

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Nutrient Content Claims; Definition of Term “Healthy”

Docket No. FDA-2016-D-2335

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

FDA is proposing to redefine the implied nutrient content claim “healthy” to make it more consistent with current nutrition science and federal dietary guidance. The “healthy” claim is a voluntary label that food manufacturers can use on FDA-regulated food products that meet the criteria defined in 21 CFR 101.65(d). In the current marketplace, about five percent of foods are labeled as “healthy.” Because nutritional science has evolved over time, updating the definition of the implied nutrient content claim “healthy” to more closely align with the current nutrition science underpinning current federal dietary guidance will better inform consumers who are selecting those products to choose a more healthful diet, which may result in lower incidence of diet-related chronic diseases, including cardiovascular disease and type 2 diabetes. Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity stemming from consumers that currently use the “healthy” implied nutrient content claim selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Quantifiable costs to manufacturers associated with updating the “healthy” claim are reformulating, labeling, and recordkeeping. Discounted at three percent over 20 years, the mean present value of costs is estimated at \$276 million, or \$19 million annualized. Potential costs of rebranding certain foods are discussed qualitatively. Discounted at three percent over 20 years, the mean present value of benefits is estimated at \$455 million, or \$31 million annualized. Net benefits are estimated at \$180 million, or \$12 million annualized.

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Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a large proportion of covered entities are small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Quantified Costs and Benefits

Some consumers use nutrient content claims such as “healthy” to inform their food purchases. We estimate that a small number (0 to 0.4 percent of people that try to follow current dietary guidelines) of these consumers would use the “healthy” implied nutrient content claim to make meaningful, long-lasting food purchasing decisions. If the foods using the “healthy” claim more closely align with federal dietary guidance, the claim can assist consumers who are selecting those products in choosing a more healthful diet, which may result in lower chronic, diet-related diseases, including cardiovascular disease and type 2 diabetes.¹ Quantifiable benefits of the proposed rule are the estimated reduction over time in all-cause morbidity and mortality stemming from consumers selecting and consuming more healthful foods. This is calculated through the negative association between a Healthy Eating Index score and all-cause mortality. Discounted at three percent over 20 years, the mean present value of benefits accrued to consumers using the “healthy” nutrient content claim is \$455 million, with a lower bound estimate of \$15 million and an upper bound estimate of \$1.3 billion. Discounted at seven percent over 20 years, the mean present value of benefits of the proposed rule is \$290 million, with a lower bound estimate of \$9 million and an upper bound estimate of \$857 million.

¹ For more information on the association between following a healthful diet and reduction in chronic, diet-related diseases, see Dietary Guidelines for Americans 2020-2025, downloaded here <https://www.dietaryguidelines.gov/>.

Quantified costs to manufacturers associated with updating the “healthy” claim are labeling, reformulating, and recordkeeping. Overall, about 34,000 UPCs, or 14 percent of total UPCs, qualify for the existing “healthy” implied nutrient content claim but only 5 percent (12,000 UPCs) choose to label. The use of the “healthy” nutrient content claim is voluntary, but if the proposed rule results in some products needing to remove the claim to avoid being mis-branded, manufacturers would incur costs due to the rule. Manufacturers with food products currently using the “healthy” nutrient content claim would need to confirm whether the products meet the proposed criteria and decide whether a label change is needed. Manufacturers with products that currently do not meet the “healthy” criteria but do meet the proposed criteria have the option of labeling these products. In some cases, manufacturers may choose to reformulate a product so that it meets the proposed criteria. Some recordkeeping is required for certain products using the proposed “healthy” claim because the required food components equivalents are likely to increase time spent on recordkeeping. It is possible that manufacturers of products that include the term “healthy” within the brand name may choose to re-brand products instead of reformulating. We lack the data to quantify this effect but discuss it qualitatively. Discounted at three percent over 20 years, the mean present value of costs accrued to manufacturers using the “healthy” nutrient content claim, assuming the current 5 percent adoption rate, is \$276 million, with a lower bound of \$128 million and an upper bound of \$505 million. Discounted at seven percent over 20 years, the mean present value of costs of the proposed rule is \$237 million, with a lower bound of \$110 million and an upper bound of \$434 million. We request comment on our estimates of costs and benefits of this proposed rule.

Table 1: Summary of benefits, costs, and distributional effects of proposed rule, in millions 2020\$

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$27.4	\$0.89	\$80.9	2020	7%	20	Monetized benefits account for consumer's lost pleasure from eating less healthy foods they may nevertheless prefer.
		\$30.6	\$0.99	\$90.4	2020	3%	20	
	Annualized Quantified					7%		
						3%		
	Qualitative	To the extent consumers use the "healthy" nutrient content claim to maintain healthy dietary practices, following a healthy diet could reduce the risk of morbidity and prolong life.						
Costs	Annualized Monetized \$millions/year	\$22.3	\$10.4	\$40.9	2020	7%	20	
		\$18.5	\$8.6	\$33.9	2020	3%	20	
	Annualized Quantified					7%		
	Qualitative					3%		
Transfers	Federal Annualized Monetized \$millions/year					7%		
	From/ To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
	From/To	From:			To:			
Effects	<p>State, Local or Tribal Government: None</p> <p>Distributional: American Indian, Alaskan Native, Hispanic, and Non-Hispanic Black adults and children, as well as the lower-income or publicly insured may accrue a larger proportion of the estimated health benefits. However, this distributional shift may be reduced if these populations do not use, or do not have access to, products that bear the "healthy" nutrient content claim to meaningfully change their diet. Finally, any distributional shift may be dampened if costs are passed onto consumers in the form of increased prices of foods labeled as "healthy".</p> <p>Small Business: Potential impacts on small manufacturers of packaged food and beverages due to removing the "healthy" claim or reformulating some products.</p> <p>Wages: None</p> <p>Growth: None</p>							

A. Background

FDA is proposing to redefine the implied nutrient content claim “healthy” to make it more consistent with current nutrition science and federal dietary guidance, including those captured in recent changes to the Nutrition Facts Label (NFL) and the *Dietary Guidelines, 2020-2025*.² The “healthy” claim is a voluntary claim that food manufacturers can use on FDA-regulated food products that meet the criteria defined in 21 CFR 101.65(d). In the current marketplace, about one-third of all foods that meet the criteria are labeled as “healthy.”

The existing definition for “healthy” was promulgated in 1994 and based on the nutrition science at that time. The regulation set limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts (10 percent of Daily Value (DV)) of nutrients to encourage, for vitamin A, vitamin C, calcium, iron, protein, and/or dietary fiber. The definition was linked to certain requirements in the NFL and serving size regulations that were in effect at the time that the final rule was published (see 21 CFR 101.9 and 101.12). For instance, the existing “healthy” regulation requires that a product provide a specified percentage of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) for nutrients that were of “sufficient public health significance to warrant their inclusion on the nutrition label.”

Recently issued final rules have updated the NFL and serving size information, including removing the mandatory vitamin A and C declarations on the NFL, as they are no longer considered nutrients of public health significance (see 81 FR 33742 and 81 FR 34000). The NFL declaration requirements and DVs for individual nutrients significantly inform the regulations for nutrient content claims such as “healthy,” including the updated criteria in this proposed rule. The existing “healthy” definition is also inherently linked to the serving size information because the requirements are defined per reference amount customarily consumed (RACC). The 2016 final rule for serving size information updated or modified several existing RACC and established others. An increase in RACC (i.e., increasing a serving size from four ounces to six ounces) may impact the qualification for “healthy” because a larger portion may not meet all of the criteria. For example, imagine a packaged food with a four-ounce serving size that contained 400 milligrams of sodium per serving. If the 2016 final rule updated the serving size for that product to six ounces, without reformulating, the packaged food would then have 600 milligrams of sodium per serving.

While nearly all foods can be incorporated into a healthy dietary pattern, current nutrition science and federal dietary guidance emphasize nutrient-dense foods as key elements of such patterns. The proposed criteria for “healthy” move from recommendations based solely on nutrients to also include those based on food groups and their subgroups recommended as part of healthy dietary patterns, many of which, such as vegetables, fruits, dairy, seafood, and whole grains, are currently under consumed. Consistent with current nutrition science and federal dietary guidance, especially the *Dietary Guidelines for Americans, 2020-2025*, and the NFL rules, the proposed criteria generally reduce the maximum allowable amount of sodium and saturated fat and limit the maximum allowable amount of added sugars. The proposed criteria also eliminate the current

² See *Dietary Guidelines for Americans 2020-2025*, downloaded here <https://www.dietaryguidelines.gov/>

limitation on total fat because the focus of the most recent dietary fat recommendations has moved away from limiting total fat intake to replacing intakes of saturated fats with mono- and polyunsaturated fats. The proposed definition of “healthy” also eliminates the current cholesterol criteria because dietary cholesterol is present in animal-source foods that are commonly also sources of saturated fat.³ Since foods that will meet the proposed criteria of “healthy” are low in saturated fat, dietary cholesterol will already be sufficiently limited by the proposed limits for saturated fat.

Chronic diseases, such as heart disease, cancer, and stroke, are one of the leading causes of death and disability in the United States and diet is a contributing factor to these diseases.⁴ Claims on food packages, such as “healthy,” can provide quick signals to consumers about the healthfulness of a food or beverage, thereby making it easier for consumers to make healthy choices. This proposed rule aims to align the “healthy” claim with nutrition recommendations regarding what is considered healthy today. For instance, in 1994, shell eggs were not considered healthy and did not meet the “healthy” claim. Current dietary research suggests that eggs can be a part of a healthy dietary pattern.

While many food products can be incorporated into a healthy dietary pattern in moderation, about 15 percent meet the current “healthy” criteria and only five percent use the voluntary “healthy” label.⁵ FDA anticipates that the proposed, updated criteria for “healthy” would encourage industry innovation towards healthier food choices as recommended by the *Dietary Guidelines, 2020-2025* and the updated NFL regulation, thereby expanding the availability of healthy options in the marketplace.

A variety of stakeholders, including industry, consumers, and academia, have requested updates to the implied nutrient content claim “healthy.” Since 2016, FDA has taken public actions towards updating the “healthy” implied nutrient content claim. First, a final guidance for industry was published in September 2016⁶. This guidance describes FDA’s intent to reevaluate the existing criteria for “healthy,” considering the changes to the NFL and serving size regulations, as well as the changes in nutrition science as reflected in the current federal dietary guidance. The guidance also advises food manufacturers of FDA’s intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which: (1) are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least 10 percent of the Daily Value (DV) per RACC of potassium or vitamin D.

3 See the 2020 Dietary Guidelines Advisory Committee Report at: <https://www.dietaryguidelines.gov/2020-advisory-committee-report>

4 See the *Dietary Guidelines, 2020-2025*, <https://www.dietaryguidelines.gov/>.

5 These estimates are calculated by FDA using Mintel Global New Products Database. For more information, see Section D: Baseline Conditions, below.

6 See “Use of the Term ‘Healthy’ in the Labeling of Human Food Products: Guidance for Industry,” at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf>

Second, in September 2016, the FDA established a request for information (RFI) on the use of the term “healthy” in the labeling of human food products (81 FR 66562, September 28, 2016) and invited comment on the use of the term “healthy” as a nutrient content claim in the labeling of human food products; and when, if ever, the use of the term “healthy” may be false or misleading. Lastly, in March 2017, FDA held a public meeting, entitled “Use of the Term ‘Healthy’ in the Labeling of Human Food Products.” The purpose of the public meeting was to give interested persons an opportunity to discuss the use of the term “healthy” in the labeling of human food. FDA incorporated public comments received into updating the criteria for “healthy” as proposed in this regulation.

B. Need for Federal Regulatory Action

As described above, some food products that meet the current “healthy” claim criteria and are labeled as such do not align with current nutrition science or the current Nutrition Facts Label (NFL) regulations, updated in 2016 and effective in 2021. In addition, some food products that are considered part of a healthy dietary pattern, such as shell eggs or olive oil, are currently ineligible to bear the “healthy” claim. This discrepancy may cause consumers to purchase foods that meet the “healthy” claim as it exists in current regulation but are not supported by current nutrition science or related to information on the current NFL. The proposed rule aligns the definition of “healthy” to current nutrition science. Because the claim is already defined by FDA, federal regulatory action is required to lessen the extent of this government failure.

C. Purpose of the Proposed Rule

The definition in 21 CFR 101.65(d) establishes parameters for the voluntary use of the implied nutrient content claim “healthy” or related terms (such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) on the label or in the labeling of a food to suggest that a food, because of its nutrient content, may be useful in creating a diet that is consistent with current nutrition science and federal dietary guidance, if the food meets certain nutrient conditions, and the claim is made with an explicit or implicit claim or statement about a nutrient (*e.g.*, “healthy, contains three grams of fat”). Under the existing regulation, these conditions include specific criteria for nutrients that must be met in the food for it to bear such claims. These criteria include limits on total fat, saturated fat, cholesterol, and sodium, and minimum amounts (ten percent of DV) of nutrients to encourage. Under the regulation, foods must meet all limits and contain at least the minimum amount of at least one nutrient-to-encourage to bear the “healthy” claim. The required nutrient criteria vary for certain food categories (*e.g.*, there are different criteria for seafood, game meat, and raw, whole fruits and vegetables) (21 CFR 101.65(d)(2)).

Under proposed §101.65(d)(3), manufacturers may use the term “healthy” or related terms as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with current nutrition science and federal dietary guidance if the food meets the requirements laid out in proposed § 101.65(d)(3)(i)-(vi). Foods that may bear the nutrient content claim “healthy” under the proposed, updated criteria are broken out into several categories: (1) raw, whole fruits and vegetables; (2) individual food products; (3) combination foods, which

encompasses mixed products, main dish products, and meal products; and (4) water. The healthy dietary patterns articulated by the *Dietary Guidelines, 2020-2025* are emphasized through the recommended food groups: vegetables, fruits, grains, dairy, protein foods, as well as oils.⁷ For individual food products and combination foods, the proposed rule requires a certain amount of at least one of the recommended food groups, with the exception of oil. The proposed definition also sets default values of each criteria to limit, but adjusts the values based on the different food groups and/or subcategories of food groups as warranted. The proposed nutrients to limit are added sugars, sodium, and saturated fat because current nutrition science and federal dietary guidance continue to recommend limiting these nutrients as a key component in healthy dietary patterns. Based on current nutrition science, limiting certain types of fat (e.g., saturated fat) is more important than limiting the total amount of fat, therefore the restriction on total fat has been removed. The proposed definition of “healthy” also eliminates the current cholesterol criteria because it is sufficiently limited by the proposed limits for saturated fat.

As with most other nutrient content claims, the current definition for the nutrient content claim “healthy” does not include provisions for foods intended specifically for use by infants and children less than two years of age. The proposed criteria for “healthy” continues to limit the use of the claim to foods directed to children and adults two years of age and older.

The compliance date is proposed for three years after the effective date of the final rule which is 60 days after publication of the final rule, allowing manufacturers time to determine which “healthy” claims no longer comply and to adopt the claim under its new framework. A compliance date that is three years after the effective date is intended to provide industry time to coordinate labeling changes to come into compliance with the new labeling requirements with nonregulatory label changes, thus reducing costs to industry of compliance while balancing the need for consumers to have the information in a timely manner.

D. Baseline Conditions

Packaged Food Products

In addition to the NFL requirement on almost all foods in the marketplace, there are a variety of FDA-regulated claims manufacturers may include on packaged foods. These include health claims (e.g., “Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.”), structure/function claims (e.g., “calcium builds strong bones”) and nutrient content claims (e.g., “low calorie”).⁸ Nutrient content claims characterize the level of a nutrient in a food product using terms such as free, high, or, low. Alternatively, they may compare the level of a nutrient in a food to that of another food using terms such as more, reduced, and lite. The

⁷ In this rule, the phrase “food group” refers to the groups of foods recommended in the *Dietary Guidelines, 2020-2025*: Vegetables, Fruits, Dairy, Grains, Protein Foods, as well as Oils. The *Dietary Guidelines, 2020-2025* do not refer to oils as a “food group,” but they emphasize oils as part of a healthy dietary pattern, so we will refer to them as a food group for purposes of this rule. The specific food group criteria and the nutrients to limit are discussed in further detail in sections V.A.1 and V.A.2 (“Food Groups” and “Nutrients to Limit”) of the proposed rule.

⁸ See FDA’s *Guidance for Industry: Food Labeling Guide*, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide>.

current definition of “healthy” is an implied nutrient content claim that characterizes a food as useful in creating a diet that is consistent with dietary recommendations because of the levels of total fat, saturated fat, cholesterol, and sodium, as defined in the regulation authorizing use of the claim.

FDA does not actively track use of claims in the marketplace but claim use is captured in FDA’s Food Label and Package Survey (FLAPS). The FLAPS is a unique survey that FDA conducts periodically to obtain almost all food label characteristics of FDA-regulated packaged conventional food products in the United States. The Center for Food Safety and Applied Nutrition (CFSAN) uses the FLAPS data to monitor the food industry’s response to CFSAN’s food labeling regulations and to support agency policy, regulatory, and food safety decisions.⁹ Using 2001 FLAPS data, a study estimated that half of all food products had at least one nutrient content claim [Ref. 1]. The most common nutrient content claims were total fat claims such as “fat-free” (17 percent of products sold), sodium claims such as “low-sodium” (9.7 percent), and energy-related claims such as “reduced-calorie” (7.6 percent). Only 3.3 percent of all products sold were labeled as “healthy.”

An analysis using the 2007 FLAPS found that the percent of all food products with a nutrient content claim increased 3.5 percent [Ref. 2]. Total fat claims remained the most common nutrient content claim (22.4 percent), but energy-related claims became the second most prevalent (10.3 percent) and sodium claims came third (7.5 percent). Interestingly, the use of the term “healthy” as an implied nutrient content claim increased two-fold to 7.6. While more than half of FDA-regulated conventional food products have nutrient content claims on the package, such as “low-calorie,” “fat-free,” or “reduced saturated fat,” only 7.6 percent include the implied nutrient content claim “healthy.” Using the most recent 2010 FLAPS, we estimate that 5.5 percent of all products included the term “healthy.”

We use Mintel Global New Products Database (GNPD) to evaluate the current trends in packaged foods bearing the “healthy” implied nutrient content claim.¹⁰ While the FLAPS data provide a representative sample of packaged foods in the United States, we chose to use Mintel GNPD because it includes food products more recently on the shelves (as of May 14, 2018) and it includes a much larger number of food products, including those sold at a small number of stores. This database includes information on the products, ingredients, package, serving size, and nutrition information on the NFL for all packaged food and drink products. It does not include raw, whole fruits and vegetables that are not packaged. We analyzed over 200,000 branded and private label universal product codes (UPCs) representing roughly 90 percent of the total packaged foods

⁹ FDA has conducted FLAPS 14 times since 1976. The baseline section describes estimates from the three most recent surveys, conducted in 2010, 2007, and 2001. While FLAPS data is helpful in observing the trends in nutrient content claim usage overtime, we rely on additional data sources for our primary analysis. Because nutrient content claim prevalence changes over time, the primary analysis is calculated using more recent data. Also, FLAPS data does not include low-sales food products, including low-sales products from small or regional stores. Thus, the primary analysis is conducted using Mintel Global New Products Database (GNPD) from 2018 (described in detail below).

¹⁰ See Mintel Global New Products Database (GNPD), <http://www.mintel.com/global-new-products-database>, downloaded on May 14, 2018.

available in the marketplace. Using information from the NFL for each product, we estimated the percent of packaged food products that currently qualify as “healthy” as defined in §101.65 and described above. For instance, for a box of cereal to qualify as “healthy,” it must meet the following criteria:¹¹

- 1) No more than three grams of total fat per RACC and
- 2) No more than one gram of saturated fat per RACC and
- 3) Saturated fat as a percent of total calories does not exceed 15 percent and
- 4) No more than 480 milligrams of sodium per RACC and
- 5) Contains at least ten percent of the established daily value per RACC for vitamins A, C, calcium, iron, protein, *or* dietary fiber.

Then, we used a text search for the word “healthy” and related words within the product description of each UPC. We use SAS 9.3 to analyze all data.

Table 2 shows the number of UPCs in 18 individual foods and beverages categories, mixed products, main dishes, and meals. These baseline estimates do not include the 2016 enforcement discretion described in section A above. While some manufacturers have added the “healthy” claim to food products that fall under the enforcement discretion criteria, other manufacturers may be waiting to add the “healthy” label in coordination with another scheduled label change.¹² Similarly, we do not include recent changes to RACCs because compliance with these changes is not required until at least 2020 and, thus, is not fully captured in the database. As a sensitivity analysis in the Uncertainty and Sensitivity Analysis, below, we present the net benefits when the baseline includes enforcement discretion.

Because Mintel GNPD only covers 90 percent of the product marketplace, we increase the total UPC count. Inflating the UPC count by exactly 11 percent would imply that the products not included in Mintel GNPD are distributed across the product categories identically to those products that are included in the database. If this is not the case, we may under- or over-estimate the total UPCs and “healthy” labels within each of the packaged food categories. Thus, we adjust the total UPC count up by zero to 20 percent, 10 percent on average.

Overall, about 34,000 UPCs, or 14 percent of total UPCs, qualify for the “healthy” implied nutrient content claim, but only 5 percent (12,000 UPCs) choose to label. This is in line with the 2010 FLAPS estimation. This percentage varies across categories in predictable ways. About two percent of confectionary food products, including candy and sweets, qualify as “healthy,” while more than half of baby and young children food, breakfast cereals, and juice drinks qualify. The other beverages category contains about 3,000 UPCs labeled “healthy,” or about 12 percent of the category. Oil-based salad dressing contains the least UPCs labeled “healthy.” This category, along with sweet spreads, sweeteners and sugars, and plain and plain, carbonated water contain more foods labeled “healthy” than qualify. There are a few possible explanations for this. First, some products may use the term “healthy” on a label, even if it is not used as a nutrient content claim.

11 See “Conditions for the Use of “Healthy” on page 94 of the FDA’s *Guidance for Industry: Food Labeling Guide*, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide>.

12 Available data show that most products are voluntarily relabeled in a two- to five-year cycle, with private-label products less likely to be relabeled in any given year than branded products [Ref. 13]. For more information, see the Labeling Costs section on page 28.

For instance, use of the phrase “heart healthy” would not be a nutrient content claim, but rather an implied health claim for risk of heart disease. The methodology used would not pick up these nuances. Second, coding errors in Mintel GNPD are possible. Lastly, it is possible that products are mislabeled as “healthy” without qualifying as “healthy.” This uncertainty has a very minor impact on the overall estimate: only one percent of UPCs that are labeled “healthy” do not qualify as such. The numbers above form the baseline of our estimated cost of updating the “healthy” implied nutrient content claim.

Table 2: Number of UPCs currently qualifying for and using "healthy" claim

Product Categories	Total UPCs	Qualify as “healthy”	Labeled as “healthy”
Individual Foods & Beverages			
<i>Baby and young children food</i>	1,494	810	224
<i>Bakery</i>	33,420	1,796	901
<i>Breakfast cereal</i>	6,730	3,498	878
<i>Confectionary</i>	18,207	344	207
<i>Dairy</i>	17,244	3,025	730
<i>Dessert/ice cream</i>	11,000	1,018	246
<i>Juice drinks</i>	6,917	4,243	802
<i>Oil-based salad dressing</i>	1,860	5	30
<i>Other Beverages</i>	25,054	6,650	3,122
<i>Packaged fruit/vegetable</i>	8,558	4,628	535
<i>Processed fish/meat/egg</i>	18,462	1,297	532
<i>Sauce/seasoning</i>	25,564	2,605	651
<i>Savory spreads</i>	3,086	142	54
<i>Snacks</i>	31,276	2,209	1,969
<i>Soup</i>	4,073	451	226
<i>Sweet spread</i>	4,868	162	192
<i>Sweeteners and sugars</i>	1,100	9	49
Combination Foods			
<i>Mixed Products</i>	4,866	222	111
<i>Main Dishes</i>	5,374	408	255
<i>Meals</i>	14,763	889	431
Plain and Plain, Carbonated Water			
<i>Plain and Plain, Carbonated Water</i>	1,358	0	50
Total	245,274	34,409	12,196

See Appendix A for full list of subcategories included within each product category.

We also consider an alternative baseline where we include products that qualify for the “healthy” claim under the 2016 enforcement discretion, described above. Including enforcement discretion increases the total number of qualifying products to about 37,000. The product categories with the largest differences include other beverages, processed fish/meat/eggs, and snacks. In the Uncertainty and Sensitivity Analysis section below, we estimate the net benefits using this alternative baseline.

Consumer Health and Label Use

The rate of chronic, diet-related diseases in the United States has increased in the past century, due in part to poor eating and physical activity patterns [Ref. 3]. About half of all American adults have one or more preventable, diet-related chronic diseases, including cardiovascular disease and type 2 diabetes.¹³ The Healthy Eating Index is a measure of diet quality measuring a consumer's conformity to the Dietary Guidelines.¹⁴ The *Dietary Guidelines, 2020-2025* states that the average HEI-2015 score was 59 out of a maximum of 100, suggesting room for improved food choices.

Consumers have access to many sources of nutrition information to help inform food purchases: interested consumers can consider the nutrition information on the packaging, either on the front of the package, or in more detail through the NFL. For unpackaged raw, whole fruits and vegetables, there may be signage or promotional marketing material on display. While this information is available to everyone, it is not the only factor used to decide food purchases. Personal tastes, costs, and other factors play a large role in which foods consumers choose [Ref. 4, 5].

Results from FDA's Health and Diet Survey (HDS) and Food Safety and Nutrition Survey (FSANS) suggest that consumers are aware of many nutrient content claims, such as "low-fat" and "reduced sodium," and purchase products with nutrient content claims.¹⁵ For instance, the 2014 HDS found that 93 percent of respondents had seen food products "labeled 'low fat' or 'fat free' or something like that" and 22 percent of respondents purchased these foods regularly. The percent of respondents that had seen food products labeled as "low fat" was basically unchanged from survey results in 1995 and 2002. However, in 1995, 42 percent of respondents stated they would regularly purchase these products. The 2019 FSANS surveyed consumers about the "healthy" claim specifically. Sixty-one percent of respondents self-reported having seen the "healthy" claim on a food package; 31 percent of respondents reported that the "healthy" claim would increase their likelihood of purchasing "that product compared to a similar product without" the claim. However, only 9 percent of respondents selected the "healthy" claim as the "most important" statement on the food package. This suggests that while most consumers are aware of nutrient content claims, including "healthy," other factors play a role in their purchasing decisions as well.

A review of the literature finds many articles regarding the efficacy of nutrient content claims, but none that look specifically at the nutrient content claim "healthy." A systematic review of nutrition labels worldwide, including the United States, determines that nutrition labels are used for selection decisions and finds consistent evidence that use of nutrition labels is associated with

13 See the National Center for Chronic Disease Prevention and Health Promotion <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/nutrition.htm>.

14 See <https://www.fns.usda.gov/healthy-eating-index-hei> for more information.

15 The Health and Diet Survey is a nationally representative survey of consumers' self-reported awareness, attitudes and practices related to food safety and nutrition-related topics. The Food Safety and Nutrition Survey is a similar nationally representative survey that premiered in 2019. It covers consumers' practices and attitudes related to food safety as well as nutrition-related topics. See <https://www.fda.gov/food/science-research-food/cfsan-consumer-behavior-research> for more information on both surveys.

healthier diets [Ref. 6]. Packaged foods can include different sources of nutrition information, including the Nutrition Facts Label that is required to appear on most packaged food products, as well as voluntary front-of-package (FOP) labeling. The Guiding Stars Program (GSP) is a front-of-package label used by the food industry to signify nutritious food products.¹⁶ One study finds that GSP increased the demand for ready-to-eat cereals considered more nutritious [Ref. 7]. While this is not an FDA regulated nutrient content claim, it provides evidence that consumers use food labels and labeling to identify and ultimately purchase healthy foods. However, there is also evidence that label use varies across subgroups: consumers with higher education levels and more nutrition knowledge use nutrition labels more often [Ref. 8, 9], while adolescents and older adults who are obese use nutrition labels less frequently [Ref. 6].

Further, a focus group led by FDA in 2017 found that while participants acknowledged that claims often influence them to purchase the product, most believed that all front of package labeling is marketing that is meant to influence them and is not necessarily true [Ref. 10]. When asked specifically about the “healthy” claim, it seemed that many considered the presence of any front of pack claim, including food label graphics and even product placement, to convey that the product is being marketed as “healthy.”

Two studies suggest that nutrient content claims placed on vitamin-fortified snack foods increase the perceived healthfulness of the product, decrease the likelihood that a consumer looks at the NFL for additional nutritional information, and increases the likelihood the consumer would purchase the snack food [Ref. 11, 12]. However, this may result in some consumers over-indulging on foods labeled with nutrient content claims. A 2006 study found that consumers may underestimate the number of calories in foods considered healthy, potentially resulting in overeating [Ref. 13]. Other studies have found similar “health halos” present for foods labeled “low calorie” and “good source of protein” [Ref. 14, 15]. While there are no studies evaluating the presence of a “health halo” around food products labeled “healthy,” it is possible that this consumer behavior impacts these foods as well.

A 2019 meta-analysis of 60 studies on food labeling effects on consumer behaviors concludes that food labeling works to reduce consumer intake of certain nutrients (e.g. calories and total fat) [Ref. 16]. The researchers examined food and menu labeling interventions in restaurants, controlled laboratory settings, cafeterias, and other settings. Outcomes included differences in consumer’s dietary behavior (e.g., change in consumer’s calorie consumption or purchase decisions) and diet-related health outcomes (e.g., cardiovascular health, adiposity) pre- and post-labeling intervention. Relevant to this rule, the meta-analysis found that food labeling reduced intake of energy (calories) and fat and increased vegetable consumption. Further, the meta-analysis found that food labels that use a three-tier “traffic light system” to indicate the healthfulness of a food resulted in some substitution from unhealthy to healthy products, but the response is relatively modest. Labeling increased the selections of healthier “green” options and mid-level “yellow” options by about two percent and 0.4 percent, respectively, and reduced selection of less healthy “red” options by more than two percent.

Looking at nutrition knowledge more broadly, a 2018 study indicates that the use of nutrition information is positively associated with the healthfulness of food purchases at high- and low-

¹⁶ See <https://guidingstars.com/> for more information.

income levels [Ref. 17].¹⁷ Households with low nutrition information use had an HEI-2010 score of 48.1, compared to 53.8 for households with medium nutrition information use. These differences can potentially result in differences in overall health, including decreased risk in mortality. For example, a 2014 study observing mortality and morbidity rates over 15 years found that compared to study participants with the lowest HEI-2010 scores (ranging from 18.2 to 55.2), those with the highest HEI-2010 scores (ranging from 74.1 to 96.1) had a 22 percent reduction in all-cause mortality, 15 percent reduction in CVD mortality, and 24 percent reduction in cancer mortality rates [Ref. 18]. A 2017 meta-analysis found results of similar magnitude for reduced risk of all-cause mortality over 15 or 20 years [Ref. 19].

Overall, these studies suggest that the nutrition information conveyed through the implied nutrient content claim “healthy” can help consumers make healthful food choices and that eating a more healthful diet increases consumers’ overall health. On the other hand, there is some evidence from the 2017 consumer study that consumers may misinterpret what the “healthy” claim implies about the nutritional content of the food and may ignore it as a marketing technique [Ref. 5, 10]. We lack data on the precise magnitude of the relationship between use of the “healthy” claim and increased diet quality.

E. Benefits of the Proposed Rule

While we do not know the precise relationship between the use of the “healthy” nutrient content claim and increased diet quality, the literature suggests that there is an association between healthy eating, measured by adherence to federal dietary guidance articulated by the *Dietary Guidelines, 2020-2025*, and reduced diet-related diseases. We expect that consumers currently using the “healthy” claim would continue to use it to help inform food purchases and consumption. Thus, it stands to reason that if the definition of “healthy” is updated to align with current nutrition science and federal dietary guidance, consumers using the label currently would shift their food purchases towards healthier foods that cannot be labeled as such under the current definition, such as low-fat dairy, healthy oils, and some seafood. For instance, say a shopper wants to follow current dietary recommendations and searches for a snack bar labeled “healthy.” They select a granola bar labeled “healthy” instead of a nut-based snack bar without a “healthy” claim on the label. Now say, for this example, the granola bar has a high sugar content and would need to reformulate or remove the implied nutrient content claim “healthy,” but the nut-based bar could be labeled “healthy” under the updated definition. If the proposed rule was finalized, the shopper would now select the nut-based bar labeled “healthy” instead of the high sugar granola bar, thus shifting their food purchase towards healthier food. Manufacturers may also reformulate food products in order to use “healthy” as an implied nutrient content claim, so consumers may have more “healthy” options available that fit their preferences.

Benefits of the proposed rule are estimated through the monetized valuation of the reduction in chronic, diet-related disease. However, we include broad ranges when estimating benefits because we remain uncertain about the baseline use of the “healthy” claim, how consumers currently use it to make purchasing decisions, and how the proposed rule may affect their decisions.

¹⁷ The literature reviewed in this paragraph did not attempt to determine causation.

We use NHANES 2017-18 to estimate the affected population. NHANES does not ask respondents about the “healthy” claim specifically, but about seven percent of respondents said they had “tried to follow the recommendations in the MyPlate plan.”¹⁸ MyPlate is a symbol created by the USDA that serves as a reminder to build healthy dietary patterns based on Dietary Guidelines. These recommendations include limiting foods and beverages higher in added sugars, saturated fat, and sodium and focusing on nutrient dense foods and beverages such as fruits and vegetables, whole grains, low-fat dairy, lean protein, and oils.¹⁹ Thus, we use this NHANES estimate as a proxy for the percent of the population that have tried to follow a healthy diet as defined by the current recommendations.

Supporting this assertion, we find that NHANES participants who respond that they have tried to follow MyPlate have higher Healthy Eating Index scores than those who did not. In order to make lasting changes to dietary behavior, a consumer would need to not just “try” to follow the recommendations, but also succeed in selecting healthier food choices. Shangguan et al. (2019) estimate that labeling increased the selections of healthier “green” options and mid-level “yellow” options by about two percent and 0.4 percent. We use this a proxy for the effect of a label change on consumers that are already trying to follow the recommended diet. Specifically, we assume that 0 to 0.4 percent of the consumers trying to follow recommendations will succeed in selecting healthier foods in a meaningful way. Zero is the estimated lower bound to account for the possibility of no change in behavior. We request comment on this proxy for the effect of updating the definition of “healthy” on selection and consumption of healthier foods.

Using population estimates from US Census,²⁰ we estimate the total population to be around 349 million when the proposed compliance date occurs and benefits begin to accrue (roughly 2027). We limit the population to those two and older because the proposed use of the “healthy” claim is limited to foods directed to children and adults two years of age and older. While adults make the vast majority of food purchase decisions at grocery stores, children would also benefit from the household’s decision towards more healthful eating. To the extent that the estimated benefits rely on surveys and studies of an adult population, the benefits may be over- or under-estimated. As a sensitivity analysis in the Uncertainty and Sensitivity Analysis, below, we present the benefits when the population is limited to adults 18 years or older. Since a substantial portion of the U.S. population doesn’t speak English, we adjust this population estimate down to omit individuals with limited English proficiency. The 2009-2013 American Community Survey identified 8.6 percent of the population above the age of five spoke English less than “very well.”²¹ Using the

18 NHANES 2017-18 calculations are by the author, using weights to estimate sample means.

19 MyPlate is a Federal symbol that serves as a reminder to build healthy dietary patterns by making healthy choices across the food groups. NHANES 2017-18 describes this as the “MyPlate plan,” but the recommendations are based on the most current Dietary Guidelines for Americans and MyPlate is a symbol of those recommendations. For consistency with the NHANES questionnaire, we use the term “MyPlate plan” to refer to the symbol. See <https://www.choosemyplate.gov/MyPlate> for more information.

20 See US Census table 1, “Projected Population by Single Year of Age, Sex, Race, and Hispanic Origin for the United States: 2016 to 2060”, downloaded at https://www2.census.gov/programs-surveys/popproj/datasets/2017/2017-popproj/np2017_d1.csv

21 See US Census table 1, Detailed Languages Spoken at Home and Ability to Speak English for the Population 5

estimates described above, the estimated number of people that use or are impacted by use of the “healthy” nutrient content claim in a meaningful way to adhere to the *Dietary Guidelines, 2020-2025* over time is 43,757 people on average ($\approx 338 \text{ million} * 0.07 * 0.004 * 0.914$).

The literature suggests that high adherence to the Dietary Guidelines over a long time frame (10-20 years) is associated with roughly 20 percent reduced risk in all-cause mortality [Ref. 18, 19]. In one study, Reedy et al. [Ref. 18] use a cohort study design to investigate diet and cancer. The sample of 424,662 men and women ages 50 to 71 were followed over 15 years, between 1995 through 2011. Multiple diet-quality indices were examined, including HEI-2010. The authors found that, after adjusting for age, race/ethnicity, education, marital status, physical activity, smoking, energy intake, BMI, diabetes, and alcohol intake, people with higher HEI-2010 scores had lower all-cause mortality. Specifically, compared to the lowest scoring participants with HEI scores between 18.2 and 55.2, participants with HEI scores between 55.2 and 62.6 had a nine percent decrease in all-cause mortality over the 15-year study period. Participants with the highest HEI scores between, 74.1 and 96.1, had a 22 percent reduction in all-cause morbidity relative to the lowest scoring group. The authors supplement the primary analysis with estimated hazard risks (HR) for all-cause mortality due to a one-point increase in each component score [Ref. 20]. The weighted average HR across men and women within the sample was 0.991, with a confidence interval of 0.985 to 0.997. This result suggests that over 15 years, a one-point increase in the total HEI-score is associated with a 0.3 to 1.5 percent decrease in risk of all-cause mortality, or 0.9 percent on average.

The results from Reedy et al. (2014) are consistent with other literature on the benefits of a healthy diet [Ref. 19]. However, the study lacks an identification strategy that allows a causal interpretation. For instance, the authors note that other behaviors that increase health and well-being, such as access to health care, are not completely captured in the study. We lack causal data at this time and request comment and data on this issue.

We utilize the result from Reedy et al. (2014) to estimate the marginal effect of an increase in HEI-2010 due to changes to the “healthy” definition and estimate that a one-point increase in HEI score decreases all-cause mortality by zero to 0.3 percent over 15 years, or 0.015 percent on average. We use zero as a lower bound estimate to provide for the possibilities that either 1) changes to the healthy definition do not change the HEI score and/or 2) that a 1-point increase in HEI score has no effect on all-cause mortality. We use the lower bound from Reedy et al., 0.03, as an upper bound.

Multiplying the affected population of about 43,757 children and adults by the reduction in risk for a one-point HEI-score increase of 0.15 percent, we estimate a 90 percent confidence interval between 2 and 188, with a mean estimate of 68 statistical lives saved per HEI point gained and maintained for 15 years. This confidence interval incorporates the uncertainty bounds described above: a one-point increase in HEI score decreases all-cause mortality by zero to 0.3 percent over 15 years, and zero to 0.4 percent of these consumers would use “healthy” claims to inform food selection and consumption consistently over time.

Years and Over for United States: 2009-2013”, downloaded at <https://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html>

The approach outlined above focuses on the proportion of consumers that currently use the healthy claim to make diet-related decisions; we assume the proportion of consumers using the “healthy” implied nutrient content claim is constant over time. The accrued benefits stem from a shift from foods currently labeled as “healthy” that do not contribute to a healthful diet towards foods that, if the proposed rule was finalized, contribute to a healthful diet and could be labeled as such. This approach is not refined enough to map into specific changes in all-cause morbidity and mortality. We request comments and data regarding these assumptions and our estimation of the potential benefits of this proposed rule.

Table 3 shows the 20-year stream of benefits under these assumptions. The affected population, derived above, increases each year as the population estimated by US Census increases. Thus, if the proportion of consumers that use the “healthy” claim in a meaningful way increases (or decreases), the estimated benefits will be under-estimated (or over-estimated). To monetize the annual health benefit, the primary benefits analysis uses US Health and Human Services’ (HHS) mean value of a statistical life (VSL) estimates, which increase annually. We assume health benefits begin to accrue in the year after the compliance date and that they accrue gradually. Thus, instead of all health benefits being accrued at the end of 15-years, we assume benefits are accrued annually the year the relevant food is consumed.

Table 3. 20-year stream of estimated gross benefits, in 2020\$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Gross Benefits (millions)
2023	42,581	0	\$11.0	\$0.00
2024	42,879	0	\$11.1	\$0.00
2025	43,175	0	\$11.2	\$0.00
2026	43,467	0	\$11.4	\$0.00
2027	43,757	68	\$11.5	\$51.81
2028	44,042	68	\$11.6	\$52.72
2029	44,324	68	\$11.7	\$53.64
2030	44,600	69	\$11.9	\$54.57
2031	44,871	69	\$12.0	\$55.50
2032	45,135	70	\$12.1	\$56.45
2033	45,394	70	\$12.3	\$57.39
2034	45,647	71	\$12.4	\$58.35
2035	45,893	71	\$12.5	\$59.31
2036	46,133	71	\$12.7	\$60.27
2037	46,367	72	\$12.8	\$61.25
2038	46,594	72	\$13.0	\$62.22
2039	46,817	72	\$13.1	\$63.21
2040	47,034	73	\$13.3	\$64.20
2041	47,246	73	\$13.4	\$65.20
2042	47,454	73	\$13.5	\$66.21
		1,130		\$942.30

As described above, we estimate the benefits of the proposed rule by monetizing the value of reductions in chronic, diet-related disease. Since these health benefits would, in many cases, accrue through voluntary choices from consumers that adopt healthier options in line with their own preferences, we anticipate that the redefinition of the “healthy” labeling claim would often result in positive welfare gains to consumers that adopt healthier choices, no change in welfare for other consumers that do not alter their choices, and potentially negative welfare effects for consumers whose preferred products are reformulated. We acknowledge and incorporate several sources of uncertainty into these monetized benefit estimates, and discuss an additional consideration related to these welfare impacts.

Specifically, the stream of gross benefits presented above does not explicitly account for the possibility of an individual consumer’s lost pleasure from eating less healthy foods they may nevertheless prefer. For instance, a consumer that substitutes whole wheat bread for white bread daily will have a higher HEI-score, which over time is associated with health gains in the form of decreases in all-cause mortality, quantified above. However, this consumer may prefer the taste of white bread to whole wheat and thus derives less enjoyment, or utility, from consuming the bread. Thus, the consumer’s overall welfare improvement, estimated on an intermediate basis as consisting only of beneficial health gains, may be dampened by the lost shorter-term utility.²²

While we are unaware of any research literature that directly quantifies such lost utility in the context of food label changes, one estimate of lost utility in the context of increased taxes on sugar-sweetened beverage (SSB) consumption should be noted. Kalamov and Runkel (2021), citing Allcott et al.’s (2019) estimates, suggest externalities (representing the harm consumers of less healthy foods sub-optimally impose on their future selves) could be 30- to 50-percent of gross health impacts [Ref. 22, 23]. This is equivalent to stating that consumers’ overall welfare improvement, estimated on an intermediate basis as consisting only of beneficial health gains, may be dampened 50 to 70 percent due to lost shorter-term utility from consuming fewer SSBs.

This estimate may be relevant for foods labeled healthy whose added sugar would need to be reduced to continue qualifying for the healthy labeling claim. It is unclear the extent to which this estimate would be applicable to foods whose sodium or saturated fat levels would need to be reduced to continue qualifying for the healthy labeling claim. In addition to the reductions above, this proposed rule removes the current limit on total fat and cholesterol, allowing the use of eggs and healthy oils that may provide consumers more, rather than less, utility from their foods. Furthermore, the proposed requirement for half a cup of fruits, vegetables, or dairy per serving may provide consumers with reformulated products that they prefer to the previously labeled healthy food products.

²² FDA has addressed this issue of lost consumer surplus in the Final Regulatory Impact Analysis (FRIA) covering two final rules that modified the nutrition information and serving sizes presented on food labels by directly referencing a welfare analysis based on observations of the choices made by consumers. Under the standard assumptions of revealed preference theory, these estimates should be inclusive of the health effects, taste, and other factors that affect dietary decisions (Just, Hueth, Schmitz 2005). In the FRIA covering the nutrition labeling of menu items in restaurants and similar retail food establishments, FDA performed a sensitivity analysis that illustrated the potential consumer surplus loss as equal to about half of the monetized health benefits. For complete analyses, see <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>

To account for lost consumer utility, we use the mid-point from Kalamov and Runkel (2021), 60 percent, as the high end of our range. We set the lower bound at zero percent because there is no obvious non-arbitrary alternative as regards net lost consumer utility. Using the mid-point of this range, we estimate that health gains may be dampened by 30 percent, on net, due to lost shorter-term consumer utility from consuming foods now labeled “healthy” that the consumer does not prefer. Table 4 shows the stream of benefits accounting for lost consumer utility.

Table 4. 20-year stream of estimated benefits, accounting for lost immediate-upon-eating consumer utility, in 2020\$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Benefits, Accounting for Lost Immediate-Upon-Eating Consumer Utility (millions)
2023	42,581	0	\$11.0	\$0.00
2024	42,879	0	\$11.1	\$0.00
2025	43,175	0	\$11.2	\$0.00
2026	43,467	0	\$11.4	\$0.00
2027	43,757	68	\$11.5	\$36.27
2028	44,042	68	\$11.6	\$36.90
2029	44,324	68	\$11.7	\$37.55
2030	44,600	69	\$11.9	\$38.20
2031	44,871	69	\$12.0	\$38.85
2032	45,135	70	\$12.1	\$39.52
2033	45,394	70	\$12.3	\$40.17
2034	45,647	71	\$12.4	\$40.85
2035	45,893	71	\$12.5	\$41.52
2036	46,133	71	\$12.7	\$42.19
2037	46,367	72	\$12.8	\$42.88
2038	46,594	72	\$13.0	\$43.55
2039	46,817	72	\$13.1	\$44.25
2040	47,034	73	\$13.3	\$44.94
2041	47,246	73	\$13.4	\$45.64
2042	47,454	73	\$13.5	\$46.35
		1,130		\$659.61

We use Palisades @Risk 7.5 software to run a Monte Carlo simulation to calculate the 90 percent confidence interval for the upper and lower bounds of the benefits.²³ Present discounted values over a 20-year period are presented in Table 5. Discounted at three percent, the mean present value of benefits accrued to consumers using the “healthy” nutrient content claim is \$455 million, with a lower bound of \$15 million and an upper bound of \$1.3 billion. Discounted at seven percent, the

²³ For more information on @Risk 7.5 software, see <https://www.palisade.com/risk/default.asp>

mean present value of benefits of the proposed rule is \$290 million, with a lower bound estimate of \$9 million and an upper bound estimate of \$857 billion.

Table 5. Present discounted values of benefits over 20-years, accounting for lost immediate-upon-eating consumer utility, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	\$14.75	\$455.40	\$1,344.39
Present value, discounted at 7%	\$9.40	\$290.29	\$856.96
Annualized value at 3%	\$0.99	\$30.61	\$90.36
Annualized value at 7%	\$0.89	\$27.40	\$80.89

We request comment on the expected magnitude of a consumer’s lost utility from choosing to eat additional healthy-labeled foods that are less preferable than their less healthy alternatives and the applicability to this proposed rule. We welcome feedback connecting existing research to this regulatory context, given key differences between the two, including how:

- The benefits approach in this RIA focuses on a subpopulation that has used the dietary guidelines to make healthy food choices consistently over many years, whereas study populations (with imperfect nutritional knowledge and imperfect self-control²⁴) may be substantially different.
- Producers can choose to label products “healthy” or not. It is not entirely clear how these circumstances should be compared to the producer and consumer choices in the context of taxation of sugar-sweetened beverages.
- The proposed rule limits the use of some “preferred” ingredients, e.g., refined grains, added sugar, and salt, but also *removes* the limit of other “preferred” nutrient dense ingredients, e.g., healthy oils, eggs, and some seafood, allowing for both losses or gains in utility for consumers for this label change.

In addition to comments related to the underlying health benefit estimates, we also welcome data and other evidence on the *total* welfare impacts of the proposed rule. We welcome feedback on whether to adjust the health benefit estimates by applying other benefit-transfer methods that apply existing estimates from welfare analyses of other nutrition policies, or whether an explicit adjustment for lost consumer surplus, would be appropriate.

Other Sources of Benefits

An additional potential benefit is that by updating the definition of “healthy” to align with current public health standards, knowledgeable consumers may increase trust in and usage of the implied nutrient content claim. Currently, a consumer could see that some products labeled as “healthy” are not among those recommended in the current federal dietary guidance, while other products that are recommended cannot currently qualify for the claim, and consequently place less trust in the use of the “healthy” claim on other food products, even if appropriate. By reducing the chance

²⁴ A potential corollary is that internalities could be smaller for the population whose consumption choices might change in response to a new “healthy” definition than for the population captured in the Kalamov and Runkel (2021) study.

of this occurrence, this proposed rule may increase use of the “healthy” nutrient content claim to guide healthy eating decisions. The estimated benefits above assumes that label usage remains constant over time. To the extent this occurs, the benefits are underestimated. We request comment on this assumption.

In addition to reducing the risk of all-cause mortality, following a healthy diet could reduce the risk of morbidity and prolong life to the extent consumers use the “healthy” nutrient content claim to maintain healthy dietary practices. Research has demonstrated links between diet and excess body weight (overweight and obesity), CVD (which includes CHD, heart attack, stroke, and high blood pressure), type 2 diabetes (or non-insulin dependent diabetes mellitus), some cancers, cognitive decline, osteoporosis, and dental disease [Ref. 3, 22, 23, 24]. Each of these conditions may cause some degree of disability, impairment, discomfort, and anxiety among sufferers, and may also involve a significant amount of time for daily treatment or management. However, due to data limitations, we are unable to directly quantify the effect of the proposed rule on reduced morbidity. These effects are not captured within the benefit stream estimated above.

F. Costs of the Proposed Rule

Costs of the proposed rule are incurred by the food manufacturers that may be affected by the proposed rule. The three main quantifiable costs of the proposed rule are labeling, reformulating, and recordkeeping. The “healthy” nutrient content claim is voluntary, but if the proposed rule results in some products needing to remove the claim to avoid being misbranded, manufacturers would incur costs due to the rule. Manufacturers with food products currently using the “healthy” nutrient content claim would need to confirm whether the products meet the proposed criteria and decide whether a label change is needed. Manufacturers with products that currently do not meet the “healthy” criteria but do meet the proposed criteria have the option of labeling these products. Also, in some cases, manufacturers may choose to reformulate a product so that it meets the proposed criteria. Lastly, some recordkeeping is required for certain products using the proposed “healthy” claim because the required food components equivalents are likely to increase time spent on recordkeeping. Because the “healthy” claim is voluntary, manufacturers may incur additional labor costs when determining when any of these steps is necessary. We expect these costs are nominal because much of the information can probably be found in data already generated by producers to meet other labeling requirements. We do not quantify these costs at this time but seek comment on this assumption.

In addition, we qualitatively discuss the potential costs to manufacturers of re-branding “healthy” branded products that no longer qualify under the proposed criteria. Some brands include “healthy” or related words in their brand name, which could be considered an implied nutrient content claim based on the context in which the claim is made; i.e., when information about the nutrition content of the food is also available. If these “healthy” branded products would not qualify under the proposed definition, manufacturers may choose to reformulate the product (described above) or remove the “healthy” brand name and not reformulate. We lack the data to quantify the potential costs of re-branding and solicit data and information that could help us quantify this potential cost. The proposed rule covers raw, whole fruits and vegetables, individual products, combination foods and plain water. Mintel GNPD only covers packaged foods, not raw, whole fruits and vegetables. Typically, these products do not carry label claims, but they may appear on other materials in the

stores and elsewhere that may constitute labeling. To the extent that this occurs, the costs may be underestimated.

Labeling Costs

In order to comply with the proposed rule, some manufacturers using the “healthy” claim would need to remove the claim. Other manufacturers may choose to add the “healthy” claim to foods that meet the proposed criteria. We estimate the number of products that would need to remove the “healthy” claim and the number of products that may choose to add the “healthy” claim using Mintel GNPD. Relabeling costs were estimated using FDA’s Labeling Cost Model [Ref. 25]. The model, which was built based on discussions with trade associations and product manufacturers in 2014, provides estimates of the costs of making labeling changes for a range of food products. Because of the number of steps involved in changing the information on food packaging and labeling, the entire labeling change process generally takes several months [Ref. 25].

Labeling costs, which include labor, materials, inventory (discarded inventory and disposal costs), recordkeeping,²⁵ and, in certain cases, recurring costs associated with package size increases, are first calculated on a per-UPC basis and then aggregated across each product category, and are calculated separately as low, mean, and high cost estimates.

Available data show that most products that are voluntarily relabeled are relabeled in a two- to five-year cycle, with private-label products less likely to be relabeled in any given year than branded products [Ref. 25]. Manufacturers who can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) would incur lower costs associated with the required labeling change than they would otherwise. Longer compliance periods increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling changes. However, even if manufacturers can coordinate a required labeling change, the FDA Labeling Cost Model includes costs of administrative and recordkeeping activities associated with labeling changes because manufacturers would still incur costs associated with understanding the regulation, determining their response, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels. Other types of costs, though, such as prepress, graphic design, and engraving plates or cylinders, are not attributable to the regulation if the required labeling change is coordinated with a planned voluntary label change.

With a three year compliance period after the effective date, the FDA Labeling Cost Model estimates that 43 percent of private-label conventional food products would have to undertake an uncoordinated labeling change [Ref. 25]. Manufacturers of food products that currently do not qualify as “healthy” but would qualify under the proposed criteria may choose to reduce costs by waiting for a coordinated change before adding the “healthy” claim. Thus, we assume that 100 percent of these products will be coordinated changes. Table 6 shows the mean costs per uncoordinated and coordinated UPC assuming a major label change, described as “a major change

²⁵ The labeling model includes administrative and recordkeeping costs associated with understanding the regulation, determining their responses, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels. These costs are in addition to the recordkeeping costs we estimate manufacturers will incur to keep written records to verify that the food meets the food group equivalent requirements when it is not apparent from the label of the food.

requires multiple color changes and label redesign” such as “modifying the front of a package” [Ref. 25].

Table 6. Average labeling costs per UPC, in 2020\$

Product Category	Mean Costs / Uncoordinated UPC	Mean Costs / Coordinated UPC	Percent uncoordinated UPC
Individual Foods & Beverages			
<i>Baby and young children food</i>	\$9,240	\$1,432	11%
<i>Bakery</i>	\$11,102	\$1,638	21%
<i>Breakfast cereal</i>	\$11,418	\$1,868	25%
<i>Confectionary</i>	\$11,662	\$1,641	22%
<i>Dairy</i>	\$10,032	\$1,459	20%
<i>Dessert/ice cream</i>	\$11,662	\$1,641	22%
<i>Juice drinks</i>	\$11,518	\$1,555	17%
<i>Oil-based salad dressing</i>	\$9,535	\$1,432	14%
<i>Other Beverages</i>	\$11,518	\$1,555	17%
<i>Packaged fruit/vegetable</i>	\$10,390	\$1,558	20%
<i>Processed fish/meat/egg</i>	\$9,715	\$1,432	15%
<i>Sauce/seasoning</i>	\$9,535	\$1,432	14%
<i>Savory spreads</i>	\$9,587	\$1,470	15%
<i>Snacks</i>	\$11,630	\$1,572	11%
<i>Soup</i>	\$9,302	\$1,432	20%
<i>Sweet spread</i>	\$9,587	\$1,470	15%
<i>Sweeteners and sugars</i>	\$12,194	\$1,799	21%
Combination Foods			
<i>Mixed Products</i>	\$10,424	\$1,502	14%
<i>Main Dishes</i>	\$8,925	\$1,432	15%
<i>Meals</i>	\$8,925	\$1,432	15%
Plain and Plain, Carbonated Water	\$11,518	\$1,555	17%
Average	\$10,449	\$1,539	17%

We use Mintel GNPD to estimate the total number of UPCs that would qualify for the proposed criteria. Information for two of the proposed nutrients to limit, saturated fat and sodium, are readily available on the NFL and were captured in about half of Mintel GNPD. However, at the time the data was collected, not all packaged food products included added sugars in the NFL. In addition, the NFL and ingredients list does not specify the exact amount of each food group used in the food. For example, it is unclear whether multi-grain bread has enough whole grains to qualify within the grain food group in the proposed criteria. For each product category, subject matter experts in FDA’s Office of Nutrition and Food Labeling (ONFL) estimated the proportion of products that may be affected by both proposed criteria (i.e. products that include levels of added sugars above the criteria or do not include an equivalent measure of a food group) [Ref. 26]. Table 7 presents the estimated number of UPCs in the current marketplace that would qualify for and use the

proposed “healthy” claim. We estimate that the number of total qualifying UPCs decreased from 34,000 to 26,000 UPCs, or from 14 percent to 11 percent of total UPCs (see Table 2 for the percent of UPCs that currently qualify).

Table 7. Estimated number of UPCs would qualify and use proposed "healthy" claim

Product Categories	Total UPCs	Would qualify as proposed “healthy”	Would label as “healthy”
Individual Foods & Beverages			
<i>Baby and young children food</i>	1,494	402	111
<i>Bakery</i>	33,420	1,087	546
<i>Breakfast cereal</i>	6,730	1,391	349
<i>Confectionary</i>	18,207	-	-
<i>Dairy</i>	17,244	3,564	860
<i>Dessert/ice cream</i>	11,000	301	73
<i>Juice drinks</i>	6,917	1,618	306
<i>Oil-based salad dressing</i>	1,860	26	26
<i>Other Beverages</i>	25,054	1,326	622
<i>Packaged fruit/vegetable</i>	8,558	4,238	490
<i>Processed fish/meat/egg</i>	18,462	2,362	969
<i>Sauce/seasoning</i>	25,564	2,857	714
<i>Savory spreads</i>	3,086	907	347
<i>Snacks</i>	31,276	3,675	3,277
<i>Soup</i>	4,073	102	51
<i>Sweet spread</i>	4,868	226	226
<i>Sweeteners and sugars</i>	1,100	-	-
Combination Foods			
<i>Mixed Products</i>	4,866	72	36
<i>Main Dishes</i>	5,374	203	127
<i>Meals</i>	14,763	523	253
Plain and Plain, Carbonated Water	1,358	1,358	1,358
Total	245,274	26,238	10,741

Total UPCs are identical to those presented in Table 2. See Appendix A for full list of subcategories included within each product category.

We assume that conditional on qualifying as “healthy,” the proportion of food products within each category that choose to label remains unchanged. For instance, 25 percent of breakfast cereals that currently qualify to use the “healthy” claim currently bear the “healthy” claim. Thus, we assume that of the 1,391 breakfast cereals that qualify to use the proposed “healthy” claim, 25 percent, or 349 products, will label as “healthy.”

The total number of UPCs that use the “healthy” claim decreases slightly to 10,741 (four percent). Two categories, confectionary and sweeteners and sugars, have zero qualifying products. Juice

drinks and other beverages see the largest decline in terms of the number of UPCs that would qualify for the “healthy” claim: juice drinks lose about 2,600 UPCs and other beverages lose about 5,000 UPCs. In eight categories, the number of UPCs that qualify for the “healthy” claim increased: dairy (+539 UPCs), oil-based salad dressings (+21 UPCs), processed fish/meat/egg (+1,066 UPCs), sauce/seasoning (+252 UPCs), savory spreads (+766 UPCs), snacks (+1,467 UPCs), sweet spread (+64 UPCs), and plain and plain, carbonated water (+1,358 UPCs). In the case of three categories that currently label more UPCs than qualify (i.e., oil-based salad dressings, sweet spreads, and plain and plain, carbonated water; see Table 2), we assume that 100 percent of UPCs that qualify for the proposed definition would continue to use the “healthy” claim.

We assume there are two categories of UPCs that could require re-labeling. First, if a UPC currently labeled “healthy” does not meet the proposed criteria, the manufacturer could choose to remove the “healthy” claim or reformulate. In either case, the label would need to be changed, either to remove the “healthy” claim or to change the NFL after reformulation. Given the current UPCs labeled “healthy” that would not qualify for the proposed criteria, we estimate the number of UPCs that would remove the “healthy” claim or reformulate. Second, if a UPC does not currently qualify as “healthy” but would meet the proposed criteria, the manufacturer could choose to add the “healthy” claim. Assuming that manufacturers will continue to label the same proportion of qualifying products, we estimate the number of UPCs that would add the “healthy” claim.

For each product category, Table 8 also shows the total label changes (calculated as the sum of the first two columns) and the net change in UPCs labeled “healthy”, relative to the baseline presented in Table 2. In eight categories, the estimated number of UPCs that qualify for the “healthy” claim increases under the proposed rule. Total mean costs per product category are presented in the final column. Total labeling costs are estimated to be \$44 million, or \$2,500 per re-labeled UPC.

There are a couple areas of uncertainty. First, if manufacturers choose to label a larger (or smaller) set of qualifying products as “healthy,” these cost estimates underestimate (or overestimate) the true cost of labeling due to updating the definition of “healthy.” Second, the baby and young children food category may include some products intended for children under two years of age and therefore not able to use the “healthy” claim. To the extent this occurs, the total labeling costs (and subsequent reformulate and recordkeeping costs) may be overestimated for this product category.

Table 8. Total labeling costs per product category, in 2020\$

Product Category	UPCs would remove “healthy” claim or reformulate	UPCs would add “healthy” claim	Total label changes	Net change in UPCs labeled “healthy”	Total Mean Cost
Individual Foods & Beverages					
<i>Baby and young children food</i>	161	48	210	(113)	\$439,618
<i>Bakery</i>	843	488	1,331	(355)	\$3,839,636
<i>Breakfast cereal</i>	691	162	852	(529)	\$3,255,753
<i>Confectionary</i>	207	-	207	(207)	\$802,341
<i>Dairy</i>	544	674	1,218	130	\$2,724,700
<i>Dessert/ice cream</i>	228	55	283	(173)	\$973,078
<i>Juice drinks</i>	612	116	728	(496)	\$2,172,706
<i>Oil-based salad dressing</i>	29	24	53	(4)	\$108,162
<i>Other Beverages</i>	2,912	412	3,324	(2,499)	\$10,125,475
<i>Packaged fruit/vegetable</i>	221	176	398	(45)	\$1,008,782
<i>Processed fish/meat/egg</i>	403	840	1,244	437	\$2,268,786
<i>Sauce/seasoning</i>	585	648	1,233	63	\$2,418,662
<i>Savory spreads</i>	28	321	349	293	\$546,267
<i>Snacks</i>	1,692	2,999	4,691	1,308	\$9,245,139
<i>Soup</i>	220	45	264	(175)	\$730,635
<i>Sweet spread</i>	186	219	405	33	\$816,171
<i>Sweeteners and sugars</i>	49	-	49	(49)	\$192,478
Combination Foods					
<i>Mixed Products</i>	108	33	141	(75)	\$351,791
<i>Main Dishes</i>	242	115	357	(128)	\$784,894
<i>Meals</i>	400	223	623	(177)	\$1,342,655
Plain and Plain, Carbonated Water	-	1,307	1,307	1,307	\$2,033,320
Total	10,361	7,599	17,960	(2,762)	\$44,147,727

Reformulation Costs

The proposed rule could result in food manufacturers reformulating their products in response to the updated criteria. For example, manufacturers could choose to reduce the added sugars content in a food that otherwise meets the new criteria in order to a) keep using the “healthy” claim or b) begin using the “healthy” claim.

Reformulation costs are estimated using the FDA Reformulation Cost Model [Ref. 27]. The FDA Reformulation Cost Model, the development of which was based on an expert panel of individuals who previously oversaw product reformulation at major food manufacturing companies or who currently provide formulation consulting services to small and large food manufacturers, estimates the costs to food manufacturers of reformulating foods based on variations in (i) food product complexity (some products are more easily reformulated than others), (ii) company size (larger companies put substantially more effort into reformulation than smaller companies), (iii) reformulation types (reformulation of a non-critical minor ingredient, of a critical minor ingredient, and of a major ingredient) and activities (determination of response to regulation; project

management; product reformulation/process modification; packaging assessment and development; product and package performance testing; sensory evaluation; analytical testing; production scale-up; discarding of unused inventory of raw materials, packaging, and labels; and updating product records), and (iv) compliance period (costs are higher for shorter compliance periods because if the compliance period is short, manufacturers would incur increased costs for overtime labor, additional staffing, and rush charges with vendors and suppliers). There are many possible ways a manufacturer may choose to reformulate a product, from reducing added sugars to increasing the amount of whole grains. We estimate, with some potential for overstatement of costs, that reformulation would include substitution of a major ingredient. To the extent that reformulation includes changes to minor ingredients, these costs are over-estimated. Table 9 presents the total cost per formula of reformulation.

It is difficult to predict how the updated definition of “healthy” would influence manufacturers’ decisions to reformulate or remove the claim from the product label. We therefore estimate that, given the updated definition, some manufacturers would reformulate while others would remove the claim from their product’s label. Specifically, of the food products currently labeled “healthy” that do not qualify under the proposed definition, manufacturers of between three and 7.5 percent of formulas, five percent on average, would choose to reformulate instead of removing the “healthy” claim. This range is based on two sources. First, the lower bound is the estimated percent of new food products created within the “fruits and vegetables” product category between 2008 and 2012 [Ref. 28]. Second, the high bound is borrowed from the Final Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Final Rule [Ref. 29]; the analysis estimated that 7.5 to 9 percent of formulas that significantly contribute added sugars to diets would be reformulated once added sugars are required on the NFL. Because the “healthy” claim is voluntary, we anticipate fewer manufacturers would reformulate and the lower bound for the NFL estimate becomes the upper bound here.

Mintel GNPD does not track formula counts, only UPC counts. For many foods, one formula may be sold in a variety of sizes and different packaging, therefore using the number of UPCs will lead to over-estimations of the total number of formulas on the market, and thus the total cost of reformulating. Using the data provided in the Labeling Cost Model, we estimate the ratio of formulas to UPCs for each product category and apply this to find the estimated number of formulas.

Table 9. Reformulation costs per formula, in 2020\$

Product Categories	Total Cost/Formula		
	Low	Mean	High
Individual Foods & Beverages			
<i>Baby and young children food</i>	\$828,512	\$1,702,451	\$3,030,460
<i>Bakery</i>	\$456,467	\$958,075	\$1,727,125
<i>Breakfast cereal</i>	\$563,756	\$1,177,824	\$2,116,778
<i>Confectionary</i>	\$511,002	\$1,070,368	\$1,926,994
<i>Dairy</i>	\$439,131	\$908,823	\$1,625,711
<i>Dessert/ice cream</i>	\$511,002	\$1,070,368	\$1,926,994
<i>Juice drinks</i>	\$387,980	\$812,375	\$1,462,694
<i>Oil-based salad dressing</i>	\$360,477	\$755,858	\$1,362,234
<i>Other Beverages</i>	\$390,005	\$805,112	\$1,438,155
<i>Packaged fruit/vegetable</i>	\$387,980	\$812,375	\$1,462,694
<i>Processed fish/meat/egg</i>	\$278,654	\$582,774	\$1,048,600
<i>Sauce/seasoning</i>	\$317,326	\$663,084	\$1,193,069
<i>Savory spreads</i>	\$317,326	\$663,084	\$1,193,069
<i>Snacks</i>	\$416,349	\$867,453	\$1,557,529
<i>Soup</i>	\$570,245	\$1,190,209	\$2,138,286
<i>Sweet spread</i>	\$317,326	\$663,084	\$1,193,069
<i>Sweeteners and sugars</i>	\$475,435	\$993,008	\$1,784,929
Combination Foods			
<i>Mixed Products</i>	\$419,108	\$876,696	\$1,577,637
<i>Main Dishes</i>	\$442,108	\$925,987	\$1,667,501
<i>Meals</i>	\$442,108	\$925,987	\$1,667,501
Plain and Plain, Carbonated Water	\$390,005	\$805,112	\$1,438,155
Average	\$439,157	\$915,719	\$1,644,723

Table 10 presents the total reformulation costs per product category. Based on the proposed criteria, we expect that no products from the confectionary, other beverages, or sweeteners and sugars product categories would be able to reformulate in order to use the “healthy” claim. We also do not include reformulation costs for the plain and plain, carbonated water product category, since there is no applicable reformulation needed. Of the food products currently labeled “healthy” that we expect would no longer be able to bear the claim under the proposed criteria, we estimate that five percent on average would choose to reformulate instead of removing the “healthy” claim. The final column is the total mean cost of reformulation per category.

Table 10. Total reformulation costs per product category, in 2020\$

Product Categories	UPCs would remove “healthy” claim or reformulate	Formulas would remove “healthy” claim or reformulate	Mean # formulas would reformulate	Total mean cost
Individual Foods & Beverages				
<i>Baby and young children food</i>	161	130	7	\$11,577,000
<i>Bakery</i>	843	692	36	\$34,778,000
<i>Breakfast cereal</i>	691	471	25	\$29,092,000
<i>Confectionary</i>	207	-	-	\$0
<i>Dairy</i>	544	417	22	\$19,903,000
<i>Dessert/ice cream</i>	228	175	9	\$9,847,000
<i>Juice drinks</i>	612	412	22	\$17,547,000
<i>Oil-based salad dressing</i>	29	18	1	\$756,000
<i>Other Beverages</i>	2,912	-	-	\$0
<i>Packaged fruit/vegetable</i>	221	169	9	\$7,230,000
<i>Processed fish/meat/egg</i>	403	302	16	\$9,266,000
<i>Sauce/seasoning</i>	585	490	26	\$17,041,000
<i>Savory spreads</i>	28	21	1	\$729,000
<i>Snacks</i>	1,692	1,254	66	\$57,078,000
<i>Soup</i>	220	192	10	\$12,021,000
<i>Sweet spread</i>	186	162	9	\$5,636,000
<i>Sweeteners and sugars</i>	49	-		\$0
Combination Foods				
<i>Mixed Products</i>	108	86	5	\$3,945,000
<i>Main Dishes</i>	242	212	11	\$10,278,000
<i>Meals</i>	400	350	18	\$17,038,000
Plain and Plain, Carbonated Water	-			\$0
<i>Total</i>	10,361	5,553	292	\$263,762,000

Total reformulation costs are about \$264 million, or roughly \$905,000 per formula. Once a product is reformulated, the NFL and/or ingredients list would need to be updated, requiring a label change. For products choosing to reformulate instead of re-label, the labeling cost to change the NFL or ingredients list is already accounted for in the labeling costs presented above. To the extent that this type of label change is less costly because it does not require a label redesign, the labeling cost estimates are over-estimated.

Our model does not include food products that currently do not meet the “healthy” definition and would not meet the proposed definition. Manufacturers may choose to reformulate these products if the products are close to meeting the new "healthy" criteria. To the extent these products reformulate in order to bear the “healthy” claim, costs are underestimated.

Re-Branding Costs

Some brands include “healthy” or related words in their brand name, which could be considered an implied nutrient content claim based on the context in which the claim is made; i.e., when information about the nutrition content of the food is also available. If these “healthy” branded products would not qualify under the proposed definition, manufacturers may choose to reformulate the product (described above) or remove the “healthy” brand name and not reformulate. In making the decision to re-brand (i.e., remove the term “healthy” from the brand name), manufacturers would consider the brand value- the net economic benefit a manufacturer would gain by selling the brand. This decision may be considerably more difficult than the decision to re-label described above, in which removing the “healthy” claim from the label does not impact the brand name. Consumers of packaged food products may perceive branded products as better quality [Ref. 28] and thus may be willing to pay more for them over private label or store brands [Ref. 29, 30]. As brand value increases, a brand may become more profitable through “higher brand loyalty, premium pricing, lower price elasticity, lower advertising-to-sales ratios, and trade leverage” [Ref. 30], in turn increasing the expected revenue from selling the brand.

If manufacturers of “healthy” branded products that no longer qualify under the proposed criteria choose to keep the product line but rename the brand to avoid mis-branding (i.e., remove “healthy” or related terms from the brand name), the brand value may increase or decrease, depending on the consumer response to the new brand name. We are unable to provide an estimate to this potential change in revenue. We request comment and data regarding the brand value of “healthy” branded products.

In the extreme case, if the proposed definition of “healthy” leaves a “healthy” brand with no products that meet the criteria, the manufacturer may choose to leave the market and sell the brand. If no other manufacturer can use the “healthy” brand name either (without reformulation), then the resale value of the brand may be negatively affected. It is challenging to estimate brand value in general and the value of “healthy” branded products specifically. We were unable to find definitive industry evaluations or published literature that provided any estimations and invite comment on this estimate.

To the extent that selling a “healthy” brand name transfers profits from one manufacturer to another, there is no net social cost. However, if current “healthy” branded products were ultimately removed from the marketplace without new “healthy” branded products entering the marketplace, producer and consumer surplus may be reduced. We are not certain if this would occur or to what extent.

While we do not have data to estimate the potential cost of re-branding or loss of brand value, we can provide an estimate of the number of affected products. Mintel GNPD, used to estimate relabeling and reformulation costs above, do not distinguish between the term “healthy” used in the brand name and the term used elsewhere on the label. Instead, we use 2018 proprietary data from market research firm, Information Resources, Inc (IRi).²⁶ IRi Liquid Data is a comprehensive store-based scanner dataset providing UPC-level sales, product information, and brand name and

26 See <https://www.iriworldwide.com/en-US/Company/About-Us> for details.

manufacturer.²⁷ For about 40 percent of products, nutritional information and health claims are also provided. A text search for the term “health” (which encompasses “healthy” and related terms such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) within the field “Brand Name” finds 51 brands and 850 food product UPCs. IRi data does not include an indicator of the presence of a “healthy” implied nutrient content claim, nor does it include all the text provided on a food product package. Therefore, we cannot identify whether these products use the term “healthy” elsewhere on the label.

Total 2018 sales of these products were \$698 million, or 0.2 percent of total food product sales. Table 11 below shows the distribution of products from lowest to highest volume of sales per brand.

Table 11. Sales of “Healthy” Branded products, in thousands 2020\$

	Quintile of Sales per “Healthy” Brand				Total
	1 st	2 nd	3 rd	4 th & 5 th	
Number of Brands	26	12	4	9	51
Number of UPCs	183	239	88	340	850
Average Dollar Sales/Brand	\$53	\$1,267	\$4,013	\$111,942	\$54,915
Total Dollar Sales	\$833	\$5,451	\$14,811	\$676,775	\$697,345

Note: The fourth and fifth quintile are combined to avoid revealing confidential and proprietary data. Average dollar sales per brand and total dollar sales have been rounded.

As is typical within the packaged food industry, the nine top selling brands account for 97 percent of total sales, while the lowest selling 26 brands account for less than 0.12 percent of sales. We note that while we cannot identify brand value based on dollar sales alone, the data suggests that half of the “healthy” brands identified have low dollar sales and may not have a high brand value.

The top three categories with the largest number of “healthy” branded UPCs were snack and granola bars (121 UPCs), soup (65 UPCs), and dinner entrees (62 UPCs). We conducted a meta-analysis on these three categories to determine whether consumers paid more for “healthy” branded products. A price premium on “healthy” brands may suggest that “healthy” brands have a higher brand value than brands that do not use the term “healthy” within brand name. For each of the top three product categories, we use a hedonic model to determine the implicit price of including “healthy” or related terms within the brand name. This analysis uses observable differences in market prices to isolate the difference in the price per volume between “healthy” branded food products and other branded food products. We find that without controlling for any other product characteristics, “healthy” branded dinner entrees and soups are less expensive than other products [Ref. 31]. Given the distribution of sales per brand described above, it is likely that this effect is driven by the positive relationship between “healthy” branded products and total market share. Controlling for market share and other product characteristics, the analysis indicates that on average “healthy” branded dinner entrees and snack and granola bars have a higher price premium than other brands, but it is only statistically significant for snack and granola bars. The estimated price premiums for soups were consistently negative, whether controlling for market

27 IRi scanner data is comparable to AC Nielsen scanner data. Each dataset tracks scanned sales at the national and local levels and use a statistically accepted projection methodology. However, the sales numbers differ slightly due in part to differences in market geography. These differences are within the expected error range.

share and other characteristics or not. Overall, the analysis suggests that “healthy” branded products may receive a price premium over other products, but the value depends on the type of food product and the overall brand market share. We request comment regarding the potential impact of the proposed rule on the value of “healthy” brands.

Using the methods described within Labeling Costs, we estimate that about 25 percent of food products would meet the proposed criteria and thus not be impacted by the proposed rule. The remaining 75 percent of “healthy” brand food products would need to reformulate to meet the criteria or remove the “healthy” term from the brand name. Using the methods described within Reformulation Costs, we estimate that 67 food products would reformulate.²⁸ Assuming market coverage is similar between the two databases, this cost is already captured above because Mintel GNPD does not distinguish between brand name and other product labels (i.e., a search for the term “health” in Mintel GNPD would return both “healthy” brands and products using “health” elsewhere on the label). To the extent that manufacturers with “healthy” brands are more motivated to reformulate rather than remove the brand name or sell a product line, the total number of reformulations may be under-estimated.

There are three areas of uncertainty that may lead to under- or over-estimates. First, IRi Liquid Data includes food products regulated by both the FDA and USDA. Without full ingredient lists, it is not possible to completely separate the foods, so it is possible that these estimates are over-estimated because they include USDA regulated foods. Second, IRi does not provide projection factors or weights so it is not possible to calculate nationally representative estimates [Ref. 32]. The estimates presented within are likely to include the highest selling food products, but brands only available at smaller, independent stores may be missing from the sample [Ref. 32]. Thus, these estimates may be underestimated. Third, we are uncertain how many of these products are using “healthy” in the context of a nutrient content claim. However, it is possible that a manufacturer may choose to include “healthy” in the name of their product line based on another “healthy” attribute (e.g., for organic or sustainability concerns). In those cases, use of “healthy” would not be in the context of a nutrient content claim. Like the Mintel GNPD, IRi data is not nuanced enough to pick up this difference. While we found that some food products that currently include “healthy” within the brand name do not qualify as “healthy” under the current definition, we have not determined whether these products are using “healthy” in a different context than as a nutrient content claim. We assume any use of “healthy” is used as an implied nutrient content claim; therefore, the number of affected brands is over-estimated.

Recordkeeping Costs

The final type of cost manufacturers would incur are recordkeeping costs. The proposed rule requires that each manufacturer of a food that bears the implied nutrient content claim “healthy” must make and keep written records to verify that the food meets the food group equivalent requirements when it is not apparent from the label of the food. This requirement does not apply to raw, whole fruits and vegetables or to water. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. Other examples

²⁸ Due to the proprietary nature of the data and the small sample size within each category, we are unable to provide counts per category, as in the other sections.

of individual foods that would not be subject to the recordkeeping provision include dried fruit, plain yogurt, and brown rice.

We are uncertain how many UPCs this requirement would apply to, so we estimate that 50 percent of all UPCs would require this type of recordkeeping costs, with the exception of water and juice drinks. For plain and plain, carbonated water and juice drinks, based on the proposed criteria for “healthy,” we assume that none of these products would require recordkeeping. The relabeling and reformulation costs estimated above are limited to products that are currently in the market. The rule would require recordkeeping for some of these products and certain future products bearing the “healthy” claim. We expect that food products using the “healthy” implied nutrient content claim would increase by three to five percent annually after the compliance date, due to additional reformulations or new products entering the market. We estimate that each UPC would require 15 to 30 minutes of recordkeeping. This may over-estimate the total cost, since some UPCs share formulations. The average hourly earnings for employees in Food Manufacturing (NAICS 311) is \$22.23; after applying the standard wage multiplier of two, the hourly wage rate is \$44.46.²⁹ Thus, we estimate recordkeeping costs at between \$11.12 and \$22.23 per UPC.

Table 12 presents initial and annual costs estimated per product category. Initial costs are estimated for products on the market at the time of the compliance date and annual costs are estimated for new food products expected in future years.

The total recordkeeping costs in the first year after compliance are \$92,000. Annual costs in the following year are \$3,700 and continue to increase annually with the introduction of new products.

29 See “Earnings and Hours of All Employees”: <https://www.bls.gov/iag/tgs/iag311.htm#earnings>

Table 12. Total recordkeeping costs per product category, in 2020\$

Product Category	Estimated # UPCs would bear “healthy” claim	Need Record- keeping	Total Hours	Initial cost	Annual cost
Individual Foods & Beverages					
<i>Baby and young children food</i>	118	59	22	\$984	\$39
<i>Bakery</i>	582	291	109	\$4,851	\$194
<i>Breakfast cereal</i>	374	187	70	\$3,116	\$125
<i>Confectionary</i>	-	-	-	\$0	\$0
<i>Dairy</i>	882	441	165	\$7,353	\$294
<i>Dessert/ice cream</i>	82	41	15	\$682	\$27
<i>Juice drinks</i>	327	164	61	\$2,730	\$109
<i>Oil-based salad dressing</i>	27	13	5	\$224	\$9
<i>Other Beverages</i>	622	311	117	\$5,188	\$208
<i>Packaged fruit/vegetable</i>	499	249	94	\$4,159	\$166
<i>Processed fish/meat/egg</i>	985	493	185	\$8,213	\$329
<i>Sauce/seasoning</i>	740	370	139	\$6,168	\$247
<i>Savory spreads</i>	348	174	65	\$2,904	\$116
<i>Snacks</i>	3,343	1,671	627	\$27,867	\$1,115
<i>Soup</i>	61	31	11	\$510	\$20
<i>Sweet spread</i>	234	117	44	\$1,951	\$78
<i>Sweeteners and sugars</i>	-	-	-	\$0	\$0
Combination Foods					
<i>Mixed Products</i>	41	20	8	\$339	\$14
<i>Main Dishes</i>	138	69	26	\$1,153	\$46
<i>Meals</i>	272	136	51	\$2,263	\$91
Plain and Plain, Carbonated Water	1,358	679	255	\$11,319	\$453
Total	11,033	5,516	2,069	\$91,972	\$3,679

Table 13 summarizes the 20-year stream of average costs. We request comments on refining timing assumptions—for example, whether costs that are not mandated would stretch over multiple years, rather than cluster as much as shown in the table.

Table 13. 20-year stream of average costs, in 2020\$

Year	Total Labeling	Total Reformulation	Total Recordkeeping
1	\$0	\$0	\$0
2	\$0	\$0	\$0
3	\$0	\$0	\$0
4	\$46,181,048	\$263,762,000	\$91,972
5	\$0	\$0	\$3,679
6	\$0	\$0	\$3,826
7	\$0	\$0	\$3,979
8	\$0	\$0	\$4,138
9	\$0	\$0	\$4,304
10	\$0	\$0	\$4,476
11	\$0	\$0	\$4,655
12	\$0	\$0	\$4,841
13	\$0	\$0	\$5,035
14	\$0	\$0	\$5,236
15	\$0	\$0	\$5,446
16	\$0	\$0	\$5,663
17	\$0	\$0	\$5,890
18	\$0	\$0	\$6,126
19	\$0	\$0	\$6,371
20	\$0	\$0	\$6,625
Total	\$46,181,048	\$263,762,000	\$172,262

Total, undiscounted costs over 20 years are estimated at \$310 million. Although we anticipate very few products would reformulate, reformulation costs account for 85 percent of total costs. Labeling costs account for the second largest share, and recordkeeping costs are nominal, making up less than half a percent of total costs.

Present discounted values over a 20-year period are presented in Table 14. Discounted at three percent, the mean present value of costs accrued to manufacturers using the “healthy” nutrient content claim is \$276 million, with a lower bound of \$129 million and an upper bound of \$505 million. Discounted at seven percent, the mean present value of benefits of the proposed rule is \$237 million, with a lower bound of \$110 million and an upper bound of \$434 million. These costs translate into an annualized value, discounted at three percent, of about \$1,700 per UPC with a “healthy” claim. (= \$18 million/10,741 UPC).

Table 14. Present discounted values of costs over 20-years, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	\$128.5	\$275.5	\$504.9
Present value, discounted at 7%	\$110.3	\$236.6	\$433.5
Annualized value at 3%	\$8.6	\$18.5	\$33.9
Annualized value at 7%	\$10.4	\$22.3	\$40.9

G. Distributional Effects

Nutrition-related chronic diseases are experienced at disproportionately higher rates by racial and ethnic minority groups. For example, more than four in ten American adults have high blood pressure and that number increases to almost six in ten for non-Hispanic Black adults [Ref. 33]. Additionally, rates of diagnosed diabetes and heart disease are higher among American Indians and Alaskan Native populations in comparison to other racial and ethnic groups.³⁰ Research further suggests that children's obesity rates have risen during the COVID-19 pandemic and the increase has been more substantial in Hispanic, non-Hispanic Black, publicly insured, or lower-income children [Ref. 34].

As described in the benefit section, some studies suggest that label use is positively correlated with higher educational attainment and more nutrition knowledge and negatively correlated with adolescents and older adults who are obese. Given the disparities in chronic health conditions across certain subpopulations, non-Hispanic Black adults, American Indians and Alaskan Native populations, Hispanic, non-Hispanic Black children, and publicly insured or lower-income children may accrue a larger proportion of the estimated health benefits. However, to the extent that any of these subpopulations may be less inclined to use the “healthy” nutrition content claim to meaningfully change their diet compared to the population as a whole, this distributional shift may be reduced. We request comment on any differential impacts this policy may have on these subgroups.

H. International Effects

This rule would affect foreign entities that currently or would in the future use the “healthy” label as implied nutrition content claim; we are unsure what proportion of total entities are foreign. We request public comment on the effects that this rule may have on foreign entities. This proposed rule does not include additional regulatory requirements for foreign entities.

I. Uncertainty and Sensitivity Analysis

The low, mean, and high estimated net benefits are described in Table 15.

30 See the 2020 National Diabetes Statistics Report at: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf> and the Dietary Guidelines Advisory Committee Scientific Report 2020 at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKewil_tzNpYfzAhWpMVkFHdHpDaQQFnoECB8QAQ&url=https%3A%2F%2Fwww.dietaryguidelines.gov%2Fsites%2Fdefault%2Ffiles%2F2020-07%2FScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf&usg=AOvVaw2ctlxLtwCGTxBXdpjjZzkB

Table 15. Net benefits of proposed rule, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$113.7)	\$179.9	\$839.5
Present value, discounted at 7%	(\$100.9)	\$53.7	\$423.4
Annualized value at 3%	(\$7.6)	\$12.1	\$56.4
Annualized value at 7%	(\$9.5)	\$5.1	\$40.0

We account for uncertainty throughout the model and describe it in the benefits and costs sections above. The following data include ranges to account for uncertainty and variability in estimation:

- Of MyPlate users, respondents that use “healthy” claims to inform food consumption over time: zero to 0.4 percent
- Over 15-years, one-point increase in HEI score decreases all-cause mortality: zero to 0.3 percent
- Over 15-years, current users of “healthy” claim increase HEI score: zero to 1 point.
- Immediate-upon-eating lost consumer utility: zero to 60 percent
- Proportion of total marketplace covered by Mintel GNPD: 80 – 100 percent
- Include low and high costs of labeling and reformulation
- Number of products reformulated: three to 7.5 percent
- Time estimated for recordkeeping per UPC: 15 to 30 minutes
- Annual increase in UPCs needing recordkeeping: three to five percent

There are three additional areas of uncertainty in regard to estimating the number of current products using the “healthy” implied nutrient content claim. First, if the word “healthy” or a related word is used without any additional nutritional information such as implied or explicit references to nutrients (e.g., “low in fat,” “good source of Vitamin D”), it would not be considered an implied nutrient content claim. In these cases, it would not be subject to the definition of “healthy.” To the extent that we’ve included these products in our baseline and projected UPCs estimates, the costs are over-estimated.

Second, we discuss the potential response by manufacturers of products that use the term “healthy” within their brand name but cannot provide a quantitative estimate on the cost of potentially rebranding. If the relabeling or reformulation process is more costly with these types of products, our estimated costs are underestimated.

Lastly, we assume that conditional on qualifying as “healthy,” the proportion of food products that choose to label remains unchanged. For instance, 25 percent of breakfast cereals that currently qualify to use the “healthy” claim currently bear the “healthy” claim. If in the future manufacturers determine that adding a “healthy” claim to qualifying products is a cost-effective way to increase sales of a product, then the proportion of qualified food products bearing the “healthy” claim may increase. Because the “healthy” claim is a voluntary label, we are uncertain how manufacturers choose to apply the claim and whether this may change in the future.

We also consider uncertainty within the estimated VSL. In the first year benefits accrue, the mean VSL is \$12.1 million, with a low estimated value of \$5.6 million and a high estimated value of

\$18.4 million. Table 16 presents net benefits using the full range of VSL estimates. The mean value is the same as in Table 15 but the confidence interval is larger because it incorporates the uncertainty estimates outlined above with the range in values of a statistical life.

Table 16. Uncertainty analysis: net benefits with full range of VSL estimates, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$121.6)	\$179.9	\$1,541.6
Present value, discounted at 7%	(\$105.9)	\$53.7	\$871.0
Annualized value at 3%	(\$8.2)	\$12.1	\$103.6
Annualized value at 7%	(\$10.0)	\$5.1	\$82.2

Next, we examine if the model is sensitive to the assumption that benefits are accrued in 15 years instead of smoothed out over 15 years after the compliance date is reached, as shown in Table 17 below.

Table 17. Sensitivity analysis: 20-year stream of estimated benefits in millions 2020\$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Gross Benefits (millions)
2023	42,581	0	\$11.0	\$0.00
2024	42,879	0	\$11.1	\$0.00
2025	43,175	0	\$11.2	\$0.00
2026	43,467	0	\$11.4	\$0.00
2027	43,757	68	\$11.5	\$0.00
2028	44,042	68	\$11.6	\$0.00
2029	44,324	68	\$11.7	\$0.00
2030	44,600	69	\$11.9	\$0.00
2031	44,871	69	\$12.0	\$0.00
2032	45,135	70	\$12.1	\$0.00
2033	45,394	70	\$12.3	\$0.00
2034	45,647	71	\$12.4	\$0.00
2035	45,893	71	\$12.5	\$0.00
2036	46,133	71	\$12.7	\$0.00
2037	46,367	72	\$12.8	\$0.00
2038	46,594	72	\$13.0	\$0.00
2039	46,817	72	\$13.1	\$0.00
2040	47,034	73	\$13.3	\$0.00
2041	47,246	73	\$13.4	\$634.0
2042	47,454	73	\$13.5	\$4.2
		1,130		\$638.2

Total costs do not change, but total undiscounted benefits are smaller. We assume that benefits begin to accrue one year after the compliance date, or year 5. Under this assumption, benefits are only realized in years 19 and 20. Total undiscounted benefits decrease about \$21 million dollars to \$638 million. Table 18 presents the net benefits when benefits do not accrue for 15 years and

shows the model is sensitive to this assumption. The mean annualized net benefits with a three percent discount rate are \$9 million less. Mean annualized net benefits with a seven percent discount rate are \$1 million.

Table 18. Sensitivity analysis: net benefits when benefits accrue after 15 years, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$116.66)	\$88.38	\$569.34
Present value, discounted at 7%	(\$104.57)	(\$60.16)	\$87.21
Annualized value at 3%	(\$7.84)	\$5.94	\$38.27
Annualized value at 7%	(\$9.87)	(\$5.68)	\$8.23

We also estimate the net benefits of the proposed “healthy” rule if we did not include children under 18 in the analysis. As described in Section E above, we include children in our estimated population because children would also benefit from the household’s decision towards more healthful eating. However, we are uncertain whether the study results regarding the risk change for all-cause mortality for a one-point increase in HEI score are applicable to children. Therefore, we present the net benefits of the proposed rule when the affected population is limited to people over 18 years of age. Table 19 presents the net benefits of this sensitivity analysis. Mean annualized net benefits are \$6 million less (at both three and seven percent) than estimated in the main analysis.

Table 19. Sensitivity analysis: net benefits when population limited to ages 18+, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$116.53)	\$92.30	\$580.91
Present value, discounted at 7%	(\$102.69)	(\$2.23)	\$258.22
Annualized value at 3%	(\$7.83)	\$6.20	\$39.05
Annualized value at 7%	(\$9.69)	(\$0.21)	\$24.37

Lastly, we examine the model’s sensitivity to the baseline number of food products that currently qualify to use the “healthy” claim. A 2016 guidance advised food manufacturers of FDA’s intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least 10 percent of the Daily Value (DV) per RACC of potassium or vitamin D. We find that there are an additional 2,805 products that can currently qualify as healthy if the 2016 enforcement discretion is included in the baseline. The product categories with the largest changes are other beverages (+862 UPC compared to the primary analysis), snacks (+596 UPC), and processed fish/meat/egg (+547 UPC). The number of products currently labeled “healthy” and the estimated number of products that would qualify to use the proposed “healthy” claim remain unchanged. Overall, the estimated number of products that would use the proposed “healthy” claim decreases from 10,741 to 9,519. Table 20 illustrates these changes. The total mean undiscounted costs decrease by \$1.9 million to \$308 million. Present discounted values of costs over a 20-year period are presented in Table 21.

Table 20. Including 2016 enforcement discretion: number of UPCs would qualify and use proposed "healthy" claim

Product Categories	Currently qualify as "healthy"	Currently labeled as "healthy"	Would qualify as proposed "healthy"	Would label as "healthy"
Individual Foods & Beverages				
<i>Baby and young children food</i>	829	224	402	109
<i>Bakery</i>	2,042	901	1,087	480
<i>Breakfast cereal</i>	3,807	878	1,391	321
<i>Confectionary</i>	344	207	0	0
<i>Dairy</i>	3,145	730	3,564	827
<i>Dessert/ice cream</i>	1,023	246	301	72
<i>Juice drinks</i>	4,246	802	1,618	306
<i>Oil-based salad dressing</i>	6	30	26	26
<i>Other Beverages</i>	7,512	3,122	1,326	551
<i>Packaged fruit/vegetable</i>	4,628	535	4,238	490
<i>Processed fish/meat/egg</i>	1,843	532	2,362	682
<i>Sauce/seasoning</i>	2,629	651	2,857	708
<i>Savory spreads</i>	147	54	907	335
<i>Snacks</i>	2,805	1,969	3,675	2,581
<i>Soup</i>	451	226	102	51
<i>Sweet spread</i>	165	192	226	226
<i>Sweeteners and sugars</i>	9	49	0	0
Combination Foods				
<i>Mixed Products</i>	225	111	72	36
<i>Main Dishes</i>	425	255	203	122
<i>Meals</i>	933	431	523	241
Plain and Plain, Carbonated Water	0	50	1,358	1,358
Total	37,214	12,196	26,238	9,519

Table 21. Including 2016 enforcement discretion: present discounted values of costs over 20 years, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	\$127.9	\$273.8	\$501.1
Present value, discounted at 7%	\$109.8	\$235.1	\$430.3
Annualized value at 3%	\$8.6	\$18.4	\$33.7
Annualized value at 7%	\$10.4	\$22.2	\$40.6

The estimated benefits are not refined enough to pick up differences in the baseline usage of the “healthy” claim and thus, the benefit estimates remain the same. Table 22 presents the net benefits when the baseline includes 2016 enforcement discretion and shows the model is not sensitive to this assumption. Total mean net benefits are \$1.7 million dollars more than estimated in the primary analysis, shown in Table 15.

Table 22. Sensitivity analysis: net benefits when baseline includes 2016 enforcement discretion, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$113.2)	\$181.6	\$843.3
Present value, discounted at 7%	(\$100.4)	\$55.2	\$426.7
Annualized value at 3%	(\$7.6)	\$12.2	\$56.7
Annualized value at 7%	(\$9.5)	\$5.2	\$40.3

J. Analysis of Regulatory Alternatives to the Proposed Rule

Alternative 1: Codify the policy in the current enforcement discretion guidance

One alternative is to codify the policy in the current enforcement discretion. Although guidance is nonbinding, some packaged food manufacturers have taken advantage of the guidance and have already adjusted their products or product packaging (as shown in Table 20). If the current enforcement discretion was codified, it’s likely that additional manufacturers would make changes to their products or packaging, but we are unsure how many. We qualitatively discuss the potential costs to manufacturers and benefits to consumers.

Given the small scope of the enforcement discretion compared to the proposed rule, the costs to manufacturers would be significantly smaller. First, there would be no recordkeeping or reformulation costs. Second, labeling costs would decrease because manufacturers would not need to remove the “healthy” label from any products. The benefits to consumers of this policy alternative would likely be negligible because food products that currently qualify as “healthy” and do not align with federal dietary guidance would continue to be labeled as “healthy.” Therefore, we assume that this alternative would have small costs to industry and negligible benefits to consumers.

Alternative 2: Extend the compliance date by one year

Extending the anticipated proposed compliance date on the rule updating the definition by one year would reduce costs to industry as they would have more time to change products that may be affected by the rule or potentially coordinate label changes with already scheduled label changes. On the other hand, a longer compliance date runs the risk that consumers that may not understand whether a packaged food product labeled healthy follows the old definition or the updated one.

The net benefits of Alternative 2 are summarized in Table 23. Slightly lower net benefits are attributed to two sources. First, estimated health benefits to consumers are postponed one year, reducing total benefits. Second, with four years between publication and the compliance date, manufacturers can coordinate all label changes with other changes to the label. This reduces total labeling costs from \$46 million to about \$30 million.

Table 23. Alternative 2: net benefits with 1-year compliance date extension, in millions 2020\$

	Low	Mean	High
Present value, discounted at 3%	(\$103.0)	\$170.8	\$785.2
Present value, discounted at 7%	(\$87.9)	\$55.0	\$394.8
Annualized value at 3%	(\$6.9)	\$11.5	\$52.8
Annualized value at 7%	(\$8.3)	\$5.2	\$37.3

Initial Small Entity Analysis

The Regulatory Flexibility Act (5 U.S.C § 601 *et seq.*) requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a large proportion of covered entities are small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

A. Description and Number of Affected Small Entities

For the purposes of the Regulatory Flexibility Act analysis, we use the SBA’s definition of a small business as it applies to the relevant economic sectors, in this case, North American Industry Classification System (NAICS) 311 (food manufacturing), 312111 (soft drink manufacturing) and 312112 (bottled water manufacturing). SBA generally defines a small food manufacturer as one that has 500 or fewer employees. For soft drink manufacturing, the small business employee cutoff is 1,250 and for bottled water manufacturing the cutoff is 1,000.³¹ The 2012 Economic Census indicates that there are a total of 26,556 establishments within these manufacturing sectors; food manufacturing is 97 percent of total establishments.³²

Table 24 shows the breakdown of the sectors by number of employees. Of these establishments, we estimate that 87 percent of these establishments qualify as a small business.

Table 24. NAICS 311, 312111, and 312112 by number of employees

Size by Number of Employees	NAICS 311	NAICS 31211	NAICS 312112
Less than 20 employees	16,010	122	174
20 - 99 employees	4,231	48	24
100 - 499 employees	2,034	38	28
500 + employees	3,523	242	82
All Establishments	25,798	450	308

Table 25 shows that the average annual receipts per establishment varies substantially by size category. For food manufacturers in NAICS 311, average annual receipts for establishments with less than 20 employees is \$1.2 million and \$162 million for establishments with more than 500 employees. The average annual receipts per small business establishment in NAICS 311 is \$21 million.

31 See U.S. SBA’s Size Standards Table, https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

32 See “U.S., 6-digit NAICS”, “Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2012”, downloaded at <https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html>.

Table 25. Average estimated annual receipts per establishment by number of employees, in millions \$2020

Size by number of employees	NAICS 311	NAICS 31211	NAICS 312112
Less than 20 employees	\$1.2	\$3.9	\$1.5
20 - 99 employees	\$11.5	\$23.4	\$10.8
100 - 499 employees	\$50.7	\$62.8	\$31.7
500 + employees	\$162.4	\$156.4	\$53.8
All Establishments	\$28.8	\$92.9	\$18.9
Limited to Small Businesses	\$21.1	\$92.9	\$18.9

B. Description of the Potential Impacts of the Rule on Small Entities

The total discounted cost of the proposed rule per entity (including large firms) is approximately \$10,400. (\$275 million/26,556 establishments). We cannot estimate the exact cost per small entity because we do not know how many UPCs on average are owned by small entities as defined using the SBA definition. This number likely significantly overstates the cost per small entity because the share of firms which are small businesses is typically large and the share of sales controlled by small firms typically small. This is evident from Table 25. On the other hand, brands owned by small entities may have relatively low sales, and thus are not represented fully in our data. We request public comment on the cost of this rule on small entities.

We estimate that the labeling, reformulation, and recordkeeping costs incurred due to the proposed rule would cost roughly \$1,700 annually per UPC with a “healthy” claim, or less than a percent of estimated annual receipts. For instance, a food manufacturing establishment with less than 20 employees owning 10 UPCs with a “healthy” claim would incur a cost of \$17,000, or 1.4% of annual receipts. This estimated cost includes reformulation, which is not a requirement of the rule, but is a cost some manufacturers may incur to continue using the “healthy” claim on their products. For firms that choose not to reformulate, total costs per UPC may be much smaller because reformulation makes up 85 percent of total costs. This is the case for bottled water manufacturing (NAICS 312112) because it is not possible to reformulate plain still water to meet the proposed “healthy” criteria.

We discuss qualitatively, but do not quantify, the potential cost of rebranding products that include the term “healthy” in the brand name and would be considered an implied nutrient content claim but would no longer qualify to bear the claim. Rebranding may be too costly for small firms, who may choose to sell the brand name and exit the market. We are uncertain of the cost of rebranding in general or for small firms specifically, or the likelihood this may occur. For firms with products that do not currently qualify to bear the “healthy” claim but would under the proposed criteria, this rule may provide an additional way to inform consumers of the product’s healthfulness and potentially increase sales. We request comment on the impact to any affected small businesses of rebranding products that include the term “healthy” in the brand name.

C. Alternatives to Minimize the Burden on Small Entities

The first alternative considered is to codify the policy in the current enforcement discretion. This alternative would likely have very small costs to industry or any small entities and negligible benefits to consumers. The second alternative of extending the compliance date by one year reduces total costs to industry because manufacturers can coordinate all label changes with other changes. To the extent that small entities make these products, this would reduce overall costs to small entities from \$10,400 to \$9,500 per establishment (= \$253 million/26,556 establishments).

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Appendix A.

Table 26. Product Categories and Mintel GNPD Subcategories

Product Category	Mintel GNPD Subcategory
Individual Foods and Beverages	
<i>Baby food</i>	Baby Biscuits & Rusks, Baby Fruit Products, Desserts & Yogurts, Baby Juices & Drinks, Baby Savory Meals & Dishes, Baby Snacks, Growing Up Milk (4+ Years), Other Baby Food
<i>Bakery</i>	Baking Ingredients & Mixes, Bread & Bread Products, Cakes, Pastries & Sweet Goods, Savory Biscuits/Crackers, Sweet Biscuits/Cookies
<i>Breakfast cereal</i>	Cold Cereals, Hot Cereals
<i>Confectionary</i>	Chocolate Countlines, Chocolate Tablets, Individually Wrapped Chocolate Pieces, Non-Individually Wrapped Chocolate Pieces, Other Chocolate Confectionery, Seasonal Chocolate, Boiled Sweets, Gum, Licorice, Lollipops, Marshmallows, Medicated Confectioner, Mixed Assortments, Other Sugar Confection, Pastilles, Gums, & Jellies, Standard & Power Mints, Sticks, Liquids, And Sprays, Toffees, Caramels, & Nougats
<i>Dairy</i>	Butter, Cream, Creamers, Curd & Quark, Drinking Yogurt & Liquid Cultured Milk, Evaporated Milk, Flavored Milk, Fresh Cheese & Cream Cheese, Hard Cheese & Semi-Hard Cheese, Liquid Dairy Other, Margarine & Other Blends, Plant Based Drinks (Dairy Alternatives), Plant Based Spoonable Yogurts (Dairy Alternatives), Processed Cheese, Shortening & Lard, Soft Cheese & Semi-Soft Cheese, Soft Cheese Desserts, Spoonable Yogurt, Sweetened Condensed Milk, White Milk
<i>Dessert/ice cream</i>	Chilled Desserts, Dairy Based Ice Cream & Frozen Yogurt, Dessert Toppings, Frozen Desserts, Plant Based Ice Cream & Frozen Yogurt (Dairy Alternatives), Shelf-Stable Desserts, Water Based Ice Lollies, Pops & Sorbets
<i>Juice drinks</i>	Fruit/Flavored Still Drinks, Juice, Nectars
<i>Oil-based salad dressing</i>	Dressings & Seasonings Containing “Oil” In Ingredients
<i>Other Beverages</i>	Beverage Concentrates, Beverage Mixes, Meal Replacements & Other Drinks, Coffee, Malt & Other Hot Beverages, Tea, RTD (Iced) Coffee, RTD (Iced) Tea, Carbonated Soft Drinks, Energy Drinks, Flavored Water
<i>Packaged Fruit/vegetable</i>	Fruit, Vegetables
<i>Processed fish/meat/egg</i>	Eggs & Egg Products, Fish Products, Meat Products, Meat Substitutes, Poultry Products
<i>Sauce/seasoning (excluding oil-based salad dressings)</i>	Cooking Sauces, Dressings & Vinegar, Mayonnaise, Oils, Other Sauces & Seasonings, Pasta Sauces, Pickled Condiments, Seasonings, Stocks, Table Sauces

Product Category	Mintel GNPD Subcategory
Individual Foods and Beverages	
<i>Savory spreads</i>	Dips, Meat Pastes & Pates, Sandwich Fillers/Spreads, Savory Vegetable Pastes/Spreads, Yeast Extracts
<i>Snacks</i>	Bean-Based Snacks, Cassava & Other Root-Based Snacks, Corn-Based Snacks, Fruit Snacks, Hors D'oeuvres/Canapes, Meat Snacks, Nuts, Other Snacks, Popcorn, Potato Snacks, Rice Snacks, Snack Mixes, Snack/Cereal/Energy Bars, Vegetable Snacks, Wheat & Other Grain-Based Snacks
<i>Soup</i>	Dry Soup, Wet Soup
<i>Sweet spread</i>	Caramel & Cream Spreads, Chocolate Spreads, Confiture & Fruit Spreads, Honey, Nut Spreads, Syrups
<i>Sweeteners & Sugar</i>	Artificial Sweeteners, Other Natural Sweeteners, Sucrose
Combination Foods	
<i>Mixed Products (<6oz package)</i>	Instant Noodles, Instant Pasta, Instant Rice, Meal Kits, Pastry Dishes, Pizzas, Prepared Meals, Salads, Sandwiches/Wraps, Noodles, Pasta, Potato Products, Rice, Stuffing, Polenta & Other Side Dishes
<i>Main Dishes (6-9oz package)</i>	Instant Noodles, Instant Pasta, Instant Rice, Meal Kits, Pastry Dishes, Pizzas, Prepared Meals, Salads, Sandwiches/Wraps, Noodles, Pasta, Potato Products, Rice, Stuffing, Polenta & Other Side Dishes
<i>Meals (>= 10oz package)</i>	Instant Noodles, Instant Pasta, Instant Rice, Meal Kits, Pastry Dishes, Pizzas, Prepared Meals, Salads, Sandwiches/Wraps, Noodles, Pasta, Potato Products, Rice, Stuffing, Polenta & Other Side Dishes
<i>Plain and Plain, Carbonated Water</i>	Non-Carbonated Unflavored Water, Carbonated Unflavored Water