

FDA Proposes New “Healthy” Definition As Part of Comprehensive Biden Administration Nutrition and Health Initiatives

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Earlier this week, as part of the White House Conference on Hunger, Nutrition, and Health, President Biden [announced](#) a goal of ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases. The strategy identifies actions to be taken across five guiding pillars: first, improving food access and affordability, second, integrating nutrition and health, third, empowering all consumers to make and have access to healthy choices, fourth, supporting physical activity for all, and finally, enhancing nutrition and food security research. In order to achieve the third pillar, President Biden proposes, among other things, to develop a front-of-packaging labeling scheme for food packages, facilitate sodium reduction in the food supply by issuing longer-term, voluntary sodium targets for industry, and finally to propose an update to the nutrition criteria for a “healthy” claim on food packages. On the heels of this announcement, FDA released a proposed rule that would bring the requirements to use the word “healthy” in a claim in-line with modern dietary guidance.

What Is Changing?

The proposed rule attempts to harmonize the definition of “healthy” with the current recommendations published in the Dietary Guidelines for Americans 2020-2025. Accordingly, the proposed “healthy” definition uses a food group-based approach in addition to nutrients to limit (based on the understanding that each food group contributes an array of important nutrients to the diet), which has changed since 1994, when the current definition of “healthy” was promulgated. The proposed rule would also require a food to contain a certain amount from at least one of the food groups or subgroups (vegetables, fruits, grains, dairy, and protein foods) recommended by the Dietary Guidelines in order to use the “Healthy” claim, e.g., there must be at least ½ cup of fruits or vegetables, ¾ cup of dairy, a range of 1-1 and 1/2 ounces of protein depending on the type, or no less than ¾ ounce whole grain. Additionally, the new rule discards certain nutrient requirement provisions as no longer relevant while prescribing limits on three specific nutrients – sodium, saturated fat, and added sugar. Required amounts and limits are all adjusted for each specific food group, as well as the type of item (a mixed product, a main dish, a meal) in question. Finally, the proposed rule creates a group of foods, including raw and whole fruits and vegetables, and water, that will be automatically considered “healthy” and can use the claim without being subject to requirements for food group equivalent amounts or the nutrients to limit.

How Does The Proposed Rule Compare To The New Rule?

The current definition of “healthy” includes limits for total fat, saturated fat, cholesterol and sodium to qualify; foods must also provide at least 10% of the Daily Value for one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, and fiber. Sugar (added or naturally-occurring) is not addressed.

The proposed definition requires the following: a food must contain a certain amount of food from at least one of the food groups (fruit, vegetables, grains, dairy, and protein foods, oils, mixed products, main dish, and meals); specific limits for added sugars, saturated fat, and sodium is based on a percentage of the Daily Value for these nutrients; raw and whole fruits and vegetables automatically qualify for the “healthy” claim. These requirements and limitations are illustrated in the charts below.

Rule: A food must contain the “food group equivalent” (the minimum amount) of a food group for it to bear the “healthy” implied nutrient content claim.

Food Group	Food Group Equivalent	Examples
Vegetable	1/2 cup equivalent vegetable	1/2 cup cooked green beans; 1/2 cup raw spinach
Fruit	1/2 cup equivalent fruit	1/2 cup strawberries; 1/2 cup 100% orange juice; 1/4 cup raisins
Grains	No less than 3/4 ounce equivalent whole grain	1 slice of bread; 1/2 cup cooked brown rice
Dairy	3/4 cup equivalent dairy	6 ounces fat free yogurt; 1 1/8 ounce nonfat cheese
Protein Foods	1 1/2 ounce equivalent game meat; 1 ounce equivalent seafood; 1 ounce equivalent egg; 1 ounce equivalent beans, peas, or soy products; 1 ounce equivalent nuts and seeds	1 1/2 ounce venison; 1 ounce tuna; 1 large egg; 1/4 cup black beans; 1/2 ounce walnuts

Rule: An individual food may use the term “healthy” as an implied nutrient content claim on the label if it is a raw, whole fruit or vegetable or meets the following conditions per reference amount customarily consumed per eating occasion.

If the food is . . .	It must contain at least . . .	The added sugars content must be no greater than . . .	The sodium content must be no greater than . . .	The saturated fat content must be no greater than . . .
A vegetable product	1/2 cup equivalent vegetable	0% DV	10% DV	5% DV
A fruit product	1/2 cup equivalent fruit	0% DV	10% DV	5% DV
A grain product	No less than 3/4 ounce equivalent whole grain	5% DV	10% DV	5% DV

A dairy product	3/4 cup equivalent dairy	5% DV	10% DV	10% DV	
Game meats	1 1/2 ounce equivalent	0% DV	10% DV	10% DV	
Seafood	1 ounce equivalent	0% DV	10% DV	10% DV	
Egg	1 ounce equivalent	0% DV	10% DV	10% DV	
Protein Foods	Beans, peas, and soy products	1 ounce equivalent	0% DV	10% DV	5% DV
	Nuts and seeds	1 ounce equivalent	0% DV	10% DV	5% DV, excluding saturated fat derived from nuts and seeds
	100% Oil		0% DV	0% DV	20% of total fat
	Oil-based spreads whose fats come solely from oil		0% DV	5% DV	20% of total fat
Oils	Oil-based dressing containing at least 30% oil and oils meet the requirements in paragraph (d)(3)(ii)(F)(1) of this section		2% DV	5% DV	20% of total fat

How Will the Proposed Rule Affect Labels?

Although FDA must finalize the notice and comment process, industry now has the agency's current thinking regarding what will be required. Given the investment required to modify product labels, and the potential for false advertising litigation associated with labeling compliance in recent years, companies will want to consider whether a "healthy" claim remains an option or whether they want to pivot to a claim that is not limited by a strict regulatory definition. Either way, manufacturers will want to be mindful of the "net impression" of the label and consider not just technical label compliance, but how the watchful eye of the plaintiff's bar may interpret the claims as well.

Opportunity To Comment

Once the proposed rule is published in the *Federal Register*, the FDA will consider comments submitted within the following 90-days. Specifically, the FDA has requested comment on: Whether "nutrients-to-encourage" should be included in addition to the food groups; Whether the use of food groups would better help consumers identify foods with healthy nutrient content rather than a limited set of individual nutrients; Whether their calculations for required amounts is appropriate; The scope of nutritional context and information the rule should apply to; Whether the rule should include the addition of the automatically healthy category; Whether the various ceilings for limited nutrients are correct; What types of records should be kept; and Whether or not water should be included as automatically "Healthy."