USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 3071-S, STOP 0201
Washington, DC 20250-0201

TO: AMS Deputy Administrators

FROM: Elanor Starmer, Administrator

SUBJECT: Consistency between Bioengineered Disclosure and the National Organic Program

On July 29, 2016, the President signed a bill that amends the Agricultural Marketing Act of 1946 to include Subtitle E, the National Bioengineered Food Disclosure Standard (Pub. L. 114-216). The Agricultural Marketing Service (AMS) is issuing the following Policy Memorandum to provide clarity to AMS staff and stakeholders pursuant to the statutory requirements that the Secretary of Agriculture consider establishing consistency with the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and its implementing rules and regulations, as well as the implementation of the National Bioengineered Food Disclosure Standard (hereafter referred to as the GMO disclosure program).

To ensure consistency across AMS labeling programs and to provide clarity to AMS staff and stakeholders, we are issuing the attached Policy Memorandum. This policy specifies the criteria that AMS will use when proposing rules for mandatory bioengineered food disclosure and labeling in order to prevent conflicts between the future requirements of a proposed GMO disclosure program and the requirements of the USDA organic regulations (7 CFR 205) for the production, handling and labeling of organic food, feed, and fiber. The specific requirements of a GMO disclosure program have yet to be defined through rulemaking, whereas the U.S. Department of Agriculture organic regulations have been in place since 2002. This policy also explains how AMS views labeling options that fall outside these criteria and statutory authorities.

Each Deputy Administrator with a role in implementing organic labeling requirements and/or bioengineered disclosure requirements, or whose programs cover products that may be produced as organic or through bioengineering, shall review the attached memorandum to ensure compliance with this policy. Any new proposed regulations or specifications must comply with this policy.

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Policy Memorandum
AMS Bioengineered Foods Disclosure Program – Consistency with the AMS National Organic Program

1. Purpose

This policy describes the criteria used by the GMO disclosure program within the Agricultural Marketing Service (AMS) Livestock Poultry and Seed Program (LPS), as the basis for ensuring consistency with the Organic Foods Production Act and the AMS National Organic Program (NOP). This policy also explains how AMS views requirements that fall outside these criteria and statutory authorities.

2. Scope

This policy applies to any current and future implementing regulations and guidance for mandatory disclosure of bioengineered food or food derived from bioengineering, and its associated labeling program.

3. Background

The AMS NOP implements the Organic Foods Production Act of 1990. Acting upon recommendations from the National Organic Standards Board, a Federal Advisory Committee appointed by the Secretary, the NOP establishes, monitors, and enforces the USDA organic regulations, codified in 7 CFR 205. The organic regulations are further explained through guidance, instructions, and policy memorandums, all of which are published in the NOP Program Handbook on the AMS website. USDA's organic regulations establish criteria for the production of organic crops and livestock, processing of organic products, and labeling of organic food, fiber and livestock feed in the U.S. With rare and defined exceptions, all products sold, labeled or represented as organic in the U.S. must be certified by a USDA-accredited certifier.

The use of bioengineered products, also generally referred to as genetically modified organisms (GMOs), is prohibited in organic production and handling. The USDA organic regulations prohibit the use of GMOs as "excluded methods" under 7 CFR § 205.105, "Allowed and prohibited substances, methods, and ingredients in organic production and handling." This prohibition applies to any product certified and labeled as 100% organic, organic, or "made with organic (specified ingredients)."

AMS LPS will implement the National Bioengineered Food Disclosure Standard, which instructs USDA to establish a national mandatory bioengineered food disclosure standard, with respect to any bioengineered food and/or any food that may be bioengineered, by July 29, 2018. AMS will implement this Act through rulemaking with public notice and comment. AMS also intends to hold public stakeholder sessions to seek input prior to rulemaking.

In order to ensure consistency between organic certification and bioengineering disclosure programs, as instructed by statute, AMS is issuing the following policy.

4. Policy

When proposing standards for a national bioengineered food disclosure program, AMS' policy will be as follows:

- No certified organic products will require disclosure as bioengineered; and

- No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

4.1 Scope

Proposed rules for the GMO disclosure program will cover only food for human consumption, as defined by the authorizing legislation, whereas the organic regulations cover human food, livestock feed, feed inputs, and fiber.

4.2 Terms Defined

Both the USDA organic regulations and the National Bioengineered Food Disclosure Standard include definitions related to products of bioengineering. When proposing regulations to implement the GMO disclosure program, AMS will seek comment on further definitions of bioengineered foods requiring mandatory disclosure. The current definitions under the two programs are as follows.

- **National Bioengineered Food Disclosure Standard**: "The term bioengineering, and any similar term, as determined by the Secretary, with respect to a food, 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."

- **USDA Organic Regulations: "***Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture." (7 CFR 205.2, *Terms Defined*).

4.3 Thresholds

Some markets have established tolerance levels or thresholds for the presence of a bioengineered substance in food, both for mandatory disclosure requirements or for absence claims, such as non-GMO. USDA has not established mandatory tolerances for either positive or negative bioengineered label claims. The statute instructs AMS to propose regulations which determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to require disclosure as a bioengineered food. These proposed regulations will be open for public comment.

USDA organic regulations do not establish GMO tolerance levels. Organic standards are process based, and the regulations prohibit the use of GMOs, prohibit commingling or contamination during processing and handling, and require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal if any GMO presence.

As a part of its voluntary, user-fee-funded verification services provided under 7 CFR 62, AMS currently allows a company to label and market a product as "USDA Process Verified" to a claim of meeting a 99.1% threshold of Non-GMO/Non-GE traits. The USDA Process Verified Program (PVP) is a verification service that offers applicants a unique way to market their products to customers using clearly defined, implemented, and transparent process points that are independently verified by AMS auditors. PVP programs verify the process used to meet standards that companies set for themselves, and AMS can and does establish policies related to which marketing claims the Agency wishes to be associated with the PVP. However, with limited exceptions such as the "Organic" claim, AMS does not have statutory authority to establish regulations dictating standards behind marketing claims.

4.4 Absence Claims

As instructed by statute, USDA shall consider organic certification sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered," "non-GMO," or another similar claim. However, products that do not require mandatory disclosure as bioengineered foods or foods that contain bioengineered ingredients may not automatically qualify for absence claims.

5. References

- Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) -
- USDA Organic Regulations (7 CFR 205)
- National Organic Program Policy Memo 11-13: Genetically Modified Organizations
- National Bioengineered Food Disclosure Standard (Pub. L. 114-216)

[Signature on file] 09/19/2016

Elanor Starmer, Administrator Date