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MEMORANDUM

From: Steven B. Steinborn
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Re: **FSIS Issues Updated Labeling Guideline on Statements That Bioengineered or Genetically Modified Ingredient or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products**

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has issued an updated Labeling Guideline on Statements That Bioengineered or Genetically-Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, Or Egg Products (Guideline). 1/ The updated Guideline clarifies that FSIS will approve negative claims verified under a third-party certifying organization the same way it approves other special statements or claims and will not limit claims to those consistent with the Agricultural Marketing Service's (AMS's) definition of "bioengineering." FSIS also added information about labeling for certified organic products. This memorandum provides background on the Guideline and summarizes the changes FSIS made in response to comments received after the initial Guideline was released in August 2016.

Background

FSIS refers to claims concerning the fact that bioengineered or genetically modified (GM) ingredients were not used or that a product was produced from livestock or poultry that were not fed bioengineered or GM feed as "negative claims." While certain labels that bear only mandatory labeling features and that comply with FSIS's labeling regulations may be generically approved, labels bearing negative claims, among other special claims, must be submitted to FSIS's Office of Policy and Program Development, Labeling and Program Delivery Staff for approval. In August 2016, FSIS issued the Guideline to provide establishments guidance for making these negative claims. To receive sketch approval for a negative claim: (1) the establishment making the claim must comply with standards established by a third-party certifying organization; (2) the third-party's standards must be publicly available on a website; and (3) the label or labeling must disclose the website address of the third-party organization.

1/ Available at https://www.fsis.usda.gov/wps/wcm/connect/547972e6-cd56-4f0a-a5d5-d066ac12651b/labeling-guideline-bioengineered.pdf?MOD=AJPERES.

Updates to the Guideline

In the updated Guideline, FSIS makes clarifications to its guidance for making negative claims in two areas.

First, FSIS clarifies that it will not limit negative claims to those consistent with AMS's definition of "bioengineering." In the 2016 version of the Guideline, FSIS stated it would use AMS's definition when evaluating negative claims. This statement is absent in the updated Guideline, and in the preamble to FSIS's announcement of the updated Guideline, FSIS explains: "It was never FSIS's intention to limit negative claims to those consistent with [AMS's definition] and will continue to approve negative claims verified by a third-party certifying organization with standards based on FDA's definition of 'modern biotechnology" or with standards based on AMS's definition of "bioengineering." According to FSIS, if a negative claim is truthful and the producing establishment submits documentation demonstrating the third-party certification organization's program for the claim is being followed, FSIS will approve the negative claim.

Second, FSIS added information about the certification and labeling for certified organic products. The Guideline states that a current Organic Certificate is sufficient documentation to support a negative claim for a certified organic product. In other words, additional third-party certification or documentation is not necessary if a valid Organic Certificate is presented with the label application. Any negative claims on certified organic products must be connected by an asterisk or other symbol to the explanatory statement: "Produced in compliance with USDA Organic Regulations." Products certified as organic also do not need to disclose a website address on the label, unless otherwise required by AMS's organic regulations in 7 C.F.R. Part 205.

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We will continue to developments related to FSIS labeling requirements. Should you have any questions or require assistance validating a refining process, please do not hesitate to contact us.