

# The Long Awaited Updated “Healthy” Definition is Here

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**PRACTICES** FDA Regulatory and Compliance, Food, Beverage and Restaurant

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On Dec. 19, 2024, the FDA published the [final version](#) of its changes to 21 CFR 101.65, which governs what foods may be labeled as “healthy.” This summary provides an initial overview of the rule and how we got here. The FDA’s final rule reflects feedback from the industry by allowing more added sugar for foods labeled as “healthy” than initially proposed by the FDA in 2022 and netting in more beverages. This is one part of the FDA’s overall nutrition strategy, which is being closely scrutinized by the incoming administration.

## Why did FDA revise the standards for the “healthy” label claim?

The previous version of the rule governing “healthy” claims was promulgated in 1994, a time when low-fat foods and alternatives occupied much of the public and scientific rhetoric on healthy dietary choices. As a result, the 1994 “healthy” rule focused on limiting fat, sodium, and cholesterol, and it encouraged the intake of certain vitamins, which, in some cases, could be added to the food product through fortification. This position on “healthy” foods is now inconsistent with current nutrition science and the *Dietary Guidelines, 2020-2025*. For example, the old rule focused on daily intake of certain nutrients like vitamin A, calcium, and iron. The new rule, on the other hand, centers on food groups necessary to achieve a holistic healthy dietary pattern. The new rule also swapped cholesterol limits for caps on added sugar. These adjustments are aligned with the *Dietary Guidelines, 2020-2025*. Notably, however, they precede an anticipated update of the *Dietary Guidelines* in 2025.

## When is compliance required?

FDA expects the rule to publish in the Federal Register on Dec. 27, 2024, and to take effect 60 days later. If no significant policy changes happen (given the incoming administration’s focus on nutrition), the compliance date of the final rule is Feb. 25, 2028.

## What is the updated standard for a “healthy” nutrient content claim?

To determine if a food product can be labeled with “healthy” (or a similar term) under the new rule, the manufacturer first must determine what category the food product fits into:

- (i) Raw unprocessed whole food
- (ii) Individual food
- (iii) Mixed foods
- (iv) Main dish
- (v) Meal
- (vi) Beverage

Each category is subject to a unique set of requirements, some of which are more complicated than others. Categories (i) and (vi) bookend the rule with straightforward terms. Other kinds of food products covered by categories (ii) through (iv) have multifaceted requirements with food group equivalent (“FGE”) minimums, as well as ceilings on added sugars, sodium, and saturated fat.

If a food contains only vegetables, fruits, whole grains, fat-free or low-fat dairy, or certain lean proteins and has no added ingredients, it probably meets the requirements at the new 21 CFR 101.65(d)(3)(i) and automatically qualifies for a “healthy” label claim.

If a beverage is a water, tea, or coffee with less than five calories, it probably meets the requirements at the new 21 CFR 101.65(d)(3)(vi). Notably, this significantly expands the beverages that the FDA proposed in 2022 would qualify for the updated “healthy” claim, which included only plain water and plain carbonated water without any flavoring or additional ingredients.

## What changed from the 2022 proposed rule?

The overall framework remains consistent from the proposed to the finalized rule, but there were a few meaningful tweaks. The changes we noticed include:

- *A little less dairy* – The FGE for dairy changed from 3/4 cup to 2/3 cup (all other FGEs stayed the same).
- *More auto-healthy foods with some processing allowed* – Instead of *only* “raw, whole” fruits and vegetables getting a free “healthy” pass (and, e.g., their frozen counterparts being left behind), now any fruit, vegetable, whole grain, fat-free or low-fat dairy, or certain protein can be “healthy,” so long as it has no added ingredients (which does not include water). These foods are in category (i).
- *More added sugar for many and a boost in sodium for some* – Many individual foods, members of category (ii), got a slight boost in allowance for added sugars. For most, this meant moving from 0% to 2% Daily Value (“DV”), but notably, grain products got a significant bump in allowed added sugars – from 5% to 10% DV. Oil based individual foods also got a bump in sodium allowance, moving from 5% DV to 10% DV. Additionally, mixed products got a significant bump across added sugars, sodium, and saturated fat.
- *Calculating fat in seafood got more complicated* – Seafood individual foods in category (ii) would have been allowed to contain 10% DV saturated fat under the proposed rule. Now, these foods can only have 5% DV, but that excludes any saturated fat inherent in seafood. Since “individual foods” in category (ii) can include other ingredients, this means that only fats from added oils or other added ingredients count toward that 5% DV threshold.
- *Specifications for mixed products, main dishes, and meals were streamlined* – Instead of having different nutrient allowances for products in categories (iii) through (v) depending on what food groups their components belong to, each category now has one set of criteria. This also will allow manufacturers to be more creative with mixing and matching food groups while staying within one category and applying the same rules.
- *More beverages can be labeled as healthy* – As noted above, the proposed updated definition in 2022 only allowed plain and carbonated water to qualify as “healthy.” Now, all water, tea, and coffee that has less than 5 calories per serving can be labeled “healthy.”

## What’s next?

This final rule marks the end of a long journey, but this is just the beginning of seeing how the claim will be regulated in the future. For example, the FDA is also considering allowing industry to use a “healthy” symbol on labels to denote food that meets the definition. With the compliance deadline more than three years away and significant leadership changes coming to the administration imminently, we will be tracking this rule (and many others) closely and providing additional analysis as needed.