

USDA Releases Updated Guidance on Animal-Raising Claims

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On October 5, the **US Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS)** released an updated version of its Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission (the Guidance).¹ All labels with special claims, including animal-raising claims, must be submitted to FSIS prior to being used on a product under 9 CFR 412.1(c)(3). Examples of animal-raising claims include "grass-fed," "raised without antibiotics," and "free-range."

FSIS had previously issued compliance guidelines in 2002 on animal-raising claims. Notable changes in the current updated version include the following:

- Definitions for frequently used animal-raising claims
- Detailed supporting documentation required for each specific claim that appears on a label
- Additional information regarding the claim "grass-fed"
- Information required for duplicating raising claims from a purchased product
- Examples of labels that bear claims

Issuance of the Guidance further manifests that review and oversight of the above claims has become the major focus of the FSIS prior label approval programs. As the Agency has expanded its commitment to the concept of generic approval, which eliminates the need to specifically review labeling materials for most other product categories, the review of these and other subjective product claims (such as "natural") not defined by current regulation has come to dominate FSIS's attention span. And, somewhat ironically, the proliferation of such claims has served to negate progress in label review turnaround time. This was one goal inherent, at least from an industry perspective, in the generic label expansion effort.

Problematically for FSIS, activities that either support or raise questions about the validity of such claims generally occur on a farm, ranch, or feed lot (as opposed to being captured within the four walls of the FSIS-regulated facility). As is the case at FSIS and at other regulatory agencies, this shifts the focus from direct government oversight to the need for effective substantiation

documentation, and in that context, the Guidance provides a useful resource for companies interested in achieving appropriate compliance.

The compliance guide is available for comment until December 5, 2016 (Docket No. FSIS–2016–0021). Visit www.regulations.gov to submit your comments.

¹ <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-24067.pdf>

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