



Sargento Foods Inc.
One Persnickety Place
Plymouth, WI 53073

Submitted Electronically to:

August 24, 2017

United States Department of Agriculture
Agricultural Marketing Service
GMOLabeling@ams.usda.gov

Re: Request for Stakeholder Input in Developing a Proposed Bioengineered Food Disclosure Rule

Sargento Foods is pleased to respond to the USDA Agricultural Marketing Service's ("USDA-AMS" or "AMS") request for input on preparing the proposed rules for bioengineered food disclosure ("Rule"). Thank you very much for the opportunity.

I. EXECUTIVE SUMMARY

In its quest for promulgating the Rule, the AMS should thoroughly consider the immense benefits of biotechnology, vast amount of objective and scientific information about its safety and the general consumer opinion and reaction to biotechnology today. It is the AMS's duty to preserve and foster innovation and technology while certainly protecting the consumer health and rights for information. This is a difficult balancing act. Therefore, we request that the AMS promulgate the Rules in consistence with the National Bioengineered Food Disclosure Standard provisions, and in a manner that is not disparaging to biotechnology today or in the future.

We strongly urge the AMS to consider the following:

1. Set meaningful and practical definitions that are supported by science. More specifically, we ask that the AMS build the definition of bioengineered foods on detectable presence or absence of genetically engineered DNA material or an expressed novel protein in food.
2. Exempt certain foods and substances per our response to Question 8 on page 4 below.

3. Allow a meaningful and feasible threshold to prevent cost increase and stigmatization of the technology.
 - a. The threshold should be 0.9%, if the AMS excludes highly refined sugars and oils from the definition of bioengineered food.
 - b. If the AMS determines that the highly refined sugars and oils are considered bioengineered foods, then the threshold should be set at 5%.
4. Do not allow absence claims unless:
 - a. the food is certified Organic under the USDA's National Organic Program, or
 - b. the absence of genetically engineered ("GE") material is verified by a USDA-approved, reputable certifying body (similar to the organic certification).

II. INTRODUCTION

Sargento Foods, founded in 1953, is a family-owned and operated business headquartered in Plymouth, Wisconsin and is best known for its packaged shredded, sliced and snack natural cheeses. We operate four manufacturing facilities within the state of Wisconsin, employ more than 1,900 employees, and generate more than \$1 billion in revenue. Sargento® cheese and snack products are sold nationwide at several medium and large-scale retail, convenience and club stores. Sargento Foods partners with many dairy farms, cooperatives, cheese making and processing companies, and other raw material suppliers across the United States.

Sargento Foods commends the USDA-AMS's willingness to solicit input from the food industry and for its mission and efforts to protect consumers. From a principled regulatory perspective, we accept and embrace the AMS's identity as a science-based institution. We strongly believe that public policies that drive industry practices and impact consumers' diets must be planned and formalized with utmost care, research, sound scientific evidence, and a good understanding of consumer behavior and trends.

III. SPECIFIC COMMENTS

We are submitting responses to the following questions that are under consideration by the USDA-AMS. The numbering of our responses coincides with the AMS's published document:

1. What terms should AMS consider interchangeable with 'bioengineering' (Sec. 291(1))?

The AMS should carefully consider the scientific meaning of any alternative terms to "bioengineering" while balancing with the consumer needs. Specifically, the AMS should avoid using other terms that would stigmatize biotechnology and are not scientifically accurate. For example, the common term "GMO" stands for Genetically Modified Organism, and it only applies to an organism that has been genetically modified, and not to the substances or foods derived through genetic engineering, and certainly not to foods made from or with such organism. We would recommend that "genetic modification" and "genetic engineering" are more appropriate terms.

4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))?

The USDA-AMS should not require disclosure for foods that are derived from bioengineered crops that are processed, purified, highly refined or filtered. These foods should not be considered “bioengineered” because they do not contain detectable levels of bioengineered genetic material or its expressed proteins. Additionally, these foods are indistinguishable in composition from their conventional counterparts and do not pose any additional safety risk.

On the other hand, defining highly refined products as “bioengineered” and requiring their disclosure is a slippery slope. The definitions and disclosure requirements must be established on a scientific and *consistent* basis, i.e. on the presence of genetically engineered material or its expressed proteins. The AMS is also considering, prudently, exempting certain foods from disclosure (e.g. products of fermentation such as enzymes and vitamins) which are the products of fermentation processes where biotechnology is used. These products do not contain genetically engineered materials either, and this exemption follows the scientific basis argued above. Therefore, by applying the same logic to highly refined oils, sugars or similar foods as products of fermentation, all the Rules would be consistent, making it easier for consumers to understand and for the food industry to follow.

The food industry handled disclosure of these foods while the Vermont’s Act 120 was in effect. The Act included these products in the definition of bioengineered foods and required their disclosure if above the set threshold. This classification put the food industry under an unnecessary burden, and raised the cost for consumers. As an example, more than 94% of soy and 95% of sugar beets grown in the US is genetically engineered, and under the Vermont law, the highly-refined by-products were considered GE foods although they did not contain any altered DNA or novel proteins. The soybean oil and sugar are very important ingredients in almost all food formulas. If the food companies did not want to label a disclosure, they were forced to replace these ingredients with their conventional counterparts, which are not easily available in the market and come at a highly elevated cost. This in turn hurts the economy and consumers’ budgets.

Furthermore, if the AMS requires disclosure for these foods, the disclosure would be misleading to those consumers who, for one reason or another, may be concerned about consuming bioengineered materials. The disclosure will urge them to unnecessarily avoid these foods, even though the foods do not contain such materials. Lastly, requiring disclosure of these food as “bioengineered foods” would further denounce biotechnology and give consumers false impression of a safety risk or inferiority. The National Bioengineered Food Disclosure Standard specifically prohibits the AMS from drafting rules that disparage biotechnology and insinuate a food safety risk.

6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under FFDC. How will AMS determine the predominance of ingredients (Sec. 292(c))?

A reliable verification of the order of predominance is the ingredient statement. Accurate declaration of ingredients’ order in a formula is a requirement by the FFDC, and the violation of which results in misbranding. The food industry is well-versed in disclosing accurate ingredient statements for

years and widely complies with this regulation. Similar to the FDA's regulations on declaring dietary fiber and added sugars, the AMS should allow the food industry to self-monitor and self-determine, based on the foods' recipe, if disclosure is required.

7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed (Sec. 293(b)(2)(A))?

The USDA-AMS should craft the language in alignment and consistent with the language in the statute. This language is not only the legal basis of the Rule but also is scientifically sensible. Several scientific studies show “*substantial evidence that the genetically modified DNA or the novel proteins are not detected in animal products such as milk, meat or eggs from animals that are fed genetically engineered feed. that the chances of intact DNA (either transgenic or native) being absorbed and incorporated into the host animal's genome are highly remote*” and “*there is now supporting evidence that the products from animals that have been fed GM crops do not contain any detectable amounts of transgenic DNA or biotech protein*”¹. Other research also suggests that the normal digestion process sufficiently prevents absorption of any intact proteins in the intestinal wall². Even with very precise detection methods, the amount of genetically engineered material passed into the animal product is believed to be a minute amount (around 5 ppm)³. In a multi-ingredient food product, this amount gets further diminished, becomes non-detectable, and it would be senseless and unnecessarily costly to require its disclosure.

8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered (Sec. 293(b)(2)(B))?

The AMS should establish a threshold amount of bioengineered content in a food below which a disclosure is not required. This threshold amount should:

1. be set based on the total weight of the food directly consumed (e.g. brine, juices, marinating solutions, shells and bones, etc. would not count towards the total weight of the food);
2. include the total weight of bioengineered ingredients or components in the food's recipe; and
3. be established at 5%, if the AMS includes highly refined and processed foods in the biotechnology food definition. If highly refined and processed foods are exempted, a lower threshold at around 1% could be established for the reasons stated in our response to Question 4 above.

Additionally, AMS should not include in the bioengineered food definition, and impose subsequent disclosure requirements on the substances that are:

1. derived from bioengineered foods and processed in a manner that the genetically engineered DNA or its expressed proteins are at undetectable levels. The efficacy of the manufacturing

¹ D. E. Beever, K. Glenn¹ and R. H. Phipps Centre for Dairy Research (CEDAR), Department of Agriculture, The University of Reading. Published in *Asian-Aust. J. Anim. Sci.* 2003. Vol 16, No. 5: 764-772, 2003.

² *Id.*

³ D.E. Beever and C. Kemp, 2000. *Safety Issues associated with the DNA in animal feed derived from genetically modified crops: A review of the scientific and regulatory procedures.* Nutrition Abstracts and Reviews. Series B: Livestock Feeds and Feeding 70:175-182.

process (refining, filtering, etc.) would be substantiated by current testing methods, and the product would be excluded from the definition as long as the process parameters or efficacy remains the same. The verification tests would be conducted at a voluntary frequency.

2. products of fermentation such as enzymes, yeasts and vitamins. These substances are the products of bioengineered organisms but do not contain any genetically engineered material or expressed proteins.

Since these substances would not be considered bioengineered foods, they would not count towards the threshold determining disclosure.

9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))

The premise of the disclosure requirement is to provide transparency to the consumers and to inform them in a clear and simple way of the presence of bioengineered foods in their diet. Consumers generally are not aware of the details of food processing and the subtle differences between the terms “made with”, “produced from” or “partially produced from”, etc. These terms are not meaningful to them. The consumer interest is best served if the AMS establishes one simple disclosure statement while allowing the food manufacturers to include specific ingredient names, if so chosen. This statement should be “Produced with bioengineered ingredient(s)”. It can be used for single and multi-ingredient foods that contain bioengineered ingredients above the set threshold. Listing of particular bioengineered ingredients should be permitted.

Example 1: A bag of frozen, bioengineered corn. Labeling would be “Produced with bioengineered ingredient” or “Produced with bioengineered corn”.

Example 2: A bag of corn chips made with bioengineered corn and soybean. Labeling would be “Produced with bioengineered ingredients” or “Produced with bioengineered corn and soy”.

12. If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure (Sec. 293(b)(2)(D))?

Same comments as in Question 9.

13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))

Aligned with the AMS’s intent, the symbol must not disparage biotechnology or give any false indication to the consumers that bioengineered foods are unsafe, inferior or different than their counterparts. To that end, the AMS should avoid using symbols, colors, images or other cues that are usually associated with danger or caution, such as red color, triangular or octagonal shape (danger and stop sign), exclamation marks, crosses, etc. The symbol should be simple without too many details and can contain the letters “GE” or “GM” but not “GMO”. The standard text can wrap around the symbol. The color should be calming, such as green or light blue, and not alerting. The symbol should be placed in close proximity to the ingredient statement and the size should be scaled to the package size as defined by the FDA’s labeling regulations.

14. If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure (Sec. 293(b)(2)(D))?

The digital link on the label should be named clearly and be self-explanatory, such as www.sargento.com/GE, www.sargento.com/GE_disclosure, www.sargento.com/biotechnology, etc. The AMS should allow manufacturers flexibility with the words used in digital links.

17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages (Sec. 293(b)(2)(E))?

The AMS should adopt the same package size descriptions as the FDA's food labeling regulations.

We express our appreciation for the opportunity to comment on this issue and for the AMS's consideration of our concerns and interests.

Sincerely,

Ebru Basaran-Shull
Principal, Compliance and Government Affairs