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MEMORANDUM

From: Steven B. Steinborn
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RE: FSIS Releases Final Rule Expanding Generic Label Approval System

The Food Safety and Inspection (FSIS) will soon publish in the *Federal Register* its final rule expanding the scope of labels eligible for generic approval. Under the final rule, labels will be eligible for generic approval unless the product has been produced under a religious exemption, the label is for export only and contains deviations from U.S. requirements, the label bears a "special statement or claim," or the establishment is seeking a temporary approval of a noncompliant label. The final rule will take effect 60 days from the date it is published in the *Federal Register*. A copy of the prepublication version of the rule is attached. This memorandum highlights areas of the final rule that provide the greatest amount of flexibility for generic approval as well as other guidance conveyed in the accompanying preamble.

FSIS requires prior approval of all labels or modifications to labels, with certain categories of labels "generically approved" (i.e., the labels are prior approved without submitting such labels to FSIS). The Agency last revised generic approval in 1995, creating the current generic approval system, and it describes the new rule as "the next step in the Agency's gradual streamlining and modernizing of the prior label approval system." The new rule is largely consistent with the 2011 proposed rule, 1/ although it contains a few differences and clarifications, which are described below. Although the rule reflects a significant expansion of generic approval, the Agency's definition of "special statements or claims" requiring submission for review and approval will mean that many labels must continue to be submitted to FSIS.

Expanded Scope of Generic Approval

Under the new rule, labels will be eligible for generic approval if they contain all mandatory label elements (*i.e.*, product name, inspection legend/establishment number, handling statement, net weight statement, ingredient statement, signature line, nutrition facts, and safe-handling instructions) and do not fall into one of the following categories:

- The label is for a product produced under a religious exemption (*e.g.*, Buddhist chicken);
- The product is for export and contains deviations from U.S. labeling requirements (except that labels merely printed in a foreign language or that bear a statement of the quantity of contents in accordance with the usage of the country to which the product is being exported are eligible for generic approval);
- The label contains a "special statement or claim"; or
- The request is for a temporary approval of the use of a noncompliant label.

1/ *See* Hogan Lovells Memorandum, *FSIS Issues Proposed Rule Expanding Scope of Generic Label Approval*, December 5, 2011.

Labels falling into one of these four categories must be submitted to FSIS for sketch approval. Labels eligible for generic approval may still be submitted voluntarily for review, but FSIS will give them lower priority than labels that must be submitted.

FSIS consolidates the changes to the sketch and approval programs in a new Part 412 that addresses approval of both meat and poultry labels. The FSIS regulations governing the actual content of meat or poultry labels remain in their current parts.

Special Statements and Claims

Statements and Claims Not Eligible for Generic Approval

The final rule and the Agency's discussion define "special statements and claims" subjecting a label to sketch approval as:

- Claims, logos, trademarks, and other symbols on labels that are not defined in the meat and poultry regulations or the Food Standards and Labeling Policy Book (*e.g.*, a heart symbol, whole grain claims). This includes claims made in on-pack marketing promotions, logos from recognized third parties, and general wellness claims;
- Certain front-of-pack (FOP) labeling;
- "Natural" 2/ and negative claims (*e.g.*, "gluten-free," "no artificial coloring," or "no preservatives"). Even though these claims are addressed in FSIS policy, FSIS indicates it believes they present complicated policy questions that require Agency review;
- Health claims;
- Structure-function claims;
- Ingredient and processing method claims (*e.g.*, "high-pressure processing");
- Claims regarding the raising of animals (*e.g.*, "no antibiotics administered" or "vegetarian fed");
- Organic claims; or
- Instructional or disclaimer statements concerning pathogens (*e.g.*, "for cooking only" or "not tested for *E. coli* O157:H7").

FSIS specifically addresses FOP labeling, taking the position that "certain front-of-pack (FOP) labeling statements, such as those highlighting select nutrients from the nutrition facts panel placed on the principal display panel, [are] nutrient content claims." But, according to the Agency, "unlike traditional nutrient content claims . . . there are no guidelines for the multiple types of FOP labeling statements on labeling." Accordingly, FSIS believes it "needs to continue to require prior evaluation and approval" of labels bearing these claims.

Moreover, the preamble indicates that FSIS will not extend generic approval to special statements or claims defined in policy other than the Food Standards and Labeling Policy Book.

Statements and Claims Eligible for Generic Approval

Through examples, FSIS explains that the following types of statements are eligible for generic approval because they are not special statements or claims:

- Voluntary allergen statements; 3/

2/ In the discussion of the final rule, FSIS mentions that the Agency is "considering rulemaking" to formally define "natural," referencing 2006 and 2009 *Federal Register* notices on the topic.

- Child Nutrition labeling. FSIS explains that Child Nutrition claims are reviewed by the Agricultural Marketing Service (AMS), making FSIS review unnecessary. FSIS differentiates Child Nutrition claims from Organic claims, explaining that although AMS oversees the Organic program, it does not review individual Organic claims;
- Defined nutrient content claims (aside from certain FOP claims), such as "low fat";
- Statements of geographic significance (*e.g.*, "Italian Style"); and
- Country of origin claims for covered commodities.

FSIS clarifies that, although labels bearing special statements or claims must be submitted for sketch approval, a subsequent change to the label that does not affect the special statement or claim and that would otherwise fall under generic approval may be generically approved. FSIS also contemplates issuing a guidance document concerning claims that can and cannot be generically approved.

Temporary Label Approvals

In response to comments requesting generic approval of some or all temporary label approvals that do not pose public health risks, FSIS explained that all requests for temporary approvals must be submitted to the Agency. Expedited review will be available when appropriate (e.g., retained "tagged" product).

Movement Away from the Food Standards and Labeling Policy Book

In the preamble discussion, FSIS announces that it will no longer add new entries to the Food Standards and Labeling Policy Book, a document that collects significant portions of the Agency's informal labeling guidance. FSIS will continue to update current entries in the Policy Book as necessary, but it intends to use new vehicles, such as compliance policy guides, to issue guidance.

Implementation

The new generic label approval regime will take effect 60 days from the date the rule is published in the *Federal Register*. FSIS indicates it will develop guidance for inspection program personnel on how to verify generically approved labels under the new rule. The Agency indicates it will also develop guidance for industry identifying claims, with a particular focus on which claims require sketch approval.

Guidance for in-plant FSIS inspection program personnel (IPP) is also planned. Noting the expected increase in generic approvals, the Agency acknowledges "the need for updated labeling information and directions to IPP in appropriately assessing the accuracy of labeling records and whether the label has been generically approved."

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This rule marks the first significant expansion of generic label approval in more than two decades. Meat and poultry companies should review it carefully and consider how it might affect product development and marketing.

We will continue to monitor implementation and practical application of the final rule. Please contact us with any questions.

3/ In response to a comment, FSIS makes clear that it is not considering rulemaking to require mandatory allergen labeling, citing high industry compliance with voluntary allergen declarations.