



1 Maple Avenue, White Plains, NY 10605

SUBMITTED VIA REGULATIONS.GOV

July 3, 2018

Administrator Bruce Summers  
Agricultural Marketing Service  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250

RE: National Bioengineered Food Disclosure Standard, Proposed Rule & Doc. No. AMS-TM-17-0050, 83 Fed. Reg. 19,860 (May 4, 2018)

Dear Administrator Summers,

Danone North America respectfully submits the following comment in response to the Agriculture Marketing Service of the United States Department of Agriculture's proposed rule regarding the implementation and enforcement of the National Bioengineered Food Disclosure Standard (Pub. L. 114-216). This follows our comments submitted August 25, 2017, for the questions posed by USDA last year seeking opinions on key issues.

With our mission to bring health through food to as many people as possible, Danone is a leading global food company built on four business lines: Essential Dairy and Plant-based Products, Early Life Nutrition, Waters and Medical Nutrition. Through its mission and dual commitment to business success and social progress, the company aims to build a healthier future, thanks to better health, better lives and a better world, for all its stakeholders: its 100,000 employees, consumers, customers, suppliers and shareholders. While Danone is present in over 130 markets, our U.S. footprint is also significant. With the acquisition of WhiteWave in 2017, our U.S. footprint through Danone North America (formerly known as DanoneWave) spans various food brands such as Activia, DanActive, Danimals, Dannon, Danonino, Earthbound Farm, Horizon Organic, International Delight, Light & Fit, Oikos, Silk, So Delicious, Vega, and Wallaby. We have co-headquarters in Broomfield, Colorado and White Plains, New York, have manufacturing facilities

in 9 states, employ approximately 6,500 people; and we work directly with hundreds of U.S. farmers to help create a sustainable and economically viable supply chain.

As the largest public benefit corporation in the United States, Danone North America is putting its social missions of sustainability and nutrition at the forefront of our business strategies. Furthermore, as a public benefit corporation recently certified as a B Corp, we are continually seeking new ways to operate in the most transparent manner possible.

### **National Bioengineered Food Disclosure Standard**

We have a significant interest in the National Bioengineered Food Disclosure Standard. Transparency and commitment to more natural ingredients have long been pillars of our commitment to consumers, customers and farming partners. Additionally, many of our brands rely on USDA Organic Certification which by law cannot use ingredients made with genetic engineering. While the National Bioengineered Food Disclosure Standard passed by Congress may not be completely aligned with our approach towards communicating to the consumer (e.g. by exempting animal feed for disclosure), we believe that the intent of the statute was certainly that USDA should not create additional confusion, exemptions, or loopholes. Simply put, the scope of disclosure should be broad to cover ingredients and foods derived from biotechnology, and the communication should be consistent, simple and objective to not cause undue confusion or conflate with other private and government standards for food labeling.

#### Scope

Consumers expect clarity, and additional exemptions only raise additional questions and confusion. The statute, does provide a broad definition of “bioengineering” for USDA to ensure a broad set of disclosures:

“(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.”

As stated in our answers to questions posed by USDA last year, USDA should require disclosure for such foods and food ingredients that have been subject to novel and emerging techniques such as gene editing and synthetic biology. While new technologies may be different than conventional genetic modifications using foreign genetic material, in the vast majority of cases they still create traits which may not emerge through conventional breeding and hybridization. While it may be difficult to create one standard to identify a modified genetic trait that “could not otherwise be obtained through conventional breeding or found in nature”, USDA may have to consider various criteria and not rely on just one factor such as intellectual property law.

Furthermore, USDA can look to other genetic engineering standards and biotechnology definition such as Non-GMO Project Verified standard and the USDA Organic Certification which do not allow the use of technologies such as gene editing. The National Organic Standards Board has defined conventional breeding via the following recommendation for organic standards and certification:

“Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.”<sup>1</sup>

While obtaining organic certification certainly requires meeting more requirements than just using conventional plant breeding, the clear mandate of the National Organic Program to not allow bioengineering of any sort should provide a useful set of definitions for USDA to consider along with other bodies of standards such as Non-GMO Project, and the Codex Alimentarius<sup>2</sup>. Codex, in particular, has led a lengthy discussion about biotechnology which many of our trading partners follow.

Danone North America does not believe that the purpose of such transparency is to discourage or incentivize a particular technology. We believe in the advancement of new technologies to provide more sustainable food, especially with fewer resources and inputs, which we believe can

---

<sup>1</sup> See National Organic Standards Board Formal Recommendation (November 18, 2016) available at <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethods.pdf> (for discussion of definition of conventional breeding).

<sup>2</sup> See Food and Agriculture Organization of the United Nations, Codex Alimentarius, <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>; Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission. 2003. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) available at [www.fao.org/input/download/standards/10007/CXG\\_044e.pdf](http://www.fao.org/input/download/standards/10007/CXG_044e.pdf).

be achieved in many ways. Transparency in this case is not to compel certain types of food production, but merely to create a standard of communication to allow the consumer insight as to how food is produced; in this case whether it is derived from technology that uses bioengineering or not. And as noted in the proposed rule and by our prior comments, USDA will need a clear and consistent process to consider new and emerging technologies to determine whether it meets the statutory definition for disclosure.

### *Highly Refined Products*

Danone North America strongly encourages incorporating highly refined products derived from genetically modified crops into the final rule for disclosure. Not including such products will likely erode trust in USDA and government processes, as the rule will have a significant loophole created by USDA. It also, would be out of step with how currently existing Non-GMO standards consider such ingredients.<sup>3</sup> Also, including highly refined products derived from genetically modified crops would reflect the expectations of stakeholders and the legislative intent of Congress.<sup>4</sup>

We are concerned that when considering highly refined products, the proposed rule focuses on whether an ingredient or final product contains detectable bioengineered material. Consumers expect that the food industry understands what ingredients and products come from the use of bioengineering technology, and as such the rule should seek compatible enforcement mechanisms of recordkeeping, reporting and compliance to validate the entire process of food production that led to the final product being labeled. Highly refined products derived from genetically modified crops as well as those from emerging technologies such as gene editing, may not always have modified genetic material that is detectable. Other methods of traceability, however, can be used to demonstrate whether a producer of a final product must disclose, such as an affidavit system used in other food labeling systems. Finally, this is another aspect of the rule where USDA should seek alignment with standards used by our major trading partners such as the European Union.<sup>5</sup>

### *0.9% of weight threshold*

Danone North America strongly recommends the alternative option 1-B containing a threshold to trigger disclosure at 0.9% of the specific ingredient by weight. This threshold would allow the

---

<sup>3</sup> See Non GMO Project Verified Standards (September 22, 2017), *available at* <https://www.nongmoproject.org/wp-content/uploads/2017/09/Non-GMO-Project-Standard-Version-14.2.pdf>.

<sup>4</sup> 162 Cong. Rec. S4994 (daily ed. July 12, 2016), *available at* <https://www.congress.gov/crec/2016/07/12/CREC-2016-07-12-pt1-PgS4994.pdf>.

<sup>5</sup> 2003 J.O. (L 268) 24.

presence of a bioengineered material that is inadvertent. We agree with USDA that current standards used by much of industry and key trading partners, such as the European Union, already enforce this standard and it has proven practical. It was also the standard used by the Consumer Protection Rule of 121 by the State of Vermont.<sup>6</sup>

### *Lists of Bioengineered Foods*

Danone North America is concerned that the proposed rule may confuse implementation and communication to consumers by creating two lists of bioengineered foods and ingredients. The degree to which an ingredient or food is used or accepted within the market place should not impact the disclosure. The statute does not distinguish types of bioengineered foods and ingredients and therefore does not request USDA to differentiate with different lists. All bioengineered foods and ingredients should be treated and disclosed similarly, therefore we respectfully disagree with the proposed rule's allowance for non-high adoption bioengineered foods to use the qualifier "may" contain a bioengineered food ingredient.

### Communications

Danone North America believes that disclosure for the consumer should be simple, easily understandable, clearly identifiable, and consistent across the food industry. We also believe that the main purpose of the statute is to convey an objective fact to the consumer, not for any purpose other than to allow the consumer to make their own decision on what to do with the information.

### *Options for Disclosures*

Since the statute allows for three options to disclosure, USDA should, to the greatest extent possible, minimize and simplify the methods so that clarity for the consumer is achieved. Danone North America strongly believes that the disclosure of a bioengineered food is best done through on-pack text disclosure within the information panel and not through a symbol or an electronic or digital disclosure. We appreciate the proposed rule reinforcing that the appearance of disclosure "should be of sufficient size and clarity to appear prominently and conspicuously", and providing further detail such as minimum font size would be useful. We also believe these requirements should apply beyond disclosures on the label and via any electronic means as well.

While we do not prefer a symbol for the purpose of disclosing bioengineered foods, any symbol that USDA selects must be easily understood by consumers. As we stated in answers to questions posed by USDA last year, we believe it is important that the potential consumer understanding of the symbol be thoroughly evaluated by USDA prior to the final selection of the symbol.

---

<sup>6</sup> 6-121 Vt. Code R. §121.03(e).

A recent study conducted by International Food Information Council Foundation (IFIC) demonstrates how consumers reacted to the various proposal of this rule, and in part informs our thinking on why we do not prefer any of the symbols proposed.<sup>7</sup> They do not achieve objectivity, appear more like marketing symbols; and there is no evidence to suggest that consumers will understand what BE means since it is not commonly used already. Furthermore, USDA should consider how the chosen text option may also appear in addition to the symbol, since the recent IFIC study demonstrates that far fewer consumers understood the symbol when descriptive text is not included with the symbol.

We prefer text similar to what industry had already used under the Consumer Protection Rule 121 from the State of Vermont, such as “produced with genetic engineering”, thus hopefully ensuring that the term chosen is more commonly understood by consumers. While the statute does use “bioengineered” it clearly provided deference to USDA, and it would make more practical sense to use a term already in use by industry and is something that many consumers already know rather than introduce a new term that will require more resources to change packaging and educate the public. Additionally, as stated above, we prefer that USDA not provide the option of using “may” with disclosures.

Finally, an electronic means allowed for disclosure, while not ideal for optimal consumer access of information, must also anticipate consumers with various types of technology capabilities and limitations; therefore, the rule should contain more stringent guidelines to ensure consumers can easily obtain information.<sup>8</sup> Accessibility of the information, ease of finding the information, and consistency and quality of information should all be important principles to design uniform standards for industry to follow. For example, a consumer should simply and clearly see the same text as used on a package, immediately when engaging in an electronic form of disclosure.

#### *Outreach & Education*

In addition, USDA should plan on implementing a strong consumer education campaign to ensure that consumers learn the meaning of any symbol and terminology ultimately allowed by USDA, as well as the various ways in which they can access the information.

#### Preservation of private Non-GMO labels & Organic Certification

---

<sup>7</sup> IFIC Foundation. *Research with consumers to test perceptions and reactions to various stimuli and visuals related to bioengineered foods* (June 2018) available at <https://www.foodinsight.org/consumer-research-USDA-GMO-labeling>.

<sup>8</sup> See Pew Research Center, *Mobile Fact Sheet* (Feb. 5, 2018) available at <http://www.pewinternet.org/fact-sheet/mobile/> (demonstrating rates of smart phone accessibility).

While the National Bioengineered Food Disclosure Law addresses the disclosure of the “presence” of bioengineered material in food, it is important to note that consumers are also interested in knowing which foods do not contain bioengineered material or have not been produced through the use of biotechnology. In other words, many consumers are seeking foods labeled with “absence” claims (e.g. “Non-GMO”). The USDA’s National Organic Program (NOP) and the Non-GMO Project (NGP) verification are the most consumer-recognized certifications for the absence of the use of bioengineering in the U.S. food supply. Danone North America strongly supports USDA certified organic standard and the NGP verification. Absence claims of “not bioengineered” or “non-GMO”, for example, should be supported through rigorous third-party verification such as NOP certified organic and the NGP verification program.

It is important for USDA to clarify that because a food is exempt from disclosing the presence of bioengineered material, it does not automatically qualify for a “Non-GMO” or similar claim. Similarly, according to the statute, USDA should clarify in the final rule that nothing in the implementation of this rule will impact current or future policies under the National Organic Program.

We understand the challenges presented by this statute and a dynamic and changing food system. We hope that our commitment and history working both with our supply chains and consumers are helpful as you finalize the rule.

Sincerely,

A handwritten signature in cursive script that reads "Philippe Caradec".

Philippe Caradec

Vice President Public Affairs and Sustainable Development

Danone North America, PBC