
MEMORANDUM

TO: Just Label It

FROM: Bracewell LLP

DATE: July 1, 2016

RE: Roberts-Stabenow proposal on genetically modified food

This memorandum analyzes the draft compromise legislation proposed by Senators Roberts and Stabenow, titled “A bill to amend the Agricultural Marketing Act of 1946 to require the Secretary of Agriculture to establish a national disclosure standard for bioengineered foods, and for other purposes” (“Roberts-Stabenow bill”) and compares it to other legislation on bioengineered foods, principally Vermont General Assembly Bill No. 120 (“Vermont statute”). The memorandum focuses only on scope.

Scope

Food

The bill specifies that it only covers foods for human consumption that are “subject to the labeling requirements” under:

- 1) the Federal Food Drug and Cosmetic Act (FDCA); or
- 2) the Meat Inspection, Egg Inspection, or Poultry Inspection Acts, if the most predominant ingredient is something regulated under FDCA or, in the case of foods where the most predominant ingredient is broth, stock or water and the second most predominant ingredient would be independently subject to labeling requirements under FDCA.

Part (2) of this definition appears to be surplusage, as the labeling requirements under the FDCA broadly apply to all food.¹

¹ The FDCA’s labeling authority is set out at 21 U.S.C. §§ 331(b) and 343. Section 331 prohibits the “misbranding of any food...in interstate commerce,” and section 343 sets

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The Roberts-Stabenow bill excludes food derived from animals where the labeling requirement would apply solely because the animal consumed genetically engineered feed, foods sold in restaurants or similar retail food establishments, and very small food manufacturers,² and provides that Secretary of Agriculture will establish a threshold amount of bioengineered substance required for a food to be considered bioengineered.

The Vermont statute applies to “food intended for human consumption.” Like the Roberts-Stabenow bill, it excludes food consisting of or derived entirely from animals that are fed genetically engineered feed but are not themselves genetically engineered and food sold in restaurants. It also excludes raw agricultural commodities (or processed foods derived from raw agricultural commodities) that were produced without knowing or intentional use of genetic engineering; processed foods intended for immediate consumption; medical foods³; alcoholic beverages; and foods processed with genetically engineered processing aids and enzymes. The Vermont statute establishes a threshold that 0.9% of the total weight of processed foods must be genetically engineered in order to come within the scope of the statute.

Bioengineering

The Roberts-Stabenow bill defines “bioengineered” food as food:

out the circumstances under which a “food shall deemed to be misbranded.” 21 U.S.C. § 321(f) defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” *See also* FDA/HHS Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (June 27, 2016).

² While “very small food manufacturer” is not defined, the FDA has elsewhere defined “very small businesses” as those “averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).” 110 C.F.R. § 117.3 (definitions for FDA rule titled Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food).

³ “Medical foods” is defined in 21 U.S.C. § 360ee(b)(3) as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

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(A) that contains genetic material that has been modified through in vitro recombinant DNA techniques, and

(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.⁴

Part A of this definition excludes food that is derived from, but does not itself contain, genetically modified material. Thus, the Roberts-Stabenow bill is narrower than the Vermont statute, which applies to food “*produced from* an organism or organisms in which the genetic material has been changed through the application of” genetic modification (emphasis added). The FDA-HHS Technical Assistance observes that the Roberts-Stabenow definition would seem to exclude starches, purified proteins, and oil made from genetically modified organisms (e.g., oil made from genetically modified soybeans). The definition also likely excludes sugar derived from genetically engineered sugar beets and high fructose corn syrup from genetically engineered corn which may have no detectable levels of modified DNA.⁵ Finally, foods, like the recently-approved white button mushroom, that are altered by deleting rather than adding genes would likely fall outside the scope of this definition.⁶

Further, part A of the Roberts-Stabenow “bioengineering” definition recognizes only one form of bioengineering technology, that is, in vitro rDNA techniques. In contrast, the Vermont statute includes *all* in vitro nucleic acid techniques, *including* (but not specifically limited to) rDNA, as well as “the direct injection of nucleic acid into cells or organelles.”

⁴ This is the same definition for “bioengineering” that appeared in S. 2609, which was introduced by Senator Roberts in March 2016 but did not pass the Senate. H.R. 1599 (the so-called “DARK Act”), which passed the House but not the Senate, similarly defined a “bioengineered organism” as organism where “(1) the organism is a plant (or a seed, a fruit, or any other part thereof); (2) the organism contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (3) the modification could not otherwise be obtained using conventional breeding techniques.”

⁵ See Center for Science in the Public Interest, *Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions* at 4 (April 2015), available at <https://cspinet.org/new/pdf/biotech-faq.pdf>.

⁶ Letter from Animal and Plant Health Inspection Service to Dr. Yinong Yang, re: Request for confirmation that transgene-free, CRISPR-edited mushroom is not a regulated article (April 13, 2016), available at https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf.

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The Vermont statute also recognizes “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.”

The Roberts-Stabenow definition is also narrower than that set forth by the Codex Alimentarius Commission, a joint commission of the World Health Organization/Food and Agriculture Organization of the United Nations responsible for developing standards, codes of practice, guidelines and recommendations pertaining to food. Like the Vermont statute’s definition, the Codex definition sets out non-exclusive examples of bioengineering technology, defining “modern biotechnology” as “the application of: (i) in vitro nucleic acid techniques, *including* recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) 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.”⁷

Part B of the Roberts-Stabenow definition also contains restrictions not seen in the Vermont statute: that the “modification *could not otherwise be obtained* through conventional breeding or found in nature” (emphasis added). On this point, the FDA/HHS technical assistance notes: “It may be difficult to demonstrate that a particular modification could not be obtained through conventional breeding (or even that it could not occur in nature).”

The “could not be” language in the Roberts-Stabenow bill is arguably more limiting than either the Codex definition set out above or the definition used by the World Health Organization because it requires determination of what is theoretically possible, rather than what is possible applying current conventional agricultural techniques. The WHO broadly defines genetically modified organisms as “organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that *does not* occur naturally by mating and/or natural recombination.”⁸ Similarly, Codex defines bioengineering techniques as those that “*are not* used in traditional breeding and selection”

⁷ Codex Alimentarius Commission, Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) (adopted 2003, amended 2008 and 2011), *available at* http://www.codexalimentarius.org/download/standards/10007/CXG_044e.pdf (emphasis added).

⁸ World Health Organization, Food safety: Frequently asked questions on genetically modified foods, *available at* http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/ (emphasis added).

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(emphasis added). Both the WHO and Codex definitions require observation of what *is*, rather than what *could be*.⁹

The FDA/HHS technical assistance also identifies a potential drafting problem, noting: “In addition, it is unclear whether this [the “could not be obtained through conventional breeding or found in nature” requirement] refers to the effect of the rDNA construct or the location in the genome (i.e., the former could arguably be obtained via conventional breeding, whereas the latter cannot).” This requirement could even exclude crops that are genetically engineered to be herbicide resistant, because such herbicide resistance can develop naturally. For example, the EPSPS gene, which makes crops resistant to glyphosate, can be found in nature.¹⁰

Conclusion

The Roberts-Stabenow bill contains a narrower definition of bioengineered food than those contained in recent state legislation and used by non-governmental organizations. First, the bill recognizes only one type of genetic modification technology, and excludes other techniques that are recognized in state law. Second, the bill requires a showing that the modification “could not be” obtained through natural means or traditional breeding, whereas other definitions require only a showing that the modifications are not naturally obtained. Therefore, the bill may cover only a subset of genetically engineered food.

⁹ Similarly, the Vermont definition also refers to use of a technique “that does not occur by natural multiplication or natural recombination.” § 3042(4)(B). This clause modifies only “fusion of cells or hybridization techniques,” which, as discussed above, are not included in the Roberts-Stabenow definition.

¹⁰ See Loredano Pollegioni *et al.*, Molecular basis of glyphosate resistance: Different approaches through protein engineering, HHS Author Manuscript (June 28, 2011), *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3145815/>.