



CENTER FOR
FOOD SAFETY

Legal Analysis of Senate Bill on Genetically Engineered Food Labeling (The DARK Act)

From: Center for Food Safety Legal Team
To: Senate Agriculture Committee Members
Date: February 24, 2016
Re: Roberts DARK Act (for mark-up next week)

The recently introduced Roberts draft of the DARK (“Deny Americans the Right to Know”) Act would preempt all current and any future state labeling of genetically engineered (GE) foods, while offering the U.S. public and your constituencies nothing in return. Four states have labeling laws that would be preempted¹ and 30+ other states have introduced very similar bills in the past several years. The voluntary program that the DARK Act would set up offers consumers nothing in exchange for taking away their local sovereignty, since we already have had a system in place to permit voluntary labeling since 2001 under FDA guidance. Polls repeatedly show that 90% of Americans want GE food labeling, just like 64 countries already have, including the EU, Japan, China, and Russia.

As you know, the current draft bill would preempt any states from requiring GE food labeling. It would also strip FDA of its jurisdiction over GE food labeling; make it more difficult for companies to voluntarily label, like Campbell’s Soup has recently done; make it the statutory duty of USDA to promote agricultural biotechnology to consumers; and worsen the voluntary labeling system that exists.

Beyond these fundamental, overarching flaws, the bill is very poorly drafted, raising numerous complex and thorny legal questions that it does not answer, and as such would have numerous other intended and potentially unintended adverse consequences. Additionally, there are several aspects of the bill that are constitutionally suspect. These specific legal issues are discussed below.

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- Use of the misleading and improper term “bioengineered”. *See, e.g.*, title of the bill; *id. passim*

¹ Vermont, set to take effect July 1, 2016, Connecticut and Maine, with triggers clauses requiring neighboring states to pass similar laws, and Alaska, for GE fish only.

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The bill uses the term “bioengineered” (“establish a national voluntary labeling standard for bioengineered foods,”) rather than any of the more technically accurate, specific, and widely known terms for the issue, “genetic engineering,” “genetically engineered foods,” or “genetically engineered organisms.”

This vague term is plainly being used to try and separate the discussion from its current and past legislative history, which is misleading and inaccurate. Current state laws such as Vermont all use the terminology of GE foods, produced with genetic engineering, or the like. And past Congressional bills similarly used this terminology.

- A Westlaw search for the term “bioengineered” or “bioengineer[.]” returns only 14 search results for the term appearing in Federal Statutes, four of which are in reference to the National Institute of Biomedical Imaging and Bioengineering, and two of which are notes to Federal Rules of Evidence, none in this context. 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 designed to alleviate and minimize the effects of disability.” 51 U.S.C. § 20102(f). Similarly, the use of the term “bioengineered” shows up in federal regulations approximately seven times, none in this context.
- In contrast, according to govtrack.us, since the 98th congress (1983-84), there have been 110 bills containing the phrase “genetically engineered,”² and 52 bills containing the phrase “genetically modified.”³ In contrast, the use of the term “bioengineered” in past bills all appear related to either defense (warfare) or medical context.⁴ The few in the food context that have used this term are Mr. Pompeo’s DARK Act bills from last year.

In short, it appears “bioengineering” is a broader term that involves non-food products, including medical products. While every case of genetic engineering might be said, in the abstract, to be “bioengineering,” not every case of bioengineering is genetic engineering. The University of California Berkeley defines it as, “Bioengineering is the biological or medical application of engineering principles or engineering equipment – also called biomedical engineering.”⁵ So does the Merriam-Webster dictionary.⁶

² <https://www.govtrack.us/congress/bills/browse#text=%22genetically+engineered%22+&congress= ALL>

³ <https://www.govtrack.us/congress/bills/browse#text=%22genetically+engineered%22+&congress= ALL>

⁴ <https://www.govtrack.us/congress/bills/browse#text=bioengineering&congress= ALL>

⁵ <http://bioeng.berkeley.edu/about-us/what-is-bioengineering>

⁶ <http://www.merriam-webster.com/dictionary/bioengineering>

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A labeling bill should have definitions that are commonly accepted and accurate, not intent on shifting the perception of a product. Any law on GE food labeling should include the terminology and definition of genetic engineering, and should be a “labeling standard for genetically engineered foods and products.” If “bioengineering” and “bioengineered products” are to be included they should be clarified from genetic engineering. All references to “bioengineering” must be struck, replaced, or clarified. Otherwise any such bill is intentionally misleading and vague.

- Section 291: Definition of “bioengineering”

The bill also attempts to define “bioengineering,” but the definition it creates suffers from multiple additional problems in addition to the above. As an initial matter, the inclusion of “any similar term” in light of the above is vague and confusing.

But more generally, the definition is overly narrow in what it considers to be genetic engineering, in several ways, which would result in a standard that does not encompass many types of genetic engineering, particularly new types.

- First the definition is overly narrow at p.2, lines 10-12, in limiting the definition to “genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” As such, this would not cover many new genetic engineering gene-editing technologies and any GE foods created from them, such as RNA interference (RNAi), CRISPR-cas9, TALEN, zinc-fingered nucleases (ZNF), meganucleases, RNA-dependent DNA methylation, oligonucleotide directed mutagenesis (ODM).

In this way, the definition is contrary to numerous well established definitions of GE that properly cover these new forms of genetic engineering, and the foods that do and will come from them, including the international standards for GE labeling set by the Codex Alimentarius Commission. Documents/standards developed by the Codex Alimentarius Commission are referenced by the World Trade Organization in trade disputes involving foods and they constitute a globally accepted standard. In addition, the term “modern biotechnology,” including that of genetic engineering, as defined by Codex Alimentarius is also the same as the definition used by the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

Similarly, the current state labeling laws’ definitions, in Vermont’s Act 120⁷ and otherwise, are consistent with each other and with the international Codex standard for the definition of GE and

⁷ <http://www.leg.state.vt.us/docs/2014/Acts/ACT120.pdf>

the labeling of GE food. The Roberts bill as written is also in conflict with those state laws and their established definitions. For example Vermont's Act 120 defines genetic engineering as:

(4) "Genetic engineering" is a process by which a food is produced from an organism or organisms in which the genetic material has been changed through the application of:

(A) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or (B) fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination.

(5) "In vitro nucleic acid techniques" means techniques, including recombinant DNA or ribonucleic acid techniques, that use vector systems and techniques involving the direct introduction into the organisms of hereditary materials prepared outside the organisms such as micro-injection, chemoporation, electroporation, micro-encapsulation, and liposome fusion.

Similarly, the definition is also contrary to and in conflict with FDA's own definition of GE and what is covered by it.⁸ FDA in its new draft guidance from 2015 on voluntary labeling of the GE salmon does use the term "bioengineering," in addition to genetic engineering, both to describe "modern biotechnology". However FDA's GE definition is in accordance with Codex and the state laws; thus the bill would move jurisdiction away from FDA and give it to USDA, and set up a definition in conflict with FDA's definition.

- Second, the term "bioengineering" is overly narrow, confusing and vague, and contrary to established international, national, and state standards, at p.2, lines 10-11, in requiring that a food, to be covered, must "contain genetic material that has been modified..." (emphasis added). This conflicts with standard definitions, which all hinge on whether a food is *derived* from a GE organism, not whether when the processing is done, the final food product actually contains the GE substance. For example, sugar is so highly processed that sugar from a GE sugar beet is unlikely to actually contain GE-modified DNA, or at most trace amounts. The same can be said for many corn derivatives (cornstarch, high fructose corn syrup) that if made from GE corn would not contain GE-modified DNA. In contrast, other GE corn products, like corn flour, corn chips, tortillas, taco shells, would contain GE DNA.

The scope of the clause thus arbitrarily narrows what could be labeled. Consumers care about and want to have GE foods labeled not just because the GE content ends up in the food. They also want labeling for the environmental rationale: the choice to

⁸ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>

not support an environmentally destructive, pesticide-promoting, monoculture-creating form of agriculture. Thus, it is not just the end product that matters to the consumer – it is the entire process by which that food was created.

- Third, the definition is overly narrow, confusing, and contrary to established international, national, and state standards at p.2, lines 13-15, which requires that the “modifications could not be obtained through conventional breeding or found in nature.” As to the former clause, this would omit any GE foods made from varieties that could also be obtained through conventional breeding: so using GE techniques to create a tomato high in vitamin A could not fall under the definition of what is covered, because vitamin A (or lycopene) could be transferred via conventional breeding as well, even though it was not in that case.

As to the latter clause, “found in nature,” this clause could be read to omit GE foods made from GE crops where the GE component is otherwise “found in nature.” That is, only GE foods made from GE crops that have synthetic genes that do not occur in nature would make a food “bioengineered.” In fact, all of the “Roundup Ready” GE crops get their glyphosate tolerance gene from the *Agrobacterium* sp. strain CP4, a microorganism, and many of the Bt crops use a Bt gene, e.g. Cry1Ab, Cry1Ac, Cry3Bb; all of these traits are otherwise “found in nature” (just not engineered into food), and so they could end up not being included in the definition of “bioengineering.”

In sum, the bill uses a statutory definition based on a term for a concept that is not generally accepted, and then uses a definition for that term that is in conflict with international, national, and state definitions for that topic. Furthermore, the bill is so poorly written that it fails to include the foreseeable future of the technology, as well as most of its current forms.

- Section 292: Applicability

This section states that the bill shall apply to any claim in labeling that indicates the food is “bioengineered,” either “directly or indirectly.” It is unclear and overbroad as to what “indirectly” could encompass, what a company could do to label that would be short of labeling but that would nonetheless “indirectly” indicate the food was GE, without being at risk of violating the bill.

- Section 293: National Voluntary Standard

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This section at (b) regulations, p.3-4, specifically p.4, lines 1-4, would mandate USDA to promulgate regulations “prohibiting any express or implied claim that a food is or is not safer or of higher quality solely based on whether the food is or is not” genetically engineered.

This section appears to apply not just to the disclosure of foods that are produced with genetic engineering, but also to those companies that wish to disclose that their foods are not produced with genetic engineering. In either case, the bill would prohibit any statements that a food is safer or of a different quality because it is or is not produced with genetic engineering.

In so doing the bill raises significant First Amendment problems in prohibiting speech. For either disclosure, or more likely for non-GE product disclosures, of which there are many so certified food products in the marketplace, indeed, it is the fastest growing private label in the U.S., the bill would censor and potentially ban any such speech. In this way the bill is of a piece with industrial agriculture’s “Ag-Gag” state laws, which courts have now begun to hold unconstitutional, in violation of the First Amendment.⁹ It would also be providing a market advantage to GE foods, in hampering the speech of non-GE disclosures.

Further, p.4, lines 8-16, which have detailed requirements for determining when a food could be labeled as GE, and would require USDA to approve such a request, would make it more difficult for companies to voluntarily label in the marketplace, as Campbell’s just did. It is wholly unclear whether Campbell’s could have made the same disclosure under the bill. Again, this section may impermissibly impinge on 1st Amendment speech rights. And this section would enable the government to overreach into the conduct of corporations who are seeking to build consumer confidence in their brands through fuller disclosure.

- Section 293: preemption provision

Section 293 also includes the first of the two preemption provisions in the bill, at p.4, lines 18-23. This preemption provision, by its plain language, is very broad, well beyond the intent of the labeling issue. Like the DARK Act in the House, it can be read to encompass and preempt more than just state labeling bills, as it applies to prohibit a “state or political subdivision” from “directly or indirectly” establishing “under any authority or continuing in effect as to any food in interstate commerce any requirement for a food that is the subject of the” bill (emphases added). As such, the bill might expressly preempt and/or possibly impliedly preempt many existing and any future state and municipal regulations or conditions on the cultivation and uses of genetically engineered plants, as well as state laws on the labeling of genetically engineered foods.

⁹ <http://www.centerforfoodsafety.org/press-releases/4001/idaho-ag-gag-law-overturned-ruled-unconstitutional-in-federal-court>

- There are many states and counties that have laws and ordinances that regulate some aspect of genetically engineered organisms. **We estimated that passage of this bill might expressly or impliedly preempt around at least 137 existing statutes, regulations, and ordinances at the state and municipal level in 42 states.** This figure does not even account for the numerous municipal actions that may have occurred that are not tracked on a national level.

A few examples of existing local laws that would be engulfed by the Act include:

- Minnesota’s natural wild rice protection: Minnesota statute that requires the state to assess the environmental impact of genetically engineered wild rice before allowing its distribution within the state because of natural wild rice’s economic and ecological value, as well as spiritual and cultural importance to the Ojibwe tribe and the people of Minnesota;¹⁰
- Hawaii’s traditional food staple: the County of Maui in the State of Hawaii’s local ban on the planting, cultivation, and release of genetically engineered taro due to the cultural significance of taro to “the indigenous people of Hawaii”;¹¹
- State’s historic police powers:
 - Arizona statute requiring proof that any genetically engineered plant or product introduced in the state will be handled in compliance with “Arizona quarantine rules regulating plants, pests, or organisms being introduced into Arizona” and reserves the right to impose measures if necessary to protect local “agriculture, public health, or the environment from potential adverse effects [of genetically engineered organisms]”;¹²

As such, again, in addition to eliminating the public’s right to know through labeling, the bill also would take away local governments’ ability to enact measures to address the specific locality’s cultural, agricultural, and ecological concerns, issues that have long been recognized as falling under local governments’ traditional police powers.

- Section 294: Information for Consumers

Subsection (A) essentially would statutorily mandate USDA to become a cheerleader for agricultural biotechnology, and to use taxpayer dollars to advertise for that industry over others. It would create a statutory mandate for USDA to “promote” the technology and to address “consumer acceptance” of the technology. USDA is mandated to become the marketing arm of

¹⁰ See Minn. Stat. Ann. § 116C.92 (2007).

¹¹ Maui County, Haw., Code of Ordinances, tit. 20, ch. 20.38 (2009).

¹² Ariz. Admin. Code R3-4-901.

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the agricultural biotechnology industry. This is of course juxtaposed with Section 293, which as discussed *supra* prohibits any speech by companies against GE.

The government should not be in the business of favoring one industry over another, especially with tax dollars. It also unclear how much financial appropriation would be needed to “promote” and force “acceptance” of a technology used in food without the necessary on-package labels that over 90% of Americans want.

Subsection (B) requires a report from USDA within four years regarding the availability of information as to whether foods are genetically engineered or not, including under existing laws or private certification programs. It is wholly unclear what purpose this “report” would have, or why it would be useful so after the fact. This is clearly information that is widely available in the public domain now, information that the Congress should have at the outset, when discussing labeling decisions, not four years after the fact. The very idea of a “report” on the “availability of information” is a *non sequitur*. Further, under the earlier Section 293, any third party certifications for GE disclosure would have to go through USDA’s new voluntary standard, and as such, the agency would need to know that information well before the time of the report.

- Section 295: Federal Preemption

The bill also includes a second preemption provision, though for what purposes are unclear. Like the first, the preemption provision is very broad, preempting any “state or political subdivision” from “directly or indirectly establishing under any authority or continuing in effect as to any food or seed in interstate commerce any requirement related to the labeling of whether a food ... or seed is genetically engineered....” (emphases added). There are several differences with the first preemption provision of note. First, this preemption clause includes seeds, not just foods. There are several states with laws regulating seed labeling, including in Vermont, that would be preempted. There are at least thirteen states across the country with laws regulating seed labeling, including Vermont, Illinois, California, Texas, Minnesota, and Georgia, that would be preempted.¹³ Such laws are often intended to protect consumers and “promote fair competition among seed sellers through the establishment of minimum standards.”¹⁴ These state laws require agricultural seeds sold or transported within the state bear labels containing information such as the origin of the seeds, the percentage by weight of seeds present within the

¹³ See, e.g., Vt. Stat. tit. 6, §§611 *et seq.*; Minn. Stat. §§ 21.80 *et seq.*; 505 Ill. Comp. Stat. § 110/1 *et seq.*; Mo. Rev. Stat. §266.051; Wash. Rev. Code §§15.49.021-.031; Ga. Code Ann. § 2-11-22; Cal. Food & Agric. Code §§ 52451 *et seq.*; Ohio Rev. Code § 907.02; Texas Agric. Code § 61.004; N.C. Gen. Stat. §§106-277 *et seq.*; Or. Rev. Stat. §633.520; Nev. Rev. Stat. §§587.091 *et seq.*; Okla. Stat. tit. 2, §2-8-21 *et seq.*

¹⁴ *Seed: Selling & Labelling*, Minn. Dep’t of Agric., <http://www.mda.state.mn.us/seed> (last visited Feb. 24, 2016).

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package, the percentage of germination, germination testing information, and whether or not the seed has been treated with any chemicals and, if so, what chemical was used.¹⁵

Second, this preemption clause does seem expressly limited to preempting only labeling laws, not general regulation laws at the state and/or local level. As such, the preemption provision is overbroad and involves issues such as seeds that are not at issue. It is unclear why seed laws might be included, but such laws could include laws that indirectly establish non-GE seed husbandry, agricultural chain of custody requirements and market preservation for non-GE or GE-contamination sensitive markets, which include many important U.S. trading partners as well as domestic markets.

In general, the fact that the bill has two separate, overbroad, overlapping and unclear preemption provisions just further underscores how poorly drafted it is, and as such, how broad the potential scope of unintended effects might be.

¹⁵ See, e.g., Minn. Stat. §21.82.