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MEMORANDUM

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Re: **FSIS Proposes Revising Nutrition Facts Labels and Rules for Serving Sizes**

Following the release of the Food and Drug Administration's (FDA's) nutrition labeling revisions in May 2016, the U.S. Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS) is proposing to amend the nutrition labeling requirements for meat and poultry products. 1/ The proposed revisions parallel almost exactly FDA's final nutrition labeling revisions. 2/ Comments are due 60 days from the date the proposed rule is officially published in the *Federal Register*.

This rule proposes several significant changes for many meat and poultry product labels. As with the FDA final rule, the FSIS proposed rule would (1) require the declaration of "Added Sugars," vitamin D, and potassium and remove the requirement to declare "Calories from Fat"; (2) revise the definition of dietary fiber; (3) revise the format of the Nutrition Facts Panel (NFP); (4) require dual-column labeling for certain containers; (5) update the reference amounts customarily consumed (RACCs) for several product categories; (6) consolidate some RACCs across meat and poultry products; and (7) create several new RACCs. The new and updated RACCs include those for appetizers and candies with meat or poultry. Additionally, the proposed rule would consolidate the nutrition labeling regulations (which are currently separate for meat and poultry products) into a single part at 9 CFR part 413. FSIS proposes a two-year compliance period for large companies and a three-year period for small companies.

In this memorandum, we summarize the most significant provisions of the proposed rule.

Revisions to Nutrition Labeling

FSIS is amending its nutrition labeling regulations for many meat and poultry products to provide updated nutrition information and to improve how the information is presented to consumers. FSIS believes these changes reflect current scientific data, dietary recommendations, and consumer research.

1/ The rules have not yet been published in the *Federal Register*, but pre-publication versions are available at http://www.fsis.usda.gov/wps/wcm/connect/a8674ea1-0c26-4bf3-8413-43b6551c0680/2014-0024.pdf?MOD=AJPERES. FSIS has sent the final draft to the Office of the Federal Register, and we anticipate it will be published soon.
2/ 81 Fed. Reg. 33742 (May 27, 2016); 81 Fed. Reg. 34000 (May 27, 2016).

The following is an overview of the changes to the current requirements, followed by additional details on the added sugars declaration and dietary fiber definition. 3/ The final rule:

1. Updates the list of nutrients that must or may be declared.
    - FSIS is proposing to require an "added sugars" declaration to appear on the label, indented under the "Total Sugars" declaration and listed as "includes XX g added sugars." "Sugars" would be declared using the term "Total Sugars."
    - Potassium and vitamin D would replace vitamins A and C as mandatory nutrients to declare (although vitamins A and C become mandatory when a claim is made).
    - "Calories from fat" would no longer be declared and could no longer be declared voluntarily.
    - "Calories from saturated fat" may be declared voluntarily.
    - "Other carbohydrate" could no longer be declared voluntarily.
    - Fluoride may be declared voluntarily.
    - FSIS would no longer allow the term "folacin" to be added in parenthesis immediately following the term "folate." Instead, FSIS is proposing to require that the term "folate" be used on meat and poultry products that contain folate, folic acid, or a mixture of both.
    - *Trans* fat would still need to be declared following FDA's final determination that partially hydrogenated oils are no longer GRAS because naturally occurring *trans* fat will still be present in the food supply. The rounding rules for *trans* fat would continue to permit declaration of *trans* fat as 0 gram (g) when the food contains less than 0.5 g per serving.

Definition of Added Sugars

FSIS regulations do not currently define the term "added sugars." Under the proposed rule, added sugars are defined consistent with the new FDA definition, as "sugars [that] are either added during the processing of foods, or are packaged as such," including:

- sugars (free, mono- and disaccharides);
- sugars from syrups and honey; and
- sugars from concentrated fruit or vegetables juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type.

Definition of Dietary Fiber

Dietary fiber would remain a mandatory nutrient to declare. The definition would include only fibers that are "intrinsic and intact in plants" and those "isolated or synthetic" fibers that FDA has determined have physiological effects that are beneficial to human health, either through an authorized health claim or an agency response to a petition.

FDA's final nutrition labeling rule specified that the following fibers have been determined by FDA to have a beneficial physiological effect and fall within the second category: β-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. FDA recognized that this list is not exhaustive.

3/ The proposed rule also amends the requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women, and establishes nutrient reference values specifically for these population subgroups.

2. Updates the Reference Daily Intakes (RDI) and Dietary Reference Values (DRVs).
    - A new DRV for added sugars of 50 g would be established, equivalent to no more than 10 percent of daily calories from added sugars, and the percent Daily Value (DV) for added sugars must be declared on the label. FSIS is not proposing to establish a DRV for total sugars.
    - The DRV for sodium would decrease from 2,400 to 2,300 mg.
    - The DRVs for dietary fiber would increase from 25 to 28 g.
    - The DRV for total fat would increase from 30 to 35 percent of calories (to 78 g) and the DRV for total carbohydrate would decrease from 60 to 55 percent of calories (to 275 g).
    - FSIS proposes updating and establishing RDIs for 14 vitamins and 13 minerals. For instance, the RDIs for calcium and vitamin C will increase from 1,000 to 1,300 mg, and from 60 to 90 mg, respectively.

3. Revises the format of the Nutrition Facts label. 4/
    - The prominence of the following information would increase: "Calories" and the numeric value of calories, "__ servings per container," and the serving size.
    - The order of the "Serving size" declaration and "__ servings per container" would be reversed.
    - The quantitative amount in the serving size declaration (e.g., "2/3 cup") would be right justified to create additional white space on the label.
    - The footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets would be removed.
    - With respect to the remainder of the footnote, FSIS proposes that the footnote should read: "The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice." 5/

Although FSIS (consistent with FDA) does not require declaring quantitative amounts by weight for vitamins and minerals (aside from sodium and potassium), the updated regulations would allow these declarations on a voluntary basis. If vitamins or minerals are added or there is a claim made about them, the manufacturer must include a declaration of the nutrient as a percent DV, or alternatively, as a quantitative amount by weight and percent DV.

4. Requires recordkeeping to support the declaration of certain nutrients for which there is no reliable analytical procedure.

The proposed rule would require manufacturers to make and keep written records to verify their declarations of the relevant nutrients for products that contain (1) dietary fiber; (2) soluble fiber; (3) insoluble fiber; (4) added sugars (when the food also contains naturally occurring sugars) 6/; (5) various forms of vitamin E; and (6) folate (when the food contains both folate and folic acid).

4/ See Appendix A to this memorandum for a comparison of the original and proposed NFP formats.

5/ The footnote would not be required for products that qualify as "calorie free" under the existing regulations. If the food is represented for children ages 1-3, the footnote will use "1,000 calories" instead of "2,000 calories." Additionally, foods that qualify for the simplified format are exempt from the footnote requirement provided that they use the abbreviated footnote statement reading "% DV = % Daily Value" when the package labels do not spell out Daily Value in the column heading.

6/ Consistent with FDA's rule, if a manufacturer has a basis on which to support a declaration of added sugars based on the amount of added sugars present in a food after non-enzymatic

The proposed rule does not require manufacturers to keep any particular types of records for verifying compliance with nutrition labeling requirements, such as proprietary recipes or formulations. FSIS states the records could include analyses of nutrient databases, recipes, or formulations; batch records; or any other records that contain information to verify the nutrient content. The current retention period for nutrition labeling records remains the same. 7/

Revisions to the Serving Size Regulations

FSIS proposes amending the serving size regulations to reflect updated consumption data and consumer research. Below is a summary of the key changes that the proposed rule makes.

1. Expands the definition of a single-serving container.

All containers with less than 200 percent of the RACC would be labeled as a single-serving container, resulting in more products labeled as containing a single serving. This change removes the current flexibility for products with "large" RACCs (of 100 g or mL or larger), under which manufacturers may decide whether a package that contains more than 150 and less than 200 percent of the RACC will be labeled as 1 or 2 servings. Under the proposed rule, such products would be labeled as 1 serving. FSIS reasons that this change will help consumers understand the amount of nutrients in the food.

FSIS would allow foods with more than 150 and less than 200 percent of the RACC to use voluntary dual-column labeling on the basis of the household measure closest to the RACC, in addition to the "per container" information. For example, for a package that weighs less than 200 percent of the RACC and contains two discrete stuffed sandwiches that are individually wrapped, nutrition information could be provided "per 1 sandwich" in addition to "per container."

2. Requires dual-column labeling for certain containers.

Containers with greater than or equal to 200 and less than or equal to 300 percent of the RACC would be required to bear dual-column labeling based on both the serving size and the entire container. FSIS explains the purpose of this requirement is to provide nutrition information for multiple ways in which people are likely to consume a product. FSIS makes this proposal based on FDA's finding that more than 90 percent of products have consumption levels at the 90th percentile that are ≤ 300 percent of the RACC.

Meat and poultry products that are packaged and sold individually and contain more than 150 but less than 200 percent of the RACC may voluntarily provide an additional column that lists the quantitative amounts and percent Daily Values per common household measure.

FSIS also would exempt the following products from the dual-column labeling requirements:

- Products that qualify for the tabular or linear NFP format;
- Random weight products; and

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browning or fermentation, it must keep records demonstrating the accuracy of the amount declared, including a narrative explaining why the data and information are sufficient.

7/ The retention period differs slightly between the FDA rule and the FSIS proposed rule. Under FSIS policy, an entity must keep nutrition labeling records for two years after December 31 of the year in which the transaction to which the record relates has occurred. Under FDA's NFP final rule, records must be kept for at least 2 years after introduction or delivery for introduction of the food into interstate commerce.

- Certain products that bear voluntary dual-column labeling, including:
    - Products that require further preparation and provide labeling both “as purchased” and “as prepared,”;
    - Products that are commonly consumed in combination with other foods and that provide a second column on the basis of the combination (e.g., cream soup mix and milk);
    - Products that provide an second column for two or more groups for which RDIs are established (e.g., both infants and children ages 1-3); and

In terms of format, the dual-column label would need to include both the quantitative levels and percent DVs for all nutrients “per serving” and “per container.”

Under the proposed rule, when nutrient content claims or health claims are made for products with a dual-column nutrition label, the claim must clarify the “basis” for the claim, unless the product meets the claim criteria based on both the reference amount and the entire container amount. The statement must express the amount of the nutrient in a serving (e.g., “per serving” or “per 8 oz” or “per 1 cup serving”). For health claims, FSIS would require the following accompanying language: “A serving of __ ounces of this product conforms to such a diet.” However, if the serving size differs from the RACC, and the amount of the nutrient contained in the serving fails to meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, FSIS proposes that the claim must be followed by the criteria for the claim.

3. <u>Makes additional changes to serving size regulations.</u>

Consistent with its current policy, FSIS would allow the use of an ounce unit in the serving size (e.g., 4 oz.), instead of a household unit (e.g., 1 piece), when the size of the product naturally varies in weight or is not uniform in size. For example, poultry parts such as chicken breasts or non-formed meat cuts such as pork chops may use ounces in the serving size instead of basing the serving size on units.

FSIS also would permit the serving size to include the finished product amount when directions instruct adding a specific amount of water or other ingredient with insignificant amounts of nutrients. For example, the serving size for a condensed soup may state “1/2 cup (120g) concentrated soup (makes 1 cup prepared)” instead of “1/2 cup (120g).”

Additionally, FSIS proposes making changes to the serving size of products marketed for two different purposes (e.g., gravy or soup). Current regulations require the serving size to be based on the larger of the two RACCs. The proposed regulations would require the NFP to include the nutrient information for both serving sizes when one RACC is at least twice as large as the other. For example, a product marketed as both soup (1 cup RACC) and gravy (1/4 cup RACC) must list the nutrient data for both serving sizes.

4. <u>Updates, modifies, and establishes new reference amounts customarily consumed (RACCs)</u>.

FSIS proposes updating and modifying the RACCS based on 2003-2008 National Health and Nutrition Examination Surveys (NHANES) consumption data, as well as newer food products in the market place. In general, if the NHANES data demonstrated an increase or decrease in consumption by at least 25 percent compared to the RACCs established in 1993, FSIS is proposing to modify the existing RACC. FSIS is also establishing new RACC categories and adding to existing RACC categories for a number of foods.

Additionally, FSIS proposes combining the tables containing the RACCS for meat products and poultry products into a new table for meat and poultry products. FSIS will also include a column in

these tables titled “label statement,” which provides examples of how serving size statements may appear in the NFP as a formatted serving size. This column will resemble the one provided by FDA in its RACC tables.

FSIS is proposing to combine the meat and poultry categories into one category. For example, the meat and poultry categories for luncheon meat would be combined into one product category for all luncheon products. FSIS states that, because luncheon products made with meat and poultry are comparable products with similar dietary usage and product characteristics, having the same RACC will help consumers better compare nutrition information among these products. Other product categories being combined into one category for both meat and poultry include: egg mixtures; entrees without sauce; mixed dishes (both those measurable and not measurable with a cup); salads (all other); and soups (all varieties).

Consistent with FDA’s rule, FSIS proposes creating a new product category for appetizers that are mini mixed dishes with meat or poultry, such as mini bagel pizzas, dumplings, etc., with a RACC of 85 g. These are smaller-sized versions of foods currently in the “Mixed dishes not measurable with a cup” category. If the product is packaged with a sauce, FSIS proposes adding 35 g for the sauce. FSIS also proposes creating a new product category for appetizers that are dips with meat or poultry, such as chicken and cheese dip, etc., with a RACC of 2 tbsp. This RACC resembles that of FDA’s product category for “All dips (e.g., bean dips, dairy-based dips, salsa).”

FSIS further proposes creating a new product category for candies with meat or poultry, such as chocolate with bacon, etc., with a RACC of 30 g. This RACC matches the 30 g RACC for “All other candies,” which FDA reduced from 40 g in its final NFP rule.

Consolidation of Nutrition Labeling Requirements into 9 CFR Part 413

Currently, the nutrition labeling regulations for meat and poultry reside in separate sections of the Code of Federal Regulations (9 CFR Sections 317.300–317.400 and 381.400–381.500, respectively). FSIS proposes consolidating the two sections into a new part 9 CFR Part 413, which would contain all the nutrition labeling regulations for both meat and poultry products. This realignment is part of FSIS’s long-term policy of consolidating the regulations for meat and poultry products when possible.

Compliance Dates

FSIS anticipates allowing a 2-year compliance period, with a 3-year compliance period for small businesses. The length of the compliance dates mirrors that of the dates in FDA’s final rule. Because FDA’s rule has already been published, compliance dates have already been set for July 26, 2018 and July 27, 2019, respectively. Given that FSIS issued its proposed rule after FDA finalized its rule, there will be a period of several years in which the NFPs could be inconsistent.

To provide flexibility, FSIS has announced that meat and poultry products may bear nutrition labels complying with either the existing FSIS requirements or the new FDA nutrition labeling requirements until FSIS’s new rules take effect. If a company wishes to voluntarily use the FDA format, FSIS requires that the company submit for sketch approval at least one label bearing the new nutrition labeling format. Once FSIS has approved at least one label bearing the new FDA nutrition labeling format, the company may update the nutrition labeling for other products under generic approval. Once the final FSIS nutrition labeling rules take effect, labeling for meat and poultry products will be expected to comply with the updated FSIS requirements. 8/

8/ *See* 81 Fed. Reg. 80631 (Nov. 16, 2016).

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The proposed rule would bring significant changes to the nutrition labeling regulations. Although FSIS has signaled a strong desire to align its nutrition labeling changes with FDA's, companies should still carefully evaluate how the changes would affect product labeling and consider submitting comments, especially if the labeling of meat and poultry products presents different issues than FDA considered in developing its updated nutrition labeling rules.

Should you have any questions, or wish to discuss these issues further, please contact us.

Appendix A

Figure 1: Current NFP Format

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calone diet. Your daily values may be higher or lower depending on your calorie needs:

	Calones:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Figure 2: Proposed NFP Format

Nutrition Facts

8 servings per container
Serving size **1 cup (245g)**

Amount per serving
Calories **60**

	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0.5g	**0%**
Trans Fat 0g	
Cholesterol 10mg	**4%**
Sodium 560mg	**24%**
Total Carbohydrate 9g	**3%**
Dietary Fiber 0g	**0%**
Total Sugars less than 1gram	
Includes 0g Added Sugars	**0%**
Protein 2g	
Vitamin D 0mcg	0%
Calcium 0mcg	0%
Iron 0.5mcg	2%
Potassium 0mcg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to daily diet. 2,000 calories a day is used for general nutrition advice