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Comments submitted to:
Docket AMS-TM-17-0050, 4 May 2018, FR Vol. 83, No. 87, pages 19860-19889 (83 FR 19860)

Respectfully submitted by:
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On May 3, 2018, the USDA Agricultural Marketing Service issued a call for comments on the Proposed Rule for the National Bioengineered Food Disclosure Standard (NBFDS) (https://www.usda.gov/media/press-releases/2018/05/03/usda-seeks-comments-proposed-rule-national-bioengineered-food). The intent of the proposed rule is to provide a mandatory uniform national standard for disclosing information on labels about the bioengineered status of foods for retail sale.

The American Phytopathological Society (APS) is the premier scientific society on the biology and management of plant diseases. The following comments have been reviewed by members of APS Council, members of the APS Public Policy Board, and members of the APS Biotechnology Committee.

1. APS's position with respect to disclosure of products of bioengineering is that this disclosure should neither promote nor disparage genetic engineering technology nor products derived from it, nor should disclosure imply either improved or diminished safety or environmental impacts. It is important to note the well-established scientific finding that, as food and feed, GE crops and derivative food products are as safe as those derived from the diverse practices of conventional breeding and there is no intrinsic food-safety risk resulting from genetic engineering [1-35]. Should the federal government implement a disclosure on GE food, the federal government is responsible for representing these well-established scientific findings to citizens.

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2. The term "bioengineered" is a suitable choice of term for disclosure of foods and feed derived from genetic engineering for two reasons:
   a. It is consistent with the authorizing act, the National Bioengineered Food Disclosure Standard (https://www.ams.usda.gov/sites/default/files/media/Final%20Bill%20S764%20GMO%20Discosure.pdf);
   b. It does not disparage genetically engineered (GE) crops and associated food products. As noted above, APS supports disclosure that is neither promotional nor disparaging. The term "genetically modified organism" (GMO) has, unfortunately, become associated with negative connotations in ways that are exaggerated or unsupported by peer-reviewed research. Therefore, "bioengineered" is both accurate and neutral.

3. With respect to the symbols proposed to fulfill NBFDS disclosure requirements, all of the proposed symbols (available at https://www.agri-pulse.com/ext/resources/pdfs/p/Proposed-Bioengineered-labels-5218-508.pdf) would serve that purpose acceptably. However, the two pictured in Figure 1 (below) offer important features:
   a. They appear neutral to the technology, in comparison to those that portray a smiley face;
   b. The accompanying text helps clarify the meaning of the symbol for consumers. Without the text, concern arises that consumers would not understand the meaning of the symbol. For example, it could be misinterpreted as a commercial logo.

Figure 1. Either of these would be useful disclosure symbols, in that they are perceived as neutral (neither promoting nor disparaging GE technology) while informing consumers of the presence of bioengineered foods.

4. The intent of the proposed rule is "to provide for disclosure of foods that are or may be bioengineered in the interest of consumers". This transparency and disclosure about food production from farm to table for consumers requires that the definition of "bioengineered" reasonably capture the full spectrum of bioengineered food products. With regard to this definition:

   a. We propose a small addition so that the definition of bioengineered food reads "food (A) that contains genetic material that has been **inserted or** modified through in vitro

recombinant deoxyribonucleic acid techniques and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."

b. Many techniques are associated with genetic engineering, and not all techniques are encompassed by the current definition. When gene editing is performed in a way that leaves no remnant "foreign DNA" in the plant [36-39], the genetic changes may not be distinguishable from genetic changes that could happen without human laboratory intervention. Such foods would not require disclosure under NBFDS since the definition of "bioengineered" in the amended Act applies only to transgenic applications. It is unclear whether this was the intention of Congress in the amended Act.

5. With respect to highly refined foods and food ingredients (such as oil, sugar, etc.), two positions were outlined. Position 1 holds that disclosure is not required for highly refined products where processing has removed genetic material and in which DNA is no longer detectable by common testing procedures. Position 2 contends that "bioengineering'" includes foods produced from bioengineering, including highly refined products, regardless of whether genetic material can be detected in the refined product. Both Position 1 and Position 2 have a certain validity, with Position 2 providing the transparency that some consumers expect from the disclosure standard and avoiding the potential for changes in disclosure due to improvements in the analytical techniques for detection. However, Position 1 avoids disclosing products as bioengineered that are not meaningfully different from non-bioengineered counterparts. If Position 2 is taken, then the use of "derived from bioengineered food" would communicate that a substance is no different from a non-bioengineered counterpart *and* allow transparency for the consumer.

6. It is most appropriate that USDA-AMS establish a threshold for the adventitious (=unintentional) presence of bioengineered content in foods and food products. Competent scientists know that it is not possible to declare a sample to be free of an analyte. All one can do is declare the analyte to be below the limit of detection. That being the case, establishing a threshold value for adventitious bioengineered substances that triggers disclosure is advisable.

   The goal of this Act is to allow disclosure of bioengineering, but minimize costs for the food industry. Alternative 1-B "…would establish that food, in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient." Adopting this alternative would provide congruency with the European Union, thus likely facilitating trade [40]. However, the adoption of a 5% threshold (Alternative 1-A) would be in the interest of the food industry and would not preclude a company from adhering to a lower threshold if they have an interest in marketing their product in international markets.

Literature Cited

1. American Medical Association. Genetically Modified Crops and Foods, Summaries and Recommendations of Council on Scientific Affairs Reports, 2000, AMA Interim Meeting. p. 18-19 Available from: http://www.ilsi.org/NorthAmerica/Documents/AMA_2000InterimMeeting.pdf
2. The National Academies Press. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. **2004**, Washington, D.C. 256 pp. Available from: http://nap.edu/10977 Accessed 28 Feb 2016.
3. European Academies Science Advisory Council. **2013**. Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture. 978-3-8047-3181-3. Halle/Saale, Germany. Available from: http://www.easac.eu/fileadmin/Reports/Planting_the_Future/EASAC_Planting_the_Future_FULL_REPORT.pdf Accessed 28 Feb 2016.
4. The Royal Society. Genetically modified plants for food use and human health—an update. Report Number 0 85403 576 1. 20 pp. Available from: https://royalsociety.org/~/media/royal_society_content/policy/publications/2002/9960.pdf Accessed 28 Feb 2016.
5. The Royal Society. Reaping the Benefits: Science and the Sustainable Intensification of Global Agriculture. ISBN 978-0-85403-784-1. Available from: https://books.google.com/books?id=qpQLkgEACAAJ Accessed 28 Feb 2016.
6. Hollingworth, R. M., Bjeldanes, L. F., Bolger, M., Kimber, I., Meade, B. J., Taylor, S. L. and Wallace, K. B., Society of Toxicology position paper: the safety of genetically modified foods produced through biotechnology. *Toxicological Sciences*, **2003**, Vol. 71, p. 2-8. Available from: http://toxsci.oxfordjournals.org/content/71/1/2.full.pdf+html
7. American Association for the Advancement of Science. Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods. Available from: http://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf Accessed 28 Feb 2016.
8. American Phytopathological Society Council. Compulsory Labeling of Plants and Plant Products Derived from Biotechnology. St. Paul, MN. Available from: http://www.apsnet.org/members/outreach/ppb/positionstatements/pages/biotechnologypositionstatement.aspx Accessed 28 Feb 2016.
9. International Union of Nutritional Sciences. Statement on Benefits and Risks of Genetically Modified Foods for Human Health and Nutrition. Available from: http://www.iuns.org/statement-on-benefits-and-risks-of-genetically-modified-foods-for-human-health-and-nutrition/ Accessed 28 Feb 2016.
10. American Medical Association. H-480.958 Bioengineered (Genetically Engineered) Crops and Foods. Available from: https://www.ama-assn.org/ssl3/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=/resources/html/PolicyFinder/policyfiles/HnE/H-480.958.HTM Accessed 28 Feb 2016.
11. Britsh Medical Association, Board of Science and Education. Genetically modified foods and health: a second interim statement. Available from: http://www.argenbio.org/adc/uploads/pdf/bma.pdf Accessed 28 Feb 2016.
12. Bruhn, C., Earl, R. and American Dietetic, A., Position of the American Dietetic Association: Agricultural and food biotechnology. *J Am Diet Assoc*, **2006**, Vol. 106, p. 285-93, DOI:

10.1016/j.jada.2005.12.017. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16442880
13. Biochemical Society. Genetically Modified Crops, Feed and Food: A Biochemical Society Position Statement. Available from: http://www.biochemistry.org/Portals/0/SciencePolicy/Docs/GM%20Position%20Statement%202011%20Final.pdf Accessed 28 Feb 2016.
14. American Society for Microbiology. Statement of the American Society for Microbiology on Genetically Modified Organisms. Available from: http://www.asm.org/index.php?option=com_content&view=article&id=3656&Itemid=341 Accessed 28 Feb 2016.
15. Crop Science Society of America. Researchers and farmers utilize GM technology to address society's growing global food production, security, and safety needs. Available from: https://www.crops.org/files/science-policy/issues/reports/cssa-gmo-statement.pdf Accessed 28 Feb 2016.
16. Federation of Animal Science Societies (FASS). FASS Facts: On Biotech Crops – Impact on Meat, Milk and Eggs. Savoy, IL. Available from: http://www.fass.org/geneticcrops.pdf Accessed 28 Feb 2016.
17. National Academies Press. *Genetically Engineered Crops: Experiences and Prospects*. **2016**, ISBN 978-0-309-43738-7. Washington DC. 420 pp. Available from: http://www.nap.edu/23395 Accessed 24 May 2017.
18. Key, S., Ma, J. K. and Drake, P. M., Genetically modified plants and human health. *J R Soc Med*, **2008**, Vol. 101, p. 290-8, DOI: 10.1258/jrsm.2008.070372. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18515776
19. Nicolia, A., Manzo, A., Veronesi, F. and Rosellini, D., An overview of the last 10 years of genetically engineered crop safety research. *Crit Rev Biotechnol*, **2014**, Vol. 34, p. 77-88, DOI: 10.3109/07388551.2013.823595. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24041244
20. European Union Publications Office. A Decade of EU-Funded GMO Research (2001-2010). ISBN 978-92-79-16344-9. Luxembourg. Available from: https://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf Accessed 28 Feb 2016.
21. Van Eenennaam, A. L. and Young, A. E., Prevalence and impacts of genetically engineered feedstuffs on livestock populations. *J Anim Sci*, **2014**, Vol. 92, p. 4255-78, DOI: 10.2527/jas.2014-8124. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25184846
22. Delaney, B., Safety assessment of foods from genetically modified crops in countries with developing economies. *Food Chem Toxicol*, **2015**, Vol. 86, p. 132-143, DOI: 10.1016/j.fct.2015.10.001. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26456807
23. Snell, C., Bernheim, A., Berge, J. B., Kuntz, M., Pascal, G., Paris, A. and Ricroch, A. E., Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: a literature review. *Food Chem Toxicol*, **2012**, Vol. 50, p. 1134-48, DOI: 10.1016/j.fct.2011.11.048. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22155268
24. Ricroch, A. E., Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies. *N Biotechnol*, **2013**, Vol. 30, p. 349-54, DOI: 10.1016/j.nbt.2012.12.001. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23253614

25. Herman, R. A. and Price, W. D., Unintended compositional changes in genetically modified (GM) crops: 20 years of research. *J Agric Food Chem*, **2013**, Vol. 61, p. 11695-701, DOI: 10.1021/jf400135r. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23414177
26. Toxicology, S. o., SOT ISSUE STATEMENT: Food and Feed Safety of Genetically Engineered Food Crops. **2017**. Available from: https://www.toxicology.org/pubs/statements/SOT_Safety_of_GE_Food_Crops_Issue_Statement_FINAL.pdf
27. Sanchez, M. A. and Parrott, W. A., Characterization of scientific studies usually cited as evidence of adverse effects of GM food/feed. *Plant Biotechnol J*, **2017**, Vol. 15, p. 1227-1234, DOI: 10.1111/pbi.12798. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28710840
28. de Vos, C. J. and Swanenburg, M., Health effects of feeding genetically modified (GM) crops to livestock animals: A review. *Food Chem Toxicol*, **2017**, DOI: 10.1016/j.fct.2017.08.031. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28843598
29. Zapata, F. G. B., Transgénicos, Grandes Beneficios, Ausencia de Daños y Mitos. **2017**, Academia Mexicana de Ciencias A.C. pp, ISBN 978-607-8379-28-6.
30. Ladics, G. S., Bartholomaeus, A., Bregitzer, P., Doerrer, N. G., Gray, A., Holzhauser, T., Jordan, M., Keese, P., Kok, E., Macdonald, P., Parrott, W., Privalle, L., Raybould, A., Rhee, S. Y., Rice, E., Romeis, J., Vaughn, J., Wal, J. M. and Glenn, K., Genetic basis and detection of unintended effects in genetically modified crop plants. *Transgenic Res*, **2015**, Vol. 24, p. 587-603, DOI: 10.1007/s11248-015-9867-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25716164
31. Schnell, J., Steele, M., Bean, J., Neuspiel, M., Girard, C., Dormann, N., Pearson, C., Savoie, A., Bourbonniere, L. and Macdonald, P., A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. *Transgenic Res*, **2015**, Vol. 24, p. 1-17, DOI: 10.1007/s11248-014-9843-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25344849
32. Gao, L., Cao, Y., Xia, Z., Jiang, G., Liu, G., Zhang, W. and Zhai, W., Do transgenesis and marker-assisted backcross breeding produce substantially equivalent plants? A comparative study of transgenic and backcross rice carrying bacterial blight resistant gene Xa21. *BMC Genomics*, **2013**, Vol. 14, p. 738, DOI: 10.1186/1471-2164-14-738. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24165682
33. Lehesranta, S. J., Davies, H. V., Shepherd, L. V., Nunan, N., McNicol, J. W., Auriola, S., Koistinen, K. M., Suomalainen, S., Kokko, H. I. and Karenlampi, S. O., Comparison of tuber proteomes of potato varieties, landraces, and genetically modified lines. *Plant Physiol*, **2005**, Vol. 138, p. 1690-9, DOI: 10.1104/pp.105.060152. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15951487
34. Batista, R., Saibo, N., Lourenco, T. and Oliveira, M. M., Microarray analyses reveal that plant mutagenesis may induce more transcriptomic changes than transgene insertion. *Proc Natl Acad Sci U S A*, **2008**, Vol. 105, p. 3640-5, DOI: 10.1073/pnas.0707881105. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18303117
35. El Ouakfaoui, S. and Miki, B., The stability of the *Arabidopsis* transcriptome in transgenic plants expressing the marker genes nptII and uidA. *Plant J*, **2005**, Vol. 41, p. 791-800, DOI: 10.1111/j.1365-313X.2005.02350.x. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15743445

36. Andersson, M., Turesson, H., Nicolia, A., Falt, A. S., Samuelsson, M. and Hofvander, P., Efficient targeted multiallelic mutagenesis in tetraploid potato (Solanum tuberosum) by transient CRISPR-Cas9 expression in protoplasts. *Plant Cell Rep*, **2017**, Vol. 36, p. 117-128, DOI: 10.1007/s00299-016-2062-3. Available from: https://www.ncbi.nlm.nih.gov/pubmed/27699473
37. Nekrasov, V., Wang, C., Win, J., Lanz, C., Weigel, D. and Kamoun, S., Rapid generation of a transgene-free powdery mildew resistant tomato by genome deletion. *Sci Rep*, **2017**, Vol. 7, p. 482, DOI: 10.1038/s41598-017-00578-x. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28352080
38. Fister, A. S., Landherr, L., Maximova, S. N. and Guiltinan, M. J., Transient Expression of CRISPR/Cas9 Machinery Targeting TcNPR3 Enhances Defense Response in Theobroma cacao. *Front Plant Sci*, **2018**, Vol. 9, p. 268, DOI: 10.3389/fpls.2018.00268. Available from: https://www.ncbi.nlm.nih.gov/pubmed/29552023
39. Woo, J. W., Kim, J., Kwon, S. I., Corvalan, C., Cho, S. W., Kim, H., Kim, S. G., Kim, S. T., Choe, S. and Kim, J. S., DNA-free genome editing in plants with preassembled CRISPR-Cas9 ribonucleoproteins. *Nat Biotechnol*, **2015**, Vol. 33, p. 1162-4, DOI: 10.1038/nbt.3389. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26479191
40. European Union. REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Union. **2003**, Available from: https://publications.europa.eu/en/publication-detail/-/publication/f298e6b4-796e-4d81-bfeb-7ffb728c194f/language-en