DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Nutrient Content Claims; Definition of Term "Healthy"

Docket No. FDA-2016-D-2335

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The "healthy" claim is a voluntary label 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 five percent of foods are labeled as "healthy." Updating the definition of the implied nutrient content claim "healthy" to more closely align with the nutrition science underpinning current Federal dietary guidance will better inform consumers who are selecting those products to choose a more healthful diet. This may result in lower incidence of diet-related chronic diseases, including cardiovascular disease and type 2 diabetes. Quantifiable benefits of the rule are the estimated reduction over time in all-cause mortality stemming from consumers that currently use the "healthy" implied nutrient content claim in selecting and consuming more healthful foods. Discounted at three percent over 20 years, the mean present value of benefits is estimated at $686 million, or $46 million annualized. This is calculated through the inverse association between a Healthy Eating Index score and all-cause mortality [Ref. 1]. 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 $403 million, or $27 million annualized. Potential costs of rebranding certain foods are discussed qualitatively. Net benefits are estimated at $283 million, or $19 million annualized.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule falls within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that the economic impact of this final rule will not exceed three percent of annual revenue for small businesses, we certify that this rule will not 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 estimates of anticipated impacts, before issuing "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 $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits and Costs

This final rule is consistent with the longstanding purpose of the "healthy" implied nutrient content claim, which is to help consumers identify foods that, because of their nutrient content, are particularly useful in achieving a diet that is consistent with current dietary recommendations. Some consumers use nutrient content claims, such as the "healthy" implied nutrient content claim, to inform their food purchases. Based on a 2019 meta-analysis on the effects of food labeling, we estimate that a small number of these consumers (0 to 0.4 percent of people that try to follow current Dietary Guidelines) would use the "healthy" implied nutrient content claim to make meaningful, long-lasting food purchasing decisions [Ref. 2]. If the foods using the "healthy" claim

more closely align with Federal dietary guidance, the claim can help consumers who are selecting those products in choosing a more healthful diet, which may result in lower incidence and prevalence of chronic, diet-related diseases, including cardiovascular disease and type 2 diabetes.[1] Quantifiable benefits of the final rule are the estimated reduction over time in all-cause 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. The estimated benefits account for expected uncertainty and variability in consumer use of the "healthy" nutrient content claim and its long-term health impact. Discounted at three percent over 20 years, the mean present value of benefits accrued to consumers using the "healthy" nutrient content claim is $686 million, with a lower bound estimate of $21 million and an upper bound estimate of $1.9 billion. Discounted at seven percent over 20 years, the mean present value of benefits of the proposed rule is $438 million, with a lower bound estimate of $14 million and an upper bound estimate of $1.2 billion.

Quantified costs to manufacturers associated with updating the "healthy" claim are labeling, reformulating, and recordkeeping. Overall, about 27,000 universal product codes (UPCs), or 10 percent of total UPCs, qualify for the existing "healthy" implied nutrient content claim but only 5 percent (12,500 UPCs) choose to use the claim. The use of the "healthy" nutrient content claim is voluntary, but if the final rule results in some products needing to remove the claim to avoid being misbranded, manufacturers would incur labeling costs due to the rule. In addition, manufacturers with food products currently using the "healthy" nutrient content claim would need to confirm whether the products meet the criteria for the use of the claim and decide whether a label change is needed.

Manufacturers with products that currently do not meet the original "healthy" criteria but do meet the updated criteria have the option of now using the "healthy" claim. In some cases, manufacturers may choose to reformulate a product so that it meets the updated criteria, thus incurring reformulation costs. Finally, for certain products using the updated "healthy" claim, meeting the required food group equivalents will increase time spent on recordkeeping. It is possible that manufacturers of products that include the term "healthy" within the brand name may choose to rebrand products instead of reformulating. We lack the data to quantify this effect but discuss it qualitatively. The estimated costs account for expected uncertainty and variability in industry use of the "healthy" nutrient content claim and industry response to the final rule, including potential reformulation. 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 $403 million, with a lower bound of $188 million and an upper bound of $737 million. Discounted at seven percent over 20 years, the mean present value of costs of the proposed rule is $346 million, with a lower bound of $161 million and an upper bound of $633 million.

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

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule, millions of 2023$

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$41.3	$1.29	$114.5	2023	7%	20	Monetized benefits account for consumer's lost pleasure from eating less healthy foods they may nevertheless prefer.
		$46.1	$1.44	$127.6	2023	3%	20	
	Annualized Quantified					7%		
						3%		
	Qualitative	To the extent consumers use the "healthy" nutrient content claim to achieve healthy dietary practices, following a healthy diet could reduce the risk of morbidity and prolong life.						
Costs	Annualized Monetized ($m/year)	$32.6	$15.2	$59.7	2023	7%	20	
		$27.1	$12.6	$49.6	2023	3%	20	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: None 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." Small Business: Potential impacts on small manufacturers of packaged food and beverages due to removing the "healthy" claim or reformulating some products. Wages: None							

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On September 29, 2022, we published the proposed rule "Nutrient Content Claims; Definition of Term 'Healthy'" (85 FR 59168). Accompanying the proposed rule was a preliminary regulatory impact analysis (PRIA) document on which we requested public comments.[2] We organize these comments and our responses by topic in the paragraphs below. The number assigned to each

[2] See Preliminary Regulatory Impact Analysis, downloaded here https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/nutrient-content-claims-definition-term-healthy-proposed-rule-regulatory-impact-analysis

comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

1. General

(Comment 1) One comment agrees with FDA's assessment regarding expected cost savings from the creation of a healthier food supply and increased consumption of healthier products. Citing Shangguan et al's 2021 research simulating the cost-effectiveness of a national sugar reduction initiative, the comment suggested that the methodology used by the study could inform FDA's analysis to calculate costs and benefits of the "healthy" definition revision [Ref. 3]. It concludes that the initiative could save $160.88 billion net costs from a societal perspective over a lifetime.

(Response 1) We agree that there could be expected cost savings from the creation of a healthier food supply and increased consumption of healthier products. However, we cannot follow the approach used in Shangguan et al because our analysis is limited to reformulation of a relatively small proportion of products currently bearing the "healthy" claim, not the impact of reformulating packaged food products across the entire market. Shangguan et al uses nationally representative dietary intake data from the National Health and Nutrition Examination Survey to simulate the effect of a national sugar reduction initiative on public health. The available dietary intake data does not identify food product labels, including which food products carry the "healthy" implied nutrient content claim. This was not a limitation in the study because the authors estimated the impact of reformulating packaged food products across the entire market. The comment does not describe how we could apply the Shangguan et al methodology to our costs and benefits of the "healthy" voluntary nutrient content claim definition. We are not able to use this study to inform the estimated benefits of the final rule.

(Comment 2) A couple of comments state the FDA's cost-benefit analysis was highly speculative and insufficient to meet the standards set by the Office of Information and Regulatory Affairs (OIRA), Department of Health and Human Services (HHS), and Executive Order 12866 directing agencies to assess all benefits, costs, and transfers of available regulatory alternatives.

(Response 2) We disagree that the cost-benefit analysis is insufficient to meet the standards set by OIRA HHS and Executive Order 12866. OIRA completed EO 12866 Regulatory Review of the proposed rule in September 2022, which included the proposed cost-benefit analysis.[3] OIRA and HHS provide guidance on best practices for regulatory impact analyses, but do not set requirements. As described in the Office of Management and Budget's guidance to developing regulatory analysis, Circular A-4, we have used the best available techniques to quantify the anticipated costs and benefits as accurately as possible given available data. In doing so, we account for uncertainty throughout the analysis and describe the uncertainty explicitly within the Uncertainty and Sensitivity Analysis below.

(Comment 3) Another comment further expresses skepticism regarding whether a system such as FDA is proposing is worth pursuing, given FDA's estimates on how many people will change their food purchasing decisions because of the rule.

(Response 3) We disagree that the proposed rule is not "worth pursuing." The original definition of "healthy" does not align with current Dietary Guidelines; therefore, FDA is updating the

[3] See https://www.reginfo.gov/public/do/eoDetails?rrid=207711

"healthy" implied nutrient content claim to be more reflective of current nutrition science. Even though the "healthy" implied nutrient content claim is currently used on only five percent of packaged foods, it is important that consumers using the claim to follow a healthful diet be provided with accurate information. The quantified benefits focus on the proportion of consumers that currently use the "healthy" claim to make diet-related decisions because we lack data to attribute benefits to consumers that are not explicitly looking for products using the "healthy" implied nutrient content claim. The accrued benefits stem from a shift from foods currently labeled as "healthy" that are not foundational to a healthful diet, according to current nutrition science and Federal dietary guidance, towards foods that are particularly useful in constructing a healthful diet and could be labeled as such. However, it is likely that other consumers will benefit from these shifts away from foods that are not the foundation of a healthful diet. Therefore, the benefits may be underestimated because we do not include benefits attributed to these consumers. We requested comment, but did not receive any, regarding these assumptions and our estimation of the potential benefits of the proposed rule.

2. Compliance Period

(Comment 4) A comment asserts that while FDA estimates an overall net benefit of $180 million as a result of the proposed rule, the primary cost will be to food manufacturers that must update their labeling. The comment suggests there be a period of time before the rule takes effect to allow for any updates or product reformulation necessary for a product to retain a "healthy" definition. Another comment suggests that the transition leading up to when the rule takes effect should provide sufficient time for food manufacturers to change their recipes to meet new "healthy" guidelines, reasoning that this could help companies avoid damage to their brands. Another comment requests FDA consider staggered implementation time-frames to give up to ten years to comply with the more complex and novel aspects of the new system.

(Response 4) We agree that there should be a period of time before the rule takes effect. As in the proposed rule, this final rule provides a compliance date that is three years after the effective date. The compliance 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 of compliance to industry while balancing the need for consumers to have the information in a timely manner. The comments received on this issue did not provide data to support extending the compliance date past three years, thus the compliance date for this final rule remains three years.

3. Food Prices and Equity Considerations

(Comment 5) A few comments express general concern about the impact that the rule may have on the cost of healthy food, which would impact consumers. One comment states that healthy foods are more expensive than unhealthy foods and suggested that since the rule does not reduce the cost of healthy foods, it will not lead to consumption of healthier foods. Multiple comments express concerns regarding issues such as the potential of increased costs being passed onto low-income consumers and access to affordable, healthy food. Multiple comments assert that although the proposed rule intends to advance health equity, it could alienate low-income and marginalized groups who may not be able to access or purchase healthy foods. Similarly, a comment suggests that affordable, packaged foods consumed by low-income and vulnerable populations should not be targeted as "unhealthy" simply because they are not considered "healthy" in the final rule.

(Response 5) We agree that cost is a significant driver of food purchasing behavior. However, we disagree that foods meeting the "healthy" implied nutrient content claim criteria are necessarily more expensive than foods that do not meet the criteria. Research from the USDA suggests that foods that contain less saturated fat, added sugar, and/or sodium may cost less than foods with more of these nutrients, if price is calculated per unit of edible weight or per portion, rather than per calorie [Ref. 4]. There are a variety of economical forms of foods that can qualify for the "healthy" claim, such as frozen or sliced fruits and vegetables, 100% whole grain flours, dried beans, peas, and lentils, frozen seafood, and certain nut butters. We further disagree that foods that do not qualify for the "healthy" claim are necessarily "unhealthy." As discussed extensively in the preamble to the final rule, foods that qualify for "healthy" are those foundational foods that are particularly useful in helping consumers in constructing healthy dietary patterns. This includes a wide variety of foods at different prices: vegetables; fruits; whole grains; fat-free and low-fat dairy; and lean meat, seafood, eggs, beans, peas, lentils, nuts, seeds, and soy products.

(Comment 6) Another comment recommends that FDA monitor the affordability of foods bearing the "healthy" claim going forward and examine key drivers of cost, due to concerns over reformulation costs being passed to consumers.

(Response 6) If manufacturers increase the price of some products labeled as "healthy" due to reformulation, consumers may choose other, lower priced foods instead. However, of the foods that are currently bearing the "healthy" implied nutrient content claim and would not qualify for the updated definition, we expect only about five percent of foods, less than 400 products, would reformulate. Thus, if manufacturers did pass reformulation costs on to consumers in the form of higher prices, there would still be many other food products available that would meet the "healthy" criteria and remain at their current prices. Furthermore, there are many foods that meet the "healthy" criteria and are low cost, including some frozen and canned fruits and vegetables that would not have any reason to be reformulated to meet the definition of "healthy."

(Comment 7) A comment discusses the challenges faced by consumers using "healthy" labels to make food purchasing decisions and discussed research on increasing rates of childhood obesity in Hispanic/Latino, Black, publicly insured, and lower income populations. The comment stresses the need to ensure that consumers have the information they need to choose a variety of healthy foods as part of a healthy dietary pattern aligned with the *Dietary Guidelines*. Another comment discusses health equity and the disproportionate rates of nutrition-related chronic diseases among certain racial and ethnic minority groups and people with low socioeconomic status. The comment also discussed research on racial health inequities related to sodium and potassium intake.

(Response 7) We agree that consumers should have access to information they need to have an overall healthy diet. An important aspect of health equity is equal access to information that allows people to make informed choices. Nutrient content claims such as "healthy" may help consumers, and particularly those with lower nutrition or health literacy, to quickly and easily identify foods that can be foundational for a healthy dietary pattern. Updating our nutrition-related labeling regulations to reflect current nutrition science and Federal dietary guidance plays a key role in empowering consumers with more informative and accessible labeling to choose healthier diets that align with current nutrition science and Federal dietary guidance.

(Comment 8) A couple of comments note that non-Hispanic Black and Asian children and adults consume the least amount of dairy compared to other groups and urged FDA to encourage

culturally appropriate dairy food consumption across age, race, and ethnic groups to achieve the daily recommendation and promote health equity (e.g., allowing plant-based dairy alternatives to qualify under the dairy group). Similarly, another comment urges FDA to ensure its "healthy" definition encourages the increased intake of dairy products, including for consumers like lacto-ovo vegetarians and others who need low-lactose dairy sources.

(Response 8) We agree that dairy products are under-consumed, with 90 percent of consumers not meeting the daily recommendations currently. In response to comments, the final rule set the food group equivalent level for dairy at two-third cup equivalent instead of the proposed three-quarter cup equivalent. The dairy food group includes fortified plant-based dairy alternatives with similar overall nutritional content to dairy. More nutrient-dense dairy options being able to be labeled as "healthy" may help consumers, including non-Hispanic Black and Asian children and adults, in identifying and choosing nutrient-dense dairy options that can help them meet the daily recommendation. The distributional analysis in the FRIA now includes an extended discussion on differences in diet across socioeconomic status, as well as race.

(Comment 9) Multiple comments discuss the high rates of consumption of Ready to Eat Cereal (RTEC) by low-income families and those with food insecurity, asserting that RTECs are an important part of USDA programs like the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and the National School Breakfast Program. These comments advocated for more RTEC to be able to qualify as "healthy." One comment states that consuming RTEC has significant effects on nutrient intake among low-income families, especially for calcium, vitamin D, fiber, and more.

(Response 9) The purpose of the "healthy" claim is to highlight those foods that are particularly useful in constructing a diet that conforms to current dietary guidelines. Many RTEC that are comprised primarily of refined grains instead of whole grains will not be able to meet the food group equivalent amount of whole grains and qualify for use of the "healthy" claim. Further, many RTEC will not be able to meet the added sugars limit for the "healthy" claim. However, it does not necessarily mean that foods that do not qualify for use of the claim are "unhealthy" or are unable to provide any nutritional benefits to consumers. RTEC, especially those without or with low levels of added sugars, sodium, and saturated fat, can provide numerous nutrients, such as iron or folate, to consumers. Those attributes can be communicated to consumers in many different ways, and consumers have the full range of RTEC available and accessible. Use of the "healthy" claim, though, will identify those foods which are particularly useful in helping consumers to meet the food group amounts that make up healthy dietary patterns, in line with the *Dietary Guidelines, 2020-2025*. In response to comments regarding allowing more nutrient-dense grains, including some RTEC, to qualify for the "healthy" claim, the final rule allows more flexibility for added sugars within the grains group. The preamble to the final rule discusses some legal and policy issues, distinct from these distributional analysis considerations, related to RTEC.

4. Reformulation

(Comment 10) One comment states that the proposed rule would "upend billions of dollars per year in commerce." The comment states that "about 90% of foods currently labeled as healthy would not qualify under the Proposed Rule."

(Response 10) We disagree that 90 percent of foods currently using the "healthy" claim would not qualify under the proposed rule. In the PRIA, we estimated that the number of qualifying UPCs decreased from 34,000 to 26,000 products, or from 14 to 11 percent of total UPCs. The changes to the final rule result in more products being able to bear the "healthy" claim than under the proposed rule, while still being consistent with the *Dietary Guidelines for Americans 2020-2025*. We find that in some food categories, such as confectionary products, cereals, and beverages, a large proportion of foods currently labeled as "healthy" would not qualify, while in other food categories, such as processed fish/meat, packaged fruits and vegetables, and savory spreads, more foods qualify than before. The comment did not provide data to support their statements, thus we decline to adjust our estimates.

(Comment 11) One comment discusses measures needed to meet the new "healthy" criteria and cites consumer studies that suggest that such reformulation would reduce consumer appeal and lead to lower sales. Another comment expresses similar concern regarding the strictness of the rule's criteria, reasoning that it would not encourage food manufacturers to innovate and make healthier products. One comment states that the proposed "healthy" criteria would result in only 5 percent of a healthy brand line of products qualifying for the "healthy" definition and that the degree of reformulation required to comply would alter foods to such a degree that customers would no longer buy them. The comment further suggests that extensive reformulation could ultimately lead to fewer healthy convenient options for consumers.

(Response 11) In response to comments, the final rule has changed some of the proposed criteria resulting in more nutrient-dense products that are encouraged by the *Dietary Guidelines for Americans, 2020-2025* qualifying to bear the claim. The criteria in the final rule provide more flexibility while still being consistent with current nutrition science and Federal dietary guidance. For example, the final rule provides additional flexibility in the minimum amounts of food group equivalents for components of combination foods, allows vegetable and fruit powders to be considered in the calculation of the vegetable and fruit food group equivalents (FGE), and provides more flexibility for some of the nutrients to limit criteria. We believe the criteria in the final rule will help provide more flexibility to reformulate and still meet the new criteria for "healthy." To the extent that this is not accurate, manufacturers may choose to remove the "healthy" nutrient content claim instead of reformulating. The comment did not provide data to estimate the rate or magnitude with which this may occur. Without evidentiary basis, we could not revise our estimates in this FRIA.

5. Other

(Comment 12) One comment states that FDA has provided no quantified data related to the cost of rebranding or changing company names in its economic analysis. The comment suggests that costs associated with this issue could significantly raise costs for businesses and requested that FDA address this issue and provide guidance and examples of when "healthy" and related terms in a company or brand name would count as creating a nutritional context or exempt company and brand names from the "healthy" definition altogether.

(Response 12) The PRIA includes a qualitative discussion of rebranding but lacked data to incorporate the cost of rebranding into the primary cost analysis. We did not receive additional data in comments to the PRIA to quantify the cost of rebranding. We decline to automatically exempt brand names that use the term "healthy" from being subject to the "healthy" criteria

altogether; they will be evaluated on a case-by-case basis. The preamble to the final rule discusses some legal and policy issues, distinct from these economic considerations, related to the use of "healthy" in company and brand names.

(Comment 13) A number of comments raise concerns that the added sugars limit of zero grams for the fruit group would prevent tart fruit products, and in particular cranberries and tart cherries, from bearing the "healthy" claim. Many comments discussed the importance of tart cherries to family farms and suggested that the proposed rule's added sugars provision could cause domestic tart cherry farmers to lose up to 50 percent of their sales, leading to the potential elimination of up to 4,000 acres of family farms.

(Response 13) In recognition that cranberry and tart cherry products, because of their nutrient composition, are foundational to a healthy dietary pattern and that their total sugar content is no greater than comparable fruit products, the final rule states the intent to exercise enforcement discretion for cranberry and tart cherry products that meet fruit FGE criteria and meet the nutrient limits for sodium and saturated fat, but contain added sugars for palatability in an amount that is no greater than the amount of total sugars in comparable products with inherent sugars, but no added sugars (e.g., unsweetened raisins, 100% grape juice). We have no reason to believe this final rule will impact cranberry and tart cherry sales volume. The preamble to the final rule discusses some legal and policy issues, distinct from these economic considerations, related to naturally tart fruits.

(Comment 14) One comment suggests that FDA set a compliance date for small businesses that is two years after the proposed compliance date and use that period to educate small businesses on the rule and associated compliance issues, arguing that small businesses are at a disadvantage compared to large companies. One comment asserts the proposed rule would benefit large consumer packaged goods companies that have the financial means to accommodate relabeling of their products, thus placing small businesses at a competitive disadvantage. The comment states the rule would have disproportionate impacts on small businesses and requests accommodations for small operators relating to compliance and the provision of education resources.

(Response 14) We estimate that at least 97 percent of food manufacturers are considered small entities. Due to the limitations in our data, we are unable to break our cost estimates down according to those associated only with small businesses. Given that the "healthy" claim is voluntary and we have provided a compliance date that is three years after the effective date, we believe there is enough flexibility built into the rule for all manufacturers to be able to meet the compliance date rather than adopting special extensions or rules for small entities.

(Comment 15) One comment asserts that the regulatory impact analysis ignored the cost of hiring professionals for renewed compliance analysis and estimates that the proposed rule would cost between 20 and 40 billable hours from legal professionals, resulting in a "$38 to $77 million handout to the legal profession."

(Response 15) We disagree with the assertion that we ignored the cost of renewed compliance analysis. The final 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. Examples of

records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records.

The FRIA includes recordkeeping costs in three ways. We explicitly estimate the additional costs of recordkeeping associated with the requirements of this final rule will be about $20 per UPC. In addition, both the labeling cost model and the reformulation cost model include administrative and managerial costs associated with each task. Specifically, the reformulation cost model includes labor costs to determine the response to a regulation (i.e., determine business and technical goals and objectives given a reformulation requirement and marketing, cost, and regulatory constraints), project management (i.e., manage and coordinate the development phase across the manufacturing, packaging, engineering and plant maintenance, purchasing, legal, marketing, warehousing and distribution, and quality control departments), and recordkeeping (i.e., updating the formula management system, process flow sheet, ingredient specifications, results of consumer tests, and label information). For each reformulation, estimated labor hours for these tasks are 112 hours for small companies, 3,876 hours for medium companies, and 9,708 hours for large companies on average. The labeling cost model includes an average of 26 hours of administrative and recordkeeping labor costs.

Like all costs estimated in these models, these recordkeeping costs are derived from discussions with manufacturers [Ref. 5, 6]. Furthermore, the final rule expands the exemption for raw, whole fruits and vegetables to include individual foods or mixed products that are comprised of one or more of the nutrient-dense foods encouraged by the Dietary Guidelines (for adults and children 2 years of age and older), with no other added ingredients except for water: vegetables; fruits; whole grains; fat-free and low-fat dairy; and lean game meat, seafood, eggs, beans, peas, lentils, nuts, and seeds. (§ 101.65(d)(3)(i)). These products will automatically qualify and therefore will not require additional written records to verify that the food meets the food group equivalent requirements. There is no requirement for renewed legal compliance analysis and the comment did not provide details as to how they estimated the 20 to 40 billable hours by legal professionals. We decline to include additional costs in the final regulatory impact analysis.

D. Summary of Changes

We have made edits to the analysis based on changes applied to the final rulemaking. Estimates in the economic analysis have been changed in accordance with changes to the final rule. These include: increased flexibility in the food group equivalent requirements, increased flexibility in the saturated fat, sodium, and added sugar criteria, expansion of the exemption for raw, whole fruits and vegetables, inclusion of a small reference amount customarily consumed (RACC) exemption, and increased flexibility and simplification of the combination products criteria. We have also updated data sources to reflect the most recent data available. This includes using the National Health and Nutrition Examination Study 2017-2020, updated U.S. Census population projections, and employment and receipts by North American Industry Classification System codes. We have updated the underlying packaged food data from 2018 to 2023 Mintel data, which now includes label information for added sugars. Given that our new data is pulled seven years after the 2016 enforcement discretion policy described in detail below, our baseline estimates now include the current market that includes the labeling of products affected by the 2016 enforcement discretion policy. In response to comments, we have extended the distributional effects section to discuss nutritional disparities across subpopulations. Finally, we have updated all dollars and wages to 2023 values and corrected some minor calculation errors.

II. Final Economic Analysis of Impacts

A. Background

FDA is updating the implied nutrient content claim "healthy" to make it more consistent with current nutrition science and Federal dietary guidance, including the Nutrition Facts Label (NFL) and the *Dietary Guidelines, 2020-2025*.[4] 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 half of all foods that meet the original 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."

More recent 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 final rule. The existing "healthy" definition is also inherently linked to the serving size information because the requirements are defined per RACC, which are used to determine serving size. The 2016 final rule for serving size information updated or modified several existing RACCs and established others. A change in a RACC (e.g., from four ounces to six ounces) may impact a product's ability to qualify for "healthy" because it may not meet all of the criteria (e.g., limits for saturated fat, sodium, or added sugars) based on the updated serving size. For example, imagine a packaged food with a four-ounce serving size that contained 230 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 345 milligrams of sodium per serving.

While all foods can be incorporated into a healthy dietary pattern, current nutrition science and Federal dietary guidance emphasize nutrient-dense foods across different foods groups, which can serve as foundations of such patterns. The final criteria for "healthy" move from requirements based solely on individual nutrients to also include requirements based on food groups and their subgroups which make up 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 final rules, the final criteria generally reduce the maximum allowable amount of sodium and limit the maximum allowable amount of added sugars, compared to the original "healthy" definition. The final criteria also eliminate the current limitation on total fat because the

[4] See *Dietary Guidelines for Americans 2020-2025*, downloaded here https://www.dietaryguidelines.gov/

focus of current nutrition science and dietary fat recommendations has moved away from limiting total fat intake to replacing intakes of saturated fats with mono- and polyunsaturated fats. The updated definition of "healthy" largely maintains the original limits on saturated fat and also eliminates the cholesterol criteria because dietary cholesterol is present in animal-source foods that are commonly also sources of saturated fat.[5] Since most foods that will meet the final criteria of "healthy" are low in saturated fat, dietary cholesterol will already be sufficiently limited by the saturated fat limits for "healthy."

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.[6] 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 final rule aims to align the "healthy" claim with current nutrition science and Federal dietary guidance to help consumers identify foods that can be a foundation for healthy dietary patterns. 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 foundational to a healthy dietary pattern.

While all food products can be incorporated into a healthy dietary pattern in moderation, about ten percent meet the current "healthy" criteria and only five percent use the voluntary "healthy" claim.[7] FDA anticipates that the updated criteria for "healthy" could result in industry innovation towards healthier food choices as recommended by the *Dietary Guidelines, 2020-2025*, thereby potentially expanding the availability of healthier options in the marketplace.

A variety of interested parties, 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 2016.[8] 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.

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

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[5] See the 2020 Dietary Guidelines Advisory Committee Report at: https://www.dietaryguidelines.gov/2020-advisory-committee-report

[6] See the *Dietary Guidelines, 2020-2025*, https://www.dietaryguidelines.gov/.

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

[8] 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

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. In addition to the public comments received on the proposed rule, FDA incorporated comments received from the public meeting into updating the criteria for "healthy" in this regulation.

B. Potential Need for Federal Regulatory Action

As described above, some food products that meet the original "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 with a compliance date of 2021. In addition, some food products that are encouraged in Federal dietary recommendations as 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" criteria as they exist in the 1994 regulation but are not supported by current nutrition science or Federal dietary guidance or related to information on the current NFL. The final 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 Rule

The original 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 1994 regulation, these conditions include specific criteria for individual 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)).

This final rule updates the requirements for when the term "healthy" can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet that is consistent with dietary recommendations. Under §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 final § 101.65(d)(3)(i)-(vi). Foods that may bear the nutrient content claim "healthy" under the updated criteria are broken out into several categories: (1) single-ingredient nutrient-dense foods without added ingredients besides water; (2) individual food products; (3) combination foods, which encompasses mixed products, main dish products, and meal products; and (4) water, tea, and coffee with less than 5 calories per RACC. 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.[9] Single-ingredient nutrient-dense foods and water, tea, and coffee with less than 5 calories automatically qualify for the updated "healthy" claim. For individual food products and combination foods, the final rule requires a certain amount of at least one of the recommended food groups, with the exception of oils. The updated definition also sets baseline values for each nutrient to limit, but adjusts the values based on the different food groups and/or subcategories of food groups as warranted. The 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 definition of "healthy" also eliminates the cholesterol criteria because it is sufficiently limited by the limits for saturated fat.

This final rule codifies the complete list of derivatives for "healthy" to make clear that other terms not otherwise codified will not be considered derivatives of the "healthy" implied nutrient content claim under § 101.65(d). These derivatives of "healthy" are "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness." This final rule also revises the codified text in § 101.65(d)(1) to no longer require that the accompanying material be a "claim or statement about a *nutrient;*" instead it requires that it be "information about the *nutrition content of the food.*" This change would not limit the accompanying material on the labeling to phrases declaring presence/level of a specific nutrient (as in the "healthy, contains three grams of fat" example above), but include any material stating or implying that the nutrient content of the food would be helpful to consumers in structuring a diet that conforms to current dietary recommendations.

As with most other nutrient content claims, the 1994 definition for the nutrient content claim "healthy" did not include provisions for foods intended specifically for use by infants and children less than two years of age. The updated criteria for "healthy" continue to limit the use of the claim to foods directed to children and adults two years of age and older.

The compliance date is set 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 products using the "healthy" claim no longer comply and to adopt the claim for use on newly eligible products 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.

[9] 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* does not refer to oils as a "food group," but emphasizes 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 final rule.

D. Baseline Conditions

1. 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").[10] 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 original 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 well as the levels of the additional nutrients to get enough of, as defined in the regulation authorizing use of the claim.

We used Mintel Global New Products Database (GNPD) to evaluate the current trends in packaged foods bearing the "healthy" implied nutrient content claim.[11] We chose to use Mintel GNPD because it includes food products more recently on the shelves (as of September 2023) 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 260,000 branded and private label UPCs representing roughly 90 percent of the total packaged foods available in the marketplace. We restricted our dataset to include only products with available saturated fat, sodium, and added sugar nutrition information because we use these variables to calculate the number of products that meet the final criteria. We adjusted the total UPC count up to account for the products that are missing information.

Using information from the NFL for each product, we estimated the percent of packaged food products that qualify as "healthy" as defined in §101.65 (under the original definition) and described above. For instance, for a box of cereal to qualify as "healthy," it must meet the following criteria:[12]

1) No more than three grams of total fat per RACC and
2) No more than one gram of saturated fat per RACC and

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[10] See FDA's *Guidance for Industry: Food Labeling Guide*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

[11] See Mintel Global New Products Database (GNPD), http://www.mintel.com/global-new-products-database, downloaded on May 2023.

[12] 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 and "Appendix B. FDA Regulatory Requirements for Nutrient Content Claims" in *Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report*, https://www.ncbi.nlm.nih.gov/books/NBK209851/.

3) No more than 480 milligrams of sodium per RACC and
4) No more than 60 milligrams of cholesterol 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 used SAS 9.3 and R to analyze all data.

As described in section A above, FDA published a guidance in 2016 advising 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. Without enforcement discretion, fewer food products would qualify to use the term "healthy: the product categories most impacted by the enforcement discretion are other beverages, snacks, and processed fish/meat/eggs.[13] 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[14] [Ref. 5]. Since our data is pulled seven years after 2016, we include products that would be covered by our enforcement discretion policy in our baseline.

Table 2 shows the number of UPCs in 18 individual foods and beverages categories, mixed products, main dishes, and meals. 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 27,000 UPCs, or 10 percent of total UPCs, qualify for the "healthy" implied nutrient content claim, but only 5 percent (12,500 UPCs) choose to use the "healthy" label claim. This percentage varies across categories in predictable ways. About four percent of confectionary food products, including candy and sweets, currently qualify as "healthy," while more than half of food and juice drinks marketed specifically for babies and young children qualify. The other beverages category contains about 3,000 UPCs labeled "healthy," or about eight percent of the category. Oil-based salad dressing and savory spreads contain the fewest UPCs labeled "healthy" (41 and 13 UPC, respectively). There are nine categories that contain more foods labeled "healthy" than qualify: oil-based salad dressing, sauce/seasoning, snacks, soup, sweet spread, sweeteners and sugars, main dishes, meals, and plain and plain, carbonated water. 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. For instance, use of the phrase "heart healthy" would not necessarily be a nutrient content claim, but rather could be just an implied health claim for risk of heart disease. The methodology used would not pick up these nuances. Second, coding errors in

[13] For discussion of regulatory effects as compared with a second baseline—reflecting hypothetical continuation of the 2016 enforcement discretion policy—please see the Baseline and Uncertainty sections of the proposed rule's preliminary regulatory impact analysis, available at https://www.fda.gov/media/161850/download?attachment.

[14] For more information, see the Labeling Costs section on page 28.

Mintel GNPD are possible. Lastly, it is possible that products are mislabeled as "healthy" without qualifying as "healthy." The numbers in Table 2 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			
Baby and young children food	1,636	792	118
Bakery	36,594	1,879	728
Breakfast cereal	7,369	2,587	1,347
Confectionary	19,936	810	140
Dairy	18,882	1,992	611
Dessert/ice cream	12,045	452	144
Juice drinks	7,574	3,766	559
Oil-based salad dressing	2,037	2	41
Other Beverages	27,281	5,597	2,200
Packaged fruit/vegetable	9,371	3,176	350
Processed fish/meat/egg	20,216	1,470	526
Sauce/seasoning	27,993	314	529
Savory spreads	3,379	19	13
Snacks	34,246	1,015	2,012
Soup	4,460	167	197
Sweet spread	5,330	81	377
Sweeteners and sugars	1,204	10	53
Combination Foods			
Mixed Products	5,328	1,123	791
Main Dishes	5,885	548	563
Meals	16,166	995	1,143
Plain and Plain, Carbonated Water	1,487	0	93
Total	268,419	26,793	12,537

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

2. 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 diet quality and physical activity patterns [Ref. 7]. About half of all American adults have one or more preventable, diet-related chronic diseases, including cardiovascular disease and type 2 diabetes.[15] The Healthy Eating Index is a measure of diet quality measuring a consumer's conformity to the Dietary Guidelines. The HEI-2020 is the most current version of the HEI and

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

aligns with the *Dietary Guidelines for Americans, 2020-2025* edition. The total HEI-2020 score for ages 2 and older is 58 out of 100, suggesting room for improved food choices.[16]

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. 8, 9].

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.[17] 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 few 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 healthier diets [Ref. 10]. 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 privately developed front-of-package label used by the food industry to signify nutritious food products.[18] One study finds that GSP increased the demand for ready-to-eat cereals considered more nutritious [Ref. 11], providing evidence that consumers use food labels and labeling to identify and ultimately purchase healthier foods. However, there is also evidence that label use varies across subgroups: consumers with higher education levels and more nutrition knowledge use nutrition

[16] See https://www.fns.usda.gov/healthy-eating-index-hei for more information.

[17] 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.

[18] See https://guidingstars.com/ for more information.

labels more often [Ref. 12, 13], while adolescents and older adults who are obese use nutrition labels less frequently [Ref. 10].

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 FOP labeling is marketing that is meant to influence them and is not necessarily true [Ref. 14]. When asked specifically about the "healthy" claim, it seemed that many considered the presence of any FOP claim, including food label graphics and even product placement, to convey that the product is being marketed as "healthy." In a nationwide survey conducted in 2018, respondents were asked questions about their perceptions of "healthy" foods [Ref. 15]. About half of consumers felt that only "one's overall diet" could be considered healthy, not an individual food.

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. 16, 17]. However, some studies suggest 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. 18]. Other studies have found similar "health halos" present for foods labeled "low calorie" and "good source of protein" [Ref. 19, 20]. While there are no studies evaluating the presence of a "health halo" around food products labeled "healthy," a 2018 survey suggests that for some respondents, the "healthy" claim implies they can eat an unlimited amount of foods bearing the claim [Ref. 15].

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. 2]. 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 to healthier 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-income levels [Ref. 21].[19] 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

[19] The literature reviewed in this paragraph did not attempt to determine causation.

all-cause mortality, 15 percent reduction in CVD mortality, and 24 percent reduction in cancer mortality rates [Ref. 1]. A 2017 meta-analysis found results of similar magnitude for reduced risk of all-cause mortality over 15 or 20 years [Ref. 22].

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 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. 9, 14, 15]. We lack data on the precise magnitude of the relationship between use of the "healthy" claim and increased diet quality.

E. Benefits of the 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 original 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 based on the original definition of "healthy." Now say, for this example, the granola bar has high added sugars 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. With the updated definition, 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, as identified by current nutrition science and Federal dietary guidelines. Manufacturers may also choose to reformulate food products in order to use "healthy" as an implied nutrient content claim, so consumers may have more "healthy" options available to choose from that are in line with current nutrition science and Federal dietary guidelines.

Benefits of the final rule are estimated through the monetized valuation of the reduction in chronic, diet-related disease. 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 final rule may affect their decisions.

We use NHANES 2017-20 to estimate the affected population. NHANES does not ask respondents about the "healthy" claim specifically, but about eight percent of respondents said they had "tried to follow the recommendations in the MyPlate plan."[20] 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

[20] NHANES 2017-20 calculations are by the author, using weights to estimate sample means.

grains, low-fat dairy, lean protein, and oils.[21] 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 [Ref. 23]. 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, respectively. We use this as 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. Note we do not expect this rule will have zero impact on public health. We use zero as an absolute minimum to capture the entire range of uncertainty and to allow for the possibility of even a very small effect. We use 0.4 percent as an upper bound because we are uncertain that Shangguan's results can be applied directly to the "healthy" claim. It is possible that each of these assumptions under- or over- estimates the total monetized benefits of the "healthy" claim.

Using population estimates from US Census,[22] we estimate the total population to be around 340 million when the final compliance date occurs and benefits begin to accrue (roughly 2027). We limit the population to those two and older because the 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 2017-2020 NHANES estimates that less than half a percent of primary shoppers stated that they rarely or never check the food label when deciding to buy a food product because they cannot read English that well. Using the 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 56,000 people on average (≈ 340 million*0.08*0.002*0.997).

[21] 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.

[22] 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

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. 1, 22]. In one study, Reedy et al. [Ref. 1] 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. 24]. 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. 22]. 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 requested, but did not receive, 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 0.15 percent on average.[23] 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., 0.3 percent, as an upper bound because we are uncertain that Reedy et al.'s results can be applied directly to the "healthy" claim. It is possible that this assumption underestimates the total monetized benefits of the "healthy" claim.

Multiplying the affected population of about 56,000 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 3 and 246, with a mean estimate of 87 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. Note we do not expect this rule will have zero impact on public health. We use zero as an absolute minimum to capture the entire range of uncertainty and to allow for the possibility of even a very small effect.

[23] We requested comment that would allow for refinement of the estimation approach, including potential revision of the one-point HEI score increase to more closely capture the effects of this "Healthy" definition change. However, no public comment or newly-available evidence has allowed for such refinement.

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 are particularly useful for building healthy dietary patterns, consistent with current nutrition science and Federal dietary guidance, and could be labeled as such. This approach is not refined enough to map into specific changes in all-cause morbidity and mortality.

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.[24] 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 2023$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Gross Benefits (millions)
2024	55,230	0	$13.1	$0.0
2025	55,604	0	$13.2	$0.0
2026	55,975	0	$13.4	$0.0
2027	56,340	0	$13.5	$0.0
2028	56,700	88	$13.6	$78.6
2029	57,053	88	$13.8	$79.9
2030	57,399	89	$13.9	$81.2
2031	57,738	89	$14.0	$82.6
2032	58,069	90	$14.2	$83.9
2033	58,392	90	$14.3	$85.2
2034	58,707	91	$14.5	$86.6
2035	59,014	91	$14.6	$87.9
2036	59,313	92	$14.8	$89.3
2037	59,605	92	$14.9	$90.6
2038	59,889	93	$15.1	$92.0
2039	60,167	93	$15.2	$93.4
2040	60,439	93	$15.4	$94.8
2041	60,705	94	$15.5	$96.2
2042	60,966	94	$15.7	$97.6
2043	61,223	95	$15.8	$99.0
Total		1,461		$1,418.7

[24] See Department of Health and Human Services Standard Values for Regulatory Analysis, downloaded here https://aspe.hhs.gov/reports/standard-ria-values.

As described above, we estimate the benefits of the final 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 updated definition of the "healthy" 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.[25]

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 internalities (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].[26] 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" with amounts of added sugars that would need to be reduced to continue qualifying for the "healthy" 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,

[25] 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

[26] 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 may be substantially different, especially as regards nutritional knowledge and self-control. 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 Allcott et al. (2019) and Kalamov and Runkel (2021) studies.

this final rule removes the current limit on total fat and cholesterol, allowing the use of eggs and healthy oils, for example, that may provide consumers more, rather than less, utility from their foods. Furthermore, the requirement for half a cup of fruits, vegetables, or dairy per serving, for example, may provide consumers with reformulated products that they prefer to the food products that previously qualified for the "healthy" claim.

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. (The rule limits the use of some "preferred" ingredients, e.g., refined grains, added sugar, and salt, in foods labeled "healthy" 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.) 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 2023$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Benefits, Accounting for Lost Immediate-Upon-Eating Consumer Utility (millions)
2024	55,230	0	$13.1	$0.0
2025	55,604	0	$13.2	$0.0
2026	55,975	0	$13.4	$0.0
2027	56,340	0	$13.5	$0.0
2028	56,700	88	$13.6	$55.0
2029	57,053	88	$13.8	$55.9
2030	57,399	89	$13.9	$56.9
2031	57,738	89	$14.0	$57.8
2032	58,069	90	$14.2	$58.7
2033	58,392	90	$14.3	$59.7
2034	58,707	91	$14.5	$60.6
2035	59,014	91	$14.6	$61.5
2036	59,313	92	$14.8	$62.5
2037	59,605	92	$14.9	$63.5
2038	59,889	93	$15.1	$64.4
2039	60,167	93	$15.2	$65.4
2040	60,439	93	$15.4	$66.3
2041	60,705	94	$15.5	$67.3
2042	60,966	94	$15.7	$68.3
2043	61,223	95	$15.8	$69.3
Total		1,461		$993.1

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[27] (see the Uncertainty and Sensitivity Analysis for a full discussion of parameters incorporated into the simulation). 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 $686 million, with a lower bound of $21 million and an upper bound of $1.9 billion. Discounted at seven percent, the mean present value of benefits of the final rule is $438 million, with a lower bound estimate of $14 million and an upper bound estimate of $1.2 billion.

Table 5. Present discounted values of benefits over 20-years, accounting for lost immediate-upon-eating consumer utility, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	$21.4	$686.1	$1,898.1
Present value, discounted at 7%	$13.7	$437.7	$1,212.8
Annualized value at 3%	$1.4	$46.1	$127.6
Annualized value at 7%	$1.3	$41.3	$114.5

3. 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 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 of this occurrence, this final 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.

In addition to reducing the risk of all-cause mortality, following a healthy dietary pattern 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. 7, 26, 27, 28]. 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 final rule on reduced morbidity. These effects are not captured within the benefit stream estimated above.

F. Costs of the Rule

Costs of the final rule are incurred by the food manufacturers that may be affected by the final rule. The three main quantifiable costs of the final rule are labeling, reformulating, and

[27] For more information on @Risk 7.5 software, see https://www.palisade.com/risk/default.asp

recordkeeping. The "healthy" nutrient content claim is voluntary, but if the final 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 final updated criteria and decide whether a label change is needed. Manufacturers with products that currently do not meet the "healthy" criteria but do meet the final updated criteria have the option of labeling these products. Also, in some cases, manufacturers may choose to reformulate a product so that it meets the updated criteria. Lastly, some recordkeeping is required for certain products using the "healthy" claim, therefore the required food components equivalents are likely to increase time spent on recordkeeping. Manufacturers using the "healthy" implied nutrient content claim 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 manufacturers to meet other labeling requirements.

In addition, we qualitatively discuss the potential costs to manufacturers of rebranding "healthy" branded products that no longer qualify under the final updated 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 other information on the label or labeling puts the term into a nutritional context. If these "healthy" branded products would not qualify under the final 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 rebranding.

The final rule covers single-ingredient nutrient-dense foods including raw, whole fruits and vegetables, individual products, combination foods and plain water and select beverages with fewer than five calories. 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.

1. Labeling Costs

In order to comply with the final rule, some manufacturers using the "healthy" claim would need to remove the claim. Other manufacturers may voluntarily choose to add the "healthy" claim to foods that meet the final criteria. We estimate the number of products that would need to remove the "healthy" claim and the number of products that may voluntarily choose to add the "healthy" claim using Mintel GNPD. Relabeling costs were estimated using FDA's Labeling Cost Model [Ref. 5]. 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. 5].

Labeling costs, which include labor, materials, inventory (discarded inventory and disposal costs), recordkeeping,[28] and, in certain cases, recurring costs associated with package size increases, are

[28] The labeling model includes administrative and recordkeeping costs associated with

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. 5]. 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 periods between the effective date and the compliance date 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. 5]. Manufacturers of food products that currently do not qualify as "healthy" but would qualify under the final 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 requires multiple color changes and label redesign" such as "modifying the front of a package" [Ref. 5].

We use Mintel GNPD to estimate the total number of UPCs that would qualify for the final updated criteria. Information for the nutrients to limit, saturated fat, sodium, and added sugars, are readily available on the NFL and were captured in about half of Mintel GNPD products. The NFL and ingredients list does not specify the exact amount of each food group or food groups 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 final updated 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 the food group equivalent criteria (i.e., the proportion of products that do not include enough of a food group or food groups to meet the food group equivalent requirements) [Ref. 29].

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.

Table 6. Average labeling costs per UPC, in 2023$

Product Category	Mean Costs / Uncoordinated UPC	Mean Costs / Coordinated UPC	Percent uncoordinated UPC
Individual Foods & Beverages			
Baby and young children food	$11,021	$1,708	11%
Bakery	$13,242	$1,954	21%
Breakfast cereal	$13,619	$2,228	25%
Confectionary	$13,909	$1,957	22%
Dairy	$11,966	$1,741	20%
Dessert/ice cream	$13,909	$1,957	22%
Juice drinks	$13,738	$1,855	17%
Oil-based salad dressing	$11,373	$1,708	14%
Other Beverages	$13,738	$1,855	17%
Packaged fruit/vegetable	$12,392	$1,858	20%
Processed fish/meat/egg	$11,587	$1,708	15%
Sauce/seasoning	$11,373	$1,708	14%
Savory spreads	$11,435	$1,753	15%
Snacks	$13,871	$1,875	11%
Soup	$11,095	$1,708	20%
Sweet spread	$11,435	$1,753	15%
Sweeteners and sugars	$17,347	$2,560	21%
Combination Foods			
Mixed Products	$12,433	$1,791	14%
Main Dishes	$10,645	$1,708	15%
Meals	$10,645	$1,708	15%
Plain and Plain, Carbonated Water	$13,738	$1,855	17%
Average	$12,596	$1,855	17%

Table 7 presents the estimated number of UPCs in the current marketplace that would qualify for and use the "healthy" claim. We estimate that the number of total qualifying UPCs remains roughly the same, increasing by 1,800 UPC, but the distribution of qualifying UPCs changes across product categories (see Table 2 for the percent of UPCs that currently qualify).

We assume that conditional on qualifying as "healthy," the proportion of food products within each category that choose to label remains unchanged. For instance, 30 percent of dairy products that currently qualify to use the "healthy" claim under the original definition currently bear the "healthy" claim. Thus, we assume that of the 2,194 dairy products that qualify to use the updated "healthy" claim, 30 percent, or 673 products, will label as "healthy."

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

Product Categories	Total UPCs	Would qualify as final "healthy"	Would label as "healthy"
Individual Foods & Beverages			
Baby and young children food	1,636	917	137
Bakery	36,594	2,083	808
Breakfast cereal	7,369	576	300
Confectionary	19,936	-	-
Dairy	18,882	2,194	673
Dessert/ice cream	12,045	40	13
Juice drinks	7,574	2,595	385
Oil-based salad dressing	2,037	58	58
Other Beverages	27,281	624	245
Packaged fruit/vegetable	9,371	4,936	544
Processed fish/meat/egg	20,216	7,983	2,856
Sauce/seasoning	27,993	874	874
Savory spreads	3,379	911	607
Snacks	34,246	1,882	1,882
Soup	4,460	31	31
Sweet spread	5,330	318	318
Sweeteners and sugars	1,204	-	-
Combination Foods			
Mixed Products	5,328	522	368
Main Dishes	5,885	890	890
Meals	16,166	450	450
Plain and Plain, Carbonated Water	1,487	743	743
Total	268,419	28,629	12,184

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

The total number of products that use the "healthy" claim remains roughly the same, 12,184 or 4.5 percent of total UPCs. Two categories, confectionary and sweeteners and sugars, have zero qualifying products. Other beverages, breakfast cereals, and juice drinks see the largest decline in terms of the number of UPCs that would qualify for the "healthy" claim: other beverages lose almost 5,000 UPCs, breakfast cereals lose 2,000 UPCs and juice drinks lose about 1,000 UPCs. In a majority of categories, the number of UPCs that qualify for the "healthy" claim increased. The largest gains were in processed fish/meat/egg categories (+6,513 UPC), packaged fruit/vegetable categories (+1,760 UPC), savory spreads category (+892 UPC), snacks category (+867 UPC), and plain and plain, carbonated water category (+743 UPC). In the case of nine categories that currently label more UPCs than qualify (i.e., oil-based salad dressing, sauce/seasoning, snacks, soup, sweet spread, sweeteners and sugars, main dishes, meals, and plain and plain, carbonated water; see Table 2), we assume that 100 percent of UPCs that qualify for the 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" under the original definition does not meet the final updated 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 final updated 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 final updated 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. Total mean costs per product category are presented in the final column. Total labeling costs are estimated to be $59 million, or $2,800 per re-labeled UPC.

Table 8. Total labeling costs per product category, in 2023$

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					
Baby and young children food	62	80	142	19	$305,698
Bakery	648	727	1,375	79	$4,205,982
Breakfast cereal	1,181	133	1,314	(1,047)	$6,319,081
Confectionary	140	-	140	(140)	$647,551
Dairy	533	595	1,127	62	$3,066,635
Dessert/ice cream	144	12	156	(131)	$686,241
Juice drinks	374	201	575	(174)	$1,826,891
Oil-based salad dressing	40	58	98	18	$221,338
Other Beverages	2,149	194	2,343	(1,955)	$8,708,844
Packaged fruit/vegetable	130	324	455	194	$1,118,500
Processed fish/meat/egg	340	2,671	3,011	2,330	$5,634,258
Sauce/seasoning	511	856	1,368	345	$3,015,793
Savory spreads	8	602	610	594	$1,081,336
Snacks	1,872	1,742	3,615	(130)	$9,248,351
Soup	193	28	221	(165)	$746,989
Sweet spread	358	299	657	(60)	$1,659,842
Sweeteners and sugars	53	-	53	(53)	$299,828
Combination Foods					
Mixed Products	765	342	1,107	(423)	$3,163,064
Main Dishes	543	870	1,413	327	$3,144,343
Meals	1,121	428	1,548	(693)	$4,152,326
Plain and Plain, Carbonated Water	-	650	650	650	$1,206,491
Total	11,166	10,162	21,328	(1,004)	$59,252,892

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.

2. Reformulation Costs

The final 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. 6]. 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) period of time between the effective date and compliance date of the rule (costs are higher for shorter periods because if the period between the effective date and the compliance date 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 to bear the updated "healthy" claim, 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 final definition, we estimate that 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 2023$

	Total Cost/Formula		
Product Categories	Low	Mean	High
Individual Foods & Beverages			
Baby and young children food	$988,188	$2,030,558	$3,614,509
Bakery	$544,440	$1,142,721	$2,059,987
Breakfast cereal	$672,407	$1,404,821	$2,524,737
Confectionary	$609,486	$1,276,656	$2,298,377
Dairy	$523,764	$1,083,977	$1,939,029
Dessert/ice cream	$609,486	$1,276,656	$2,298,377
Juice drinks	$462,754	$968,942	$1,744,593
Oil-based salad dressing	$429,950	$901,531	$1,624,772
Other Beverages	$465,169	$960,279	$1,715,325
Packaged fruit/vegetable	$462,754	$968,942	$1,744,593
Processed fish/meat/egg	$332,357	$695,089	$1,250,693
Sauce/seasoning	$378,484	$790,877	$1,423,005
Savory spreads	$378,484	$790,877	$1,423,005
Snacks	$496,590	$1,034,635	$1,857,705
Soup	$680,147	$1,419,594	$2,550,390
Sweet spread	$378,484	$790,877	$1,423,005
Sweeteners and sugars	$567,064	$1,184,386	$2,128,932
Combination Foods			
Mixed Products	$499,881	$1,045,658	$1,881,689
Main Dishes	$527,313	$1,104,449	$1,988,872
Meals	$527,313	$1,104,449	$1,988,872
Plain and Plain, Carbonated Water	$465,169	$960,279	$1,715,325
Average	$523,794	$1,092,203	$1,961,704

Table 10 presents the total reformulation costs per product category. Based on the final 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 such products automatically qualify for the claim under the updated criteria and 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 final 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 2023$

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				
Baby and young children food	62	50	3	$5,279,000
Bakery	648	532	28	$31,882,000
Breakfast cereal	1,181	805	42	$59,424,000
Confectionary	140	-	-	$0
Dairy	533	408	21	$23,197,000
Dessert/ice cream	144	110	6	$7,405,000
Juice drinks	374	252	13	$12,790,000
Oil-based salad dressing	40	25	1	$1,172,000
Other Beverages	2,149	-	-	$0
Packaged fruit/vegetable	130	100	5	$5,038,000
Processed fish/meat/egg	340	255	13	$9,314,000
Sauce/seasoning	511	428	23	$17,795,000
Savory spreads	8	6	0	$237,000
Snacks	1,872	1,388	73	$75,425,000
Soup	193	169	9	$12,634,000
Sweet spread	358	311	16	$12,970,000
Sweeteners and sugars	53	-		$0
Combination Foods				
Mixed Products	765	611	32	$33,566,000
Main Dishes	543	475	25	$27,501,000
Meals	1,121	980	51	$56,769,000
Plain and Plain, Carbonated Water	-			$0
Total	11,166	6,904	363	$392,398,000

Total reformulation costs are about $392 million, or roughly $1 million 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 original "healthy" definition and would not meet the final updated 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.

3. Rebranding 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 other information on the label or labeling puts the term into a nutritional context. If these "healthy" branded products would not qualify under the final updated definition, manufacturers may choose to reformulate the product (described above) or remove the "healthy" brand name and not reformulate. In making the decision to rebrand (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. 30] and thus may be willing to pay more for them over private label or store brands [Ref. 31, 32]. 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. 32], in turn increasing the expected revenue from selling the brand.

If manufacturers of "healthy" branded products that no longer qualify under the final updated criteria choose to keep the product line but rename the brand to avoid misbranding (i.e., remove "healthy" or derivative 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.

In the extreme case, if the final 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.

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 rebranding 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, does not distinguish between the term "healthy" used in the brand name and the term used elsewhere on the label. Instead, we use proprietary data from market research firm, Circana.[29] Circana's Liquid Data Go is a comprehensive store-based scanner

[29] See https://www.iriworldwide.com/en-US/Company/About-Us for details.

dataset providing UPC-level sales, product information, and brand name and manufacturer.[30] 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 derivative 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. Circana 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 sales of these products were $820 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 2023$

	Quintile of Sales per "Healthy" Brand				
	1st	2nd	3rd	4th & 5th	Total
Number of Brands	26	12	4	9	51
Number of UPCs	183	239	88	340	850
Average Dollar Sales/Brand	$61	$1,452	$4,598	$128,260	$62,920
Total Dollar Sales	$980	$6,413	$17,424	$796,180	$820,380

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. Data is from 2018.

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 comparable products without "healthy" in the brand name [Ref. 33]. 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

[30] Circana's Liquid Data Go, previously known as IRi Liquid Data, is scanner data 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.

negative, whether controlling for market 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.

Using the methods described within Labeling Costs, we estimate that about 25 percent of "healthy" branded food products would meet the final updated criteria and thus not be impacted by the final 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.[31] 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 GNDP 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, Circana 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 foods subject to USDA labeling regulations. Second, Circana does not provide projection factors or weights so it is not possible to calculate nationally representative estimates [Ref. 34]. 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. 34]. Thus, these estimates may be underestimated. Third, we are uncertain how many of these products are using "healthy" as 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 attribute related to the term "healthy" (e.g., for organic or sustainability concerns). In those cases, use of "healthy" may not be a nutrient content claim. Like the Mintel GNPD, Circana 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 original 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.

4. Recordkeeping Costs

The final type of cost manufacturers would incur are recordkeeping costs. The final 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 nutrient-dense single-ingredient foods with no added ingredients, except for water; water; or other coffee and tea beverages with less than 5 calories per RACC. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records.

[31] 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.

Examples 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 using the voluntary "healthy" implied nutrient content claim would require this type of recordkeeping costs. We were unable to account for all nutrient-dense single ingredient foods and coffee and tea beverages with less than 5 calories that are exempt from recordkeeping. Thus, the estimated recordkeeping costs are overestimated, particularly within food categories that have a higher proportion of products that fall within the single-ingredient exemption, such as packaged fruits and vegetables. For plain and plain, carbonated water and juice drinks, based on the final updated 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 $26.28; after applying the standard wage multiplier of two, the hourly wage rate is $52.56.[32] Thus, we estimate recordkeeping costs at between $13.14 and $26.28 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 $124,000. Annual costs in the following year are $5,000 and continue to increase annually with the introduction of new products.

[32] 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 2023$

Product Category	Estimated # UPCs would bear "healthy" claim	Need Record-keeping	Total Hours	Initial cost	Annual cost
Individual Foods & Beverages					
Baby and young children food	139	70	26	$1,375	$55
Bakery	836	418	157	$8,234	$329
Breakfast cereal	342	171	64	$3,374	$135
Confectionary	-	-	-	$0	$0
Dairy	695	347	130	$6,848	$274
Dessert/ice cream	19	9	3	$184	$7
Juice drinks	398	-	-	$0	$0
Oil-based salad dressing	60	30	11	$589	$24
Other Beverages	245	123	46	$2,417	$97
Packaged fruit/vegetable	549	274	103	$5,410	$216
Processed fish/meat/egg	2,870	1,435	538	$28,282	$1,131
Sauce/seasoning	897	448	168	$8,839	$354
Savory spreads	607	304	114	$5,987	$239
Snacks	1,955	977	367	$19,264	$771
Soup	40	20	8	$395	$16
Sweet spread	334	167	63	$3,292	$132
Sweeteners and sugars	-	-	-	$0	$0
Combination Foods					
Mixed Products	522	200	75	$3,944	$158
Main Dishes	890	457	172	$9,015	$361
Meals	450	251	94	$4,939	$198
Plain and Plain, Carbonated Water	743	-	-	$0	$0
Total	12,592	5,702	2,138	$112,389	$4,496

Table 13 summarizes the 20-year stream of average costs. Total, undiscounted costs over 20 years are estimated at $453 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.

Table 13. 20-year stream of average costs, in 2023$

Year	Total Labeling	Total Reformulation	Total Recordkeeping
1	$0	$0	$0
2	$0	$0	$0
3	$0	$0	$0
4	$60,459,384	$392,398,000	$112,389
5	$0	$0	$4,496
6	$0	$0	$4,675
7	$0	$0	$4,862
8	$0	$0	$5,057
9	$0	$0	$5,259
10	$0	$0	$5,470
11	$0	$0	$5,688
12	$0	$0	$5,916
13	$0	$0	$6,152
14	$0	$0	$6,399
15	$0	$0	$6,655
16	$0	$0	$6,921
17	$0	$0	$7,198
18	$0	$0	$7,485
19	$0	$0	$7,785
20	$0	$0	$8,096
Total	$60,459,384	$392,398,000	$210,502

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 $403 million, with a lower bound of $188 million and an upper bound of $737 million. Discounted at seven percent, the mean present value of costs of the final rule is $346 million, with a lower bound of $161 million and an upper bound of $633 million. These costs translate into an annualized value, discounted at three percent, of about $2,200 per UPC with a "healthy" claim. (=$27 million/12,184 UPC).

Table 14. Present discounted values of costs over 20-years, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	$188	$403	$737
Present value, discounted at 7%	$161	$346	$633
Annualized value at 3%	$13	$27	$50
Annualized value at 7%	$15	$33	$60

G. Summary of Benefits and Costs

This section provides a summary of the estimated average benefits and costs. Table 15 lists the undiscounted benefits and costs over 20 years and total benefits and costs discounted at three and seven percent.

Table 15. 20-year stream of average costs and benefits, in 2023$

Year	Total Benefits	Total Costs
1	$0	$0
2	$0	$0
3	$0	$0
4	$0	$452,981,000
5	$55,028,600	$4,900
6	$55,941,600	$5,100
7	$56,861,700	$5,300
8	$57,788,200	$5,600
9	$58,720,400	$5,800
10	$59,657,800	$6,000
11	$60,599,800	$6,300
12	$61,546,300	$6,500
13	$62,496,900	$6,800
14	$63,451,800	$7,000
15	$64,411,100	$7,300
16	$65,374,900	$7,600
17	$66,343,800	$7,900
18	$67,318,100	$8,200
19	$68,298,400	$8,600
20	$69,285,100	$8,900
Total undiscounted value	$993,124,600	$453,088,800
Present value, discounted at 3%	*$686,093,400*	*$402,541,200*
Present value, discounted at 7%	*$437,681,000*	*$345,623,000*

H. Analysis of Regulatory Alternatives to the Rule

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

One alternative is to codify the policy in the current enforcement discretion guidance. Although guidance is nonbinding, some packaged food manufacturers have acted in accordance with the enforcement policy stated in the guidance and have already adjusted their products or product packaging. 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 guidance compared to the final rule, the costs to manufacturers would be significantly smaller. First, there would be no recordkeeping costs since

the enforcement discretion does not require recordkeeping. Second, because fewer changes would be made, there would be significantly less opportunity to reformulate in order to meet the "healthy" criteria (i.e., there would be no change in the sodium criteria and no added sugar criteria). Thus, reformulation costs would likely be close to zero. 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 qualify for the original "healthy" definition and do not align with current nutrition science and Federal dietary guidance would continue to be labeled as "healthy." The overall framework for the definition would also not align with current nutrition science and Federal dietary guidance (e.g., shifts to recommend healthy dietary patterns and the consumption of food groups in certain quantities to achieve adequate nutrient intake, based on the understanding that each food group contributes an array of important nutrients to the diet) and as a result, some foods that are encouraged by current Federal dietary guidance would be unable to bear the "healthy" claim. Therefore, we assume that this alternative would have small costs to industry and negligible benefits to consumers.

2. Alternative 2: Extend the compliance date by one year

Extending the anticipated final compliance date for the rule 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 compliance date further from the effective date runs the risk that consumers may not understand whether a packaged food product labeled "healthy" follows the original definition or the updated one for a longer period of time.

The 20-year stream of benefits and costs of Alternative 2 are summarized in Table 16. 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 $61 million to about $40 million.

Table 16. Alternative 2: 20-year stream of average costs and benefits, in 2023$

Year	Total Benefits	Total Costs
1	$0	$0
2	$0	$0
3	$0	$0
4	$0	$0
5	$0	$432,584,100
6	$55,941,600	$4,900
7	$56,861,700	$5,100
8	$57,788,200	$5,300
9	$58,720,400	$5,600
10	$59,657,800	$5,800
11	$60,599,800	$6,000
12	$61,546,300	$6,300
13	$62,496,900	$6,500
14	$63,451,800	$6,800
15	$64,411,100	$7,000
16	$65,374,900	$7,300
17	$66,343,800	$7,600
18	$67,318,100	$7,900
19	$68,298,400	$8,200
20	$69,285,100	$8,600
Total undiscounted value	$938,096,013	$432,683,000
Present value, discounted at 3%	*$638,625,300*	*$373,217,400*
Present value, discounted at 7%	*$398,446,400*	*$308,467,300*

3. Alternative 3: Finalizing the proposed rule as drafted

The final alternative would be to finalize the proposed rule as drafted. In response to comments, the final rule has changed some of the proposed criteria resulting in more nutrient-dense products that are encouraged by the *Dietary Guidelines for Americans, 2020-2025* qualifying to bear the claim. For example, the final rule provides additional flexibility in the minimum amounts of food group equivalents for components of combination foods, allows vegetable and fruit powders to be considered in the calculation of the vegetable and fruit FGEs, and provides more flexibility for some of the nutrients to limit criteria.

Fewer packaged food products would qualify and use the "healthy" nutrient content claim if the proposed rule was finalized as drafted. Thus, recordkeeping costs would be less than in the final rule. Because a label change is required for both adding and removing a "healthy" claim, labeling costs remain about the same as estimated in the final rule. Finally, if the proposed rule was finalized as drafted, more products currently using the "healthy" claim would need to remove the claim or reformulate, thus increasing the total reformulation costs. Our estimated benefits are not granular enough to pick up the differences in expected benefits between the final rule and the proposed rule. The 20-year stream of benefits and costs of Alternative 3 are summarized in Table 17.

Table 17. Alternative 3: 20-year stream of average costs and benefits, in 2023$

Year	Total Benefits	Total Costs
1	$0	$0
2	$0	$0
3	$0	$0
4	$0	$479,998,390
5	$55,028,600	$4,654
6	$55,941,600	$4,840
7	$56,861,700	$5,033
8	$57,788,200	$5,235
9	$58,720,400	$5,444
10	$59,657,800	$5,663
11	$60,599,800	$5,889
12	$61,546,300	$6,125
13	$62,496,900	$6,369
14	$63,451,800	$6,625
15	$64,411,100	$6,890
16	$65,374,900	$7,165
17	$66,343,800	$7,452
18	$67,318,100	$7,749
19	$68,298,400	$8,059
20	$69,285,100	$8,381
Total undiscounted value	$993,124,600	$480,099,963
Present value, discounted at 3%	*$686,093,400*	*$426,536,842*
Present value, discounted at 7%	*$437,681,000*	*$366,229,572*

I. Distributional Effects

Nutrition-related chronic diseases are experienced at disproportionally 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. 35]. 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.[33] Research further suggests that children's obesity rates have risen during the COVID-19 pandemic and the increase

[33] 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

has been more substantial in Hispanic, non-Hispanic Black, publicly insured, or lower-income children [Ref. 36].

Underlying these findings are small but statistically significant differences in nutrition intake, identified through dietary recall data collected in NHANES and reported in Table 18 below. For instance, non-Hispanic Asians consume the least total calories but more sodium than non-Hispanic White or Non-Hispanic Black respondents. Non-Hispanic White respondents consume the most saturated fat but the least sodium. Non-Hispanic Black respondents consume the most total sugar.

Table 18. Average Calories and Select Nutrients per 1000 kcal Consumed

	Calories (kcal)		Saturated Fat (g)		Sodium (mg)		Total Sugar (g)	
Non-Hispanic White	2,097	(16.0)	13.7	(0.1)	1,619	(18.2)	51	(0.9)
Non-Hispanic Black	2,055	(24.3)	12.6	(0.1)	1,657	(39.6)	54	(0.7)
Non-Hispanic Asian	1,921	(35.9)	11.3	(0.3)	1,817	(34.0)	46	(0.9)
Hispanic	2,107	(34.8)	12.5	(0.2)	1,723	(121.0)	52	(0.6)

Notes: Standard errors reported in parentheses. All statistics compiled from *What We Eat in America,* NHANES 2017-March 2020 Pre-pandemic, individuals 2 years and over, available here https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-data-tables/.

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. As described in the benefits section, in FDA's FSANS survey, 9 percent of respondents selected the "healthy" claim as the "most important" statement on the food package. This varied across demographic variables, seen in Table 19. For instance, non-Hispanic Black and Hispanic respondents were more likely to state the "healthy" claim was most important. This suggests that these demographic groups may accrue a larger proportion of the estimated health benefits. Similarly, respondents with lower education attainment and lower income were more likely to state the "healthy" claim was most important. If these populations use the "healthy" nutrient content claim to meaningfully change their diet, it is possible that underlying nutrition-related inequities could be reduced. We do not have the data to estimate the magnitude of this potential shift.

Table 19. Importance of "Healthy" Claim by select demographic variables

Demographic	Percent selected "Healthy" claim as most important
Race	
Non-Hispanic White	8
Non-Hispanic Black	18
Non-Hispanic Other	9
Hispanic	11
Educational Attainment	
Less than high school degree	25
High school graduate or GED	14
Some college	7
College graduate	6
Postgraduate degree	3
Income	
Less than $25,000	15
$25,000 to 34,999	10
$35,000 to $49,999	13
$50,000 to $74,999	10
$75,000 to $99,999	7
$100,000 or more	6

Notes: All statistics compiled from FDA's Food Safety and Nutrition Survey 2019 (FSANS), available here https://fsans-explorer.fda.gov/. Chi-squared tests for independence for each demographic group have a p-value <.001

J. International Effects

This rule will affect foreign entities that currently or will in the future use the "healthy" label as an implied nutrition content claim; we are unsure what proportion of total entities are foreign. This final rule does not include additional regulatory requirements for foreign entities.

K. Uncertainty and Sensitivity Analysis

The low, mean, and high estimated net benefits are described in Table 20.

Table 20. Net benefits of final rule, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	($166.4)	$283.6	$1,160.9
Present value, discounted at 7%	($147.5)	$92.1	$579.8
Annualized value at 3%	($11.2)	$19.1	$78.0
Annualized value at 7%	($13.9)	$8.7	$54.7

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 (Uniform distribution)
- Over 15-years, one-point increase in HEI score decreases all-cause mortality: zero to 0.3 percent (Uniform distribution)
- Over 15-years, current users of "healthy" claim increase HEI score: zero to 1 point (Uniform distribution)
- Immediate-upon-eating lost consumer utility: zero to 60 percent (Uniform distribution)
- Proportion of total marketplace covered by Mintel GNPD: 80 – 100 percent (Uniform distribution)
- Include low and high costs of labeling and reformulation (ranges provided within models)
- Number of products reformulated: three to 7.5 percent (Uniform distribution)
- Time estimated for recordkeeping per UPC: 15 to 30 minutes (Uniform distribution)
- Annual increase in UPCs needing recordkeeping: three to five percent (Uniform distribution)

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 derivative word is used outside of the nutritional context, for example, without implied or explicit references to the nutrient content of the food (e.g., graphic featuring food groups, "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 updated criteria for the "healthy" implied nutrient content claim. To the extent that we have 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 of 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 voluntary, we are uncertain how manufacturers choose to use the claim and whether this may change in the future.

We also consider uncertainty within the estimated VSL. In the first year that benefits accrue, the mean VSL is $13.6 million, with a low estimated value of $6.3 million and a high estimated value of $20.55 million. Table 21 presents net benefits using the full range of VSL estimates. The mean value is the same as in Table 20 but the confidence interval is larger because it incorporates the uncertainty estimates outlined above with the range in values of a statistical life.

Table 21. Uncertainty analysis: net benefits with full range of VSL estimates, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	($177.0)	$283.6	$2,365.6
Present value, discounted at 7%	($154.3)	$92.1	$1,347.0
Annualized value at 3%	($11.9)	$19.1	$159.0
Annualized value at 7%	($14.6)	$8.7	$127.1

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 22 below.

Table 22. Sensitivity analysis: 20-year stream of estimated benefits in millions 2023$

Year	Affected Population	Statistical Lives Saved	Mean VSL (millions)	Estimated Gross Benefits (millions)
2024	55,230	0	$13.1	$0.00
2025	55,604	0	$13.2	$0.00
2026	55,975	0	$13.4	$0.00
2027	56,340	0	$13.5	$0.00
2028	56,700	88	$13.6	$0.00
2029	57,053	88	$13.8	$0.00
2030	57,399	89	$13.9	$0.00
2031	57,738	89	$14.0	$0.00
2032	58,069	90	$14.2	$0.00
2033	58,392	90	$14.3	$0.00
2034	58,707	91	$14.5	$0.00
2035	59,014	91	$14.6	$0.00
2036	59,313	92	$14.8	$0.00
2037	59,605	92	$14.9	$0.00
2038	59,889	93	$15.1	$0.00
2039	60,167	93	$15.2	$0.00
2040	60,439	93	$15.4	$0.00
2041	60,705	94	$15.5	$0.00
2042	60,966	94	$15.7	$961.1
2043	61,223	95	$15.8	$6.0
Total		1,461		$967.1

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 $25 million dollars to $967 million. Table 23 presents the net benefits when benefits do not accrue for 15 years and shows the model is sensitive to this assumption, particularly at the smaller three percent discount rate. 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 $7 million, or $1.3 million less than the primary estimate.

Table 23. Sensitivity analysis: net benefits when benefits accrue after 15 years, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	($170.79)	$148.91	$766.62
Present value, discounted at 7%	($152.97)	($78.31)	$96.00
Annualized value at 3%	($11.48)	$10.01	$51.53
Annualized value at 7%	($14.44)	($7.39)	$9.06

Finally, we also estimate the net benefits of the final "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 final rule when the affected population is limited to people over 18 years of age. Table 24 presents the net benefits of this sensitivity analysis. Mean annualized net benefits are $8 million less (at both three and seven percent) than estimated in the main analysis.

Table 24. Sensitivity analysis: net benefits when population limited to ages 18+, in millions 2023$

	Low	Mean	High
Present value, discounted at 3%	($170.25)	$158.32	$814.39
Present value, discounted at 7%	($150.02)	$12.05	$358.05
Annualized value at 3%	($11.44)	$10.64	$54.74
Annualized value at 7%	($14.16)	$1.14	$33.80

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Department of Health and Human Services (HHS) has determined that a rule is significant if it would reduce revenues or raise costs of any class of affected entities by more than 3 to 5 percent within five years.[34] Because we estimate that the economic impact of this final rule will not exceed three percent of annual revenue, we certify that this rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

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 food manufacturing (37 industries within North American Industry Classification System (NAICS) 311), soft drink manufacturing (NAICS 312111), and bottled water manufacturing (NAICS 312112). 2021 U.S. Census Bureau Statistics of U.S. Businesses (SUSB) data indicate that there are a total of 22,460 firms within these manufacturing sectors; food manufacturing accounts for 97 percent of total establishments.[35]

SBA defines a small food manufacturer as one that has between 500 and 1,400 employees, depending on industry type. For example, for breakfast cereal manufacturing (NAICS 311230) the cutoff is 1,300 employees while for mayonnaise, dressing, and other prepared sauce manufacturing (NAICS 311941) the cutoff is 650 employees. For soft drink manufacturing, the small business employee cutoff is 1,400 and for bottled water manufacturing the cutoff is 1,100.[36] Table 25 shows the breakdown of the sectors by number of employees. Of these establishments, we estimate that at least 97 percent of these establishments qualify as a small business. Moreover, there are just 332 establishments with more than 500 employees.

Table 26 shows that the average annual receipts per establishment varies substantially across NAICS as well as across size category.[37] Average annual receipts average from about $23 million for establishments with less than 500 employees to $353 million for establishments with 1,000-1,499 employees. However, within each size category, annual receipts vary drastically across industry. For example, for the 96 percent of establishments with less than 500 employees, average annual receipts range from $764,000 (NAICS 311811: Retail bakeries) to $79 million (NAICS

[34] See U.S. SBA's "A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act", https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/.

[35] See "U.S. & States, 6-digit NAICS", downloaded at https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.

[36] See U.S. SBA's Size Standards Table, https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. The size standards presented here are based on the SBA's March 17, 2023 table.

[37] See "U.S. & States, 6-digit NAICS", downloaded at https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.

311314: Cane sugar manufacturing). Finally, within each industry, annual receipts can vary across size category. For example, for retail bakeries, average annual receipts range from $764,000 (for firms with less than 500 employees) and $16,920,000 (for firms with 500 to 749 employees).

Table 25. Food, soft drink and bottled water manufacturing sectors by number of employees

			Number of firms by employee size					
NAICS	**NAICS Industry Description**	**Total Firms**	**< 500**	**500-749**	**750-999**	**1,000-1,499**	**Qualify as small business**	***SBA small business size standard***
311211	Flour Milling	197	172	n/a	n/a	n/a	87%	*1,050*
311212	Rice Milling	59	51	n/a	n/a	n/a	86%	*750*
311213	Malt Manufacturing	27	26	n/a	n/a	n/a	96%	*500*
311221	Wet Corn Milling and Starch Manufacturing	31	25	n/a	n/a	n/a	81%	*1,300*
311224	Soybean and Other Oilseed Processing	106	90	n/a	n/a	4	89%	*1,250*
311225	Fats and Oils Refining and Blending	87	71	n/a	n/a	4	86%	*1,100*
311230	Breakfast Cereal Manufacturing	72	59	n/a	n/a	n/a	82%	*1,300*
311313	Beet Sugar Manufacturing	16	10	n/a	n/a	n/a	63%	*1,150*
311314	Cane Sugar Manufacturing	41	34	n/a	n/a	n/a	83%	*1,050*
311340	Nonchocolate Confectionery Manufacturing	497	474	4	3	n/a	97%	*1,000*
311351	Chocolate and Confectionery Manufacturing from Cacao Beans	239	226	3	n/a	n/a	96%	*1,250*
311352	Confectionery Manufacturing from Purchased Chocolate	931	914	n/a	n/a	n/a	98%	*1,000*
311411	Frozen Fruit, Juice and Vegetable Manufacturing	136	115	4	3	3	90%	*1,100*
311412	Frozen Specialty Food Manufacturing	433	391	12	5		94%	*1,250*
311421	Fruit and Vegetable Canning	1,003	934	11	4	17	95%	*1,000*
311422	Specialty Canning	111	97	n/a	n/a	4	91%	*1,400*
311423	Dried and Dehydrated Food Manufacturing	206	182	4	n/a	4	90%	*750*
311511	Fluid Milk Manufacturing	224	180	9	3	n/a	86%	*1,150*
311512	Creamery Butter Manufacturing	46	36	n/a	5	n/a	89%	*750*
311513	Cheese Manufacturing	407	371	8	11	n/a	96%	*1,250*
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	125	94		8	n/a	82%	*1,000*
311520	Ice Cream and Frozen Dessert Manufacturing	404	379	3	n/a	n/a	95%	*1,000*
311710	Seafood Product Preparation and Packaging	447	426	8	3	3	97%	*750*
311811	Retail Bakeries	8366	8333	6	n/a	3	100%	*500*
311812	Commercial Bakeries	2,461	2384	16	13	7	98%	*1,000*
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	191	172	3	3	n/a	92%	*750*
311821	Cookie and Cracker Manufacturing	347	326	6	n/a	n/a	96%	*1,250*

			Number of firms by employee size					
NAICS	**NAICS Industry Description**	**Total Firms**	**< 500**	**500-749**	**750-999**	**1,000-1,499**	**Qualify as small business**	***SBA small business size standard***
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour	340	307	8	6	3	94%	*850*
311830	Tortilla Manufacturing	365	354	3	n/a	n/a	98%	*1,250*
311911	Roasted Nuts and Peanut Butter Manufacturing	227	208		n/a	n/a	92%	*750*
311919	Other Snack Food Manufacturing	362	336	6	n/a	4	96%	*1,250*
311920	Coffee and Tea Manufacturing	910	888	4	3	3	98%	*1,000*
311930	Flavoring Syrup and Concentrate Manufacturing	144	130	n/a	n/a	n/a	90%	*1,100*
311941	Mayonnaise, Dressing and Other Prepared Sauce Manufacturing	343	318	3		3	94%	*650*
311942	Spice and Extract Manufacturing	413	375	8	5		94%	*500*
311991	Perishable Prepared Food Manufacturing	817	749	17	7	6	94%	*700*
311999	All Other Miscellaneous Food Manufacturing	732	692	6	4	5	95%	*700*
312111	Soft Drink Manufacturing	376	327	10	6	5	93%	*1,400*
312112	Bottled Water Manufacturing	221	212	n/a	n/a	n/a	96%	*1,100*
	Total Number of Firms	***22,460***	***21,468***	***162***	***92***	***78***	***97%***	

Note: The U.S. Census SUSB data provide limited enterprise size options. n/a indicates that the number of firms for that employee size category is not available. The SBA size standards are based on the U.S. SBA's Size Standards Table.

Table 26. Average estimated annual receipts per firm by number of employees, in thousands $2023

			Average annual receipts by employee size				
NAICS	**NAICS Industry Description**	**Average annual receipts**	**< 500**	**500-749**	**750-999**	**1,000-1,499**	***SBA small business size standard***
311211	Flour Milling	$68,846	$26,356	$182,291	$408,279	n/a	*1,050*
311212	Rice Milling	$75,216	$42,895	n/a	n/a	n/a	*750*
311213	Malt Manufacturing	$55,964	$45,137	n/a	n/a	n/a	*500*
311221	Wet Corn Milling and Starch Manufacturing	$339,421	$15,579	n/a	n/a	n/a	*1,300*
311224	Soybean and Other Oilseed Processing	$452,889	$58,653	$1,650,054	n/a	n/a	*1,250*
311225	Fats and Oils Refining and Blending	$158,969	$55,315	n/a	$141,107	n/a	*1,100*
311230	Breakfast Cereal Manufacturing	$222,316	$18,421	n/a	n/a	n/a	*1,300*
311313	Beet Sugar Manufacturing	$328,144	$63,285	n/a	n/a	n/a	*1,150*
311314	Cane Sugar Manufacturing	$222,964	$79,220	n/a	n/a	n/a	*1,050*
311340	Nonchocolate Confectionery Manufacturing	$25,519	$7,926	$121,857	$156,843	n/a	*1,000*
311351	Chocolate and Confectionery Manufacturing from Cacao Beans	$28,503	$5,508	$210,028	n/a	n/a	*1,250*
311352	Confectionery Manufacturing from Purchased Chocolate	$14,083	$3,775	$101,495	n/a	$187,534	*1,000*
311411	Frozen Fruit, Juice and Vegetable Manufacturing	$108,195	$32,323	$177,561	n/a	$455,050	*1,100*
311412	Frozen Specialty Food Manufacturing	$58,594	$15,138	$139,048	$222,256	n/a	*1,250*
311421	Fruit and Vegetable Canning	$40,629	$11,603	$273,316	$348,330	$380,638	*1,000*
311422	Specialty Canning	$112,182	$14,502	n/a	n/a	$149,798	*1,400*
311423	Dried and Dehydrated Food Manufacturing	$44,634	$17,880	$195,125	n/a	$319,668	*750*
311511	Fluid Milk Manufacturing	$177,982	$41,237	$290,982	$0	$248,539	*1,150*
311512	Creamery Butter Manufacturing	$206,081	$31,646	$874,183	n/a	n/a	*750*
311513	Cheese Manufacturing	$140,766	$32,313	$336,227	$839,387	$1,323,794	*1,250*
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	$164,521	$38,269	n/a	$145,715	$318,638	*1,000*
311520	Ice Cream and Frozen Dessert Manufacturing	$24,531	$5,564	$96,849	n/a	n/a	*1,000*
311710	Seafood Product Preparation and Packaging	$36,524	$19,059	$217,250	$320,053	n/a	*750*
311811	Retail Bakeries	$795	$764	$16,920	n/a	$11,032	*500*
311812	Commercial Bakeries	$14,546	$4,241	$83,448	$164,312	$188,096	*1,000*
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	$39,346	$13,646	$55,080	$142,586	n/a	*750*
311821	Cookie and Cracker Manufacturing	$40,422	$6,705	$125,915	n/a	n/a	*1,250*

			Average annual receipts by employee size				
NAICS	**NAICS Industry Description**	**Average annual receipts**	**< 500**	**500-749**	**750-999**	**1,000-1,499**	***SBA small business size standard***
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour	$41,900	$14,761	$106,845	$330,378	$69,930	*850*
311830	Tortilla Manufacturing	$14,205	$4,775	n/a	$0	n/a	*1,250*
311911	Roasted Nuts and Peanut Butter Manufacturing	$83,228	$36,079	$215,399	$325,049	$1,205,270	*750*
311919	Other Snack Food Manufacturing	$89,476	$10,981	n/a	$352,306	n/a	*1,250*
311920	Coffee and Tea Manufacturing	$26,277	$7,558	$176,723	n/a	n/a	*1,000*
311930	Flavoring Syrup and Concentrate Manufacturing	$100,245	$19,045	n/a	$155,365	n/a	*1,100*
311941	Mayonnaise, Dressing and Other Prepared Sauce Manufacturing	$41,282	$14,517	n/a	$165,278	n/a	*650*
311942	Spice and Extract Manufacturing	$37,618	$15,386	$120,421	$171,330	$144,844	*500*
311991	Perishable Prepared Food Manufacturing	$28,648	$8,408	$93,435	$0	$203,018	*700*
311999	All Other Miscellaneous Food Manufacturing	$23,308	$11,972	$91,395	$187,432	$77,643	*700*
312111	Soft Drink Manufacturing	$142,749	$20,076	$129,833	$185,215	$358,684	*1,400*
312112	Bottled Water Manufacturing	$33,499	$7,574	n/a	n/a	n/a	*1,100*
	Average annual receipts per firm	***$99,103***	***$22,515***	***$243,267***	***$226,725***	***$352,636***	

Note: The U.S. Census SUSB data provide limited enterprise size options. n/a indicates that the number of firms for that employee size category is not available. The SBA size standards are based on the U.S. SBA's Size Standards Table.

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

The total discounted cost of the final rule per entity (including large firms) is approximately $17,900 (=$403 million/22,460 firms). However, it is unlikely that all firms will face the same cost, as costs will vary by the size of the firm. 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 is typically small. This is evident from Table 26. On the other hand, brands owned by small entities may have relatively low sales, and thus are not represented fully in our data.

We estimate that the labeling, reformulation, and recordkeeping costs incurred due to the final rule would cost roughly $2,000 annually per UPC with a "healthy" claim, or less than a percent of estimated annual receipts. For instance, a retail bakery firm with less than 500 employees owning 10 UPCs with a "healthy" claim would incur a cost of $20,000, or three percent 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 necessary or possible to reformulate plain, still water to meet the final updated "healthy" criteria (such products will meet the criteria automatically).

We discuss qualitatively, but do not quantify, the potential cost of rebranding products that include the term "healthy" in the brand name, where the use of "healthy" 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 final criteria, this rule may provide an additional way to inform consumers of the product's healthfulness and potentially increase sales. We asked for, but did not receive, comments on the Regulatory Flexibility analysis.

C. Alternatives to Minimize the Burden on Small Entities

The first alternative considered is to codify the policy in the current enforcement discretion guidance. 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 $17,900 to $16,607 per firm (=$373 million/22,460 firms). The third alternative of finalizing the rule as proposed increases total costs to industry because fewer products would qualify as "healthy" and thus more products would either remove the "healthy" nutrient content claim or reformulate. To the extent that small entities make these products, this would increase overall costs to small entities from $17,900 to $19,012 per firm (=$427 million/22,460 firm).

We received public comments suggesting that FDA set a compliance date for small businesses that is two years after the proposed compliance date and other comments requesting accommodations

for small operators relating to compliance and the provision of education resources. We cannot estimate the exact cost per small entity of these alternatives because we do not know how many UPCs on average are owned by small entities. Extending the compliance date for small businesses would reduce overall costs as they would have more time to relabel impacted products. Given that the "healthy" claim is voluntary and we have provided a compliance date that is three years after the effective date, we believe there is enough flexibility built into the rule for all manufacturers to be able to meet the compliance date rather than adopting special extensions or provisions for small entities.

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Appendix A. Product Categories and Mintel GNPD Subcategories

Product Category	Mintel GNPD Subcategory
Individual Foods and Beverages	
Baby food	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
Bakery	Baking Ingredients & Mixes, Bread & Bread Products, Cakes, Pastries & Sweet Goods, Savory Biscuits/Crackers, Sweet Biscuits/Cookies
Breakfast cereal	Cold Cereals, Hot Cereals
Confectionary	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
Dairy	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
Dessert/ice cream	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
Juice drinks	Fruit/Flavored Still Drinks, Juice, Nectars
Oil-based salad dressing	Dressings & Seasonings Containing “Oil” In Ingredients
Other Beverages	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, Carbonated Plain Water
Packaged Fruit/vegetable	Fruit, Vegetables

Product Category	Mintel GNPD Subcategory
Individual Foods and Beverages	
Processed fish/meat/egg	Eggs & Egg Products, Fish Products, Meat Products, Meat Substitutes, Poultry Products
Sauce/seasoning (excluding oil-based salad dressings)	Cooking Sauces, Dressings & Vinegar, Mayonnaise, Oils, Other Sauces & Seasonings, Pasta Sauces, Pickled Condiments, Seasonings, Stocks, Table Sauces
Savory spreads	Dips, Meat Pastes & Pates, Sandwich Fillers/Spreads, Savory Vegetable Pastes/Spreads, Yeast Extracts
Snacks	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
Soup	Dry Soup, Wet Soup
Sweet spread	Caramel & Cream Spreads, Chocolate Spreads, Confiture & Fruit Spreads, Honey, Nut Spreads, Syrups
Sweeteners & Sugar	Artificial Sweeteners, Other Natural Sweeteners, Sucrose
Combination Foods	
Mixed Products *(<6oz package)*	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
Main Dishes *(6-9oz package)*	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
Meals *(>= 10oz package)*	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
Plain Non-Carbonated Water	Non-Carbonated Unflavored Water