From: JLI Legal Team
Date: June 29, 2016
Re: Bioengineering definition in Stabenow-Roberts Compromise

I. Question

What kinds of foods could be excluded from the definition of bioengineering included in the compromise GE labeling bill released by Senators Stabenow (D-Mich.) and Roberts (R-Kans.) on June 23, 2016?

II. Short answer

Without greater clarification, the definition could exclude a significant number of foods or food ingredients from labeling, including foods made with GE beet sugar, GE soy oils, or even high fructose corn syrup.

III. Analysis

a. Definition

The proposed labeling bill defines bioengineering as follows:

> 1) Bioengineering.—The term 'bioengineering', and any similar term, as determined by the Secretary, with respect to a food, refers to a food—
> (A) That contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and
> (B) For which the modification could not otherwise be obtained through conventional breeding or found in nature.[1]

For a food to be considered genetically engineered it must meet the criteria in both subparts (A) and (B). Unfortunately, many foods that have been produced with genetic engineering would not meet both requirements and would not have to be labeled under this proposal.

In technical assistance dated June 27, 2016, the Food and Drug Administration underscored this point. Specifically, it explained that, "the definition of 'bioengineering' would result in a somewhat narrow scope of coverage" which "will likely mean that many foods from GE sources will not be subject to this bill."[2]

b. The food must "contain" modified genetic material

The requirement in subsection (A) actually has two parts: the food must contain the genetic material and the genetic material must have been modified through recombinant DNA (rDNA) techniques. The subparts are looked at separately in this memo.

[1] Senate Agriculture Committee draft legislation, EDW16734 http://www.agriculture.senate.gov/imo/media/doc/Mandatory%20Labeling%20Bill.pdf

[2] FDA Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734) (June 27, 2016).

Subpart (A) may require that a food still contain the genetic material that was modified in order to be bioengineered. If so, this excludes some methods of genetic engineering and also foods that do not retain detectable amounts of genetic material after processing, even if those foods were derived from genetically engineered crops.

In April 2016, the USDA approved a white button mushroom that was edited with a controversial gene-editing tool called CRISPR/Cas9 to reduce browning.[3] The mushroom was modified, not by adding new DNA to the mushroom, but rather by small deletions of a specific gene.[4] Because no genes were added to the food, one could argue that these mushrooms do not "contain" modified genetic material. Therefore, they might fall outside the scope of the definition and would not have to be labeled.

Additionally, processed food ingredients derived from genetically modified crops often no longer contain detectable amounts of the genetically modified gene. The FDA, in its technical assistance, notes that oil made from GE soybeans would not have any detectable genetic material in it, nor would GE starches or purified proteins.[5] The genetic modification may also removed when sugar is derived from GE sugar beets.[6] Products made with sugar from those GE sugar beets may no longer contain the modified genetic material and would likely be excluded. Even high fructose corn syrup, which makes up a large part of GE field corn used in food, may not have detectable levels of modified DNA.[7]

c. The genetic material must have been modified through recombinant DNA techniques

The second part of subsection (A) requires that the genetic material contained in the food be modified through recombinant deoxyribonucleic acid (rDNA) techniques—a process that brings together genetic material from multiple sources. This greatly narrows the scope of genetic engineering techniques covered by the bill and excludes new technologies like CRISPR gene editing that would not be considered rDNA. It also fails to allow for potential future advances in biotechnology. If the industry shifts away from rDNA, even fewer foods derived from genetic engineering may fall under this proposal's labeling requirements.

This narrow scope is also a departure from the approach taken by state GE labeling bills and the Codex Alimentarius, which included a much broader range of biotechnologies.

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[3] 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), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf

[4] *Id.*

[5] FDA Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734) (June 27, 2016).

[6] *See* Center for Science in the Public Interest, *Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions* (April 2015), p. 10, https://cspinet.org/new/pdf/biotech-faq.pdf ("Although products such as soy oil, beet sugar, and fructose sweeteners are produced from GE crops, the process of producing the oil, sugar, and HFCS from the crop eliminates all of the DNA and protein, including the transgene and its protein product. So although Americans consume thousands of foods with ingredients derived from GE crops daily, our diets actually expose us to very little of the engineered genes or their protein products.")

[7] *Id.* at 9-10.

For example, Vermont's GE labeling law uses the following definition:

> "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:
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> (A) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or
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> (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.[8]

The Codex Alimentarius, or "Food Code," developed by the World Health Organization to develop harmonized food standards[9], uses the following definitions:

> ***genetically engineered/modified organisms.*** The following provisional definition is provided for genetically/modified organisms. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
>
> ***Techniques of genetic engineering/***modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.[10]

Both Vermont and the Codex Alimentarius clearly include direct injection, cell fusion and hybridization among other techniques. The Codex definition also says that the genetic engineering techniques "include, but are not limited to" the methods listed in its definition. This leaves room for interpretation and also new technologies. Both Vermont and the Codex definitions also focus on modification that occurs in a way that does not occur through natural mating or recombination- emphasizing the mixing of genetic traits that wouldn't occur naturally. The Codex definition also explicitly includes gene deletion, which would cover gene editing technologies like the CRISPR modification used to stop mushrooms from browning.

d. The modification could not have otherwise be obtained through conventional breeding or found in nature

Subpart (B) means that a food would not have to be labeled if the genetic modification "could not" have been obtained through traditional breeding or found in nature. Vermont's GE labeling law and the Codex Alimentarius, which focus on mating, multiplication, or recombination that

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[8] Vermont State Legislature, Act 120, An Act Relating to the Labeling of Food Produced With Genetic Engineering (signed May 8, 2014), http://www.leg.state.vt.us/docs/2014/Acts/ACT120.pdf.

[9] World Health Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius, http://www.fao.org/fao-who-codexalimentarius/en/.

[10] World Health Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius, Organically Produced Foods, Section 2: Description and Definitions, http://www.fao.org/docrep/005/y2772e/y2772e04.htm.

would not occur naturally, the Stabenow-Roberts proposal instead focuses on modifications that could not be "found in nature." Because the modifications utilized in biotechnology are often found in nature, a narrow read of this provision could exempt nearly all GE foods from labeling.

As the FDA points out in its technical assistance, "[i]t 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)."[11]

For example, crops like corn and sugar beets designed to be herbicide-resistant may fall outside the scope of this definition because herbicide resistance can develop naturally.[12] The EPSPS gene, which makes crops resistant to glyphosate, is found in nature,[13] potentially exempting those crops from labeling. Likewise, so-called Bt crops also likely would be excluded from GMO labeling. Bt stands for "Bacillus thuringiensis," and is a bacteria that naturally produces a crystal protein that is toxic to pests.[14] Bt crops are crops like corn that have been genetically engineered to produce this same toxin to ward off pests.[15] Because Bt genetic material is found in nature, Bt crops like corn may fall outside the scope of this requirement and would not be subject to labeling.

IV. Conclusion

Without greater clarification, the definition of bioengineering in the Stabenow-Roberts proposal could be read very narrowly to exempt many GE foods from the rest of the proposal's labeling requirements.

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[11] FDA Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734) (June 27, 2016).
[12] Timothy S. Prather, Joseph M. Ditomaso, & Jodie S. Holt, *Herbicide Resistance: Definition and Management Strategies*, Publication 8012, University of California (2000), http://anrcatalog.ucanr.edu/pdf/8012.pdf ("In a plant, resistance may occur naturally due to selection or it may be induced through techniques such as genetic engineering").
[13] Loredano Pollegioni, Ernst Schonbrunn, & Daniel Siehl**,** *Molecular basis of glyphosate resistance: Different approaches through protein engineering*, HHS Author Manuscript (June 28, 2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3145815/.
[14] Matthew Niederhuber, Insecticidal Plants: The Tech and Safety of GM Bt Crops, Harvard University Graduate School of Arts and Sciences (August 10, 2015), http://sitn.hms.harvard.edu/flash/2015/insecticidal-plants/.
[15] *Id.*