kalsec®

July 17, 2017

The Honorable Sonny Perdue Secretary of Agriculture
U.S. Department of Agriculture 1400 Independence Ave., S.W. Washington, DC 20250
Via electronic mail to GMOlabeling@ams.usda.gov

RE: Proposed Rule Questions Under Consideration for GMO Disclosure and Labeling (June 28, 2017) https://www.ams.usda.gov/rules-regulations/gmo-questions

Dear Secretary Perdue,

Kalsec®, Inc. ("Kalsec®") appreciates the opportunity to respond to USDA's Agricultural Marketing Service (AMS) on the implementation of the National Bioengineered Food Disclosure Standard. Kalsec® has produced flavors and colors from natural sources for over 50 years and has contributed to the development of standards for their safe use and quality through our work within trade associations and directly with regulatory bodies. The clarity and utility of these standards are of great importance to us and to the consumers and markets that we serve.

As a manufacturer of natural food ingredients, Kalsec® is committed to providing its customers with ingredients that are familiar, safe and wholesome as well as innovative and effective. Moreover, we are a global company with interest in competitive, free and fair trade that promotes job growth in our industry. These intentions guide our thoughts on the USDA rulemaking process.

USDA AMS is challenged to satisfy public desire for more detailed food labeling without stifling US progress and leadership in gene modification technologies that offer safer, healthier, more enjoyable and more sustainable foods. Although some may seek to use the labeling bill to inhibit bioengineering methods in food production altogether, USDA must effectively choose how to balance disclosure with innovation. Importantly and simultaneously, consumers must be educated by USDA and FDA to understand that bioengineered foods offer the same safety and nutrition as conventionally-produced foods.

Definition and Identification of Bioengineered Foods for Mandatory Disclosure
USDA's questions #1-11 seek input on the definition of a bioengineered food and potential exemptions or limits to the disclosure requirement. The definition of bioengineering in Section 291 of the National Bioengineered Food Disclosure Law (Pub. L. 114-216) provides two conditions. A bioengineered food is 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.*

P.O. Box 50511
Kalamazoo, MI 49005-0511
3713 West Main Street
Kalamazoo, MI 49006

269.349.9711
800.323.9320
www.kalsec.com

FAX NUMBERS
Sales and Marketing 269.382.3060
Hop Sales 269.349.9055
Customer Service 269.349.1195
Purchasing 269.349.1558
Accounting 269.349.1558
Lab 269.349.1178
Technical Request 269.216.4048

In a letter to Senator Debbie Stabenow dated July 1, 2016,[1] USDA General Counsel Jeffery Prieto wrote that Section 291 of the regulation provides USDA with authority to (1) establish labeling requirements for other modern genetic modification methods not stated in the regulation such as gene editing techniques and (2) require disclosure of highly refined ingredients, which derive from bioengineered foods but do not contain genetic material from those foods.

In response to USDA Question #2, we understand that new gene editing methods such as CRISPR cannot be considered conventional at this early stage in their development (USDA Question #2). However, a strong argument can be made that CRISPR is an improvement on conventional breeding, and will inevitably become 'conventional'. The genetic material of two plants with identical endowed traits, one achieved via cross-pollination and one achieved via the CRISPR-Cas9 system, would be genetically indistinguishable (except for the unwanted or unnecessary traits transferred via cross-pollination that would be lacking in a CRISPR plant). Both plants were created via human tools with deliberate intention. Furthermore, conventional plant breeding and CRISPR technology share the same desired outcome: enhancing the expression of genetic material already present in organisms. Thus, it can be said that CRISPR and conventional breeding can achieve identical outcomes, although CRISPR achieves these outcomes in a more precise and efficient manner.

In response to USDA Question #3, we believe that modification methods which enhance expression of a gene and modifications which remove a gene should be considered 'natural', as they are indistinguishable from the natural changes in gene expression that are dictated by environmental factors (time, temperature, signal chemicals produced by plant/microbe, etc.). For consistency with other regulations, we point out that USDA APHIS has regarded CRISPR-edited waxy corn and white mushrooms to be exempt from regulation under the Plant Protection Act of 2000.[2] The rationale for this decision was that there was no introduced genetic material in either organism, and no reason to believe that either were pests.

In response to USDA Question #4, we recognize that disclosure of highly refined ingredients such as soybean oil and high fructose corn syrup from recombinant DNA varieties was a driving motive for the current legislation. Consequently, we recommend required labeling of such ingredients and encourage USDA to align its rules accordingly where possible with other international regulatory bodies such as the European Union.

In Questions #5, 9 and 10, USDA anticipates confusion between new labeling criteria and other regulations. For example, the definition of excluded bioengineering methods in the National Organic Program (NOP) is more stringent than most international GMO labeling laws. If the USDA were to harmonize its definition with the NOP most of the cheese made in the United States (with bioengineered enzymes) would require disclosure. This seems to us to be outside of

[1] See 162 Cong. Rec. S4994 (daily ed. July 12, 2016).

[2] (a) Dr. Michael Firko (USDA) letter to Dr. Daria Schmidt (DuPont Pioneer), April 18, 2016. (b) Dr. Michael Firko (USDA) letter to Dr. Yinong Yang (Penn St. University), April 13, 2016.

P.O. Box 50511
Kalamazoo, MI 49005-0511
3713 West Main Street
Kalamazoo, MI 49006

269.349.9711
800.323.9320
www.kalsec.com

FAX NUMBERS
Sales and Marketing 269.382.3060
Hop Sales 269.349.9055
Customer Service 269.349.1195
Purchasing 269.349.1558
Accounting 269.349.1558
Lab 269.349.1178
Technical Request 269.216.4048

the intent of the law and could result in barriers to fair trade for similar foods from other countries.

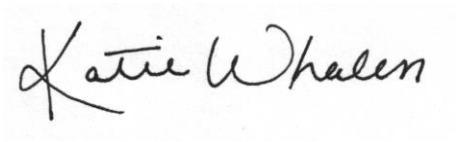
At present, we do not have substantive answers to Question #9 about possible disclosure categories. Instead, we ask AMS to provide more details about what disclosure categories the agency contemplates and its rationale for differentiating between them. Additionally, we ask AMS to explain how the agency will educate consumers about the distinctions between any proposed disclosure categories.

Compliance and Enforcement Provisions

In response to USDA Question #30, we ask the agency to ensure that disclosure requirements for imported foods are equivalent to those for domestically-sourced foods. Although we do not address Questions #26-29 explicitly in these remarks, we anticipate that USDA will consider a recordkeeping, examination and audit program like the third-party verification system administered by the NOP, in which we already participate. Recordkeeping and compliance standards for bioengineered food labeling must be the same regardless of food origin.

Thank you again for the opportunity to respond. We look forward to collaborating with you in the rulemaking steps.

Respectfully submitted,



P. Douglas Williams, Ph.D.
Research Fellow – Kalsec®, Inc.
Regulatory Affairs

Katie Whalen
Contracted Research Scientist – Kalsec®, Inc.
Whalen Biochemical, LLC