

July 3, 2018
US Department of Agriculture
Docket Clerk
1400 Independence Ave. SW, Room 4543-South
Washington, DC 20250

These comments refer to Docket No. AMS-TM-17-0050, from Federal Register 2018-09389 of May 4, 2018. This letter responds to a request for comments by the Agricultural Marketing Service (AMS) on draft proposed regulations “that would require food manufacturers and other entities that label foods for retail sale to disclose information about BE food and BE food ingredient content... [in order] to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods.”

There is a profound and fundamental problem with mandatory food labels based on the process of production. A production process is not an ingredient, and knowing the type of breeding method used to produce a food tells consumers nothing about the safety or nutritional value of that food. It is, therefore, altogether too easy for consumers to be misled and confused by a breeding-process-based food label, particularly when there is an enormous and ongoing campaign aimed directly at misleading consumers on the safety, nutritional value, and sustainability of foods derived from crops and livestock improved through biotechnology.¹ Congress chose to avoid some of these complications by charging USDA AMS with implementing these rules, rather than FDA, to which Congress has repeatedly given clear and unambiguous instructions over the past century to ensure labels are not used to mislead consumers.² But AMS still faces significant challenges in complying with Congress’ instructions without creating opportunities for consumers to be confused and misled. The proposal on which AMS has invited comments must be improved if the Congressional mandate is to be fulfilled.

In the present case it is useful to bear in mind the Hippocratic Oath that guides medical professionals, in its admonition to “First: Do no harm.” Whatever requirements AMS develops for disclosure here should also

¹ Academics Review, “Organic Marketing Report,” (2014), http://academicsreview.org/wp-content/uploads/2014/04/Academics-Review_Organic-Marketing-Report1.pdf.

² Frederick L. Degnan, “Labeling Genetically Modified Food: The Philosophical and Legal Debate,” *Biotechnology and the Food Label*, (Oxford University Press, 2007), 17 – 31; “The Food Label and the Right to Know,” *Food Drug Law Journal*, (1997): 52(1):49-60.

follow the standards for labeling Congress has repeatedly conveyed and reaffirmed to FDA over the past century to ensure that labels are accurate, informative, and not misleading.³ With that in mind, the symbols proposed by AMS as candidates for inclusion on labels to indicate “bioengineered” food represent a step in the right direction. Decades of deceptive and misleading brand building and disparagement by segments of the organic food industry targeting competing conventional foods in general and foods derived from biotechnology improved seeds or livestock in particular have created widespread fear and misunderstanding and tarnished the terms “genetically engineered” and “genetically modified” in ways that cannot quickly be undone.⁴ The Food and Drug Administration has not lived up to its responsibility to protect consumers against such propaganda, but the new, neutral, and/or appropriately positive symbols as proposed would be helpful in preventing vested interests from hijacking the terms to serve in their ongoing disinformation campaigns. AMS will no doubt be heavily criticized for this, but such criticisms should be seen for what they are – special pleadings from illegitimate rent seekers and anti-innovation neo-Luddites – and ignored.

However, comparing the proposal from AMS with the authorizing legislation, it is clear that portions of the proposed draft regulations go substantially beyond what was authorized and contemplated by Congress under the law. It seems as if AMS has bent over backwards in an attempt to placate a small minority of extreme voices at the expense of reason and the public good. This is neither necessary nor advisable.

The first decision AMS must make relates to the definition of bioengineering. The legislation mandates consumers be informed when a “...food (A) that contains genetic material... has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques...” This definition clearly excludes labeling of highly refined or processed foods that do not contain DNA, such as sugar or cooking oils from which genetic material is generally absent. In some cases, DNA fragments can be recovered from such materials; but just as a brick is not a building, fragments of DNA components do not constitute the presence of “DNA” which in common usage refers to nucleotide base sequences of sufficient length as to be functional. Furthermore, the techniques for detecting fragmentary DNA constituents are complicated, inconsistent, expensive, and they routinely fail to produce sufficient information to enable identification of the original sources. In other words, there is no diagnostic test that could discern whether sugar or cooking oils were derived from bioengineered sources or otherwise. Mandating unverifiable labels charts a short path to undermining the credibility of and public confidence in the label, which is clearly the opposite of Congress’ intent.

³ Frederick L. Degnan, “The Food Label and the Right to Know,” *Food Drug Law Journal*, (1997): 52(1):49-60.

⁴ “Organic Marketing Report,” *Academics Review*, (2014), http://academicsreview.org/wp-content/uploads/2014/04/Academics-Review_Organic-Marketing-Report1.pdf.

The logic is clear: among the different definitions AMS presents, only the first listed is consistent with the mandate and the obvious intent of Congress, while the second represents a significant overreach that would create far more problems than it could solve. Experience with similarly unenforceable labeling mandates around the globe demonstrates such provisions would be certain to deliver only one result - an incentive to mislead and deceive consumers, which does nothing but invite fraud. AMS already has, in the USDA organic label, one label where fraud and abuse are widespread.⁵ The public good would in no way be served by adding another.

AMS also seeks input relating to the definition/meaning of the term in the authorizing legislation that defines “bioengineered” material subject to labeling to substances “(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.” This language is problematic in multiple ways; it presupposes nature to be in fact different than we find it, and conventional breeding more limited than in fact it is. Conventional breeding includes not merely the hybridization of one plant or animal variety to another that is closely related; it also embraces wide crosses and bridging crosses which are routinely used to move genes between organisms not commonly part of a single, breeding or reproductively compatible (panmictic) population but nonetheless capable of extensive genetic exchange over substantial phylogenetic distances. Conventional breeding includes protoplast fusion and embryo rescue, which routinely lead to novel combinations of genes not previously encountered in nature; and conventional breeding includes grafting, which can result in substantial genomic commingling.

Furthermore, the notion that what genetic engineers do in the laboratory is substantially different and distinguishable from what we find in nature is robustly contradicted by what we actually find in nature. Every mechanism researchers use in the laboratory to manipulate genes and/or move them within or between lineages is done with enzymes and reagents discovered in and extracted from nature. Every mechanism of gene transfer in the lab mimics or echoes mechanisms of gene flow first discovered in nature, and scientists have learned how to effect these genetic exchanges by understanding the many and varied natural phenomena by which mother nature has moved genes within and between not just species, but taxa at all levels, since the

⁵ U.S. Department of Agriculture, Agriculture Marketing Service, “Fraudulent Organic Certificates,” at <https://www.ams.usda.gov/services/enforcement/organic/fraudulent-certificates>; John Vogel, “Organic Labeling Fraud is Booming: While Organic Market Growth is at a Double-digit Pace, Not All That’s Labeled Organic is So; Fraud and Food Safety Issues Abound,” *American Agriculturalist*, (May 30, 2017), <http://www.americanagriculturalist.com/marketing/organic-labeling-fraud-booming>.

dawn of life on earth. The avalanche of DNA sequence data that has been accumulated with the advent of inexpensive genome sequencing methods has demonstrated that Mother Nature is genetically promiscuous, frequently and repeatedly moving genes within and between lineages in ways that we never imagined and which would have beggared belief just a few short years ago. The import of this for the bioengineered food labeling rules is that if comparison is invoked to what could be “found in nature” then that should be construed as broadly as possible; all the more so as observations confirm that life in the natural world is a robust engine for generating novel, never before seen combinations of genes and of moving DNA sequences of varying sizes up to and including entire genomes between lineages. Few individuals who understand what we have learned through modern molecular biological analysis of natural populations would confidently assert that what bioengineers develop in the laboratory could not be found in nature. So this yardstick, whenever applied by AMS, must be construed as liberally as possible if it is to have any hope of being justified by a claim it could not be found in nature. This argues for the narrowest possible scope of items captured for notification under the proposed rules.

AMS also requests comments on the threshold level of bioengineered ingredients that should trigger the disclosure requirement. As AMS has made clear, this disclosure exercise is entirely unrelated to any issues related to safety or nutrition, and is undertaken as a consequence of a politically driven tasking from Congress. Any threshold level, then, would be arbitrary. Logic would therefore dictate selecting a threshold level that is least likely to result in misleading consumers or disrupting commerce. Following the model used in the USDA Organic Standard under which a product cannot carry the USDA Organic label unless it is at least 95% produced under organic practices would, at least, honor (arbitrary) precedent. In other words, to be required to carry an AMS “BE” label, a product must be at least 95% from a bioengineered source. Under this option coexistence and identity preservation requirements would be less onerous and fewer foods would be compelled to carry the label, vs. the first two (arbitrary and capricious) proposed thresholds. Given estimates that implementing AMS’ proposals here could cost well into the billions of dollars, again, with no benefit to food safety or nutrition, any opportunity to reduce the costs and burdens, which will inevitably be passed on to consumers and have the most serious impacts on those least able to bear them, should be seized.⁶

AMS also asks for comments on its proposal to compile lists of presumptively bioengineered/not bioengineered crops, and proposes a demarcation threshold of 85% adoption (by land area). In the first

⁶ Dan Flynn, “‘BE’ Label Launch May Cost More than Feds Yearly Spend on Food Safety,” *Food Safety News*, May 30, 2018, http://www.foodsafetynews.com/2018/05/be-label-launch-may-cost-more-than-feds-yearly-spend-on-food-safety/#.Ww7S_VMvyF1.

instance, 85% is arbitrary – no explanation or rationale is offered to show why it should not be 80%, or 90, or some other number. Second, most of the widely adopted bioengineered crops are used either as animal feed (which is excluded) or as highly refined products (oils, starches, syrup or sugar) which clearly fall outside Congress’ intent, as discussed above. And third, an adoption/acreage threshold is irrelevant to crops grown for export to countries where the AMS regulations will not apply, and difficult or impossible to apply to imports. And fourth, such an area based standard is not easily applied to foods derived from animals, which are close to reaching the market. In view of the numerous complications and pitfalls of making the proposed lists implementable, the simpler solution, which happens to be more closely aligned with the Congressional intent manifest in the legislative record, would be to simply have one, single list for crops from which derived foods would be required to carry a “may contain BE ingredients” unless they can demonstrate otherwise.

Thank you for the opportunity to provide comments.

Sincerely,

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And

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