1639i(b) under the Tenth Amendment, or, alternatively, the Fifth Amendment, with regards to GE seeds. *Murphy*, 138 S. Ct. at 1482.

CONCLUSION

USDA's Disclosure Standard creates loopholes for food companies and confusion for consumers. Left standing, the Disclosure Standard will result not only in *de facto* concealment of GE disclosures, but also a dangerous precedent for truthful and non-misleading commercial speech and for Congress's power to commandeer state governments. Accordingly, this Court should set aside the arbitrary and unconstitutional Disclosure Standard and sever and declare invalid constitutionally infirm provisions of the Disclosure Act.

Respectfully submitted this 23rd day of November, 2021.

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