Organic & Natural Health Association
3924 W St. NW Ste. 7
Washington DC 20007
www.organicandnatural.org

July 3, 2018

U.S. Department of Agriculture
Agricultural Marketing Service

Docket No.: AMS-TM-17-0050

RE: Comments on proposed regulations to implement the National Bioengineered Food Disclosure Standard

The Organic & Natural Health Association appreciates the opportunity to comment in response to the FDA's proposed regulations to implement the "National Bioengineered Food Disclosure Standard " published in May, 2018.

Our mission is to unite consumers and corporations and transform business practices in alignment with regenerative systems to support the health of people and planet. Through a unique partnership between companies and consumers, the Organic & Natural Health Association (O&N) brings together raw ingredient suppliers, manufacturers, finished product companies, retailers and consumer organizations to promote and advance the health and well-being of people, animals and plants, and the planet. Our work to advance this mission is rooted in research to redefine how health care is delivered, providing quality education to inform and empower conscious consumer choice, and advocating for meaningful public policy to improve consumer health and support the health and resiliency of the planet.

The NBFDS, and underlying statutory law, stand as example of how the nutrient value of food can be compromised by what is characterized as progressive agricultural practice. Genetically modified, or bioengineered crops significantly reduce the micronutrient value of soil, and increase reliance on pesticides and fertilizers. Crop diversity continues to diminish, and the world population of pollinators bees is on the edge of collapse. The debate on value, safety and efficacy of genetically modified/engineered crops is not technically up for discussion in the consideration of this proposed regulation. However, O&N's commitment is to ensure consumer interests, and that of the planet, are fully represented in public discourse and the legislative and regulatory arenas.

Eliminate the Term Bioengineered

A stated intent of this initiative is to provide Americans a GMO labeling standard that is clear, meaningful and accessible. This proposed standard fails that objective, primarily in its reinvention of terminology (bioengineered) that is foreign to consumers who for the past 20 years have grown

increasingly familiar with the use of Genetically Modified Organism (GMO). Major corporations have adopted voluntary labeling of non-GMO, and Campbell Soup, the first major American corporation to begin voluntary labeling of GMO ingredients, was quickly followed by General Mills. The European Union adopted strict standards for labeling of food containing 1% GMO material in January 2000. GMO is now part of the European and American lexicons.

While there has been considerable debate on whether mandated labeling increases or decreases support for GE foods, a recent study published in *Science Advances* comparing a control group to one in Vermont, (the only state to implement mandatory GMO labeling), indicates the labeling policy led to a 19% decrease in opposition to GE food. The study authors note that results are consistent with prior research findings that "labels give consumers a sense of control, which has been shown to be related to risk perception."

The effort to abandon precedence is neither fair nor transparent and will certainly result in further consumer confusion and mistrust. Without transparency and regulation that embraces standard and agreed upon verbiage, this initiative is destined for failure.

We strongly suggest the proposed standard be rewritten to eliminate the use of bioengineered, and offer additional comments on promulgation of the proposed regulation and its inability to serve the public's interests in the following areas:

- Inclusionary definition of GM/genetically engineered food and ingredients;
- Terminology and proposed program logos;
- Universal consumer accessibility to available information, and
- Insufficient Agency guidance and the need for additional comment.

1. Inclusionary definition of GMO/Genetically Engineered Food and Ingredients

The standard must require that all foods containing genetically engineered ingredients, including refined oils and sugars, to be labeled under the guidelines.

Over the past 20 years, consumers have gained clear knowledge on GMO crops, and food corporations have responded by institution of labeling of both non-GMO and GMO products. It is well documented that virtually 100% of canola crops are GMO. Yet, testing of processed foods containing GMO canola often cannot detect this ingredient. The fact that some companies will elect to label a product as having GMO canola, while others with like-product elect to not label, will further confuse the public. In addition, technology is advancing far faster than the pace of the regulatory process. Proposed testing and threshold requirements simply will not work for GMO crops developed with new technology, such as CRISPR and synthetic biology. These provisions in the standard lack transparency.

O&N suggests adoption of the Codex Alimentarious definition of Biotechnology as the source definition of Bioengineering. This definition is internationally recognized and has been adopted by the Non-GMO Project, the most established industry protocol for GMO avoidance.

The Codex definition is as follows:

Modern Biotechnology – the application of:

a. *in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or*
b. *fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.*

The proposed standard contains three options for defining the threshold for the amount of GMO ingredient to qualify as exempt. O&N is committed to continual quality control efforts for the supply chain and thus believes each ingredient contained in a food product must be individually evaluated. Assuming all documented GMO source ingredients are mandated to be labeled, we would support option #2 of the three proposed threshold definitions with the following corrections:

Food in which any ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.09%) ~~by weight~~ of the specific ingredient.

2. Consumer Consideration for Terminology and Proposed Logos

O&N suggests that the terminology and proposed marketing contained in the proposal are misleading and confusing. As noted above, the final rule should eliminate the use of bioengineered in favor of genetically engineered and genetically modified.

Thousands of brands and multiple retailers have invested in voluntary education and marketing campaigns over the past 20 years using the term “genetically engineered.” The highly restrictive use of a single term, ‘bioengineered’ will result in enormous consumer confusion, as well as increase finished product cost.

Per the use of logo as an identifier, use of any of the proposed BE logos or derivatives will prove ineffective given the fact bioengineered has no meaning in the marketplace. In addition, the aesthetic nature of these logos lack gravitas and neutrality as compared with other government logos, such as Certified Organic.

3. Universal Consumer Accessibility to Available Information

Reliance on QR Codes and text messaging as tools for disclosing relevant law are ineffective and discriminatory.

The Agency’s own study, mandated by the law, determined 85% of the population struggles with the use of mobile software applications. Not one of 40 people who completed in-depth interviews for the study associated QR codes with food, and no retailers visited in the study had scanners capable of accessing information with a digital link. The proposed standard suggests, as an alternative, use of text messages. This is unacceptable. Messages sent and received will result in increased costs for many. The availability of wireless or cellular access makes this proposal highly discriminatory towards rural, low-income, minority and elderly populations.

4. Insufficient Standards Compromise Integrity

Potential degradation of the Organic standard

The National Organic Program (NOP) prohibits certified products ("100% Organic", "Organic" and "Made with Organic") from using methods to genetically modify organisms that are incompatible with the natural boundaries on reproduction, including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology. The final rule must clarify that any adopted definitional language will not circumvent the letter or intent of the organic standard; affirm that organic certification is equivalent to any and all 'bioengineered' (or its GE and GMO replacement) definitions, and will not in any way require amendment to the organic standard.

Accountability Standards are Nonexistent

As is noted, enforcement standards are limited to "records audits and examinations, hearings, and public disclosure of the results of audits, examinations, and hearings. A typical grocery store carries 30,000-50,000 SKUs, leaving ample opportunity for violation of labeling requirements. Given the growing prevalence of GMO products, this is inexcusable and denigrates all efforts to ensure accountability and consumer confidence in the standard.

Updating the List of 'bioengineered foods' Once Per Year in Insufficient

As noted, GMO foods are being introduced into the marketplace on a daily. New technologies are being utilized at an alarmingly rate and will continue to increase the number of GMO products in the market. Updating a standard list once per year is insufficient. The list must be updated on a quarterly basis.

Additional Comment is Required

There is substantial complexity in the draft that will require new consideration by the Agency and additional public comment. The simple adoption of one particular option, such as defining a threshold, will necessitate changes that should not be deemed final without additional comment. With so many outstanding and critical issues requiring further work, it requires an additional draft prior to final release.