July 3, 2018

U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Re: National Bioengineered Food Disclosure Standard (Pub. L. 114-216): Proposed Rule Comments, 83 Federal Register 19860 (Friday May 4, 2018), Docket Number AMS-TM-17-0050, 7 C.F.R. Part 66

Center for Food Safety (CFS), on behalf of its 950,000 consumer and farmer members and supporters, submits the following comments on USDA's implementation rule proposal for the National Bioengineered Food Disclosure Standard, 7 U.S.C. §§ 1639-1639c (hereafter NBFDS or the "Act"); 7 C.F.R. Part 66, 83 Fed. Reg. 19860 (2018).

Overview and CFS Expertise

Americans have called upon the U.S. government to label GE foods for many years, to secure access to the same information enjoyed by the residents of 64 other countries around the world.[1] Polls consistently show that nearly 90 percent of Americans want to know whether the foods they purchase are produced using genetic engineering, through clear, on-package labeling disclosures.[2] Congress recognized the public's right to know in passing the Act. USDA's regulations and implementation of the Act must reflect the intent of Congress, provide consistency with international standards, and provide access to this information to all U.S. residents.

CFS's mission is to empower people, support farmers, and protect the environment from harmful industrial agriculture, while supporting sustainable ecological and organic farming. As part of this overall mission, for two decades, CFS has been the leading U.S. public interest organization working on the issue of GE organisms and their oversight, at the state and federal level. Part of CFS's programmatic mission is to ensure that genetically engineered organisms that could adversely impact public health, agriculture, and the environment are adequately labeled and properly regulated, and to provide the public information needed to make informed shopping choices. 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 are recognized experts in the field and intimately familiar with the issue of GE organisms, the inadequacy of their oversight, their risks, and their adverse impacts.

CFS takes a multi-faceted approach in pursuing its mission, utilizing legal, political, and grassroots strategies, including public and policymaker education, outreach, and campaigning. CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and

[1] CFS, *International Labeling Laws*, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws.
[2] CFS, *U.S. Polls on GE Food Labeling*, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling.

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the general public regarding the adverse effects of industrial food production—such as genetically engineered agricultural products and pesticides—on public health, the environment, farmers, and on 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. To give one example, in 2007, CFS Executive Director Andrew Kimbrell authored, and CFS staff edited, the book *Your Right to Know: Genetic Engineering and the Secret Changes in Your Food* (Earth Aware Press, 2007).

CFS has long been committed to securing mandatory GE labeling across the country, and worked closely with dozens of states 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 formal legal rulemaking petition with the Food and Drug Administration (FDA), on behalf of over 650 companies and organizations calling on the FDA to require the mandatory labeling of GE foods for all Americans, which garnered over 1.4 million comments in support.

Without any federal legislation to protect the peoples' right to know, states stepped into the breach to address the demands of their residents, and CFS assisted in the successful passage of several state labeling laws. To that end, CFS has provided policy and legal expertise, and engaged in grassroots lobbying in support of numerous GE labeling bills and ballot initiatives across the country, informing its members in these states how to get involved and support such efforts. More than 30 states introduced such GE food labeling bills in 2013 and 2014 alone.[3] Connecticut[4] and Maine[5] passed labeling laws in 2013, albeit with clauses tying their effective dates to the passage of similar laws in other states, and in May 2014, Vermont became the first state[6] to pass a stand-alone labeling law, which went into effect in July 2016. Despite spending over $100 million dollars,[7] crushing election spending records, the biotechnology industry just barely beat back three state ballot initiatives, in California (2012),[8] Washington (2013),[9] and

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[3] CFS, *GE Food Labeling: States Take Action* (Jun. 10, 2014), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/fact-sheets/3067/ge-food-labeling-states-take-action.

[4] CFS, *More States Support GMO Labeling Bills* (May 22, 2013), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/2240/more-states-support-gmo-labeling-bills.

[5] CFS, *Maine Legislature Passes Center for Food Safety Supported GE Labeling Law* (Jun. 12, 2013), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/2297/maine-legislature-passes-center-for-food-safety-supported-ge-labeling-law.

[6] CFS, *Victory for the Food Movement in Vermont on GE Food Labeling* (May 8, 2014), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/3136/victory-for-the-food-movement-in-vermont-on-ge-food-labeling.

[7] CFS, *Anti-Labeling Campaign Tries To Buy Oregon Election With Record Setting $19 Million in Misleading Advertising* (Oct. 29, 2014), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/3577/anti-labeling-campaign-tries-to-buy-oregon-election-with-record-setting-19-million-in-misleading-advertising.

[8] CFS, *Statement on Results of California's Vote on Proposition 37: Chemical Industry Spends its Way to Denying Californians' Right to Know* (Nov. 7, 2012), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/734/center-for-food-safetys-statement-on-the-results-of-californias-vote-on-proposition-37-chemical-industry-spends-its-way-to-denying-californians-right-to-know; *California Proposition 37, Mandatory Labeling of Genetically Engineered Food (2012),* Ballotpedia, https://ballotpedia.org/California_Proposition_37,_Mandatory_Labeling_of_Genetically_Engineered_Food_(2012).

Oregon (2014)[10] by narrow margins. As to the Vermont labeling law, CFS made significant contributions to the legislative process that culminated in its passage and CFS legal staff provided expert knowledge throughout the committee process in the Vermont State Legislature, and joined the effort to defend Vermont's labeling law when the Grocery Manufacturers Association unsuccessfully challenged the law in federal court.[11] All of these state laws were substantially identical in their coverage, definitions, scope, and manner of their on-package labeling.

CFS has always supported, and continues to support, mandatory GE labeling nationwide, to ensure the public's right to know what is in their food, and to provide the same transparency enjoyed by residents of 64 other nations, including all of the Europe Union, Japan, New Zealand, Australia, Brazil, Russia, China, and many others. However, to live up to the intent of Congress in passing the GE Labeling Act, labels must be accessible to all, clear and informative, and cover all genetically engineered foods.

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[9] CFS, *Agribusiness Spends $22 Million, $25 per Vote, to Keep Consumers in the Dark* (Nov. 14, 2013), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/2711/agribusiness-spends-22-million-25-per-vote-to-keep-consumers-in-the-dark; *Washington Mandatory Labeling of Genetically Engineered Food Measure, Initiative 522 (2013),* Ballotpedia, https://ballotpedia.org/Washington_Mandatory_Labeling_of_Genetically_Engineered_Food_Measure,_Initiative_522_(2013). Indeed, the Grocery Manufacturers Association violated Washington's campaign finance laws in its opposition to Initiative 522, and was ordered to pay $18 million, the largest campaign finance penalty in U.S. history. Wash. State Office of Attorney General, *AG: Grocery Manufacturers Assoc. to Pay $18M, Largest Campaign Finance Penalty in US History* (Nov. 2, 2016), https://www.atg.wa.gov/news/news-releases/ag-grocery-manufacturers-assoc-pay-18m-largest-campaign-finance-penalty-us.

[10] CFS, *Food Movement Vows to Keep Fighting After Corporate Backed Campaign Buys Narrow Win in Oregon* (Dec. 11, 2014), http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/3649/food-movement-vows-to-keep-fighting-after-corporate-backed-campaign-buys-narrow-win-in-oregon (Oregon ballot initiative lost by 812 votes, total).

[11] *Grocery Mfrs. Ass'n v. Sorrell,* 102 F. Supp. 3d 583 (D. Vt. 2015); Amici Curiae Vermont Public Interest Research Group & Center for Food Safety's Memorandum in Support of Defendant's Motion to Dismiss, *Grocery Mfrs. Ass'n v. Sorrell*, No. 5:14-cv-00117-CR, 102 F. Supp. 3d 583 (Nov. 14, 2014), *available at* http://www.centerforfoodsafety.org/files/64--amici-pi-opp-and-mtd-reply_82223.pdf; Brief of Amicus Curiae Dr. Ramon J. Seidler, *et al.*, *Grocery Mfrs. Ass'n v. Sorrell,* No. 15-1504-CV (2nd Cir. Aug. 31, 2015), *available at* http://www.centerforfoodsafety.org/files/2015-8-31-dkt-114--cfs-amicus-brief_57471.pdf.

Table of Contents

COMMENTS

In July 2017 CFS submitted detailed comments for USDA's scoping "30 questions" notice and comment period, and incorporates those comments here.[12]

I. FORMS OF DISCLOSURE

A. Electronic or Digital Disclosures

The NBFDS generally establishes three possible forms of GE disclosure: text, symbols, and indirect electronic or digital disclosures.[13] However Congress did not give USDA *carte blanche* on what would be permissible. The opposite is true: understanding the unprecedented nature of indirect electronic or digital disclosures and anticipating problems and significant unknowns about such disclosure forms, Congress required USDA to undertake a specific study to inform this rulemaking, on this exact point: "identify[ing] the potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods."[14] 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 it.[15] Congress further required that USDA "shall" solicit and consider public comments on the study, further underscoring its importance (though the agency has not complied with this requirement, except by also saying it was simultaneously seeking comment on the study during this May-July 2018 proposed rulemaking comment period, despite the study being completed and made public early in fall 2017).[16] And Congress laid out in minute detail the specific factors that USDA had to analyze and consider in the USDA 2017 study, in considering "whether consumer access to the bioengineering disclosure through electronic or digital disclosure methods under this subchapter would be affected."[17] These factors include the availability of wireless Internet or cellular networks; the availability of landline telephones in stores; the challenges facing small retailer and rural retailers; the 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 electronic or digital link scanners or other technology to provide disclosure information.[18]

Legislative enactments are never to be read as presenting empty mandates, like an advisory study for no purpose, but to remove any doubt, Congress mandated that USDA take action based on the USDA 2017 study's analysis and conclusions and inform this rulemaking accordingly. Namely, if the USDA 2017 study shows that "consumers, while shopping, would not have sufficient access to the

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[12] CFS, *Comments Re: Implementation of the National Bioengineered Food Disclosure Standard (Pub. L. 114-216)* (July 17, 2017), submitted to USDA via GMOlabeling@ams.usda.gov.
[13] 7 U.S.C. § 1639b(b)(2)(D). There will also be additional options permitted for small food manufacturers, *id.* § 1639b(b)(2)(F), and for very small packages, *id.* § 1639b(b)(2)(E).
[14] *Id.* § 1639b(c)(1).
[15] *Id.*
[16] *Id*. § 1639b(c)(2); 83 Fed. Reg. at 19875; Deloitte, *Study of Electronic or Digital Link Disclosure* (Jul. 2017) (hereinafter "USDA 2017 Study"), *available at* https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf.
[17] 7 U.S.C. § 1639b(c)(3).
[18] *Id*. § 1639b(c)(3)(A)-(E).

bioengineering disclosure through electronic or digital methods," then USDA, after consulting stakeholders, "*shall* provide additional and comparable options to access the bioengineering disclosure."[19]

USDA acknowledges all this in the proposed rule.[20] However, despite having the completed USDA 2017 study since at least July 27, 2017, the proposed rule does not attempt to grapple with the USDA 2017 study or its findings in any meaningful way or with any detail. Instead the notice simply says the agency is "reviewing the study and its results to decide whether to make that determination."[21] Nonetheless, the agency presumptively floats 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.[22] This would require manufacturers to place instructions "text [number] for more food information" and an automated response.[23]

It is unknown why USDA did not release the USDA 2017 study publicly until forced to do so through litigation, or why it did not meaningfully engage with the study in this proposal, which is supposed to be a proposed rule.[24] But very likely it is because the USDA 2017 study is not at all supportive of the use of electronic or digital disclosures for the NBFDS. Among other relevant findings, all of which go to the factors specifically enumerated by Congress in the law, the USDA 2017 study concluded that:

- "[R]esearchers observed key technological challenges that prevented nearly all participants from obtaining the information through electronic or digital disclosure methods."[25]
- "Digital links are not inherently associated with additional food information, and consumers often assume they are for marketing and industry use."[26]
- "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."[27]
- Zero percent of the stores visited were equipped with scanners capable of accessing info on a digital link.[28]
- "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."[29]

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[19] *Id.* § 1639b(c)(4) (emphasis added).
[20] 83 Fed. Reg. at 19870 & 19875.
[21] *Id.* at 19875.
[22] *Id.*
[23] *Id.* at 19876.
[24] This also creates a procedural problem, which is that USDA never held independent comment on the study itself, and now has withheld any of its own analysis or conclusions based on the study from this comment period. This lack of timely decision-making has injured the public's ability to meaningfully comment on the study and USDA's conclusions/proposal based on it.
[25] USDA 2017 study at 4.
[26] *Id.*
[27] *Id.*
[28] *Id.*

- "85 percent of consumers struggled with complicated mobile software applications ("apps") regardless of their comfort using technology."[30]

- "Consumers may be unable to connect to broadband, or connect at speed that is so slow that they cannot load information."[31]

- "20 percent of retail stores do not currently have in-store WiFi, including 63 percent of small retailers."[32]

- 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."[33]

- 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."[34]

- 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."[35]

- 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.[36]

- "[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."[37]

- "Scanning digital links is not an intuitive process for many consumers who lack technical knowledge on how to download and use scanner apps"[38]

- The study identified multiple app design issues that frustrated consumers, sometimes to the point of abandoning attempts to obtain information. These include inadequate or unclear

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[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.* at 5.
[34] *Id.*
[35] *Id.*
[36] *Id.* at 17
[37] *Id.* at 46.
[38] *Id.* at 40.

instructions, embedded and pop-up advertisements, delays in loading, special requirements for labels, and variance in display of results.[39]

- "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."[40]

- 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."[41]

- 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."[42]

- "[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 . . .."[43]

- "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 . . .."[44]

- 100 percent of consumers polled did not recognize digital links were associated with food info.[45]

- "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."[46]

- 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."[47]

- "[B]oth retailers and consumers in the field tended to overlook guiding words surrounding the digital link . . .."[48]

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[39] *Id.* at 52.
[40] *Id.* at 55.
[41] *Id.*
[42] *Id.* at 59.
[43] *Id.*
[44] *Id.* at 67.
[45] *Id.* at 4.
[46] *Id.* at 43.
[47] *Id.* at 45.

- "Consumers may recognize electronic or digital links, but do not know how to access information due to a lack of familiarity with scanning."[49]

As these non-exhaustive examples show, the USDA 2017 study found significant problems with the efficacy of digital and electronic disclosures; its analysis of every factor enumerated by Congress in the NBFDS weighed against such disclosures being sufficient. Thus the USDA 2017 study strongly supports a conclusion by USDA that American consumers will *not* have sufficient access to the bioengineered disclosure through only electronic or digital disclosures.

Moreover the USDA 2017 study is only one piece of (albeit critical, Congressionally-charged) evidence, and USDA's decision must be based on all the evidence in the record, including comments on the study. The USDA 2017 study echoes and supports existing secondary sources on the lack of efficacy of these types of indirect disclosure for consumers. In sum, existing evidence shows that digital and electronic labeling, like QR codes or websites, will not provide disclosure to a large portion of Americans, disproportionally affecting 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, only 77 percent of Americans own a smart phone.[50] For these reasons electronic and digital disclosure is inherently discriminatory against all of these demographics. 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.[51] Even those who have the phones and service plans are not guaranteed consistent access to the internet.[52] 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.[53] As such, allowing labeling based on QR codes is discriminatory against the poor, 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.

Smartphone ownership and access to reliable broadband is only the tip of the iceberg. Among those who own smartphones, there are varying degrees of digital readiness. "Digital readiness" describes

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[48] *Id.*

[49] *Id.* at 40.

[50] *Id.* at 17, citing Pew Research Center, U.S. Smartphone Use in 2015, http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/.

[51] 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/.

[52] 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/.

[53] 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.

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.[54] 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 inform themselves. The cautious clickers make up 31 percent of owners and have knowledge but do not use 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. 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. Not only does this Pew study show that digital GE disclosure would be ineffective for many, it further supports the contention 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.

Moreover, as the USDA 2017 study confirmed, Americans simply do not associate QR codes with information about the contents of food products (this is unsurprising given the unprecedented proposed form of this disclosure). Not only do very few Americans regularly use QR codes,[55] the majority of QR code scans came from magazines, websites, mail, billboards or signs, and emails, and *not* on packages.[56] When you remove the Americans who do not own smartphones (33 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*.

In addition, electronic labeling disclosures put an undue burden on the shopper. Even if supermarkets were required by law to include QR scanners in every aisle (an absurdly expensive proposition that would burden many small retailers), it is completely unrealistic for a shopper to scan all of the many items s/he is shopping for on any given shopping trip (which for a family of 4 could easily amount to more than 50 items). Additionally, what happens when more than one customer seeks to use such a scanner at one time? This idea of forcing people to seek out, probably wait for, and then use a store scanner for every item they are considering is ridiculous. This would be an undue burden on the

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

[55] The Mellman Group, *supra* note 53, at 21.

[56] 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 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).

consumer and greatly impede access to information that is currently required for all other forms of food labeling.

Proposals to use QR code technology in lieu of on-package labeling also raise serious questions about the privacy of consumer data. Americans have many legitimate concerns with this scheme: What data would be exchanged and how might companies be able to use that data? For instance, would a company be able to determine which customers are viewing their products through QR codes or websites, or capture their phone numbers when calling an 800 number? Could they use that data to target consumers through advertising? Would any personal data be exchanged? The government thus far has a poor track record of protecting consumer data and curbing the massive marketing machines of the food industry. This system only opens consumers up to further exploitation.

Accordingly, any determination by USDA that electronic and digital disclosures alone would provide sufficient access to the bioengineering disclosures would be arbitrary and capricious, contrary to the evidence, and contrary to law.

Instead, USDA must conclude that, based on its own USDA 2017 study, these forms of disclosures will not be sufficient. In such circumstances, Congress provided the statutory remedy: USDA must instead provide consumers "additional and comparable options."[57] Here, the proper solution is require that manufacturers that wish to use electronic or digital disclosures *also be required to provide consumers one of the two other methods Congress approved*: on-package text or symbol. Bioengineered ingredient disclosures should consist of clearly worded, on-package text labels indicating the presence of these GE ingredients. Digital disclosures cannot be used alone, only in conjunction with one of the other two disclosure methods. In general, no legally mandated information, such as whether a product is produced with genetic engineering, should be allowed to be only in digital or electronic disclosures, only supplemental, voluntary information the company wishes to present. The statutory text supports this conclusion: On-package symbols and text are the only "comparable" options, as both are part of the NBFDS. To require them to be used "additionally" with the electronic and digital disclosures also fulfills Congressional intent in the provision.

A Text Message Alternative Should Also Be Rejected

Instead of on-package text or symbols, USDA's proposal posits a potential text message option. Such a decision would not comply with the NBFDS, and would be arbitrary and capricious rulemaking. Congress never approved of or conceived of a text message disclosure, unlike on-package text or symbols. Moreover such a method would suffer from many of the same fatal flaws as QR codes or URLs. Many Americans who live in rural areas may not have reliable cellphone service that would allow them to send or receive text messages. Instructions to "text here for more food information" would suffer from the same flaws the USDA 2017 study found for other indirect electronic or digital disclosures: neither consumers nor retailers associate such messaging with basic food ingredient information (again unsurprising and logical, given the unprecedented nature of presenting food ingredient information in such a manner). Moreover as to what on-package text is proposed to be included, as with the on-package language for QR codes, 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 produced is produced

[57] 7 U.S.C. § 1639b(c)(4).

with genetic engineering.[58] And 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 they purchase are unworkable in the real world.

Similar issues that arise with QR code disclosure are repeated with text messaging disclosure, making it insufficient as the alternative for QR codes. Many consumers polled in the USDA 2017 study were concerned with their ability to receive information on their phones due to lack of reception.[59] Text 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.[60] 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, you still need to have a charged cellphone with text messaging capabilities and good service to be able to receive the GE disclosure information. This proposed alternative barely differs from QR codes, including many of the same barriers, making the information inaccessible to the same people from either source.

Further, text messaging would disadvantage the same population groups as the QR code option: low income people, people who live in rural areas, and older citizens. Lower income people, less educated people, people of color, people in rural communities, and older citizens are less likely to own cellphones.[61] These groups overlap with those who viewed technological challenges as a set back to the QR code system. For example, the USDA 2017 study shows that lower income participants were more likely to be concerned with their ability to access QR scanning tools.[62] The same set back would apply to a text message option. Lower income communities experience 15 percent less coverage from cell providers, be it because there are less telecom bases in low income areas or because the telecom bases are located closer to suburban areas.[63] Either way, low income communities get worse service and will therefore be less able to send or receive text messages inside grocery stores. Without service, text messaging for GE information is not a feasible alternative for these communities for the same reason QR codes is not a feasible option in the first place: lack of access to technology.

With text messaging as an alternative, inconsistency in cellular plans will make this information more accessible to some than others. For example, not all Americans have unlimited texting.[64] For consumers who have pay-as-you-go texting, they would have to pay for each text they send to get

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[58] The problem of inadequate, vague explanatory accompanying on-package text is an independent rationale showing why the electronic and digital disclosures would not inform consumers, failing to pass muster.

[59] USDA 2017 study at 39, 54, 57.

[60] 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.

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

[62] USDA 2017 study at 48.

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

[64] 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.

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.

Even when people have 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.[65] 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. Further just as with the QR code option, having to text a number for every product greatly increases the amount of shopping time. The average grocery store visit lasts under an hour,[66] and even that amount of time is probably too long for the busy family member doing the shopping.[67]

Even with younger generations who use their phones more often, it is unlikely that consumers will associate a phone number listed on-package with access to GE disclosure information.[68] Furthermore, the younger generations who are more likely to send text messages are less likely to be the ones shopping for food, as the average age of grocery shoppers is 48 years old.[69]

In 2016, 89 percent of people who identified 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.[70] This shows that people who are aware of GE ingredients in food rely on labels to help them make these decisions. Hiding information about GE contents by only providing it through a QR code or text would prevent these 89 percent of concerned consumers from being able to make a quick decision in the store. Hiding this information through QR code or text does not provide the statutorily-mandated access because a digital link or text does not indicate *what* information will be provided, nor does this technology make the information accessible to all.

Finally, in addition to all the above problems, putting a phone number on a package for consumers to text is not really an "additional" option at all—the law *already requires* that the QR code disclosures also list a toll-free phone number.[71] Accordingly USDA must reject any text message option and instead require on-package text or symbols be required in conjunction with any electronic or digital disclosures. Failure to so conclude would be arbitrary and capricious and contrary to law.

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[65] 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/.
[66] 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.
[67] *Id*.
[68] USDA 2017 study at 40.
[69] Goodman, *supra* note 66, at 2.
[70] 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/.
[71] 7 U.S.C. § 1639b(d)(4).

B. On-Package Disclosure

1. Symbols

Unlike electronic or digital disclosures alone, CFS supports the use of on-package symbols for the NBFDS. However USDA's proposal for NBFDS symbols suffers from two major problems.

First, the proposed symbols use only the "BE" acronym. They do not include "GE" or "GMO," despite the history and common knowledge of those terms. As discussed elsewhere in these comments, the terms "genetically engineered" and "genetically modified organism" must be included as "similar terms," as contemplated by Congress in the NBFDS.[72] Thus their acronyms must be included as well.

Indeed, "BE" alone, even more than "bioengineered," would be false, confusing, and misleading to consumers, who are unfamiliar with that term generally in this context; the same is even more true for any acronym symbol based on it. The purpose of the NBFDS is to inform consumers meaningfully about whether a food product was produced with genetic engineering, and the unknown symbols "BE" do not fulfill that purpose. The symbols GE and GMO do.

More on why bioengineering and BE are confusing and misleading terms is discussed in the text and terminology sections *infra.* To give one example, with regards to the term "bioengineering" and the acronym BE specifically, such a symbol would also cause confusion—in addition to being generally unknown—as it is very similar to some European countries' symbol for organic food products ("biologique"). This of course would be extremely misleading, as organic prohibits the use of genetic engineering. For example:

Figure 1: German organic symbol

Figure 2: French organic symbol

USDA gives no rationale for why it abandoned "GE" and "GMO" as similar and permissible terms. But its *own website for this entire rulemaking* was entitled "GMO Disclosure and Labeling" up until at least February 9, 2018; hence USDA apparently considered these proper terms for the NBFDS at least

[72] *Id.* § 1639(1).

until then.[73] Moreover, USDA submitted to the U.S. Patent and Trademark office at least one proposed "GMO" symbol:[74]

USDA does not explain why it nonetheless has now proposed to prohibit the use of GE or GMO instead, after going to all the effort of creating and trademarking such symbols themselves.

USDA's proposed symbols use the wrong terminology and do not include as an option the terminology that stakeholders and consumers know, have used for several decades, and are currently used in the marketplace. USDA's failure to permit the use of GE and GMO symbols and instead use a BE symbol is confusing and misleading to consumers.

Second, the proposed symbols do not *simply* provide consumers the information of whether a food product is produced with genetic engineering. Instead, they are indisputably biased representations. For example, the proposal symbols are not simply circles with "BE" inserted. Instead, they are cartoonishly pro-biotech.[75] Two of them, alternatives B and C, are literally smiley faces. Alternative B is a smiling sun, reminiscent of the Kellogg's Raisin Brain smiling sun advertising.[76] (That USDA refers to the line as an "inverted arch" does not negate that consumers will very plainly interpret it to be a smiley face.) Alternative C is similarly a circle with a BE smiley face inside it, again with the "b" and "e" as eyes and an "inverted arch" mouth line below them, a leaf winking from the "b" eye. These are laughably biased symbols. Alternative A is perhaps the least biased representation, but it is still a far cry from neutral. The letters BE rest comfortably on the earth's surface, with a sun and green plant arching towards it and a 4 point star directly above the letters.

These proposed symbols violate the express direction of Congress in the NBDS statute. As the regulatory proposal acknowledges at the very outset of the section on forms of disclosure, the statute expressly requires that the disclosure form not treat any GE food "as safer than, or not as safe as, a non-bioengineered counterpart."[77] That is, the disclosure must be neutral—it must not directly or implicitly

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[73] *GMO Disclosure & Labeling*, USDA Agric. Marketing Service (Feb. 9, 2018), https://web.archive.org/web/20180209001825/https://www.ams.usda.gov/rules-regulations/gmo (accessed by searching in the Internet Archive index).

[74] *See* Cardinal Intellectual Property, Invoice to USDA for U.S. Comprehensive Trademark and Design Search (12/12/2016) and attached "GMO" label design; Email from Craig Morris, AMS to Elanor Starmer, AMS; Bruce Summers, AMS, Re: GMO Disclosure Odds and Ends (Nov. 22, 2016) (discussing findings by General Mills that symbols using GMO are most recognizable to consumers) (submitted as exhibits simultaneously with these comments, received through Freedom of Information Act Request).

[75] *National Bioengineered Food Disclosure Standard Proposed Symbols*, USDA Agric. Marketing Service (May 2018), https://www.ams.usda.gov/sites/default/files/media/ProposedBioengineeredLabels.pdf.

[76] *Id.*

[77] 83 Fed. Reg. at 19869; 7 U.S.C. § 1639b(b)(3).

give consumers the impression of a significant difference between GE and non-GE foods. Yet these symbols by any reasonable, commonsense understanding would be a governmental endorsement of these genetically engineered foods. The message given to the shopping consumer is an advertisement for the foods' safety and that they are an improvement on non-GE, traditional foods (foods that do not have the government-stamped smiley face, or rising green plant and shining star). Just as a skull and crossbones with a GE in the middle would not be permissible as a symbol, neither is a sunny smiley face.

One has to look no further than the other types of food symbols approved by the government for food labeling to see how ridiculously non-neutral the proposed symbols are. These other USDA and other government-approved information symbols simply provide consumers the factual information, without taking sides in the debate. For example:

Figure 3: Kosher symbols

Finally, in addition to the statutory violations of the NBFDS and Administrative Procedure Act, the proposed NBFDS symbols do not pass Constitutional muster under the First Amendment. The biased proposed symbols would be impermissible viewpoint discrimination; they are not content-neutral. The government may not regulate or compel speech based on the substantive content of the message or the viewpoint of the speaker. The pro-GE symbols discriminate in favor of genetically engineered foods, and those that support them in the substantial controversy around them, and discriminate against traditional, non-GE foods. There are many well-established and scientifically sound reasons why many consumers, manufacturers, and retailers do not support GE food production and instead think that traditional, non-GE food production is better, including, *inter alia* that GE crops, being overwhelmingly created by pesticide companies to be resistant to their pesticides, are instead more harmful to the environment and have dramatically increased pesticide output into the environment; have led to substantial agricultural consolidation in the hands of a few chemical companies; and raise significant health unknowns, given the lack of independent governmental health assessments of their safety. The proposed symbols are both content discrimination (having to do with a particular topic) and viewpoint discrimination, attempting to tilt the public debate in a preferred direction. There is no justification for the proposed smiling sun symbol without admitting the pro-GE food message it conveys. This forced, value-based viewpoint discriminates against entities wishing to label factually and accurately, without bias; against consumers relying on truthful and accurate labeling; and against entities that do not use genetic engineering and instead, for example, produce food organically, and will not have the benefit of the government's biased symbol endorsement. Indeed, when the USDA organic symbol, conveying agricultural methods that are actually beneficial to the environment, is *less* positive and earth-friendly looking compared the proposed BE symbols, there is a clear problem.

Further the biased symbols are not providing purely factual and uncontroversial information as compelled commercial speech must, which would be to simply tell consumers whether or not a food is produced with genetic engineering. Instead, they go far beyond a simple circle with GMO in it, and

convey more than just facts. The express and implicit message is an endorsement. Unlike the State of Vermont's Act 120's uncontroversial and purely factual disclosures of "produced with genetic engineering," the proposed symbols by their GE-promotional nature instead weigh into the debate and controversy over genetically engineered foods, and put the government's imprimatur on the merit of genetic engineering and GE foods. In short, the proposed symbols would turn a bag of potato chips or a can of soda into a controversial message that genetically engineered foods are better than traditional foods such as organic foods. The biased, promotional aspects of the symbols do not further any governmental purpose in this way (let alone are tailored to further it); the opposite is true, they violate the government's goal: as explained above, the statute expressly forbids the disclosures from distinguishing between GE and non-GE foods as far as their safety. Finally, in this way and for all the reasons explained above, the compelled speech would also be false and misleading to consumers. For all of these reasons, they would violate the First Amendment.

In sum, these symbols would be unprecedented in their unabashed bias and endorsement. Unlike other symbols in the food context, shown above, the proposed "BE" symbols are not neutral information but very biased. There is no precedent for what USDA has proposed in any other government disclosure, and it would violate both the Act and First Amendment constitutional standards if not corrected. CFS urges USDA to reject these symbols and instead use simply a circle with GE or GMO in it.

2. Text Disclosure

CFS supports the proposed regulatory requirements that the disclosure be of sufficient size and clarity, and that the disclosure appear prominently and conspicuously, as the NBFDS requires.[78] CFS also supports the proposal that the placement of the disclosure be required to be in a prominent place on the package, as the statute requires, the information panel or the principal display panel.[79]

As to the text of disclosures, CFS strongly urges USDA to use the terms "genetically engineered" or "genetically modified" rather than "bioengineered," or at a minimum, as permitted alternatives to that term. The NBFDS will fulfill its purpose only if consumers *can understand what information is being disclosed*. As explained further below, "bioengineered" is not a term Americans are familiar with, especially not in the food context, and its exclusive use would be misleading and confusing. Indeed, many companies are already out in the marketplace labeling with the text "produced with genetic engineering" or "may be produced with genetic engineering." These companies should be permitted to keep their current labels, and other companies to adopt similar labels.

USDA says it considered using GE and GMO, then says it is not proposing any similar terms, because the agency "believe[s] that the statutory term, 'bioengineering,' adequately describes food products of the technology that Congress intended to be within the scope of the NBFDS."[80] Thus, USDA's proposal is to limit textual disclosures to "bioengineered food" or "bioengineered food ingredient."[81] USDA does not explain why or how it came to this arbitrary conclusion, nor supports it with any rationale or data.

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[78] 83 Fed. Reg. at 19870.

[79] *Id.* at 19871.

[80] *Id.*

[81] *Id.* USDA's proposal to bifurcate and label differently based on its "highly adopted" and "non-highly adopted" lists are addressed separately *infra.*

First, the NBFDS specifically refers to "any similar term," in instructing the agency to create the standard and disclosures. USDA's refusal would improperly turn this phrase into surplusage. Second, USDA's proposed determination that bioengineering fulfills the statutory goal of adequately informing consumers would be arbitrary and capricious. Bioengineering is not a term currently used by consumers, regulators, or companies involved with genetically engineered foods. *See infra.* 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. Thus bioengineering alone, without the other terms, does not adequately describe the disclosures at issue.

Indeed the statutory scheme itself recognizes the other terms, using GE and GMO at several other places in the statute, showing Congress's awareness of the common usage of these terms. In the directly mirrored context of absence labeling, also covered by the statute, Congress used the known GMO terminology, directing that having organic certification for a food product is *per se* sufficient also to label that product as "non-GMO," without anything further.[82] A second provision of the statute that speaks to absence labeling clarifies that just because a particular food product is not classified as bioengineered, that "solely" is insufficient for the food to be labeled as non-GMO or not bioengineered.[83] Here Congress itself grouped together "not bioengineered" and "non-GMO," and "any other similar claim, describing the absence of bioengineering," meaning that Congress considers "not bioengineered" and "non-GMO" as "similar claim[s]." There is no logical distinction between these being similar terms but "bioengineered" and "GMO" not being similar terms. Further, Congress saw the need to provide clarity by using "GMO" in this context, supporting the conclusion that such clarity is needed to meaningful inform consumers in the GE presence labeling context as well.

Not just Congress but sister agencies support applying the well-known GE terminology and text here. FDA's existing guidance on voluntary GE food labeling also concludes that the terms are interchangeable: FDA equates the terms "genetic engineering" and "bioengineering" to both describe "modern biotechnology."[84] FDA:

> Modern biotechnology means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (Ref. 1). The term "modern biotechnology" *may alternatively be described as* "recombinant DNA (rDNA) technology," "genetic engineering," or "bioengineering."[85]

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[82] 7 U.S.C. § 6524.

[83] 7 U.S.C. § 1639c(c).

[84] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* 3 (Nov. 24, 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm.

[84] *Id.*

[85] *Id.* (emphasis added).

FDA elsewhere stated that "[t]hese terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders. . .."[86]

The 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."[87]

Similarly, with regards to presence GE labeling, in the guidance FDA applied the same principles and gave examples it believe were not misleading:

> "Genetically engineered"
> "This product contains cornmeal from corn that was produced using modern biotechnology."[88]

Similarly, another sub-agency in USDA, FSIS is the agency responsible for regulating meat, poultry, and egg products, pursuant to the Federal Meat Inspection Act (FMIA)[89], the Poultry Products Inspection Act (PPIA),[90] and the Egg Products Inspection Act (EPIA).[91] This authority includes the labeling of meat, poultry, and egg products, which must be approved by USDA before products can enter commerce.[92] Thus these are products (in the main) do not fall under the scope of the NBFDS,[93] and instead will remain regulated in labeling by FSIS. Pursuant to these standards, FSIS has a compliance guide for companies seeking to make a label or labeling claims concerning GE absence 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.[94] Examples include:

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[86] *Id.*; FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon* (Nov. 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm.
[87] *Supra* n.84.
[88] *Id.*
[89] 21 U.S.C. §§ 601–695.
[90] 21 U.S.C. §§ 451–470.
[91] 21 U.S.C. §§ 1031–1056.
[92] *See* 21 U.S.C. § 607; 21 U.S.C. § 457; 21 U.S.C. § 1036.
[93] 7 U.S.C. § 1639a(c)(2).
[94] *See* United States Department of Agriculture, *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 (last modified Aug. 29, 2016).

"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 biotechnology."[95]

Like FDA, these examples show that USDA's Agricultural Marketing Service (AMS)'s sister sub-agency FSIS does consider GMO and genetically engineered to be similar terms to bioengineered and allows their interchangable use. (In fact even after the passage of the NBFDS, in August 2016, FSIS amended their compliance guide to revise it but did *not* remove the GE terminology).[96]

Finally, it is important to underscore what these agency guidance statements do. In both cases, the agencies are applying their statutory mandates, under the Federal Food, Drug and Cosmetic Act (FFDCA), the FMIA, the PPIA, and the EPIA, respectively, that prohibit foods from being misbranded,[97] and a food is misbranded if its labeling is "false or misleading in any particular."[98] Thus 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.[99]

All of these examples belie USDA's prohibition on text language terms here. Mandating the use of the bioengineered term alone would be contrary to precedent, the Act itself and Congressional intent, and confusing and misleading to consumers.

C. Terminology

1. Bioengineered Is Confusing and Misleading

As discussed in the textual on-package language section above, USDA seeks comment on its proposal more generally as to the terminology and definitions it will use in the rules of the NBFDS scheme. The same rationale explained above applies to terminology restrictions more generally: Restricting disclosure terms in the NBFDS statutory scheme to "bioengineered" is unacceptable because most Americans are either not familiar with the term, or will misunderstand its meaning.

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[95] *Id.*
[96] *Id.*
[97] 21 U.S.C. § 331(a).
[98] 21 U.S.C. § 343(a)(1).
[99] Notably the NBFDS 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 there is no regulatory shield simply because a product is classified and labeled under the NBFDS. 7 U.S.C. § 1639c(b)(1).

First, the root term bioengineering is far too vague and broad to serve as a stand-alone signifier for genetically engineered foods. Etymologically, the term means "engineering life,"[100] 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." Because consumers, as the FDA found in focus group testing, "tended to evaluate the terms" used to signify genetically modified foods "linguistically," the vagueness and breadth of "bioengineered" as "engineered life" would confuse many consumers.[101]

While bioengineering is etymologically broad and vague, the history of its use makes it affirmatively misleading. The term was coined in 1954 by British scientist Heinz Wolff to mean the application of engineering principles to biological and medical sciences.[102] Ever since that time, bioengineering has been associated with either medical science and technology, or space exploration, not food production.

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."[103] MIT's biological engineering program likewise has a strong biomedical focus, with research areas including biomaterials, biophysics, cell & tissue engineering, pharmacology and toxicology. Tellingly, MIT refers to this program by the initials "BE," the same acronym that USDA proposes as a symbol for GE foods.[104] The other major use relates to space exploration. The National Aeronautics and Space Administration has a Bioengineering Branch whose mission is "developing next generation technologies to enable humans to live beyond low Earth orbit for extended periods."[105]

A Westlaw search for the term "bioengineered" or "bioengineer[]" returns only 12 prior search results for the term appearing in federal statutes beyond the NBFDS, four of which are in reference to the National Institute of Biomedical Imaging and Bioengineering, and none in the context of food or genetically engineered food or bioengineered food. For example, the Congressional declaration of policy and purpose for the "National and Commercial Space Program," "declares that the general welfare of the United States requires that the unique competence of the Administration in science and engineering systems be directed to assisting in bioengineering research, development, and demonstration programs

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[100] 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.

[101] 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).

[102] 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.

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

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

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

designed to alleviate and minimize the effects of disability."[106] Similarly, the use of the term "bioengineered" shows up in federal regulations approximately seven times, *none* in this context.

Instead, the primary dictionary definition of bioengineering logically reflects this long history of medical usage: "the application of engineering principles, practices, and technologies to the fields of medicine and biology, especially in solving problems and improving care (as in the design of medical devices and diagnostic equipment or the creation of biomaterials and pharmaceuticals)."[107]

It is thus not surprising that this is how the term is understood by the general public. A Google search elicits 2.5 times more hits for bioengineered human and various bioengineered organs than for bioengineered food and crop.[108] Figure 4, below, shows that in U.S. books, only roughly 1 in 20 occurrences of "bioengineered" is conjoined with food, in the term "bioengineered food."

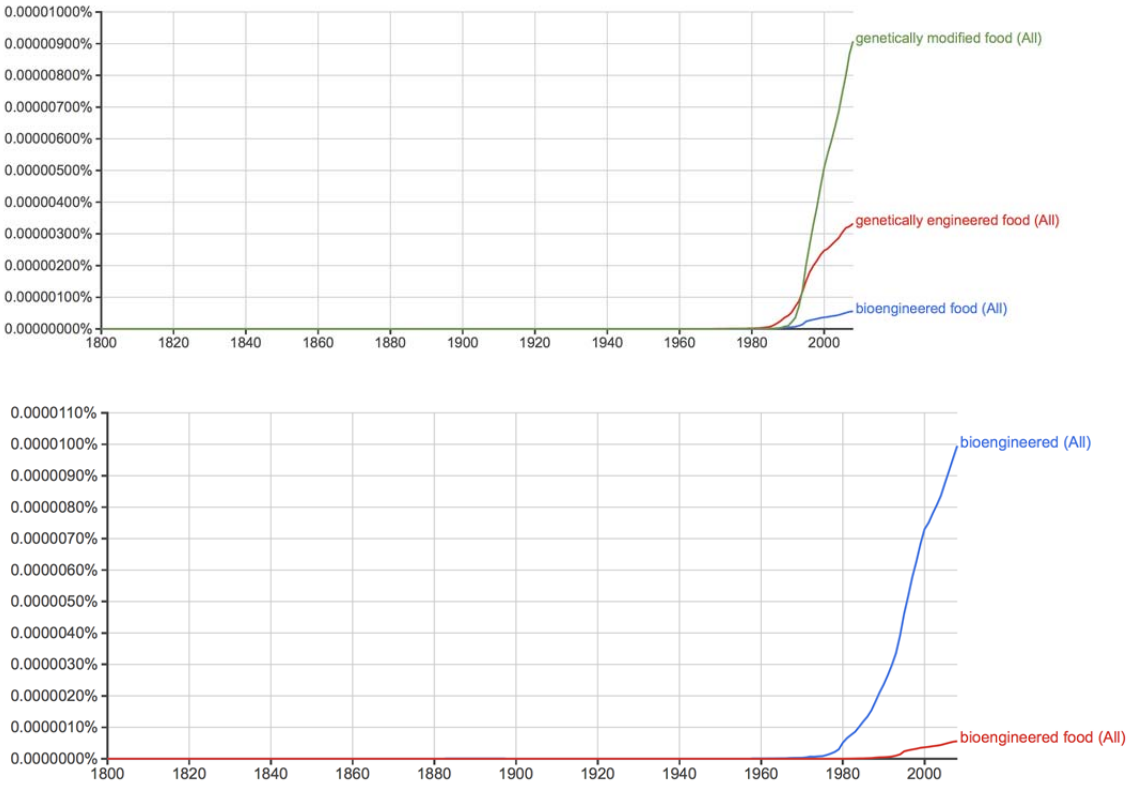

Figure 4: Search of U.S. Books for Use of "Bioengineered" With "Food", Source: Google Books Ngram Viewer (June 18, 2018), https://goo.gl/LzKYqJ; https://goo.gl/qQA4BK.

[106] 51 U.S.C. § 20102(f).

[107] Bioengineering, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/bioengineering (last updated June 19, 2018).

[108] Figure 5, *infra*; CFS, *Use of Various Terms to Designate GMOs* (June 23, 2018).

FDA used "genetic modification" in early explanations of its role in regulating GE foods.[109] In a consumer focus group study, FDA and its contractor relied primarily on the terms genetically engineered and genetically modified in screening potential participants and questioning them about their attitudes. The same focus group study, however, indicates why FDA favors "bioengineered food," despite its unfamiliarity to consumers: "the 'bio-' prefix had a positive connotation for some [focus group] participants."[110] However, misleading consumers with a little-understood but positive-sounding term is not the goal of the disclosure.[111] The goal should be conveying GE ingredient content information in an objective manner, using terms that are neutral, accurate, and readily understood.

In sum, sole use of bioengineering for terminology, and as the textual disclosure, will defeat the disclosure purpose of the NBFDS. In addition to not fulfilling the NBFDS's statutory mandate, it will allow and place USDA's imprimatur on confusing and misleading labeling. For these reasons USDA must instead allow universally acknowledged similar terms that are familiar to consumers.

2. Genetically Engineered and Genetically Modified

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 NBFDS 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.

i. The federal government.

The White House Office of Science and Technology Policy (OSTP) has long provided policy direction to federal regulators of agricultural biotechnology. In its recent two-year effort to modernize the regulatory system for GE products, OSTP shuns the term bioengineering and its inflections in favor of genetic engineering.[112] Neither does USDA in other contexts use "bioengineered," but rather relies almost entirely on the term genetically engineered and the acronym "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.[113] Indeed as noted above, USDA's website referred to this very rulemaking as "GMO Disclosure" until February of this year. The same holds true of the Environmental Protection Agency[114] and the FDA.

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[109] FDA, *Statement of Policy: Foods Derived from New Plant Varieties,* 57 Fed. Reg. 22,984, 22,990 (May 29, 1992); Kessler D. et al., *The safety of foods developed by biotechnology*, 256 Science 1749 (1992). ("Bioengineered" does not appear in either document).

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

[111] It also mirrors the problems discussed above with regards to USDA's proposed symbols.

[112] Emerging Techs. Interagency Policy Coordination Comm., *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (2016). OSTP does not use the term "bioengineering" or its inflections even once in these documents, perhaps because major goals of this modernization were to "increase the transparency of" and "promote public trust in" the regulatory system, and transparency and trust begin with calling things by their proper names.

[113] *See* 40 CFR Part 340; *see also* Biotechnology Regulatory Services, https://www.aphis.usda.gov /aphis/ourfocus/biotechnology.

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

Consumer information from FDA most often refers to genetically engineered and GE plants rather than bioengineered.[115] Federal oversight agencies like the Government Accountability Office[116] favor genetically engineered.

As also noted above, FDA has stated, in two guidance documents for industry on voluntary food labeling, that "bioengineering" is an interchangeable term with the terms "modern biotechnology" and "genetic engineering" and allowed on packaging.[117] FDA stated that "[t]hese terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders. . . ."[118] Further, as also noted above, USDA's FSIS now allows use of the terms "genetically modified organism" or "GMO" for labeling of foods that were produced without genetically engineered organisms, along with other interchangeable terms like "genetically engineered."[119]

ii. The scientific community.

Committees of the National Academy of Sciences have addressed GMOs in several book-length reports, and frequently use the term genetically engineered food or crop, but seldom or never bioengineered.[120] A search of PubMed publications for use of three different search terms (singular and plural) shows clearly that the scientific community most often writes of genetically modified food(s) (96.3

Overview of Plant Incorporated Protectants, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants.

[115] FDA, How FDA Regulates Food from Genetically Engineered Plants, https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/ucm461831.htm (last updated Jan. 4, 2018); FDA, *Consumer Info About Food From Genetically Engineered Plants,* https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/ucm461805.htm (last updated Jan. 4, 2018) ("[w]e use the term "genetic engineering" to refer to genetic modification practices that utilize modern biotechnology," and refers to genetic engineering as a precise term).

[116] 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).

[117] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (Nov. 2015), https://www.fda.gov/Food/Guidance Regulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm; FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon* (Nov. 2015), https://www.fda.gov/Food/ GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm.

[118] *Id.*

[119] 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 (last modified Aug. 19, 2016).

[120] *See e.g.* Institute of Medicine and National Research Council of the the National Academies, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, National Academies Press, Washington, DC (2004); Board on Agriculture and Natural Resources; Division on Earth and Life Studies, *Genetically Engineered Crops: Experiences and Prospects,* The National Academies Press, Washington, DC (2016).

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).[121]

iii. Legislation.

According to govtrack.us, since the 98th congress (1983-84), there have been 125 bills containing the phrase "genetically engineered,"[122] and 56 bills containing the phrase "genetically modified," in the context of GE foods.[123] In contrast, the use of the term "bioengineered" in past bills all appear related to either defense (warfare) or medical contexts.

iv. The food industry and current voluntary GMO content labeling.

The companies that are labeling for GMO content – Campbell Soup; General Mills; Mars, Inc.; Frito Lay; and Dannon, among others – all use terms like "produced with genetic engineering" or "partially produced with genetic engineering,[124] while none (to our knowledge) uses "bioengineered."

Furthermore, food industry research shows that terms like GMO are far more readily understood by consumers. For instance, according to Campbell Soup Company senior manager of consumer insights Katie Cleary: "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."[125]

Finally, the food industry's use of GMO-free label 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 with sales exceeding $19.2 billion.[126]

v. The general public.

Google Trends can be used to analyze the relative frequency of various terms in Google searches over time. Figure 5 below confirms the analysis above. From 2004 to present, the relative usage of three major search terms for GMOs were "genetically modified food" > "genetically engineered food" >

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[121] *Supra* n.108.

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

[123] *Id.*

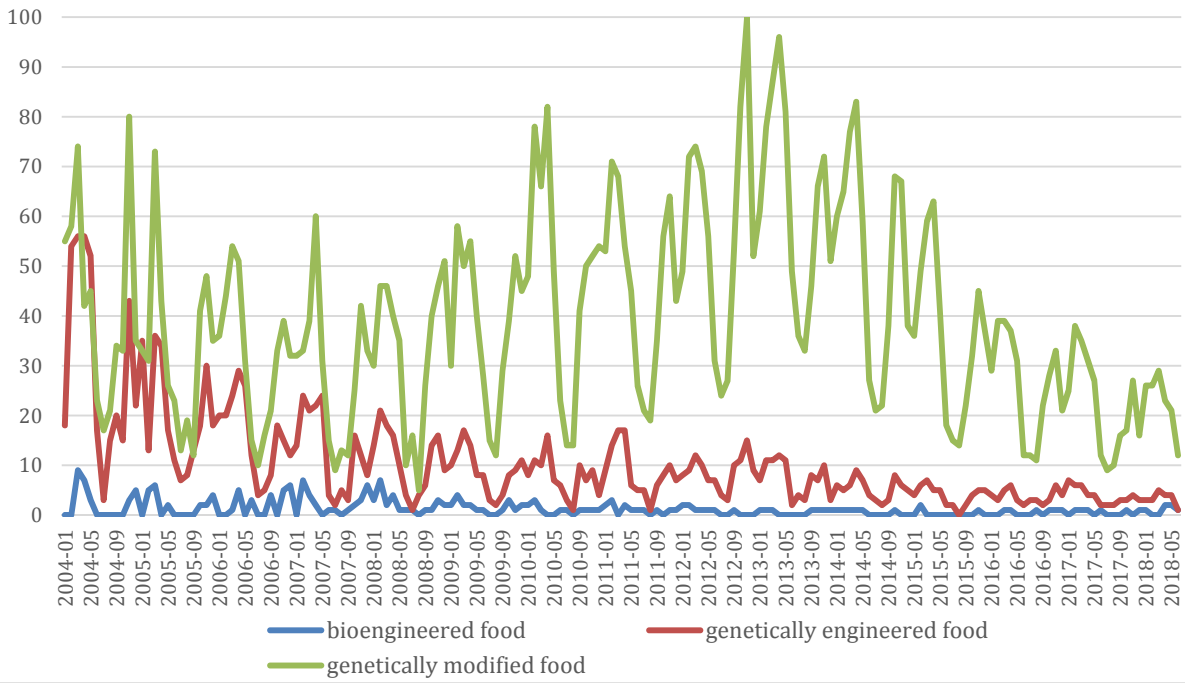
[124] Ken Roseboro, *Food companies say GMO labels having no impact on product sales*, The Organic & Non-GMO Report (Sept. 28, 2017), http://non-gmoreport.com/articles/food-companies-say-gmo-labels-no-impact-product-sales/.

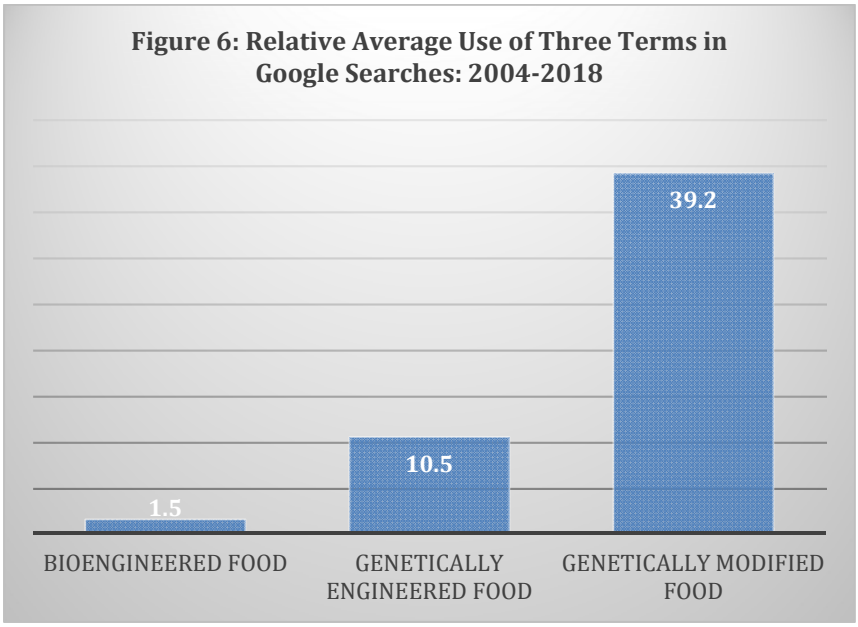
[125] J.R. Pegg, *Campbell Soup finds consumers prefer clear GMO labeling*, Food Chemical News (Sept. 8, 2016), www.agra-net.com/agra/food-chemical-news/food-safety/packaging/campbell-soup-finds-consumersprefer-clear-gmo-labeling-526281.htm.

[126] 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 (September 29, 2015), http://non-gmoreport.com/articles/new-non-gmo-certification-programs-emerging/.

"bioengineered food" for nearly every time-point, excepting brief periods from 2004 through 2008 when searches on the former two terms were conducted with roughly equal frequency. Since 2009, genetically modified food has generally widened its search frequency gap relative to the other two terms. Since 2010, the frequency of bioengineered food as a search term has been negligible. Figure 5 averages the search frequency of the three terms over the 2004 to present period. Together, genetically modified food and genetically engineered food were searched over 33 times more frequently than bioengineered food.

Figure 5: Google Trends Comparison of Three Terms to Designate GMOs: 2004-2018





In sum, the above discussion and evidence shows beyond doubt that bioengineered is an extremely poor designator of GE crop-containing foods, a term that is used overwhelmingly in medical and space exploration contexts, and is judged to be confusing and misleading in this context. Because the purpose of the Act is to educate the public and provide transparency as to whether foods were produced with genetic engineering, USDA should adopt as its terminology the most widely used and familiar words–genetically engineered, genetically modified, GE, GM and GMO–at a minimum, to be used interchangeably with "bioengineering," in order to provide the clearest information to consumers.

II. THE SCOPE OF THE CLASSIFICATION: FOODS THAT MUST BE LABELED

A. The Bioengineered Foods List(s) of Cannot OvercomeUSDA's Statutorily-Mandated Disclosure Classification

Equally important to *how* GE information is disclosed is *what* information is required. And consumers reasonably expect that *all foods* produced through genetic engineering be labeled under the NBFDS. To that end, USDA's providing illustrative lists of GE foods can be informative to consumers, but the proposal to use lists of engineered foods to cabin the universe of what must be labeled cannot overcome the statutory requirement to label all such classified foods, and it must be sufficiently comprehensive and frequently updated to capture all GE foods for full disclosure to the public.

First, the agency's proposal to limit the foods that require labeling to just two lists cannot overcome the NBFDS' requirements and Congress' purpose in enacting the disclosure law, which is that *all such foods* be disclosed. Agencies cannot not enact rules contrary to their statutory directives, nor act beyond the authority delegated to them by Congress. The NBFDS requires USDA establish a "mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered."[127] The statute defines such foods, which USDA is currently proposing to directly

[127] 7 U.S.C. § 1639b(a)(1).

incorporate.[128] However, USDA is also proposing to create two lists of "commercially available" bioengineered foods, differentiated by whether they are "highly" adopted or not.[129] And USDA is proposing that only foods listed on either list will be subject to the mandatory disclosure under the NBFDS.[130] This would be improper: In limiting the universe of what GE foods must be labeled to "commercially available" GE foods on these two lists, USDA would effectively graft onto the statutory definition of "bioengineered foods" the requirement that they be "commercially available." But this requirement is not included in the statutory definition, or the same definition that USDA proposed to directly incorporate. USDA cannot limit the universe of what must be labeled to these lists. If USDA seeks to alter the statutory definition of "bioengineered" to include commercial availability, especially at some threshold, it must make that express in its proposed regulatory definition.

In sum, CFS agrees that lists of existing GE foods could be useful for consumers and regulated entities alike, and is not opposed to the use of illustrative lists *per se*—however the mandatory disclosure requirement cannot be limited to these lists. If a given food qualifies under the GE disclosure classification created by the statute, manufacturers have an independent duty to disclose that, whether or not the food or ingredient is on USDA's current list. Failure to so disclose would be false and misleading.

Second, if lists are used and are to serve their illustrative purpose, then they must be comprehensive and frequently amended. One list rather than two would provide the most clarity, and be the simpliest for consumers. However if two different lists are to be utilized, the threshold for the "highly adopted" commercial foods list is far too high. 85 percent appears to have been arbitrarily selected by USDA; no rationale is stated. A better percentage would be 50 percent, because at an adoption rate for an individual crop of more than 50 percent, it is more likely than not that the food ingredient is bioengineered. This is also what a reasonable consumer would conclude. It would be arbitrarily inaccurate and unreasonable to claim that a GE food with, for example, a 75 percent adoption rate is not "highly adopted."

As to revision and updating of the list(s), it should be completed more frequently than once a year. If this proposal was adopted, it would mean that a given GE food product could be sold in grocery stores *for a full year* without being disclosed as GE. This is contrary to the statute and why manufacturers have an independent duty, created by the statute, to so disclose when and if they are knowingly selling a GE food product.

Instead, in order to implement Congressional will and reasonably inform consumers in a meaningful and timely manner, if USDA uses lists, then the lists should be revised as new GE foods are coming onto the market, are approved by USDA-APHIS, or reach an adoption rate of higher than 50 percent (requiring movement to the "highly adopted" list). The regulations should simply make express in the regulations what Congress did in the statute: when and if a manufacturer decides to make/sell/import a GE food or ingredient, *it must disclose*. For USDA's lists, the manufacturer should notify USDA, *pre-market* and ensure the USDA list is current. As USDA elsewhere points out the manufacturer will already know and have customary records to show their GE/non-GE status. While the duty should ultimately rest on the manufacturer, the government's own sources can also be utilized effectively: whenever USDA grants a new deregulation petition for a GE food under the Plant Protection

[128] *See* 83 Fed. Reg. 19860, 19862 (May 4, 2018).
[129] *Id.* at 19864.
[130] *Id.*

Act,[131] that crop should be placed immediately on the list (at least the "not highly adopted" list). As other GE foods are released, the lists should be updated immediately.

Further, the 18-month grace period for regulated entities to revise food labels following the effective date of a list revision is far too long. When combined with only an annual list revision, it would *take literally years for a new GE food to be disclosed*, contrary to the prompt disclosure contemplated by the statute and demanded by consumers, who have already waited decades for labeling of GE foods. As explained above, the statutory scheme establishes a disclosure scheme and classification for foods that qualify; USDA does not have discretion to effectively negate that requirement for years through a long delayed list process that Congress never mentioned, let alone envisioned. The statutory disclosure requirements apply to any and all foods that so qualify; attempts to negate that are arbitrary and capricious agency action contrary to the statute; sales of false and misleading foods would be contrary to the statute. The entire statutory scheme shows that Congress recognized that this disclosure must be done in a timely fashion: given that the statute gave USDA only two years to complete the disclosure regulations, this length of delay is contrary to the statutory scheme. Moreover, USDA appears to be proposing a definition for "Compliance Date" that would require compliance within 6 months of a revision to the two lists.[132] This is more reasonable, but directly conflicts with the 18-month grace period allowed under proposed § 66.7(c). CFS believes that the overall labeling requirements should become effective after 90 days, but in the case of a list revision for a new GE food ingredient/crop that has not previously been labeled, USDA should provide no more than the 6-month grace period for disclosure following a revision to the lists, and update the proposed § 66.7(c) accordingly.

As stated above CFS believes only one list of all foods provides the greatest clarity for consumers but if two are to be used, regarding the "not highly adopted" list, CFS does not agree that all disclosures on the "not highly adopted" list should be allowed to use the "*may* be bioengineered" phrase. Namely if the producer knows or has reason to know that its particular ingredient(s) are bioengineered, it should not be permitted to label "may." For example, a producer using as an ingredient the GE non-browning apple, or Arctic® Apple, is certainly aware that the ingredient is genetically engineered or bioengineered, even if the adoption rate of this GE non-browning apple is less than 50 percent of all apples, and should not be allowed to use the equivocal "may" in its disclosure. While Congress contemplated the potential use of "may" in the disclosure scheme, it must be done in a way that complies with the basic mandates of the FFDCA, as well as the NBFDS. That is, it must require truthful, factual labeling, that is not false and misleading. And producers cannot knowingly fail to disclose; omissions can also be false and misleading. "May" is for only when the GE content *is truly not known or ascertainable*; it is not an allowance for producers who know they are using GE content. As discussed in the enforcement and recordkeeping section, companies subject to the disclosure requirement will already be required to have records to indicate compliance with the disclosure requirement, meaning they will be required to know if their product contains, or likely contains, a GMO ingredient or is genetically engineered, through testing, chain of custody affidavits, or otherwise. Consumers deserve better and Congress required more.

Finally, as to the specific foods that should be included on the lists, the lists must be expanded to include foods produced in other countries, and not just those commercially available in the U.S. The

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[131] USDA-APHIS, Petitions for Determination of Nonregulated Status, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status (last visited June 22, 2018).

[132] 83 Fed. Reg. at 19885 (proposed § 66.1, Definitions).

overarching purpose of the disclosure law is to inform U.S. consumers, and given that GE foods are imported from other countries, there is no rational reason to exclude these foods from the lists of foods that must be disclosed. As to some of the specific foods that are genetically engineered or bioengineered, but which USDA is nonetheless proposing to leave off the lists, CFS disagrees that any engineered food should be left off the lists, because as explained above, CFS believes that under the statute, any engineered food should be labeled regardless of whether or not it appears on these two lists. For example the GE "AquAdvantage" Atlantic salmon was approved by the Food and Drug Administration,[133] and GE rice (LLRICE601) was deregulated by USDA-APHIS, as was a variety of herbicide-resistant flax, and a virus-resistant plum.[134] Further, as noted by USDA, a pink-fleshed pineapple[135] was also genetically engineered, in addition to several other crops,[136] some of which use newer engineering technologies, and all should be considered "bioengineered" and require disclosure if sold as is or used as an ingredient. These food products need to be included on any list. Again, if lists are to be used, USDA must itself source any governmental information from its own and sister agencies, as well as require manufacturers to provide them the information needed to update their list before marketing their product.

In sum, to comply with the mandatory disclosure standard, USDA cannot limit labeling to its proposed lists, any and all GE foods must be disclosed before they are sold. While governmental lists are useful and should save time for regulated entities as well as inform the public, accurate, comprehensive, and up-to-date current lists are the only way such lists can comply with the statute.

B. Definitions and Disclosure Classification Scope

1. Highly refined foods

USDA should ensure that that all foods produced in whole or in part through genetic engineering are labeled, including those – like cooking oils, sugars and corn/soybean proteins – that contain highly refined products of genetically engineered crops. Such highly refined products must be made subject to NBFDS disclosure because it was indisputably the intent of Congress to do so; American consumers expect such products to be labeled; and it is the only way to ensure compliance with the statute.

i. Legislative intent, consistency with other agencies, and precedent.

Congressional intent was explicitly to cover these types of ingredients under the scope of the Act. Statements from ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow (D-

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[133] FDA, *AquAdvantage Salmon Approval Letter and Appendix*, https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm466214.htm (last visited June 22, 2018).

[134] USDA-APHIS, *Petitions for Determination of Nonregulated Status*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status (last visited June 22, 2018).

[135] Letter from Thomas Young, Senior Vice President of Del Monte, to Michael Gregoire, Deputy Administrator of Biotechnology Regulatory Services (July 30, 2012), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/del_monte_inquiry_letter.pdf.

[136] USDA-APHIS, *Regulated Article Letters of Inquiry*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry (last visited June 22, 2018).

Mich.) clarified that "this bill 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."[137] In statements to Senate, Senator Stabenow clarified that "[NBFDS] provides authority to the USDA to label refined sugars and other processed products."[138] In fact, Senator Stabenow stated that the NBFDS would improve on the existing state labeling scope,[139] which would be impossible if the Act did not include highly refined GMO ingredients like sugar and oils in the scope of its mandatory disclosure standard.

Further, USDA's General Counsel Jeffrey M. Prieto stated that it is well within USDA's authority under the Act to broadly interpret the definition of bioengineering. In a letter to Ranking Member Stabenow on July 1, 2016, written to answer any Congressional questions on this very point, Prieto confirmed that USDA has authority to include ingredients derived from "novel gene editing techniques such as CRISPR," and products which contain "highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques."[140]

FDA's established standards also support the inclusion of highly refined foods. In its industry GE labeling guidance discussed *supra*, FDA endorsed the use of validated testing methods for confirming the presence of bioengineered material in food. That is, reliable and validated tests may be used to confirm the presence of GE material to support a claim that a food is bioengineered.[141] That said, FDA recognized the difficulty in using tests, "*particularly for highly processed foods* such as oils," where it "may be difficult to differentiate" between GE and traditional methods.[142] In addition, specific testing methodologies "likely will change" as new bioengineered varieties are introduced into the marketplace.[143] Thus, the agency concluded that it "may be more practical to substantiate a claim for such foods differently, such as documenting handling practices and procedures."[144] To this end FDA's guidance supports that documentation of handling practices and procedures can be used to substantiate disclosure claims other than testing. Thus FDA recognizes that just because a food or food ingredient may not contain detectable levels of genetic material from a bioengineered source does not meant the food does not contain any genetic material and does not mean that food is not genetically engineered; it only means that it is not detectable using present-day, readily available scientific methods.[145]

Finally, the idea that genetically engineered material is present despite a current lack of technological ability to detect it, and that it is proper to label it, was confirmed by the Sixth Circuit Court of Appeals, in a case about labeling of dairy products from animals not treated with genetically engineered growth hormone (rbGH/rbST).[146] Thus, it is line with the intent of Congress, USDA's own

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[137] 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[138] 162 Cong. Rec. S4783 (daily ed. July 6, 2016).
[139] 162 Cong. Rec. S4906 (daily ed. July 7, 2016).
[140] 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[141] FDA *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, 8 (Nov. 24, 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm.
[142] *Id* (emphasis added).
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] *Internat'l Dairy Foods Assoc. v. Boggs*, 622 F.3d 628, 637 (6th Cir. 2010).

counsel, and federal judicial precedent to include products with highly refined ingredients from genetically engineered organisms under the Act's mandatory disclosure requirement.

As such, USDA has broad authority to and should follow Congressional intent and its own past positions in interpreting the definitions and scope of the law to include products produced with genetic engineering, but contain it only at levels that are currently not generally detectable.

ii. The reasonable expectations of Americans: highly refined GE foods to be labeled.

American consumers expect foods containing highly refined products of GMOs to be labeled. This follows from the facts that: 1) The overwhelming majority of genetically engineered foods on supermarket shelves are not whole foods (like GE papaya or squash), but rather highly processed foods with refined GE crop content; and 2) The massive public support for labeling that resulted in passage of the NBFDS was based on widespread understanding of this very fact. To exclude such GE foods from the NBFDS labeling mandate would be rightly viewed by the public as an act of monumental betrayal, exacerbating Americans' already great distrust of biotechnology companies and government food regulators. It would be false and misleading labeling in the omission. USDA should recall the attitudes of FDA focus group participants nearly two decades ago:

> Some participants remarked that bioengineered foods have been "snuck in" to the food supply. They were mainly disturbed by the lack of public information and public input to a major development in the quality of their food supply. This information about prevalence served to reinforce the most negative and cynical views some participants held about food biotechnology. Some participants saw this as evidence of a conspiracy to keep consumers in the dark, that is, the rationale for not informing the public must be that there is something to hide.[147]

Growing cynicism was also buttressed by the food industry's enormous outlays on public relations to spread misinformation about, and thus narrowly defeat, several state-level labeling bills that preceded the NBFDS, as discussed at p.1 introduction *supra.* To the contrary, a recent study by the University of Vermont found that labeling GE food reduced consumer distrust of GE food by almost 20 percent.[148] Given this history, there would be no better way to entirely lose the trust of millions of American consumers in the NBFDS than for USDA to exclude highly refined GE foods from the disclosure mandate (presumably at the demands of the biotech industry). This exclusion would further alienate Americans from agricultural biotechnology and Big Food while further eroding trust in federal food and agriculture regulators, and fail to fulfil the NBFDS' purposes.

iii. Science and law also require the inclusion of highly refined foods in the classification.

Fortunately, the intent of Congress and public expectations jibe with the clear mandate of the NBFDS and the science underlying it. USDA describes three reasons raised by commenters for its

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[147] Levy, A.S., Derby, B.M., *Report on Consumer Focus Groups on Biotechnology, Consumer Studies Team*, Center for Food Safety and Nutrition, Food and Drug Administration, Washington, D.C. (2000).
[148] 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.

consideration of potentially excluding highly refined GE products from the disclosure mandate in the final rule: 1) They do not contain recombinant DNA (rDNA); 2) They contain only small, "incidental" amounts of rDNA; and 3) The products are chemically identical to those from non-GE crops, so presumably any presence of rDNA can be disregarded.[149] None of these arguments are persuasive.

The second and third considerations must be rejected based on the plain text of the statute. The first prong of the definition of bioengineering, upon which the disclosure classification mandate is based, explains that the disclosure classification includes *any* food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques."[150] The definition makes no allowance for "incidental" amounts of rDNA – if it is present, it must be disclosed, whatever the level. Later in the statute there is an allowance for a de minimis threshold for inadvertent presence of rDNA, for USDA to determine what that will be in the regulations,[151] *see infra*, but that just underscores the point: to begin with, the default set by the definition is that, contrary to points 2 and 3, *any food that contains any amount of transgenic material* is included in the classification. These foods cannot be excluded from the definition at the outset; any allowance needs a threshold exemption. The similarity (or presumed chemical identity) of a product refined from a GMO to that of one refined from a conventional plant is immaterial to the bioengineering definition's scope; it cannot be used to justify exclusion at the outset from the disclosure classification. In addition, as the second argument suggests, most (and perhaps all) highly refined products will have *some* low-level presence of DNA – and that DNA in the GMO-derived product (rDNA) will differ from that in the conventional counterpart product. The products are thus not chemically identical.

According to the first point raised by commenters, highly refined products "have undergone processes that have removed genetic material such that it cannot be detected using common testing methods."[152] However, the definition of bioengineering does not exempt foods that contain rDNA at levels "not detectable using unspecified current testing methods." Simply because current methods do not detect material does not mean that the products do not "contain" recombinant DNA. This is significant, because DNA testing methods are rapidly becoming more sensitive. Foods from GE plants that just a few years ago had no detectable rDNA are today found to contain it.

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.[153] 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.[154] 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

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[149] 83 Fed. Reg. at 19862-63

[150] 7 U.S.C. § 1639(1)(A).

[151] 7 U.S.C. § 1639b(b)(2)(B).

[152] 83 Fed. Reg. at 19862.

[153] 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).

[154] 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).

2015.[155] 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.[156]

It has often been claimed that oils from GE oilseed crops (e.g. soybeans, canola) do not contain rDNA. Yet this is not the case. The putative absence of rDNA in oils was a consequence of older, less sensitive testing methods; test method improvements have enabled detection of previously "invisible" rDNA. A frequently cited paper on the absence of DNA in soybean oil[157] was contradicted just two years later by the same Belgian research team.[158] Many other scientists have also detected DNA in refined oils: rDNA in soybean oils[159] as well as DNA in commercial sunflower and maize oils.[160]

There have been few attempts to detect DNA in sugar derived from sugar beets and sugar cane (whether GMO or conventional). Negative results were reported in papers one or two decades old.[161] Two more recent studies are divided, with one finding no rDNA in sugar from GM sugar beets,[162] and the second finding sugar cane DNA and proteins in raw sugar from conventional sugar cane.[163] The finding of DNA in raw sugarcane sugar in a recent study, together with the continually increasing sensitivity of DNA testing methods described above, makes it inevitable that rDNA will soon be detected in refined sugar from GM sugar beets.[164] This would be analogous to the rapid evolution of testing methods resulting in detection of rDNA in GMO-derived oils that was invisible to the more primitive testing methods of just a few years ago.

The intensity of research in this arena of DNA detection in crop supplies and processed foods is astounding. CFS conducted a simple PubMed search using the terms "GMO detection" (without

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[155] 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).
[156] 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).
[157] Gryson et al., *Detection of DNA during the refining of soybean oil,* 79(2) JAOCS 171-174 (2002).
[158] 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.")
[159] 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).
[160] 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).
[161] Klein et al, *Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets*, 60 J. Biotechnology 145-153 (1998); Oguchi et al., *Investigation of residual DNAs in sugar from sugar beet (Beta vulgaris L.),* 50 J. Food Hyg. Soc. Japan 41-43 (2009).
[162] Joyce et al., *Sugar from genetically modified sugarcane: tracking transgenes, transgene products and compositional analysis,* 115 International Sugar Journal 1380 (December 2013).
[163] Cullis et al., *DNA and protein analysis throughout the industrial refining process of sugar cane,* 3(2) International Journal of Agricultural and Food Research 1-15 (2014).
[164] Here and throughout this discussion, it is understood that methods designed to detect unmodified DNA are equally applicable to detection of rDNA.

quotation marks), and got 287 hits. The number of papers returned by this search has skyrocketed over time, increasing from an average of 0.44 annually in the 1990s, to 10.2 in the 2000s, to 21.2 from 2010-2017.[165] Many of these papers present new testing methods, or significant tweaks on existing methods, most of them variations on some form of PCR. 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.[166] Sensitivity is continually increasing, and can arise from improvements in DNA extraction procedures, increased ability to amplify ever-shorter DNA fragments (especially important for DNA detection in highly processed foods), more advanced statistical procedures,[167] methods to minimize PCR inhibition,[168] or increasing the amount of DNA for PCR analysis, to name just a few innovations.

iv. Petition to exempt highly refined foods from NBFDS disclosure mandate as a "factor or condition"

USDA also suggests that it might properly include highly refined GMO-derived foods in the NBFDS classification initially, but then grant a special "factor or condition" allowing companies to essentially "test out" of the disclosure mandate.[169] As proposed by USDA at the instigation of commenters, a food manufacturer would demonstrate that its refined product had no detectable rDNA according to tests conducted by an ISO/ICE 17025:2017-accredited laboratory using a Codex Alimentarius-validated methodology, and thus be exempt from labeling.

This appears to be simply a backdoor way to exclude these foods from the classification. USDA should reject this requested factor or condition because the statute's disclosure mandate would then critically and improperly hinge upon the sensitivity of the rDNA test method chosen by the food manufacturer.[170] Giving food manufacturers the authority and latitude to operationalize the statute's

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[165] CFS, *Results of PubMed Search for GMO Detection* (2018) (Search conduced on PubMed for GMO detection on June 26, 2018, the results listed 287 papers. These search results do not of course represent a complete picture of research in this area, but rather are meant only to give a rough indication of increasing research intensity).

[166] 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).

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

[168] 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).

[169] 83 Fed. Reg. at 19865-67.

[170] The Codex Alimentarius guidelines referenced by USDA do not specify the test method to be used nor its sensitivity, and indeed have virtually no substantive prescriptions of any sort. The guidelines give the test developer freedom to select or design a test of its choosing, requiring only that the test method be thoroughly described and validated for specified foods. Thus, there could theoretically be as many differing, validated test procedures as there are food manufacturer x food type combinations. Also, it should be noted that the Codex guidelines themselves (dated 2010) as well as the technical papers cited in

critical definition (what does and does not constitute a genetically engineered food) in this way would raise a host of insoluble problems based on the fact (discussed above) that there are a large and growing variety of DNA testing methods, each with differing protocol and sensitivity. It would unlawfully delegate to a private party USDA's own statutory duty, of setting the classification and determining what's included in the NBFDS. It would also be arbitrary and capricious agency action to essentially base a classification on the current status of science and technology in a field like DNA detection that is developing at such an extremely rapid clip. Several problematic scenarios can be easily foreseen.

First, a food manufacturer would be incentivized to choose a less sensitive rDNA test method that does not detect the rDNA in its refined product. It might do this because it anticipates greater sales if its product is unlabeled for GMO content, and/or because the less sensitive test method is cheaper to implement. Reliance on a private party's unilateral determination of a testing methodology is reliance on an extra-statutory factor, unlawful delegation of duty, and failure to apply Congress's mandate in the NBFDS.

Second, this course of action by one company would strongly incentivize other firms producing the same products to likewise choose less sensitive test methods, in a race to the bottom that ends with an entire class of products (e.g. soybean oil from GM soybeans) that are sold without GMO disclosure despite containing rDNA. Multiplied across the food sector by class of refined product, the result would be untruthful labels, presenting false and misleading information, that fail to disclose GE content across most processed foods found in supermarket aisles.

Third, it follows from the preceding point that food companies would have no incentive to adopt newer, more sensitive, DNA test methods as they become available – both because doing so might lead to detection of previously invisible rDNA and the unwanted duty to disclose it, and because of the expense associated with development and validation of the new DNA test protocol. On the contrary, firms would be strongly disincentivized from availing themselves of the latest in DNA detection science and technology. These absurd results are contrary to good public policy, as well as Congress's intent.

Fourth, other parties might choose to test unlabeled but rDNA-containing products with more sensitive rDNA test methods, and if positive results are obtained publicize the results. Such parties might include importers of the unlabeled products in other countries, the government food regulators in those countries, or NGOs in the U.S. or abroad. The revelation that unlabeled food products are in fact bioengineered could cause disruptions in the marketplace, including food recalls, rejected export shipments, international trade disputes, etc. Such revelations would also further erode consumer trust in major food companies and government food regulators, directly contrary to the transparency purpose of the NBFDS.

In general, the intent of including the petition process for addressing further "factors and conditions" for USDA to consider was to *broaden*, not narrow, USDA's potential scope.[171] Thus use of it to provide a second bite at the apple to exclude highly processed foods would be contrary to the statutory intent and arbitrary and capricious. In sum, there is no reasonable way to avoid these outcomes – arbitrary and capricious violations of the NBFDS statute – short of rejecting this petition factor or

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them to inform test methodology development are both nearly a decade old, and hence long superseded in this rapidly developing field.

[171] 7 U.S.C. § 1639b(b)(2)(C).

condition, and including all highly refined foods derived in whole or in part from GMOs under the classification of bioengineered food, and thus making all products that contain one or more ingredients refined from GMOs subject to mandatory disclosure.

2. Costs

As a fiscal issue, USDA's own economic analysis concluded that overall it would *not save manufacturers any money* to exclude highly processed ingredients from the disclosure mandate, because nearly all processed foods have more than one GMO ingredient that would otherwise still require disclosure.[172] Further, whatever costs might be saved through specific food manufacturers avoiding the mandatory disclosure requirement by means of this factor or condition would be more than counterbalanced by a number of other imposed costs. Litigation between firms employing different rDNA test methods with differing sensitivities is likely, with the more sensitive tester claiming damages for lost market share from the firm that utilizes less sensitive testing in order to hide the rDNA in its products. All of these food labels at issue still must pass muster under the FFDCA's standard that they not be false and misleading in any particular, by statement or by omission. Importers could sue exporters for failing to disclose rDNA content through proper labeling by intentionally choosing a substandard rDNA test method. Consumer groups might sue particular food manufacturers on the same grounds, or the USDA for regulations that do not properly implement the underlying statute. Marketplace costs such as those alluded to above (e.g. food recalls) are also highly likely, especially given the long history of similar episodes involving the presence of unauthorized GMOs in foods. USDA would also incur the costs of managing such a "test out" system, including resources devoted to adjudicating the many highly technical challenges to it that are sure to be mounted, along the lines discussed above. Perhaps most importantly, food companies that avail themselves of the proposed "test out" provisions will (further) lose the trust and patronage of their customers, and agricultural biotechnology will fall (further) into disrepute. Adopting a clean, clear policy of requiring all foods derived in whole or in part from highly refined GMOs is the only way to ensure that the NBFDS's mandate is met, the only way to avoid endless marketplace disruptions and litigation, the only way to ensure NBFDS implementation is consonant with the latest developments in the science of DNA detection, and finally the only way to win the trust of Americans in the integrity of the food supply.

3. New Forms of Genetic Engineering

The agency must ensure that foods made with newer forms of genetic engineering are covered by the disclosure standard. Failure to do so would conflict with Congressional intent in passing the NBFDS and be arbitrary and capricious.

The Act's definition of "bioengineering" (Sec. 291(1)(A)) refers to genetic material modified through recombinant deoxyribonucleic acid (rDNA) techniques—processes that result in new combinations of genetic material. USDA has copious authority to apply the definition of bioengineering in the Act broadly to include the full range of genetic engineering techniques. More generally, the Act gives USDA broad discretion in determining the requirements and procedure for the scheme. Among other things, it includes a catchall provision that commands the agency to "establish such requirements

[172] 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.

and procedures as the Secretary determines necessary to carry out the Standard."[173] This can and should include provisions to cover newer forms of genetic engineering. As discussed above, various points of legislative history support Congress's view that newer GE forms would be covered, see *supra*. Both USDA's General Counsel and Senator Stabenow confirmed that the definition of "bioengineering" includes the newer forms of genetic engineering, like gene editing. In Prieto's letter to Stabenow, he writes that the bill gives USDA the authority to include "novel gene editing techniques such as CRISPR" and "RNAi technologies."[174] In contrast, limiting the definition only to foods with ingredients derived from older rDNA techniques would unduly exclude foods derived from newer technologies like CRISPR gene editing or RNAi, and render the Act's disclosure requirement obsolete as the industry shifts and new technologies become available.

Failure to include them would also conflict with other federal definitions. The definition of "biotechnology product" put forward in the 2015 memorandum on the Coordinated Framework for the Regulation of Biotechnology, issued by the Executive Office of the President, includes all of the newer technologies used in biotechnology, such as gene editing or gene silencing.[175] Further in reference to the different methods of genetic engineering, USDA's existing definition of excluded methods also includes gene editing and gene silencing.[176] The recent recommendation by USDA's National Organic Standards Board clarifies that such forms of genetic engineering are prohibited under the organic standard.[177]

Moreover, as discussed further *infra*, USDA's regulations must be consistent with the U.S. international trade obligations, including the Codex Alimentarius, or "Food Code," was developed by the World Health Organization to develop harmonized food standards, including the Principles for Risk Analysis of Foods Derived From Modern Biotechnology adopted by the Codex Alimentarius Commission in 2003.[178] The Codex definition of GE includes newer techniques like gene editing.[179] Deviation from this accepted standard, and the one used by major trade partners, would needlessly complicate international trade and could have significant adverse impacts on U.S. agricultural interests, through product confusion, reputational harm, market rejection, or other means, contrary to the NBFDS. Documents and standards developed by Codex are referenced by the World Trade Organization in trade disputes involving food, and constitute a globally accepted standard. In addition, the Codex definition of "modern

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[173] 7 U.S.C. § 1639b(a)(2).

[174] Letter from Jeffrey M. Prieto, General Counsel, USDA, to Debbie Stabenow, Senator, U.S. Senate (July 1, 2016), http://src.bna.com/gvy.

[175] Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products, Executive Office of the President (July 2, 2015), https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

[176] *See* 7 C.F.R. § 205.105.

[177] Formal Recommendation Regarding Excluded Methods Terminology to be listed in the National Organic Program Excluded Methods Guidance Document, Nat'l Organic Standards Bd., Nov. 2, 2017, https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRec.pdf.

[178] *See* Food and Agriculture Organization of the United Nations, Codex Alimentarius, http://www.fao.org/fao-who-codexalimentarius/about-codex/en/.

[179] *See* U.N. World Health Organization, Food and Agriculture Organization, *Codex Alimentarius: Guidelines for the Production, Processing, Marketing and Labelling of Organically Produced Foods* 7 (2001), ftp://ftp.fao.org/docrep/fao/005/Y2772E/Y2772e.pdf.

biotechnology" is also the same as that used in the Cartagena Biosafety Protocol under the Convention on Biological Diversity, which also clearly shows it to be the globally accepted standard.

In sum, failure to include these forms of GE would vitiate Congressional intent to provide disclosure to consumers of GE foods, be contrary to existing national and international definitions, and fly in the face of assurances by USDA to Congress during the legislative process otherwise.[180]

4. Further Terminology Regulatory Definitions

USDA also seeks comment on whether it should further define in its regulations either the terms "found in nature" or "conventional breeding." CFS does not support USDA including such further definitions and believes them unnecessary and potentially confusing, contentious, or unnecessarily contraining to the statutory classification. An overly-broad definition of either or both could exempt nearly all GE foods from labeling, contrary to Congressional intent and consumers' need for labeling. USDA proposes to incorporate the statutory definition without further defining its terms, which CFS supports. However if USDA is to include either further definition, CFS offers the following points.

First, with regards to "found in nature," the NBFDS states that a food is bioengineered if it "(A) … contains genetic material that has been modified through in vitro rDNA techniques," and "(B) … the modification could not otherwise be obtained through conventional breeding or found in nature."[181] The the "modification" in clause (B) of the "bioengineering" definition is the *modification* of genetic material itself via rDNA. This conclusion follows directly from clause (A), in which "modified" refers to "genetic material" rather than, for instance, the trait generated by the genetic modification (see below).

Moreover, the genetic constructs[182] inserted into plant genomes to create GE plants are never "found in nature." The vast majority of these genetic constructs contain DNA sequences derived from bacterial or viral sources, such as the toxin-encoding gene derived from the soil bacterium *Bacillus thuringiensis*, or the CP4 EPSPS glyphosate resistance gene derived from *Agrobacterium*. However, the DNA sequences of these genes have to be altered, often substantially, to function effectively in a plant genome. For instance, codon optimization – in which the genetic code of the bacterial or viral gene is systematically altered, prior to insertion, to better resemble the codons (3-nucleotide DNA segments that each encode one amino acid) found in the host plant – is often necessary for expression of the intended trait.[183]

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[180] *See* 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).

[181] 7 U.S.C. § 1639(1).

[182] As the name suggests, a genetic construct is a collection of DNA sequences from various source organisms that are artificially spliced together in such a way that when the whole is inserted into a host organism via recombinant DNA techniques, the host is enabled to express a new trait (e.g. herbicide resistance).

[183] Jackson et al., *Design rules for efficient transgene expression in plants,* 12 Plant Biotechnology Journal 925-933 (2014) (explaining that "the detailed methods used by plant biotechnology companies are proprietary," and hence not made public). *See also*: Tian et al., *Predicting synonymous codon usage and optimizing the heterologous gene for expression in* E. coli, 7 Scientific Reports 9926 (2017).

Further, even in cases where the genetic material being inserted comes from the same general class of organism as the host, and codon optimization is not necessary, the full genetic construct would still not be "found in nature," even though its separate parts may be. One example is genetically engineered AquAdvantage salmon, which has a promoter and termination region (DNA sequences that act as on- and off-switches, respectively) from an ocean pout spliced to a growth hormone gene from a Chinook salmon.[184] In general, the multiplicity of source organisms used to create genetic constructs ensures that they will *never* be "found in nature." For example, the figure below shows the 14 DNA sequences conjoined to form the genetic construct used to generate glyphosate-resistant, Roundup Ready soybeans: [185]

[184] Yaskowiak et al, *Erratum to Characterization and multi-generational stability of the growth hormone transgene (EO-1α) responsible for enhanced growth rates in Atlantic Salmon*, 16 Transgenic Research 253-259 (2007).
[185] Monsanto, *Petition for Determination of Nonregulated Status: Soybeans with a Roundup Ready Gene*, 22, Monsanto# 93-089U (1992), https://www.aphis.usda.gov/brs/aphisdocs/93_25801p.pdf.

Table III.1 Summary of Sequences for PV-GMGT04

Genetic Element	Size, Kb	Function
P-E35S	0.61	The cauliflower mosaic virus (CaMV) promoter (Odell, *et al.*, 1985) with the duplicated enhancer region (Kay *et al.*, 1987).
CTP4	0.23	The N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Petunia hybrida* EPSPS gene (Shah *et al.*, 1986).
CP4 EPSPS	1.36	The C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4 EPSPS) from an *Agrobacterium* species (Barry *et al.*, 1992).
NOS 3'	0.26	The 0.26 Kb 3' nontranslated region of the nopaline synthase gene (Fraley *et al.*, 1983).
KAN	1.32	The neomycin phosphotransferase type II gene (*nptII*) from pKC7 (Rao and Rogers, 1979). The *nptII* confers bacterial kanamycin resistance.
ori-pUC	0.65	The origin of replication from the high copy *E. coli* plasmid pUC119 (Vieira and Messing, 1987).
LAC	0.24	A partial lacI coding sequence, the promoter Plac, and a partial coding sequence for ß-d-galactosidase or lacZ protein (Yanisch-Perron *et al.*, 1985).
P-MAS	0.42	The 0.42 Kb TR 2' mannopine synthase promoter region (Velten *et al.*,1984).
GUS	1.81	The 1.81 Kb coding region of the ß-glucuronidase gene (Jefferson *et al.*, 1986). The expression of the gene in plants is used as a marker for transformation.
7S 3'	0.43	The 0.43 Kb 3' nontranslated region of the soybean 7S seed storage protein alpha' subunit (Schuler *et al.*, 1982).
CMoVb	0.57	The 0.57 Kb 35S figwort mosaic virus promoter (Gowda *et al.*, 1989).
CTP4	0.22	The N-terminal 0.22 Kb chloroplast transit peptide sequence from the *Petunia hybrida* EPSPS gene (Shah *et al.*, 1986).
CP4 EPSPS	1.36	The C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4 EPSPS) from an *Agrobacterium* species (Barry *et al.*, 1992).
NOS 3'	0.26	The 0.26 Kb 3' nontranslated region of the nopaline synthase gene (Fraley *et al.*, 1983).

The source organisms of these DNA sequences include two plant viruses (cauliflower and figwort mosaic virus), two bacterial species (*E. coli* and *Agrobacterium*), petunia, and soybean. Clearly, this complex amalgam of DNA sequences spliced together from diverse sources is not something that will ever be "found in nature."

Finally, genetic constructs can break apart during the genetic engineering process, such that one or more fragments of unpredictable length are incorporated into the plant genome, and potentially fuse with the native plant DNA.[186] Thus, even in the extremely unlikely event that a biotechnology company were to build a genetic construct whose entire DNA sequence *precisely matched something found in nature*, it is probable that it would be corrupted in the insertion process and thus lose its correspondence to the natural sequence.

The discussion above is based on the language of the bioengineering definition, which makes it clear that the "found in nature" clause refers to the *modified genetic material itself*, not the trait conferred by

[186] Freese and Schubert, *Safety testing and regulation of genetically engineered foods*, 21 Biotechnology and Genetic Engineering Reviews 299-324 (2004).

the genetic alteration. Interpreting the definitional language to refer to merely the trait as found in nature would be contrary to the language's text and overall scheme, its legislative history, and sound science.[187]

However, even if one misinterpreted the definition to the effect that a GE food plant whose *trait* is found in nature is exempt from labeling, it would still not exempt from the definition a single GE food plant grown today, or any future conceivable GE plant. And this is true even when a superficial look might suggest that the GE crop trait is in fact "found in nature." Consider the GE trait of glyphosate resistance. There are glyphosate-resistant weeds, but the genetic and cellular mechanisms, as well as the levels of glyphosate resistance in various weed populations, are substantially different than the mechanisms and levels of resistance in GE crops, despite the broad general designation they share.[188] There are glyphosate-resistant bacteria. But both glyphosate-resistant bacteria and weeds proliferate not in "nature," but rather in *human-made environments* where the human-made compound, glyphosate, is ubiquitous (glyphosate manufacturing plant for bacteria,[189] farm fields where glyphosate is sprayed intensively for weeds). That is, these modifications required human intervention, and were not found in nature. The situation is similar for other GE crop traits that might at first glance be thought of as "found in nature."

On the organismal level as well, one will not "find in nature" a natural equivalent of a genetically modified plant. This is true both because of the uniqueness of the genetic construct's sequence, and the specific nature of the trait it confers, as discussed above. It is also true because the genetic engineering process causes often extensive mutations in the plant's genome. Even if "nature" were somehow able to achieve the impossible task of producing an organism that replicated the genetic construct sequence and the trait of a GE plant, the unpredictable pattern of mutations generated by genetic engineering ("transformation-induced mutations")[190] would still not be replicated, and the GE crop's putative natural doppelganger would still be identifiably different.

In short, the "found in nature" clause in the bioengineering definition only applies if the natural counterpart precisely replicates the genetic constructs, traits, and overall genetic makeup, of a GE organism. For the reasons discussed above, this will be extremely unlikely to occur, and bioengineered foods will seldom if ever be exempted from the NBFDS's disclosure mandate on these grounds. USDA should use a common sense approach to ensure that the definition of "bioengineered" covers all methods of genetic engineering as Congress intended and the public expects. Genetic engineering is not a natural process and it would be arbitrary and capricious to attempt to define it as such. None of the engineering modifications produced through genetic engineering can be "found in nature," as the term is "nature" is logically defined. Any efforts to exclude such foods from the disclosure mandate would be arbitrary and capricious and contrary to sound science.

Second, nor is it necessary or appropriate for USDA to re-define in its regulations "conventional breeding." However if USDA intends to so define the clause, it must consider the following.

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[187] The Codex Alimentarius definition also focuses on the process of modification, such as mating, multiplication, or recombination. *See supra.*

[188] V.K. Nandula, ed., *Glyphosate Resistance in Crops and Weeds* (John Wiley & Sons, Inc. 2010).

[189] Jerry Adler, *The Growing Menace from Superweeds*, Scientific American (May 2011), http://www.saynotogmos.org/ud2011/fp-content/docs/sciam_superweeds.pdf.

[190] Wilson et al, *Transformation-induced mutations in transgenic plants: analysis and biosafety implications, 23* Biotechnology and Genetic Engineering Reviews 209-234 (2006).

The NBFDS exempts from the disclosure mandate those GE food plants whose genetic modifications could have been obtained through conventional breeding.[191] Any definition of "conventional breeding" should be defined broadly. It should ensure that all products of biotechnology, including newer versions such as rDNA, CRISPR, gene editing, or RNAi, are excluded. Products of modern biotechnology, as defined by the FDA, the USDA's National Organic Standards Board (NOSB), and Codex, should not be considered "conventional breeding." Among other regulatory definitions, the NOSB recently adopted a definition for "classical/traditional plant breeding" which USDA can and should utilize, pursuant to the NBFDS's requirement to harmonize the GE labeling rules with existing organic rules.[192] The NOSB's definition is as follows:

> **Classical/Traditional plant breeding** – Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

Further, this clause should apply only if there does in fact exist a conventionally bred organism that precisely replicates the GE organism. USDA must not accept arguments about the theoretical possibility of conventionally breeding such an organism, because theoretical possibilities are quite often never realized in practice due to unforeseen technical obstacles. As with the "found in nature" exemption discussed above, the criterion should be whether the conventionally bred candidate plant *has precisely the same trai*t – conferred *by precisely the same modified genetic sequence* – and has the same genetic makeup, as the GE plant it purports to replicate. Only under these stringent conditions could USDA potentially exempt a GE food from the disclosure mandate.

C. Threshold

The statute also mandates that USDA determine in the regulations what amounts of a bioengineered substance "may be present" in a food "in order for the food to be a bioengineered food."[193] Thus USDA's regulations will establish a threshold, or *de minimis* standard for GE content in a food in order for it to meet the bioengineered labeling standard.[194]

USDA proposes three different alternatives. CFS supports as the appropriate threshold the second option: .9 percent by weight of the specific ingredient. That is, if a food has an ingredient that contains a GE substance that is inadvertent or technically unavoidable and accounts for no more than .9 percent of the specific ingredient by weight, then it is not subject to disclosure. This is the standard of the

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[191] 7 U.S.C. § 1639(1)(B).
[192] *Id.* § 1639b(f)(2).
[193] *Id.* § 1639b(b)(2)(B).
[194] 83 Fed. Reg. at 19868.

majority of the United States' trade partners. The European Union uses a .9 percent threshold per ingredient, as does the non-GMO project verified and several other private standard setting organizations. Vermont's Act 120 threshold was similar, with which many companies are already complying. Indeed, this is the standard proposed for the USDA's own Process Verified Program, to meet the European Union standard as well as existing third-party standards.[195] Further CFS agrees that disclosure be required for *each* ingredient that exceeds the 0.9 percent threshold. Not only is that standard in widespread use in the EU, it is information that consumers want to know and would facilitate tracking of any health effects that might occur, such as a possible allergic response, after post-market exposure.[196] Thus, the disclosure should be required for any ingredient in a food product that exceeds the 0.9 percent bioengineered threshold.

The other two proposed options -- 5 percent by weight of the specific ingredient or 5 percent of the total weight of the food -- would be arbitrary and capricious and not be consistent with international trade obligations and norms. They would exempt broad segments of the GE food market from disclosure and be inconsistent with widely accepted food industry and international regulation standards.

D. Exemptions/Inclusions, Voluntary Disclosures, Prohibitions, and Preemption

There are a number of express exclusions in the statute, as to types of food that are not included within the scope of the classification.[197] For example, the statute mandates that USDA's regulations shall exclude "food served in a restaurant or similar retail establishment" and "very small food manufacturers."[198] Thus USDA in the draft rule has proposed to exclude from the scope of the bioengineered labeling mandate all food served in restaurants or similar establishments and food, as well as produced by very small food manufacturers, as both are to be defined.[199] These definitions and exclusions should be interpreted narrowly, to best inform consumers by including the broadest range of coverage possible.

To give another example, the scope of the NBFDS also does not include pet food. The statute does this by defining "food" first to be "as defined by in [the FFDCA],"[200] which includes any articles "used for food or drink for man or other animals,"[201] but then cabining that definition to only food "intended for human consumption."[202] Thus pet food is not covered by the classification.

Similarly, animal products from conventional (non-GE) livestock that are fed GE feed or GE grain fall are outside the jurisdiction of the USDA disclosure classification, and into the jurisdiction of FSIS (except for multi-ingredient products whose predominant ingredient was a non-meat/FFDCA

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[195] *See* Attachment 9 (Freedom of Information Act Response from OSEC).
[196] Philip J. Landrigan, M.D., and Charles Benbrook, Ph.D., *GMOs, Herbicides, and Public Health*, New England Journal of Medicine (2015), http://www.nejm.org/doi/full/10.1056/NEJMp1505660#t=article; FAO-WHO, *Evaluation of Allergenicity of Genetically Modified Foods*, Report of a Joint FAO/WHO Expert Consultation (January 22-25, 2001).
[197] *See e.g.* 83 Fed. Reg. at 19867.
[198] 7 U.S.C. § 1639b(G)(i)-(ii) (neither of which are defined by the statute).
[199] 83 Fed. Reg. at 19867.
[200] 7 U.S.C. § 1639(2).
[201] 21 U.S.C. § 321(f).
[202] 7 U.S.C. § 1639(2).

ingredient).[203] Whole meat products under FSIS's labeling jurisdiction are not classified as a food under the new bioengineered disclosure standard and thus do not fall under its coverage. Additionally the NBFDS further declares that its regulations "shall prohibit a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance."[204] Thus animal products from animals fed GE fed or grain also cannot be labeled as "bioengineered" under the USDA scheme.[205] Further for any current future GE livestock (where the animal *itself* is genetically engineered), USDA should clarify that those foods, would fall outside the definitional scope of the standard, and under the aspeces of FSIS and meat labeling.

Unlike beef and poultry products, seafood is regulated and labeled by FDA under the FFDCA.[206] As such it unambiguously falls within the scope of the new USDA bioengineered disclosure classification,[207] and USDA should clarify and confirm that in the final rules. Similarly, any genetically engineered seafood, like the AquaBounty salmon, are classified as animal drugs and thus also under FDA oversight and labeling. Thus the current GE salmon, and any future GE seafood, fall under the disclosure standard and must be disclosed.

As these non-exhaustive examples show, there will be classes of foods that fall outside the USDA's jurisdiction, for one reason or another, and are not included in the disclosure mandate. For these foods, USDA's should clarify that nothing in its regulations prohibits producers or retailers from labeling foods that are produced with genetic engineering, so long as that disclosure is not false and misleading. USDA should further clarify that it is not (and cannot) prohibit the disclosure of GE foods, such as pet foods, animal feed, seeds, restaurant menus, or animal products fed GE grains or feed, since they are beyond the scope of the classification and thus beyond its jurisdiction. Because these foods are nonetheless produced with genetic engineering, they can and should be labeled separately, in order to meaningfully inform consumers, even if it is not using the bioengineered classification. With regards to animals fed GE grain or fed, while the statute excludes them from the bioengineered classification, there is no reason they could not have a separate disclosure, under FSIS jurisdiction, for example, "animal fed GE grain or fed," similar to FSIS's currently-approved GE absence labeling.

These categories of foods beyond the bioengineered disclosure standard that USDA sets could grow further, depending on the scope USDA sets for the classification. For example, as CFS has advocated above, USDA should set a broad definition of bioengineered; should allow for traditional terms GE and GMO to be continued to be used; should include all GE foods, including highly refined foods and whether or not current DNA testing shows that transgenic material is contained in the final product; and should include new forms of GE like gene editing. However, USDA may choose (although it should not) to narrow the classification to not include some GE foods in different ways. In those instances, USDA should clarify that producers, retailers, and consumers retain the right to disclosure of those GE foods held to be outside the USDA's NBFDS, through other means, so long as that labeling is truthful and accurate. Should USDA not allow the terms GE or GMO, then those terms are permissible

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[203] *Id.* § 1639a(c)(2).
[204] *Id.* § 1639b(b)(2)(A).
[205] 83 Fed. Reg. 19869.
[206] *See Seafood Guidance Documents & Regulatory Information*, FDA (last updated May 24, 2018), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/default.htm.
[207] 7 U.S.C. § 1639a(c)(1).

for other GE labeling, above and beyond, outside the bioengineered standard that USDA sets. The only thing that USDA governs under the NBFDS is the bioengineered classification it sets; labeling within that classification must be in accordance with USDA's regulations. But the statute does not give USDA the authority to prescript and prohibit disclosures not under its authority, if they are allowed and consistent with relevant other laws.

USDA's proposal has a section on "voluntary disclosure,"[208] purporting to address this topic in part, but it is unclear. On the one hand, USDA says it is proposing to allow generally for voluntary labeling for GE foods, but at the same time appears to imply that such labeling is limited to only foods that meet its definition of bioengineered. The agency should clarify whether it intends to attempt to prescribe any labeling for GE foods not under its jurisdiction, and any GE foods that it finds are not in the bioengineered classification as defined. Further, the proposed rule limits any such disclosure to one of the forms in the classification (text, symbol, etc).[209] The agency should clarify whether it is purporting to prohibit manufacturers from labeling products that fall beyond USDA's claimed scope, once it is determined, as produced with genetic engineering, assuming it does not allow GE terminology and only allows bioengineered.[210]

Thus one important point USDA must clarify is if the proposed regulatory scheme is intended to set a hard ceiling on what foods can be labeled as genetically engineered/bioengineered by private entities, and thus attempt to prohibit any other GE labeling different and/or beyond that standard. By only allowing limited disclosures in form and substance, the regulations de facto prohibit more clear and conspicuous labeling. This would be a restriction on speech (not a required disclosure, like other parts of the scheme). The First Amendment guarantees the right to disclose truthful and non-misleading information on food labels.[211] The rights at stake here include both the rights of producers, retailers, importers and other businesses to convey truthful and factual information concerning whether a product is genetically engineered, and the consumers' rights, to receive that information.[212] Commercial speech is protected under the First Amendment principly for the value it provides consumers.[213]

This prohibited speech would be 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 may decide to exclude them from its bioengineered disclosure classification. Many of these foods are already being labeled as "produced with genetic engineering" in the marketplace. Both FDA and USDA have guidance that discuss and allow such labeling, as not false and misleading, as discussed *supra*. Traditional definitions of "genetic engineering" are well-established, as discussed *supra*, regardless of how USDA might try and set its bioengineered standard. This included international standards, existing and past federal guidance, and state laws.

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[208] 83 Fed. Reg. at 19877.

[209] *Id.*

[210] There is a further proposed section, 66.118, that provides that the rules do not prohibit regulated entities from making other claims regarding bioengineered foods, provided they are consistent with federal law. 83 Fed. Reg. at 19888.

[211] *See, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

[212] *Stanley v. Georgia*, 394 U.S. 557, 564 (1969) (The First Amendment "protects the right to receive information and ideas.").

[213] *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

In order to pass Constitutional muster, a prohibition on speech must (1) further a "substantial" governmental interest; (2) must "directly advance" that interest; and (3) be "no more extensive than necessary," i.e. narrowly tailored, to serve that interest.[214] First, there is no governmental interest (let alone a substantial one) in USDA prohibiting GE disclosures beyond or in addition to its scheme's classification, particularly if USDA decides to set its scope overly narrow in some way, creating loopholes, leaving out many GE foods from its standard, or limit labeling to means that would not meaningfully inform consumers, such as QR codes. USDA would bear the burden to show otherwise, to show the harms it purports to address in the speech restriction are real and that the restriction will alleviate them to a material degree. The interests must be the actual interests served by the speech restriction, and it must be more than just a generalized or abstract interest, it must be actual not hypothetical.[215] And it must be a governmental interest, not that of private parties. USDA lacks any such substantial interest in attempting to prohibit further GE food disclosures. The NBFDS's purpose and interest is to inform consumers, and restricting speech does not fulfill that purpose.

Further, the NBFDS's purpose of providing GE information to consumers is not directly advanced (and instead would be arrested) by the chilling of more related information to consumers. More, not less, speech would further those purposes. Further, more robust labeling would improve transparency, particularly if USDA attempts to allow stand-alone QR code labeling. USDA's standard should be a floor, from which more specific labeling can and should be provided, if necessary. Many companies are in the marketplace right now providing such labeling, without any issue. Omitting and not disclosing various GE foods by prohibiting them from the bioengineered standard and then prohibiting their labeling as GE or otherwise would deceive and confuse consumers.

Even if the first two prongs are met, that restriction on speech must be no more extensive than necessary. If there are less burdensome alternatives to restriction on speech, those should undertaken instead of prohibition. While USDA can establish one mandatory disclosure standard for its scheme, chilling speech beyond or in addition to USDA's classification would plainly be more extensive than necessary. There would be many less extensive means at USDA's disposal rather than restricting speech, including not restricting further speech, allowing further disclosures explaining anything as necessary and providing guidance documents to industry. Again, if USDA approved QR codes alone the evidence (in the form of USDA's own study) would not support that this type of disclosure is sufficient and thus not a reasonable fit/narrowly tailored. And with regards to the scope of the disclosure prohibition and the

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[214] *Central Hudson Gas & Electric Corp. v. Public Service Comm. Of N.Y.*, 447 U.S. 557, 567-68 (1980). In contrast to a speech prohibition being discussed here, a government required disclosure, like those being established by USDA otherwise in the Bioengineered standard, need only pass muster under the *Zauderer* standard. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650-51 (1985); *see id.* at 650 (explaining that there are "material differences between disclosure requirements and outright prohibitions"); *see, e.g.*, *Discount Tobacco City & Lottery v. U.S.*, 674 F.3d 509, 552 (6th Cir. 2012) (explaining that "[l]aws that restrict speech are fundamentally different than laws that require disclosures, and so are the legal standards governing each type of law," and explaining that *Central Hudson* "set[s] forth the standard for restricting commercial speech," while *Zauderer*, "set[s] forth the standard for requiring commercial-speech disclosures"); *accord also U.S. v. Mazzarella*, 614 F.3d 85, 96 (3d Cir. 2010) ("[r]egulations on nonmisleading commercial speech trigger another form of intermediate scrutiny… whereas disclosure requirements for commercial speech trigger a rational basis test…"); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001); *see generally Grocery Mfrs. Assoc.*, 102 F. Supp. 3d 583.

[215] *Edenfield v. Fane*, 507 U.S. 761, 768 (1993).

narrowly tailored requirement, any proscription of those types of labeling beyond USDA's established bioengineered classification's scope are the opposite of narrowly tailored. If USDA is leaving an entire area without transparency for consumers, it cannot at the same time say that further labeling cannot be undertaken for it; this is the antithesis of narrowly tailored. It would also be beyond USDA's statutory authority to attempt to prescript such speech and unlawful.[216]

Finally, all of the above analysis also applies equally to the NBFDS's state labeling law preemption provisions.[217] These provisions as applied are unconstitutional restrictions on speech, causing injury to consumers' listener rights as well as the speech rights of companies currently labeling or wishing to label in the future. If USDA sets an overly narrow disclosure classification, or permits indirect electronic disclosures alone such as QR codes, consumers would lose the on-package labeling they have right now and the scope of disclosure they have right now. Prohibiting state laws from filling any gaps left by the federal scheme fails the First Amendment analysis as outlined above: it does not further any "substantial" governmental interest in the NBFDS; it does not "directly advance" that interest; and it fails to be "no more extensive than necessary" to serve that interest.[218] The only governmental interest in the NBFDS is informing consumers about foods that are produced with genetic engineering; prohibiting supplemental disclosures is contrary to, not directly advancing that interest, and prohibiting further speech is far more extensive than necessary to serve the government's interest. The federal standard should be a floor, not a ceiling.

These conclusions are particularly salient for the second preemption provision, which goes beyond just "bioengineered" and purports to preempt broadly any state laws having to do with the labeling of genetically engineered foods, including foods in restaurants, and genetically engineered seeds.[219] Assuming USDA draws bioengineered more narrowly than genetically engineered, and does not allow those terms to be used in its classification, then USDA would be attempting to prohibit speech beyond the scope of its disclosure mandate. The same is true if USDA limits the types of GE foods included in bioengineered, such as highly refined foods. Finally, some topics, such as seed labeling and restaurant labeling, are known already to be outside the scope what USDA will provide and have nothing to do with it. This broad, sweeping preemption is not connected to any statutory interest, since it is beyond the statute's scope; it does not further that interest, for the same reason. And by its nature it cannot be said to be tailored at all, instead attempting to sweep far beyond it. This violates the First Amendment.

The NBFDS's preemption provisions also are unconstitutional under the Tenth Amendment's anti-commandeering doctrine.[220] Although the Commerce clause grants Congress the power to regulate GE labeling by setting standards for private parties, "Congress cannot issue direct orders to state legislatures,"[221] which is exactly what the preemption provisions purport to do. Further, "the distinction between compelling a State to enact legislation and prohibiting a State from enacting new laws is an

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[216] In addition to this analysis, there is also the question of whether any exclusions and prohibitions created by USDA would be content-based or viewpoint discrimination, as discussed in the symbols section *supra*.

[217] 7 U.S.C. §§ 1639b(e), 1639i(b).

[218] *See Zauderer*, 471 U.S. at 650-51; *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566-68.

[219] 7 U.S.C. § 1639i.

[220] *Murphy v. NCAA*, 138 S. Ct. 1461, 1467 (2018).

[221] *Id*.

empty one. The basic principle—that Congress cannot issue direct orders to state legislatures—applies in either event."[222] Regulation of GE labeling falls within Congress's power under the Commerce Clause, but States can still regulate the issue pursuant to the Dormant Commerce Clause.[223] Further, prohibiting fraud and deception in food and beverage marketing has long been a state-held power recognized by the Courts.[224] Finally, if USDA's bioengineered disclosure does not require the labeling of GE foods as broadly defined, then States must be free to fill that void and provide that labeling on their own.

E. Enforcement and Recordkeeping

The statute establishes basic enforcement mandates, such as making it unlawful for any person to "knowingly fail" to make a disclosure as required by the Act.[225] However USDA has significant discretion in shaping the regulatory enforcement regime.[226] USDA should promptly take action in response to any specific complaints of non-compliance; a deadline for agency responses to complaints should be set, and a standard for when and why further investigation is warranted or not should be established. USDA should audit or examine the records of manufacturers, and establish fines for non-compliance violations. Penalties of $1,000 per day, per product, should be set, as was established by state labeling laws. The Department of Justice should be authorized to investigate potential violations and bring enforcement suits. The current enforcement mechanism is entirely set up to protect the rights of the regulated entity, not the consumers' right to know. Such an enforcement system is not in furthering the purpose of the statute. Protections for consumers should be implemented and codified in the regulations. The regulations should mandate the remedy for failing to comply, such as remedying that failure and disclosing that a product is GE, within a certain time period. Finally the audit hearing process should be undertaken pursuant to deadlines to ensure timely resolution, and all results must be made public.

Regarding recordkeeping, each person subject to the law is required by it to maintain, and make available to USDA on request, any records that USDA determines in the regulations to be "customary and reasonable to the food industry," in order to establish compliance with the law.[227] The proposed regulations flesh that out, and request comment on a number of points.[228] First, with regards to the role of any USDA-kept lists of GE foods, as discussed elsewhere in these comments, each GE food manufacturer has an independent duty to comply with the standard and its provisions, including record-keeping, regardless of whether and when USDA puts a food product on its lists. The records kept by the entity subject to the NBFDS must independently verify and confirm compliance; being listed (or not listed) is not sufficient. Second, as also discussed elsewhere, the "may" disclosure should only be allowed in truly unknown circumstances, not at the whim of manufacturers who simply don't want to fully disclose that their product is GE; it should not be made available to all manufacturers as a disclosure and record-keeping choice. Finally as to what records are "customary and reasonable" in this context, USDA should require companies maintain records similar to those required by private certification entities such as the Non-GMO project: for a particular crop or ingredient, companies must have the DNA testing records,

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[222] *Id*.
[223] *Grocery Mfrs. Ass'n*, 102 F. Supp. 3d at 609.
[224] *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Pacific States Box & Basket Co. v. White*, 296 U.S. 176 (1935); *Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919).
[225] 7 U.S.C. § 1639b(g)(1).
[226] 83 Fed. Reg. at 19879.
[227] 7 U.S.C. § 1639b(g)(2).
[228] 83 Fed. Reg. at 19877-78.

certifications by crop suppliers of GE/non-GE content, supply chain documents, purchase orders, bills of sale, and so forth.

F. International Trade

With regards to international trade, USDA must apply the NBFDS in a manner consistent with the United States' obligations under "international agreements."[229] That means USDA's regulations must be harmonized as to not be inconsistent with U.S. international trade obligations and agreements. This provision has significant ramifications for USDA's proposal in myriad ways: the definitions used, the terminology used, the scope of the classification, the type of labeling, the threshold, the exemptions, and enforcement, to name a few. The Codex Alimentarius, or "Food Code," (CODEX) was established by the World Health Organization to harmonize food standards,[230] and addresses and defines related terms for food regulation, such as "modern biotechnology" and "genetically engineered."[231] CODEX is recognized by the World Trade Organization as the authoritative standard for purposes of settling trade disputes. USDA's regulations must be harmonized with CODEX requirements for the U.S.

The CODEX General Guidelines on Claims sets forth the standards of how food may be presented to consumers. The general guiding CODEX principle is that the labeling or presentation of packaged foods may not be presented in a "misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect."[232] CODEX defines a claim as "any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality."[233] The guidelines prohibit all unsubstantiated and misleading claims.[234] Thus, the CODEX guidelines would clearly prohibit a mandated GE disclosure symbol in the form of a smiling sun. The standards developed by Codex are considered as globally accepted; therefore, USDA should adopt these labeling guidelines and use an alternative label that is not so deceptively misleading.

In addition to the previously noted problems posed by digital disclosure alone, such a method would not be consistent with internationally accepted standards. Codex developed clear requirements for the labeling of prepackaged foods.[235] Within these standards is the requirement that mandatory information be "clear, prominent, indelible, and readily legible by the consumer under normal conditions of purchase and sale."[236] GE labeling through QR code, text message, barcode, or any other form of digital would be inconsistent with U.S. obligations under the CODEX standards. Such an unclear,

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[229] 7 U.S.C. § 1639c(a).
[230] *See* Food and Agriculture Organization of the United Nations (FAO), *About Codex Alimentarius*, http://www.fao.org/fao-who-codexalimentarius/about-codex/en/.
[231] Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, Food and Agriculture Organization of the United Nations (2003), www.fao.org/input/download/standards/10007/CXG_044e.pdf.
[232] FAO, *Codex General Guidelines on Claims* (1991).
[233] *Id.*
[234] *Id.*
[235] Codex Alimentarius Commission, *General Standard for the Labelling of Prepackaged Foods* (1991), http://www.fao.org/docrep/005/Y2770E/y2770e02.htm.
[236] *Id.*

unprecedented, and impractical method of disclosure is not in accordance with CODEX standards, will fail to properly inform consumers, and may be detrimental to our international trade.

Further, CODEX sets forth a labeling requirement of all products that contain the biotechnology of any allergen or food known to cause hypersensitivity.[237] Not only should the USDA comply with this standard in order to maintain international consistency, but also because the cross contamination of various allergens could and possibly already is a widespread health concern.

Finally, under CODEX, prepackaged foods are required to disclose the type of treatment the product has undergone. Such disclosure is required to appear on the package in close proximity to the product name.[238] Just as consumers would like to know what type of food they are purchasing and what company it is coming from, they would like to know what type of treatment it has undergone. The logical conclusion would then be to include all of this information together in plain view.

CODEX defines "modern biotechnology." The following definition comes from the Principles for Risk Analysis of Foods Derived from Modern Biotechnology adopted by the Codex Alimentarius Commission in 2003.[239]

> **Modern biotechnology:**
> (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
> (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

At its 39th session, held in 2011, the Codex Committee on Food Labeling adopted labeling standards for genetically modified foods and specifically stated in draft language that:

> Different approaches regarding labelling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.[240]

Beyond conformity with CODEX, the proposed labeling rules would not be consistent with the U.S.'s major trading partners. Of the top U.S. trade partners for U.S. food exports, most require GE labeling, but none use the term "bioengineered" or a value-based, biased symbol like the smiling sun. Instead they require clear, on-package (not digital like QR codes) text disclosure, or a neutral symbol.

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[237] *Id.*

[238] *Id.*

[239] Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (2003), www.fao.org/input/download/standards/10007/CXG_044e.pdf.

[240] World Health Organization, FAO, Codex Alimentarius, *Report of the Thirty Ninth Session of the Codex Committee on Food Labelling*, U.N. Doc. Rep. 11/FL (2011), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/ru/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-43%252FReport%252FREP16_FLe.pdf.

Failure to use similar terminology and neutral, on-package disclosures like the rest of the world would be contrary to international norms and could cause significant U.S. trade disruptions, contrary to Congress's intent in the NBFDS.

The US is the largest food exporter in the world.[241] However the majority of our trading partners treat genetically engineered foods starkly differently in terms of their regulation, and until now, in terms of their labeling. Accordingly the failure to adequately require disclosure of some GE foods, by overly limiting the classification through definitions or thresholds, or by using improper disclosure methods, such as unknown text or symbols, or unprecedented electronic or digital means, likely would cause trade disruptions and further GE food contamination incidents and misrepresentations, the sort of which have already cost U.S. farmers and exporters literally billions of dollars of the past decade, due to GE contamination in various exports.

G. Effective and Compliance Dates Must be Prompt, Allowing Use of Existing Labels

U.S. consumers have waited decades already for mandatory GE labeling. The NBFDS included prompt deadlines for setting the detailed standards for disclosure, including a one-year deadline to conduct the study on the accessibility of electronic disclosure methods, and a two-year deadline by which time USDA "shall" have established the regulations. 7 U.S.C. § 1639b(a). Congress's use of repeated deadlines underscores that the entire statutory scheme's congressional intent: that this process should be done in a timely fashion. And for further context into reasonableness, food manufacturers have known mandatory GE labeling was coming since the enactment of the NBFDS nearly two years ago, and even before that states were passing their own labeling requirements, most notably Vermont, which enacted Act 120, a mandatory GE labeling law, in 2014, with a compliance date of July 2016. Indeed, companies have already been labeling GE ingredients in compliance with the Vermont law for years, and across the country.[242]

Accordingly, given the time companies have had to come into compliance with mandatory GE labeling and the prompt deadlines mandated by Congress for USDA to promulgate labeling regulations, the compliance date for companies must be shorter than the proposed 18-months, or January 2020 (and 2021 for small manufacturers). Instead, the overall labeling requirements should be effective within 90 days. In the interim, USDA should allow continued use of the current Vermont Act 120-compliant labels found on many products across the country. Any lengthy delay in compliance is contrary to the statutory scheme of the NBFDS given its tight deadlines.

USDA's proposed compliance date of 2020 is based on the FDA's proposed rule to extend compliance for Nutrition Facts labeling.[243] However, the NBFDS nowhere references FDA's nutrition labeling authority or allows USDA to delay otherwise required labeling for this purpose. Indeed, the

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[241] *Largest Food Exports by Country*, World Atlas, https://www.worldatlas.com/articles/the-american-food-giant-the-largest-exporter-of-food-in-the-world.html (last updated April 25, 2017).
[242] *See e.g.* CFS, *GE Food Labeling: States Take Action*, https://www.centerforfoodsafety.org/files/ge-state-labeling-fact-sheet-92014_02919.pdf; CFS, *GMO Labels Hitting the Shelves*, https://www.facebook.com/media/set/?set=a.10153723303692759.1073741850.80060992758&type=1&l=9b50b3f3a4; Stephanie Strom, *Campbell Labels Will Disclose G.M.O. Ingredients*, N.Y. Times (Jan. 7, 2016), https://www.nytimes.com/2016/01/08/business/campbell-labels-will-disclose-gmo-ingredients.html.
[243] 83 Fed. Reg. at 19879.

statute has a section regarding consistency between laws, and mentions only the Organic Foods Production Act, requiring USDA to "consider" establishing consistency between those two laws. Congress could have, but specifically did not, command USDA to consider any other federal food labeling laws. Delay on nutrition label changes (which itself is likely not in the public interest) does not provide a rational or reasonable excuse for USDA to delay GE labeling, given the length of time already passed and the relevant statutory scheme.

Finally, to add insult to injury, USDA is proposing to allow regulated entities to use labels printed "by the initial compliance date, regardless of whether they comply with the NBFDS, until the regulated entity uses up remaining label inventories, or until January 1, 2022, whichever date comes first."[244] This would allow companies, who have known for years that mandatory GE labeling was coming, to continue printing non-compliance labels for *18 months after the enactment of these rules*, and sell those products for *another two years*. Thus USDA is proposing to make consumers wait a full *six years* from when the NBFDS was passed (and when Vermont's law went into effect and spurred nationwide labeling) for disclosure. CFS strongly disagrees with this approach, and while a very short grace period may be included to allow companies time to get new labels printed and distributed, giving this many years violates the intent of the NBFDS and flies in the face of consumers' legitimate and Congressionally-mandated right to know whether their food is genetically engineered.

Respectfully submitted,

The Center for Food Safety

[244] 83 Fed. Reg. at 19879.