**MEMORANDUM**

From: Melanie Benesh, EWG Legislative Attorney
Date: March 15, 2016
Re: Roberts Amendment #3450 to House Amendment to S. 674

## I. Roberts Amendment #3450 to S. 764

### A. *Summary*

The latest version of the DARK Act filed by Senator Pat Roberts (hereinafter "amendment #3450 to S. 764") appears to be a middle ground between S. 2609, Robert's proposal introduced on February 19th, and the amendment proposed by Senator Joe Donnelly (D-Ind.). Like S. 2609, amendment #3450 to S. 764 gives jurisdiction to the U.S. Department of Agriculture, contemplates an initial voluntary labeling system, and preempts states from having their own GMO labeling laws. Like the proposed Donnelly amendment, amendment #3450 to S. 764 includes a possible mandatory label if there is not sufficient participation in the voluntary system and follows a similar timeline. However, unlike Donnelly, amendment #3450 to S. 764 does not envision a scenario where on-pack disclosures could eventually become mandatory. Instead, the mandatory program in amendment #3450 to S. 764 would offer the option of either an on-pack disclosure or virtually any other kind of GE disclosure.

Major problems with amendment #3450 to S. 764 include an overly narrow definition of bioengineering that excludes methods identified in U.S. organics regulations, state GMO labeling laws, and international guidance; presence thresholds; an unclear and likely unworkable trigger for mandatory labeling; and overly broad preemption, including unnecessary preemption of genetically engineered seed laws.

### B. *Subtitle E*

#### i. Section 291- Definitions

As in S. 2609, this section in amendment #3450 to S. 764 defines bioengineering, food, and Secretary. Bioengineering, with respect to food, is defined as food that contains genetic material modified through in vitro recombinant DNA techniques; and for which the modification could not otherwise be obtained through conventional breeding or in nature.

This definition of bioengineering is inconsistent with the definition of "excluded methods" in U.S. organic regulations. *See* 7 CFR § 205.2, Subpart A. Additionally, states that have passed GMO labeling laws have also included some form of cell fusion in their definition of genetic engineering. *See* Vermont Act No. 120 § 3042 (including in the definition of genetic engineering "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 Codex Alimentarius, also known as the international "Food Code," includes cell fusion in its guidelines on genetic engineering as well. *See* World Health

Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius, Foods Derived from Modern Biotechnology (2d edition 2009), *available at* http://www.bibliotecapleyades.net/archivos_pdf/foods-derived-modern-biotechnology.pdf (defining modern biotechnology as the application of (i) in vitro nucleic acid techniques, including 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 that are not techniques used in traditional breeding and selection). As such, the definition of "bioengineering" in amendment #3450 to S. 764 is overly narrow and likely excludes some GE foods from labeling.

The bill defines "food" in accordance with FDA law, and "Secretary" to mean the Secretary of agriculture.

ii. Section 292: Applicability

Like S. 2609, this section in amendment #3450 to S. 764 clarifies that the new subtitle applies to all food labeling that directly or indirectly indicates that food is genetically engineered or contains genetically engineered ingredients. The clause is written broadly to cover any kind of label or claim that hints at the presence of genetic engineering.

iii. Section 293: Establishment of National Voluntary Bioengineered Food Labeling Standard

This section requires the Secretary to establish standards for voluntarily labeling genetically engineered food within one year of enactment. This timeframe is one year quicker than required by S. 2609. It is also consistent with the timeline set out in the Donnelly amendment. The Secretary must also establish requirements and procedures to carry out the standards. The section states that the standards for voluntary labeling are the only way that food may be labeled as genetically engineered, thus preempting states from enacting requirements and limiting industry discretion as to how to voluntarily disclose. Additionally, there would be no way to label foods excluded from the narrow definition of bioengineering.

The standards promulgated under this section must prohibit any claims indicating that a food is safe or not safe or of higher quality solely due to genetic engineering. For example, a producer of GE potatoes would probably not be able to claim that the potatoes are safer because they produce lower levels of acrylamide. The regulations must also define a threshold level for presence of genetically engineered material or components in order to be labeled. This threshold requirement could make it *more difficult* for companies that wish to voluntarily disclose the presence of GMO ingredients if those ingredients do not meet the USDA-defined threshold. The regulations must also establish a process to request, and for the Secretary to grant, a determination on other factors and conditions when a food can be labeled as genetically engineered.

Amendment #3450 to S. 764 has a new requirement related to smart labels that was not included in S. 2609. If a food is voluntarily labeled through a scannable image or code, etc. the label must clearly indicate to consumers that more information is available about the ingredients in the food. The bill does not specify if the label must indicate that more information about genetic

engineering is available. Further, the scannable image or code must provide direct access to information regarding whether the food is genetically engineered or produced with genetic engineering.

Like S. 2609, the section reiterates more explicitly that it preempts any state law that directly or indirectly requires labeling genetically engineered food, unless that requirement is identical to the voluntary federal standards.

Amendment #3450 to S. 764 also adds a new directive requiring the Secretary to make the new voluntary genetically engineered labeling guidelines consistent with the national organic standards to the maximum extent practicable.

iv. Section 294- Rulemaking on Substantial Participation

This section was not included in S. 2609. This section requires the Secretary to promulgate regulations no later than a year after enactment defining the circumstances that constitute "substantial participation" by "labeled foods" with voluntary GE disclosures. Substantial participation is not defined. However, labeled food is defined as "food that bears, or to which is attached, any written, printed, or graphic matter, including on the immediate container or on the package of the food." This definition seems to exclude raw agricultural commodities that are not sold in containers or in packaging.

In promulgating these regulations, the Secretary is directed to consider the percentage of the labeled foods that make a GE disclosure. The section does not indicate what percentage would constitute "substantial participation." The Secretary is further, confusingly, directed to consider:

> the extent to which there is clear indication in a usual and customary form that information is available for the most frequently consumed labeled foods or direct access to disclosures for the most frequently consumed labeled foods, including through means that are clear and direct other than the label or labeling, such as responses to consumer inquiries through call centers, the Internet, websites, social media, scannable images or codes or other similar technologies that would allow consumers to access the information, or any other means the Secretary considers appropriate for disclosing the bioengineered content of food.

While the Secretary must define "most frequently consumed labeled foods," the section does little else to shed light on other ambiguous and confusing terms in the paragraph such as "clear indication," or "in a usual and customary form." It is also unclear how the Secretary would measure the extent to which the information is available either through scannable images, or as the paragraph suggests, through "call centers, the Internet, websites, social media . . . or any other means the Secretary considers appropriate." Developing a system to quantify and track participation could be unduly burdensome for USDA.

v. Section 294A: National Mandatory Bioengineered Food Labeling Standard

This is a new section that was not included in S. 2609. In this section, a national mandatory bioengineered food labeling standard can be established if there is not seventy percent "substantial participation" per the regulations promulgated in Section 294. It is not clear if this means there must be seventy percent of the market as a whole, or seventy percent of a submarket defined by the Secretary in Section 294, that is "substantially participating" in voluntary labeling of some sort. Note that the Donnelly amendment had set this threshold at 85 percent of relevant products. Either way, the Secretary can make its "substantial participation" determination no earlier than two years after regulations have been promulgated for substantial participation and for voluntary labeling. Since those regulations are supposed to be promulgated one year after enactment, the earliest the Secretary could call for national mandatory labeling would be three years post-enactment.

If the Secretary does call for national mandatory labeling, it must establish regulations. Like the voluntary labeling standards, food may be labeled as genetically engineered only in accordance with these standards, preempting the field. Also like the voluntary standards, the regulations would have to prohibit express or implied claims that the food is or is not safer or of higher quality solely based on whether the food is genetically engineered or produced with genetic engineering; include presence thresholds for labeling; and have a process for requesting and granting a determination regarding other factors and conditions under which a food may be labeled. Unlike the voluntary standards, the mandatory requirements would exclude restaurants.

Under the regulations, an "appropriate person" would have make a GE disclosure through either (i) an on-pack statement; or (ii) "means other than the label" including through "call centers, the Internet, websites, social media, scannable images or codes, or other similar technologies" or "any other means the Secretary considers appropriate." This is an extremely broad provision that could likely be met with just about any form of disclosure imaginable. The section does not explicitly require that the regulations make the disclosure be clear or conspicuous or readily accessible. For a mandatory disclosure, it sets a very low bar.

The mandatory labeling regulations should be implemented no earlier than 2 years after the later of when the regulations are finalized or when the Secretary determines that there is not substantial participation in the voluntary scheme. This would be at least five years from the date of enactment. This is consistent with the timeline for a mandatory on-pack disclosure in the Donnelly amendment, but slightly later than the Donnelly amendment's requirements for a mandatory e-label (four years).

This section again clarifies that states are preempted from directly or indirectly establishing any requirement related to GE labeling unless it is identical to the federal requirements.

This section also has a new section on enforcement that makes it illegal to knowingly fail to make a GE disclosure and imposes record-keeping requirements. The Secretary can audit records, but will have no recall authority for GE foods that are not labeled.

vi. Section 294B: Savings Provisions

Unlike S. 2609, the Robert's manager's amendment also includes savings provisions. First, the bill should be applied consistently with international trade obligations. Second, the bill is not intended to supplant the FDA's authority or "create any rights or obligations for any person under the FDCA." While this phrasing is somewhat confusing, it can be presumed to mean that this bill is meant to address USDA's authority and does not create new obligations for industry under the FDCA, which would fall outside USDA's jurisdiction. This savings clause could also be interpreted to reserve FDA's authority to create labeling guidelines for GE salmon in accordance with section 761 of the Consolidated Appropriations Act that passed in December 2015. Finally, this section saves the authority of the Secretary of Treasury and does not create any rights or obligations under the Federal Alcohol Administration Act.

C. *Subtitle F: Federal Preemption*

States are already clearly preempted from having any non-identical GE labeling rules in several places in this bill. Nonetheless, amendment #3450 to S. 764 adds another subtitle to again clarify that states may not have their own GE labeling requirements and to extend preemption to laws related to genetically engineered seeds. This subtitle states that states are preempted from having any laws or requirements on labeling whether a food, ingredient, or seed in interstate commerce is genetically engineered or was developed using genetic engineering. This includes other labeling for other terms similar to genetic engineering, as determined by the Secretary.