

MEMORANDUM

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Re: **FSIS Issues Revised Compliance Guidelines for Animal Raising Claims**

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has issued a revised compliance guideline for substantiating animal raising claims on labels for meat and poultry products. ^{1/} This updated guideline expands and, in some cases, modifies FSIS's written policies on animal raising claims made on meat and poultry products. The guideline addresses both how claims should be phrased (including necessary qualifiers or explanatory text) and what type of information the establishment must include with the label application. Although FSIS policy has remained generally consistent at a high level from the previous guideline, FSIS has indicated that it expects certain claims to include additional or updated explanatory statements. It will be important for companies making animal raising claims to review their current labels and claims to evaluate whether changes will be required and to determine an appropriate process for doing so. Companies should revisit point-of-sale claims (regulated by FSIS but not subject to preapproval) and advertising (not regulated by FSIS but assessed by the Federal Trade Commission's deceptive advertising standard) in light of the revised compliance guidelines.

Animal raising claims, which include statements about antibiotic use, specialty feeds or diets, caging and handling, animal welfare claims, and other husbandry issues, are becoming increasingly popular on labels and point-of-sale retail labeling. Animal raising claims are considered "special statements or claims" that trigger prior review and approval by FSIS. The updated compliance guideline expands on the September 2016 version of the guideline. ^{2/} The revisions will be of interest to meat and poultry processors, retailers, and restaurants making these types of claims. Compliance guidelines are technically nonbinding documents, but they explain FSIS's current thinking and

^{1/} 84 Fed. Reg. 71359-71367 (Dec. 27, 2019); Food Safety and Inspection Service Labeling Guideline for Documentation Needed to Substantiate Animal Raising Claims for Label Submissions, available at <https://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES>.

^{2/} HL Memorandum, FSIS Issues Compliance Guidelines for Animal Raising Claims (October 6, 2016).

effectively represent the policies applied when the Agency reviews and approves labels bearing these claims. FSIS is accepting comments until February 25, 2020. 3/

This memorandum explains key changes to the guidelines, with a focus on FSIS's expectations for how claims should be phrased on product labels. The guideline also identifies the type of information that should be included in a label application for each type of claim. Although this information generally remains unchanged from the 2016 version of the guideline, establishments not familiar with the requirements should consult the guideline before submitting a label for sketch approval.

Updates to Specific Types of Animal Raising Claims

FSIS provides guidance on its expectations for certain types of claims commonly made on labels. In each instance, the basic substantiation outlined in our October 2016 memo is also required. Below we highlight some of the more significant changes included in the revised guidance.

Age of Animal – removed

FSIS has removed this claim from the compliance guideline on the basis that establishments are not using the claim.

Animal Welfare and Environmental Stewardship – updated

Animal welfare claims describe how animals are raised based on the care they receive, such as “raised with care” or “humanely raised.” Environmental stewardship claims refer to how the producer maintains the land and otherwise replenishes the environment during its production process, such as “humanely raised,” “sustainably farmed,” or “raised with environmental stewardship.”

In the revised compliance guideline FSIS declined to require animal welfare and environmental stewardship claims be limited to those certified by independent third-party certifying organizations, stating that “claims mean different things to different people.” Claims must, however, be sufficiently described on-label for consumers to determine whether the claim meets their expectations, which is intended to provide consumers who have specific expectations for a claim the opportunity to select meat and poultry products that meet their expectations based on the information included in the product's labeling.

The label must provide (1) the name of the entity that established the standard; and (2) either a statement explaining the meaning of the claim as applied to that particular product or a website address that provides the entity's standards for defining the claim. For example, “Raised with Care: TMB Ranch Defines Raised with Care as [explain meaning]” or “Raised with Care as defined by TMB Ranch at [web address].” This qualifier must appear on the same panel as the claim but may be separated and linked to the claim using a symbol.

If the claim is affiliated with a certifying third-party organization the label must provide: (1) the third-party certifying organization's name, (2) the website address providing the standards for defining the claim, and (3) the organization's logo, if applicable.

3/ Comments can be submitted on regulations.gov docket FSIS-2016-0021.

Diet – updated

The updated guidance clarifies that FSIS views “100% Grass Fed” and “Grass Fed” as synonymous, with both requiring that the animal be fed only grass (forage) after weaning. FSIS will not permit a “100% Grass Fed” claim for animals that spend time on feedlots. The guideline indicates that “grass fed” claims can be used for products that are not 100% grass fed, provided the claim is appropriately qualified to disclose the use of other grains in the diet (e.g., “Made from cows that are fed 85% grass and 15% corn”). FSIS also differentiates between the claims “Grass Fed” and “Grass Finished,” and the guideline indicates FSIS would accept a claim such as “Grain Fed, Grass Finished” (provided it is true).

Finally, through an example, FSIS reinforces its policy requiring that claims about “vegetarian feeds” be accompanied by disclaimers reflecting that the animal was nursed or was bottle fed dairy products before weaning, if applicable. FSIS provides as examples of acceptable qualification, “except for dairy products fed from birth to eight weeks” and “after 8 weeks.”

Living / Raising / Raising Conditions – updated

The updated guideline requires claims such as “Cage Free” to include additional language explaining what the statement means. As an example, FSIS provides, “Cage Free. Chickens were never confined to cages during raising.” This explanatory statement must appear on the same panel, but it can be separated from the claim and linked using a symbol. Alternatively, the label can reference that the claims have been certified by a third-party certifying organization that posts its standards on its website, in which case the label would need to include the certifier’s name, website, and logo (if it has a logo). The certifier’s information can be linked to the claim using a symbol but must appear on the same panel of the label.

The updated guideline identifies a specific instance in which an explanatory statement is not needed: “Free Range” claims made for poultry products are not required to be accompanied by clarifying language. According to FSIS, “Free Range” claims include the following synonymous claims: “Pasture Fed,” “Pasture Grown,” “Pasture Raised,” and “Meadow Raised.” Explanatory statements are required for meat products. FSIS has specifically requested comments on its approach to “Free Range” claims.

Raised Without Antibiotics – updated

FSIS largely maintains its current policy about antibiotic claims, with modest updates. The guideline adds “Raised Antibiotic Free” and “No added antibiotics” as additional examples of negative antibiotic claims that can be approved. The updated guideline also expands FSIS’s guidance on claims about “sub-therapeutic” claims. Specifically, companies making “no sub-therapeutic” use claims must include a statement explaining what sub-therapeutic use means. As examples, FSIS provides, “Beef Raised with No Sub-Therapeutic Antibiotics, Animal do not receive antibiotics on a daily basis only in the case of illness” or “Turkey Raised with No Sub-Therapeutic Antibiotics Ever, birds may be given antibiotics for the treatment of illness.”

Raised Without Hormones (No Hormones Administered or No Steroids Administered) – updated

The updated guideline clarifies that the qualifying statement “Federal regulations prohibit the use of hormones in [species]” is no longer applicable to pork products because several hormones have

been approved for use in swine. The guideline confirms that changes to labels to remove this statement are generically approved, and the *Federal Register* notice announcing the availability of the guideline explains that establishments may make this change at the next label printing.

For other species for which hormones are still not approved (poultry, veal, goats, mature sheep, and exotic species (such as buffalo and elk)), FSIS continues to require the explanatory statement. Historically, FSIS has required that no-hormone claims for these labels be accompanied by the qualifier, “Federal regulations do not permit the use of hormones in [name the species or kind],” and the *Federal Register* notice accompanying the guideline reflects this. The guideline, however, states that FSIS will approve such a label only if the claim is accompanied by the qualifier, “There are no hormones approved for use in [kind or species] by Federal Regulations.” The guideline does not explain whether FSIS intends for all establishments with labels that already received sketch approval to change the qualifier for these claims, nor the timeline or process for doing so.

Third Party Certification – updated

The updated compliance guideline addresses several issues related to third-party certifications.

First, the guideline clarifies that an Organic certification may be used to support a claim that is consistent with the National Organic Program regulations. The guideline cites as examples of such claims “raised without antibiotics,” “no added hormones,” “vegetarian diet,” “no animal byproducts,” and “non-GMO.” If making these claims for a certified Organic product, the establishment can submit the Organic certification rather than the other required supply chain substantiation.

Second, the guideline clarifies that for all third-party certifications, the label must include the certifying entity’s name, the certifier’s website, and the certifier’s logo (if the certifier has a logo). This information must be included on the same label panel as the certification statement, but it may be placed separate from the claim and linked with a symbol. These requirements apply to Organic certifications, except that the Organic certifier’s website is required only if National Organic Program regulations require it.

Procedural Updates for Certain Types of Changes

The guideline addresses several procedural issues that appear intended to streamline label applications in certain situations.

Carrying Forward Claims

The guideline allows establishments to carry forward claims made on a supplier’s label in many circumstances without needing to provide supporting documentation showing how the supplier was able to ensure the claim was accurate. (The idea being that the supplier presumably would have already submitted that information to FSIS when obtaining its own sketch approval.) Therefore, the guideline clarifies that when carrying forward a supplier’s label claim, the establishment typically needs to submit documentation showing how it maintains segregation for that product during its production process, but does not need to submit other supporting information.

If, however, the carried-over claim involves a third-party certification (including Organic certification), the establishment must demonstrate that it also has the same certification.

Adding New Suppliers When a Product Makes an Animal Raising Claim

The guideline formalizes FSIS's policy for adding new suppliers for a product with an already-approved animal raising claim. Because animal raising claims require substantiation specific to an individual supplier, FSIS expects to review the supporting supply-chain substantiation for each supplier that provides the product about which the animal raising claim is being made. FSIS does not, however, require establishments to submit a new sketch approval application each time a supplier is changed. Rather, an establishment may submit to FSIS a signed and dated request, by email or letter, requesting that FSIS approve the new supplier. The letter must contain the following information:

1. The product name;
2. The producing establishment's name, address, and establishment number; the prior label approval number; and a copy of the previously approved label application;
3. The specific claims being used on the product label containing material from the new supplier;
4. The new supplier's name, address, and one copy of any labels with the same claims previously approved by FSIS associated with the supplier or other documentation to support why the claims also apply to the new supplier; and
5. For third-party-certified claims, a copy of the third-party certification.

FSIS will review the submitted materials and provide a written response indicating whether FSIS approves the new supplier. The establishment should keep the FSIS response letter as part of its label approval file for the product.

Timing for Label Changes

FSIS generally does not address the timing or process for making updates to labels based on updated policies in the guidelines. In the *Federal Register* notice announcing the updated guideline, FSIS explains that establishments producing pork products with negative hormone claims may update their labels at the next label printing and that removing the qualifier may be done under generic approval. FSIS does not, however, address the process and timing for making any necessary updates more broadly.

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Overall, while FSIS policy has generally remained consistent at a high level, the updated guideline calls for new or changed qualifiers or explanatory statements in several situations. Some changes in record-keeping, required documentation and other obligations also merit careful review. We anticipate that in some instances questions will arise in how the revised guidelines are applied. Companies already making claims contemplated by the guidelines should determine an appropriate process for reviewing internal procedures, the process for submitting label applications to facilitate timely agency review, and most importantly, for addressing necessary or prudent changes in current labels, point-of-sale materials and related advertising.

Please contact us if you have any questions.