ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

Comments of Consumers Union on the U.S. Department of Agriculture Food Safety and Inspection Service Compliance Guide on Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products
Docket No. FSIS-2016-0027

Prepared by
Michael Hansen, Ph.D., Senior Scientist
October 24, 2016

Summary

We appreciate the opportunity to comment on the Food Safety and Inspection Service (FSIS) labeling guidance for products that do not contain genetically engineered (GE) ingredients or were not produced with animals fed GE animal feed. Many polls, including from Consumer Reports,[1] have shown that consumers want to know whether or not the food they are buying is genetically engineered.[2] This research indicates that consumers are concerned about both the products themselves and the methods involved in producing them.

Given this concern, it is critical for negative claims such as "non-GMO" to have a consistent meaning across all product categories, including all categories regulated by the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA), so that consumers are not confused or misled. We are concerned that the current FSIS guidance does not ensure this consistency, both among USDA-regulated products and with FDA-regulated food products. Instead, the FSIS guidance appears to leave room for many more products to carry a non-GMO label than is allowed under the standards set by the FDA or the current largest independent certifier, Non-GMO Project Verified.

To address this potential for inconsistency and labels that mislead or confuse consumers, we urge FSIS to amend its guidance in several ways. First, FSIS should not use the definition of "bioengineering" from Pub. L. 114-216 to evaluate negative claims, as doing so would be inconsistent with Section 294(c) of the law, create confusion, and complicate international trade. FSIS should instead use the FDA's definition, a widely accepted definition that numerous products already follow and which matches the definition used by key trade partners.

---

[1] Consumer Reports National Research Center, *Consumer Support for Standardization and Labeling of Genetically Engineered Food: 2014 Nationally-Representative Phone Survey*, Survey Research Report (June 9, 2016) (online at consumersunion.org/wp-content/uploads/2014/06/2014_GMO_survey_report.pdf).

[2] Center for Food Safety, "U.S. Polls on GE Food Labeling" (Nov. 23, 2015) (online at www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling#).

Second, we urge FSIS to establish a threshold of 0.9% that each GE ingredient—in a human food or in animal feed—cannot exceed in order for the ultimate product to be labeled with a negative claim like "non-GMO." A consistent threshold is fundamental to preventing consumer confusion and ensuring that these labels have a consistent meaning for consumers, and the 0.9% level is widely used as a reasonable threshold by Non-GMO Project Verified, the European Union, and NSF International, among others.

Third, while we support that FSIS will keep requiring companies making a negative claim to comply with the standards of a third-party certifier and include on the label a link to a web address where the text of the standards is available, FSIS also should require these standards to meet principles for credible labeling.

Finally, we support that FSIS will allow, in negative claims on labels, the various common terms for GE food that are currently familiar to consumers, so that products may be labeled with terms like "non-GMO," "not genetically engineered," or "not genetically modified," as well as terms that may appear more in the future such as "not bioengineered" or "not a product of modern biotechnology."

I. FSIS Should Not Use the Definition of "Bioengineering" from Pub. L. 114-216 to Evaluate Negative Claims, as Doing So Would Be Inconsistent with the Law, Create Confusion, and Complicate International Trade

When evaluating negative labeling claims involving genetic engineering, FSIS states that it "will utilize the definition of 'bioengineering' in Pub. L. 114-216." In that law, the term "bioengineering" refers to a food that "contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature."[3] But this definition is still in flux; the USDA Agricultural Marketing Service (AMS) has not yet detailed how it will interpret it for purposes of positive disclosures, and may not do so for another two years. We strongly oppose FSIS using this definition for the purpose of evaluating negative claims, as it is inconsistent with a different section of the new law and would create consumer confusion and complicate international trade.

First, using the definition of bioengineered in Pub. L. 114-216 to evaluate negative claims like "non-GMO," rather than adopting a definition that narrows the group of products that can be labeled with these claims, is inconsistent with the law. Doing so may violate Section 294(c), which explicitly deals with negative label claims. This part of the law states that "[a] food may not be considered to be 'not bioengineered' or 'non-GMO', or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle."[4] Congress has made clear in this

[3] Food Safety and Inspection Service, *Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products*, 81 Fed. Reg. 57880 et seq. (Aug. 24, 2016) (online at www.fsis.usda.gov/wps/wcm/connect/70fd4b42-5dce-463a-9041-a4d6918ec6ae/2016-0027.pdf?MOD=AJPERES) (Docket No. FSIS–2016–0027).

[4] Pub. L. 114-216, Sec. 294, codified at 7 U.S.C. 1639c(c).

provision that it would not be appropriate to use the definition of "bioengineering" in Pub. L. 114-216 for negative claims, and instead that the purpose of the definition is to determine which products are required to bear a positive disclosure.

Second, using the definition of "bioengineering" in Pub. L. 114-216 to evaluate negative claims would create confusion by deviating from the standard set by the FDA—which is already followed by numerous products and several private non-GMO labeling certification programs—in favor of a definition that is not settled and may not be fully resolved for another two years as AMS promulgates regulations pursuant to the new law. We therefore strongly urge FSIS to evaluate negative claims using the definition of "bioengineering" and "genetic engineering" that the FDA uses when evaluating such claims to ensure consistency in the marketplace. This definition can be found where the FDA defines "modern biotechnology" in its guidance on voluntary labeling of products from GE sources:

> Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (Ref. 1). The term "modern biotechnology" may alternatively be described as "recombinant DNA (rDNA) technology," "genetic engineering," or "bioengineering."[5]

We note that all the products on the market that currently make negative GE claims under this definition—as well as those that are labeled USDA Organic, which also may be labeled as non-GMO under the provisions of Pub. L. 114-216[6]—are not permitted to claim that they are "non-GMO" simply because no GE DNA is detectable. On the contrary, these products can fail to meet the standards established for their labeling if they contain highly processed, purified, or refined ingredients like oils, syrups, or sugars if these ingredients are derived from GE crops. For its part, the FDA states in its guidance for voluntary labeling of whether or not foods have been derived from GE plants:

> For many foods ... particularly for highly processed foods such as oils, it may be difficult to differentiate, through validated analytical methods, between plant-derived food developed through bioengineering and plant-derived food developed using traditional breeding methods. ... If validated test methods are not available or reliable because of the way a plant-derived food is produced or processed, it may be more practical to substantiate a claim for such foods differently, such as documenting handling practices and procedures. For example, statements indicating that a food has not been produced using bioengineering could be substantiated through documentation of practices and

[5] Food and Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (Nov. 19, 2015) (online at www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm).

[6] Pub. L. 114-216, Sec. 2, codified at 7 U.S.C. 6524.

handling procedures or documentation of compliance with USDA organic certification requirements.[7]

In this statement, the FDA makes two points clear. First, in the absence of detectable DNA, a derivative of a GE plant is still considered to be GE. Second, companies making a negative GE claim would need documentation to substantiate that claim if validated test methods cannot reliably show that the food is non-GE, as can be the case with highly processed ingredients. FSIS should ensure consistency between the products it oversees and those already using "non-GMO" and similar labels by prohibiting a negative claim on any product that contains ingredients from a GE source, whether or not GE DNA is detectable. We think the most straightforward way to accomplish this would be for FSIS to use the FDA definition in its evaluation of negative claims.

Third, we also support FSIS using FDA's definition of "modern biotechnology" because it is the same as the definition in the Principles for Risk Analysis of Foods Derived From Modern Biotechnology developed by the Codex Alimentarius Commission, and note that deviating from this standard would needlessly complicate international trade.[8] Documents and standards developed by Codex are referenced by the World Trade Organization in trade disputes involving food, and constitute a globally accepted standard. In addition, the term "modern biotechnology" defined by Codex Alimentarius is also the same as the definition used in the Cartagena Biosafety Protocol under the Convention on Biological Diversity, which also clearly shows it to be a globally accepted standard.[9] Therefore, FSIS should use the definition of "modern biotechnology" used by FDA and Codex Alimentarius because it is the globally accepted standard.

Additionally, FSIS should apply the same FDA definition discussed above to its evaluation of non-GE feed claims on meat and poultry. To ensure the clearest possible communication to consumers, FSIS also should indicate that meat in a multi-ingredient product that bears a "no GE ingredients" or similar label, such as the sausage in label example 2 of the guidance, must come from an animal that has not been fed GE feed ingredients. This would address a potential gap that currently exists in the guidance.

II. FSIS Should Set a Threshold for GE Content, and Not Allow Negative Claims on Products with an Ingredient that Has More Than 0.9% GE Content

Some products labeled with the claim "no GMOs" in fact contain no genetically engineered content at all. However, contamination of non-GE soy, corn and other food ingredients does occur, and is sometimes difficult to avoid. We therefore believe that USDA

---

[7] Food and Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (Nov. 19, 2015) (online at www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm).

[8] Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (July 2011) (online at www.fao.org/input/download/standards/10007/CXG_044e.pdf) (CAC/GL 44-2003).

[9] Convention on Biological Diversity, *Text of the Cartagena Protocol on Biosafety* (2000) (online at bch.cbd.int/protocol/text).

should set a threshold for how much contamination may be tolerated in products with a negative claim. Without a set threshold, a certifier could conceivably specify any maximum level, or none at all, with little to prevent products containing 5%, 10%, 20% or even 45% GE content from being labeled "non-GMO."

We therefore urge FSIS to set a threshold for the amount of GE ingredients in a food, or amount of GE components in animal feed, above which a company would not be allowed to make a negative label claim. We believe FSIS should set that threshold at 0.9% of each ingredient.

This is a reasonable threshold for several reasons. First, this is the threshold for labeling GE ingredients in the European Union, one of our main trading partners. In addition, a number of "non-GMO" labels already use the threshold of 0.9%, above which the product cannot be labeled as non-GMO.[10] The Non-GMO Project Verified label, which is on more than 40,000 products with annual sales of $20 billion,[11] uses a 0.9% threshold for ingredients, above which a product cannot get a Non-GMO Project Verified label. NSF International, an international standard development organization, has a Non-GMO True North program that uses the 0.9% threshold for finished products, above which a product cannot get the NSF Non-GMO label.[12] The company SunOpta, which sells non-GE soy, uses a threshold of 0.9%, above which its soybeans cannot be labeled as non-GMO. The company's soybeans use an in-house verification process and quality management system that is based on USDA's Process Verified Program (PVP) and utilizes the USDA Process Verified shield.[13]

The threshold for non-GMO animal feed should also be 0.9%, as it could be confusing or misleading to consumers if the threshold level of GE ingredients allowed in animal feed—beyond which a non-GE animal fed that feed would not allowed to be labeled as non-GE—differs from the level allowed for other human food ingredients.

III. FSIS Should Keep Requiring That Negative Claims Comply with Third-Party Standards, but Also Should Require These Standards to Meet Principles for Credible Labeling

FSIS rightly recognizes that it currently does not have the ability to independently verify negative claims for ingredients or feed, such as, "from animals not fed genetically engineered feed," or "contains no genetically engineered ingredients." We support that FSIS plans to continue requiring companies that want to make such negative claims to comply with standards established by a third-party certifying organization, and to require that companies include on the label a link to the web address of the third-party certifier where the text of the standards is publicly available. We agree with FSIS that companies that want to make negative claims

---

[10] "New non-GMO certification programs emerging," *Organic and Non-GMO Report* (Sept. 29, 2015) (online at non-gmoreport.com/articles/new-non-gmo-certification-programs-emerging).

[11] Non-GMO Project, "Product Verification" (2015) (online at www.nongmoproject.org/product-verification).

[12] "New non-GMO certification programs emerging," *Organic and Non-GMO Report* (Sept. 29, 2015) (online at non-gmoreport.com/articles/new-non-gmo-certification-programs-emerging).

[13] *Id.*

should not be allowed to establish such label claims themselves, given FSIS's current oversight capacity. It also means that companies should not solely use the USDA's Process Verified Program (PVP) for non-GMO meat, poultry, and egg products, since PVP essentially allows companies to make their own decisions as to what their labels mean.[14]

In addition to requiring that a company that wants to make a non-GE label claim for meat, poultry, and egg products must use a third-party certifying organization, we believe that the standards that are developed by this third-party certifying organization for negative claims should be set according to principles for credible standard setting. Consumer Reports' criteria for credible labels are that they be based on meaningful, verifiable standards and that they embody consistency, transparency, independence from conflicts of interest, and openness to public comment.[15] This view of appropriate standards is consistent with the Credibility Principles developed by the International Social and Environmental Alliance for Labeling (ISEAL),[16] which include rigor, engagement, impartiality (lack of conflict of interest) and transparency and represent the gold standard for how to develop credible standards. These should be the principles that are required for the development of negative claims about use of GE in meat, poultry, and egg products.

IV. FSIS Is Right to Allow Use of the Term "Non-GMO"

We support that FSIS will be allowing the use of the terms "genetically modified organism" or "GMO" in addition to terms such as "bioengineering," "genetically engineered," and "modern biotechnology." Previously, FSIS had not allowed use of the terms "genetically modified organism" or "GMO" in making negative claims. Among other studies, research done by Campbell Soup Company, discussed on an August 30, 2016, webinar by the Food and Drug Law Institute (FDLI), shows that consumers prefer these terms. As Katie Cleary, Campbell's senior manager of consumer and consumer insights stated, "Campbell has tested nine labels related to GE food ingredients in the past few months and found individuals viewed use of terms like 'bioengineered or genetically engineered' confusing ... The feedback has been very consistent in our research that the preferred language is GMO."[17] Thus, we support FSIS allowing use of the terms "genetically modified organism" and "GMO," provided that the label is otherwise truthful and not misleading.

Conclusion

In closing, we are concerned that the current FSIS guidance does not ensure consistency across the market. Instead, the FSIS guidance appears to leave room for many more products to carry a non-GMO label than is currently allowed under the standards set by the FDA and other

---

[14] *Id.*

[15] Consumer Reports, Greener Choices, "What Makes a Good Label?" (2016) (online at greenerchoices.org/2016/03/08/make-another-good-label).

[16] International Social and Environmental Alliance for Labeling, "Credibility Principles" (June 12, 2013) (online at www.isealalliance.org/our-work/defining-credibility/credibility-principles).

[17] "Campbell Soup finds consumers prefer clear GMO labeling," Food Chemical News (Sept. 8, 2016) (online at www.agra-net.com/agra/food-chemical-news/food-safety/packaging/campbell-soup-finds-consumers-prefer-clear-gmo-labeling-526281.htm).

entities. To address this potential for similar labels to have different meanings, and thus labels that mislead or confuse consumers, we urge FSIS to amend its guidance by:

- Using the FDA definition of "modern biotechnology" when evaluating negative claims instead of the Pub. L. 114-216 definition of "bioengineering," which would be inconsistent with the law, create confusion, and complicate international trade;

- Setting a threshold for GE content and not allow negative claims on products with an ingredient that has more than 0.9% GE content; and

- Keep requiring that negative claims comply with third-party standards, but also require these standards to meet principles for credible labeling.

Thank you for your consideration of our comments.

Respectfully submitted,

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union