U.S. FOOD & DRUG ADMINISTRATION

Office of the Commissioner
Office of Policy, Legislation, and International Affairs
Office of Economics and Analysis
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Docket No. FDA 2024 N 2910

Food Labeling: Front-of-Package Nutrition Information

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

Executive Summary

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box (Nutrition Info box) on the front of most foods bearing a Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. The proposed rule, if finalized, would also amend low sodium and low saturated fat nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. We quantify costs to the packaged food industry from updating labeling to meet the proposed requirements. Annualized costs from relabeling over ten years would range from $66 million to $154 million at a 2 percent discount rate, with a primary estimate of $105 million per year.

Although reformulation is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation as the rule may result in some food manufacturers reformulating some food products. We estimate that the annualized costs for reformulation over 10 years would range from $125 million to $377 million at a 2 percent discount rate, with a primary estimate of $227 million. Combined, we estimate the annualized costs of the proposed rule over 10 years would range from $191 to $530 million at a 2 percent discount rate, with a primary estimate of $333 million.

The benefits of this proposed rule, if finalized, would come from the value consumers receive from the information provided by the interpretive front-of-package (FOP) label on food packages. The proposed rule may result in industry voluntarily reformulating products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 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 proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

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 annual economic impact of this proposed rule is less than 3 percent of annual revenue, we propose to certify that this proposed 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 proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits and Costs

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box (Nutrition Info box) on the front, or principal display panel, of most foods bearing a Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. The proposed rule, if finalized, would also amend low sodium and low saturated fat nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. The proposed rule, if finalized, may result in industry reformulating products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

We quantify costs to packaged food manufacturers from updating labeling to meet the proposed requirements. Although reformulation is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation as the rule could result in some food manufacturers reformulating some food products. Over 10 years, the total undiscounted cost is $3.2 billion. Updating labeling to meet the proposed requirements accounts for 32 percent of total costs ($1 billion), while voluntary reformulation accounts for the other 68 percent of total costs over 10 years ($2.2 billion). The present value of costs over 10 years would range from $1.7 billion to $4.9 billion at a 2 percent discount rate, with a primary estimate of $3.1 billion. Annualized costs over 10 years would range from $191 to $530 million at a 2 percent discount rate, with a primary estimate of $333 million.

The proposed Nutrition Info box would give consumers additional standardized context about certain nutrients that appear in the Nutrition Facts label and allow them to compare this nutrition information across foods. Benefits of this proposed rule would come from the value consumers receive from the information provided by the FOP label. If some packaged food manufacturers chose to reformulate products to maintain current nutrient content claims or move into a “Low” or “Med” interpretive description, consumers whose nutritional intake changes accordingly would also benefit from a healthier food supply. The proposed rule, if finalized, would provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. We undertake a break-even calculation to describe the magnitude of non-quantified benefits required for the benefits to equal or exceed the costs of the regulation.

Table 1. Summary of the Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2023 dollars)

Category	Primary Estimate	Low Estimate	High Estimate	Dollar Year	Discount Rate	Time Horizon	Notes
BENEFITS							
Annualized monetized benefits							
Annualized quantified, but non-monetized, benefits							
Unquantified benefits	The benefits of this proposed rule would come from the value consumers receive from the information provided in the interpretive label on food packages.						
COSTS							
Annualized monetized costs	$333	$191	$530	2023	2%	2025 - 2034	Although reformulation is not a requirement or goal of the proposed rule, reformulation costs are estimated to be 68% of total quantified costs. Costs may, at least partially, be passed through to consumers in the form of price increases.
Annualized quantified, but non-monetized, costs							
Unquantified costs							
TRANSFERS							
Annualized monetized Federal budgetary transfers							
Other annualized monetized transfers							
NET BENEFITS							
Annualized monetized net benefits							
Category	Effects			Notes			
Effects on State, local, or Tribal governments							
Effects on small businesses	The total discounted cost of the proposed rule per entity (including large firms) is approximately $100,253. 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.						
Effects on wages							
Effects on growth							

II. Preliminary Economic Analysis of Impacts

A. Background

FDA is proposing to amend its regulations by adding a requirement for certain nutrition information to appear in a compact informational box on the principal display panel or bulk food labeling (for purposes of this document, referred to collectively as the front of the food package, principal display panel, or similar) of most foods bearing a Nutrition Facts label. FDA is also proposing to amend the nutrient content claim definitions for low sodium (which includes the terms "low sodium," "low in sodium," "little sodium," "contains a small amount of sodium," and "low source of sodium") and low saturated fat (which includes the terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," and "a little saturated fat") to align with current nutrition science and avoid within-label inconsistencies.

The Nutrition Labeling and Education Act of 1990 (NLEA) directed FDA to require certain nutrition information be conveyed in a manner that allows the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. Under authority of the NLEA and the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA established various requirements related to nutrition information of food labels, including the declaration of nutrients (including saturated fat and sodium), the definition of nutrient content claims (including low saturated fat and low sodium), the format for nutrition labeling (including the Nutrition Facts label), reference values for use in declaring the nutrient content, and allowances for certain specified products to be exempt from nutrition labeling.

The Nutrition Facts label has been mandatory for most food packaging since 1994, providing consumers information about serving size, calories, and nutrients for the foods they are purchasing. The current regulations related to the Nutrition Facts label were most recently amended in 2016 to, among other things, require the declaration of added sugars. Consumers can use the current Nutrition Facts label to identify foods that contain more of the nutrients to get enough of and less of the nutrients to limit. Eating too much saturated fat and sodium, for example, is associated with an increased risk of developing some health conditions, like cardiovascular disease and high blood pressure. Consuming too much added sugars can make it hard to meet important nutrient needs while staying within calorie limits.[1]

The Nutrition Facts label also includes the percent Daily Value (DV) for each nutrient in a serving of the food. The percent DV shows consumers how much a nutrient in a serving of a food contributes to a total daily diet. For instance, if a nutrition label states that the amount of sodium in a serving of food is 850 milligrams (mg) and 37% DV, a consumer

[1] See "How to Understand and Use the Nutrition Facts Label" at https://www.fda.gov/food/nutrition-facts-label/how-understand-and-use-nutrition-facts-label.

can use that quantitative information to compare food products and identify foods that could help them maintain healthy dietary practices.

The Nutrition Facts label provides valuable, standardized nutrition information to consumers, and nearly 80 percent of U.S. food shoppers use it sometimes or often [Ref. 1]. Using the Nutrition Facts label frequently is associated with healthier dietary patterns [Ref. 2]. However, while many consumers use and benefit from the Nutrition Facts label, far fewer people who ever look at the Nutrition Facts label look at nutrients to limit [Ref. 1]. Nutrition Facts label use also differs by sex, race/ethnicity, education level, and household income. Specifically, regular use of the Nutrition Facts label is lower among men, those with lower education levels, and those with lower income [Ref. 2, 3, 4]. Additional nutrition labeling that is interpretive and prominently displayed on the front of food packaging could help improve consumer awareness of nutrients to limit by providing a more accessible description of certain information contained in the Nutrition Facts label. For example, it could put the percent DV of a nutrient into context by interpreting for consumers whether that number contributes a little or a lot of that nutrient to the daily diet. Thus, FOP labeling can supplement the Nutrition Facts label by providing additional, interpretive context for consumers at the point of decision-making (i.e., when a consumer is deciding whether to buy, use, or eat the food) that can help them quickly and easily identify how foods can be part of a healthy diet.

Many interested parties have expressed interest in FOP labeling, including both governmental and non-governmental groups. FDA has been interested in the possible use of FOP labeling since at least 2007. In 2010, FDA established a docket to ask questions and obtain data and other information about ways to enhance the usefulness of point-of-purchase nutrition information, such as through FOP labeling. In 2011, we announced our intent to exercise enforcement discretion with respect to certain FDA nutrition labeling regulations so that some interested food processors could introduce and use their Facts up Front FOP labeling program. In 2011, FDA commissioned a literature review to learn about different systems of providing information to consumers at the point of purchase. FDA commissioned an update to the literature review in 2016.

Congress has also shown interest in FOP labeling. In 2010, the Institute of Medicine (IOM, now the National Academies of Sciences, Engineering, and Medicine (NASEM)) released a report, at the direction of Congress, which found, among other things, that FOP systems may have the greatest potential benefit if the nutrition components included are limited to those most closely related to prominent public health conditions, and that research was needed to determine the most effective way of presenting nutrition ratings to consumers so they could make food choices that contribute to a healthy diet [Ref. 5]. In 2012, the IOM released a second report, concluding that a single, standardized system regulated by FDA that is easily understood by most age groups and appears on all products would be the best option for public health.

Additionally, in 2022, the White House released a National Strategy on Hunger, Nutrition, and Health. The National Strategy included FDA's work to, among other things, conduct

research on and propose a standardized FOP system for food packages to help consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern.

Finally, a 2022 citizen petition from the Center for Science in the Public Interest, the Association of SNAP Nutrition Education Administrators, and the Association of State Public Health Nutritionists asked that we amend our regulations to require an easy-to-understand, standardized system of nutrition labeling on the principal display panel of foods that is "1) mandatory, 2) nutrient-specific, 3) includes calories, and is 4) interpretative with respect to the levels of added sugars, sodium, and saturated fat per serving."[2] The petition claimed that experimental and real-world evidence shows that policies that aim to give consumers information about the healthfulness of foods that is clear, quick, and easy to access and understand, such as interpretive FOP nutrition labeling, can improve consumer understanding and encourage healthier diets.

B. Potential Need for Federal Regulatory Action

FDA implemented its first mandatory nutrition labeling for almost all foods it regulates 32 years ago. The resulting Nutrition Facts label is widely recognized, and 80 percent of American consumers report using the label [Ref. 1]. However, many consumers, particularly those with lower nutrition knowledge, may find additional information on food packaging helpful in identifying foods that are part of a healthy diet. This proposed rule, if finalized, would provide consumers, including those who have limited nutrition knowledge, with interpretive information about the amounts of three nutrients—saturated fat, sodium, and added sugars—in covered products so that they can quickly and easily identify how foods can be part of a healthy diet.

Currently, under most circumstances, manufacturers may voluntarily use FOP labeling systems as long as they adhere to FDA's nutrient content claim requirements. However, international studies conducted in countries with existing voluntary FOP rating systems suggest that having multiple labeling systems makes it more difficult for consumers to interpret nutrition information from a label [Ref. 6, 7]. A 2009 report from the United Kingdom Food Standards Agency and the 2012 NASEM report concluded that a standardized FOP labeling system would enhance consumer comprehension and use of FOP labels [Ref. 5, 6]. To create a consistent FOP scheme across most or all food products, federal action is required.

If finalized, this proposed rule would amend the existing low sodium and low saturated fat claims. As described above, the current definition for low sodium does not fully align with current nutrition science. The proposed rule would align the definition of this nutrient content claim with current nutrition science. Because the claim is already defined by FDA, federal regulatory action is required to do so. In addition, these amendments would

[2] See docket FDA-2022-P-1832 at https://www.regulations.gov/docket/FDA-2022-P-1832.

ensure consistency between existing nutrient content claims and the proposed FOP labeling.

C. Purpose of the Proposed Rule

This proposed rule, if finalized, would add a requirement for certain nutrition information to appear in a compact informational graphic on the front of most foods bearing a Nutrition Facts label. This information would help consumers identify how a food fits into their overall diet by giving consumers additional context on the front of most food packages about certain nutrients that appear on the label. The proposed rule, if finalized, would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health.

In addition, the proposed rule would update the definitions for the low sodium and low saturated fat nutrient content claims to align with current nutrition science and avoid within-label inconsistencies. FDA proposes to update the low sodium nutrient content claim so that it may be used on the label or in the labeling of a food other than a meal product or main dish if it contains 115 mg or less sodium per reference amount customarily consumed (RACC) and on the label or labeling of a food that is a meal product or main dish if it contains 115 mg or less sodium per 100 grams. The updated definition for the low sodium nutrient content claim is consistent with the updated 2016 Nutrition Facts rule and based on scientific evidence and consensus recommendations. Further, FDA proposes amending both nutrient content claim definitions to require that, in order to bear a low sodium or a low saturated fat nutrient content claim, a food must display "Low" in accordance with proposed § 101.6 for sodium or saturated fat in the Nutrition Info box, respectively.

The proposed informational graphic would detail and interpret the relative amount of saturated fat, sodium, and added sugars in a serving of the food. The graphic would include both the percent DV as well as an interpretive description (i.e., Low, Med, High), for each of these three nutrients to limit. FDA is proposing a range of 5% DV or less for "Low"; 6% to 19% DV for "Med"; and 20% DV or more for "High." The use of 5% DV or less to describe "Low" for sodium, saturated fat, and added sugars in the Nutrition Info box will help consumers identify foods low in these nutrients to limit. Similarly, the use of 20% DV or more to describe "High" in the Nutrition Info box will help consumers identify foods that are high in sodium, saturated fat, and added sugars.

Including the quantitative percent DV in addition to the "Low," "Med," or "High" descriptions in the Nutrition Info box would allow consumers to quickly compare the provided nutrient levels between products, particularly if the products have the same interpretive description for a given nutrient. For example, two products may both have "high" added sugars interpretive descriptions, but one may contain 30% DV added sugars, while the other contains 60% DV added sugars. The proposed rule details how to determine the interpretive descriptions and specifies the required contents and format of the FOP nutrition label. As limitation of these three nutrients is recommended by current

nutrition science and Federal dietary guidance to achieve a nutrient-dense diet within calorie limits, the inclusion of this information in the graphic is intended to help consumers understand how the levels of such nutrients in a food fit in the context of a total daily diet.

FDA is proposing a compliance date of three years after the final rule's effective date for manufacturers with $10 million of more in annual food sales, and a compliance date of four years after the final rule's effective date for manufacturers with less than $10 million in annual food sales. A compliance date that is three years after the effective date is intended to provide industry time to coordinate the labeling change to come into compliance with the new labeling requirement with any planned nonregulatory label changes. Providing smaller manufacturers an additional year to comply allows these firms further flexibility while balancing the need for consumers to have the information in a timely manner.

D. Baseline Conditions

1. Packaged Food Products

In order to understand the impact of the proposed rule, we first describe the number of packages that may already contain some interpretive information on the front of the package. In addition to displaying the mandatory Nutrition Facts label, food manufacturers can currently choose to include other voluntary claims on packaged foods, such as nutrient content claims, provided that they meet the regulatory criteria for the claims. These nutrient content claims characterize the level of any nutrient in a food product using terms such as "free," "high," "low," etc.[3] Manufacturers may choose to label their products using voluntary nutrient content claims in order to differentiate their products within the competitive market and inform consumers about the nutritional value of their products [Ref. 8, 9].

We use Nielsen IQ Label Insight data[4] to evaluate the current prevalence of packaged foods bearing these claims. These proprietary data pull from various sources to provide food product label information for a majority of the food market.[5] The data are structured in a relational database so that every row corresponds to an individual Universal Product Code (UPC),[6] with multiple entries per UPC over time if the label of the product changes. For example, if one product changes the design of the package, ingredients, warning

[3] Other terms include but are not limited to "no", "zero", "negligible", "insignificant", "small amount of", etc. consistent with 21 CFR 101.13. Relative terms such as "reduced" are not considered in our filtering of the Nielsen Label Insights data below.
[4] Available at: https://nielseniq.com/global/en/landing-page/label-insight/.
[5] Nielsen IQ claims that the Label Insight data covers "99% of consumer queries" but is unclear about what a consumer query is or how that reflects the market. Nonetheless, it is the best data available to us and we assume the full market is accurately reflected in the data.
[6] A Universal Product Code, or UPC, is a series of black lines commonly used to identify a food product. It is also referred to as a barcode.

labels, or anything else on the package of the product, that UPC will receive a new row in the Nielsen IQ Label Insight data.

In order to best reflect the current food marketplace, we use data from January 2019 through December 2023 and keep only the most recent observation per UPC. If a product's packaging has changed, we only consider the most recent version of the product, which is the version most likely to be displayed on shelves and available to consumers. We sorted all food categories as reported by Nielsen IQ Label Insights into one of the ten categories used for this analysis. Next, we removed categories in the Nielsen IQ Label Insights data that are either exempt from this proposed rule or not a covered FDA product. Specifically, baby food and dietary supplements are removed because those products are exempt from the proposed nutrition labeling requirements in this rule and alcohol products are removed because the majority of those products are not regulated by the FDA; similarly, food products regulated by the U.S. Department of Agriculture are excluded from this analysis. Removing these product categories potentially leads to an underestimate of the number of UPCs (e.g., hard seltzer products are regulated by the FDA and are subject to this rule but are not included in the data set). Finally, we filtered out observations that have incomplete information for sodium, saturated fat, and added sugars, and then scaled up the count of remaining products by the number of products that had incomplete information. This results in the implicit assumption that having missing nutrient information in the database is uncorrelated with the nutrient levels of the product but allows us to work with a more accurate number of products in the marketplace.

We note that the data we have do not indicate whether products have been discontinued.[7] Some UPCs may leave the market periodically, but because we do not observe that in the data, we are potentially *over*estimating the number of products on the market. However, we may also be *under*estimating the number of products because Nielsen IQ Label Insights data are not a complete census of UPCs in the food marketplace. We are nonetheless confident that the Nielsen IQ Label Insights dataset is the most comprehensive dataset available to study the food marketplace. Table 2 describes the number of UPCs within each of ten food categories and the percent of these UPCs with any one of the nutrient content claims, percent of UPCs with a low sodium claim, and the percent of UPCs with a low saturated fat claim. The Nielsen IQ Label Insight data is not sales weighted and thus does not take into account the total sales of each UPC.

[7] The unit of observation of Nielsen IQ Label Insight data is a single UPC with a timestamp. The timestamp indicates when a label is updated with some new information, which can come from a label re-design, altered ingredients or nutrients, addition or removal of claims, or any other change to any text on the package. We use only the most recent observation per UPC to reflect what is currently in the food marketplace. However, if a product is discontinued, there is still an observation of that product in the data from its most recent label. For example, suppose the label for a UPC was most recently issued in September 2020. Suppose further that the product was discontinued or removed from shelves in October 2021. We do not observe the discontinuation, we only observe the most recent label. Thus, that UPC would be included in our analysis even though the product is not currently available for purchase.

Close to 15 percent of "breakfast cereal" products include saturated fat, sodium, or added sugars nutrient content claims. More specifically, 11 percent of "breakfast cereal" products include a low saturated fat nutrient content claim, and about three percent of breakfast cereals include a low sodium nutrient content claim. Conversely, less than one percent of "dairy" products[8] and about one percent of "confectionary/dessert/sweeteners and sugars" include any saturated fat, sodium, or added sugars nutrient content claims.

Table 2. Percent of UPCs with Nutrient Content Claims, by Food Category

Food Category	Number of UPCs	Percent with any Claim†	Percent with Low Sodium Claim	Percent with Low Saturated Fat Claim
Bakery	37,268	2.3	0.6	0.4
Beverages	19,302	3.6	2.2	0.6
Breakfast Cereal	9,096	14.8	2.6	11.1
Confectionary/Dessert/Sweeteners and Sugars	69,680	1.1	0.5	0.1
Dairy	33,974	0.5	0.1	0.0
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	31,823	2.6	1.1	0.2
Main Dishes and Meals	28,538	4.2	0.9	0.3
Packaged fruit/vegetable	27,057	6.8	2.1	0.2
Processed fish/meat/egg*	10,287	2.7	0.5	0.7
Snacks and Soup	55,301	5.1	1.9	1.8
Total	322,326	3.3	1.1	0.8

Notes:
Data source: Nielsen IQ Label Insight data
† Full list of claims searched in Nielsen data: low sodium, low in sodium, little sodium, sodium free, free of sodium, no sodium, zero sodium, without sodium, trivial source of sodium, negligible source of sodium, dietary insignificant source of sodium, very low sodium, very low in sodium, salt free, unsalted, without added salt, no salt added, saturated fat free, free of saturated fat, no saturated fat, zero saturated fat, without saturated fat, trivial source of saturated fat, negligible source of saturated fat, dietarily insignificant source of saturated fat, low in saturated fat, low saturated fat, contains a small amount of saturated fat, low source of saturated fat, a little saturated fat
*Processed fish/meat/egg products that are regulated by the FDA (and thus are included in this analysis) include vegetable-based meat alternatives, fish except for catfish, and some egg products.

[8] The "dairy" product category includes traditional dairy as well as plant-based dairy alternatives, with the exception of plant-based milk, which we place in the "beverage" category for this analysis.

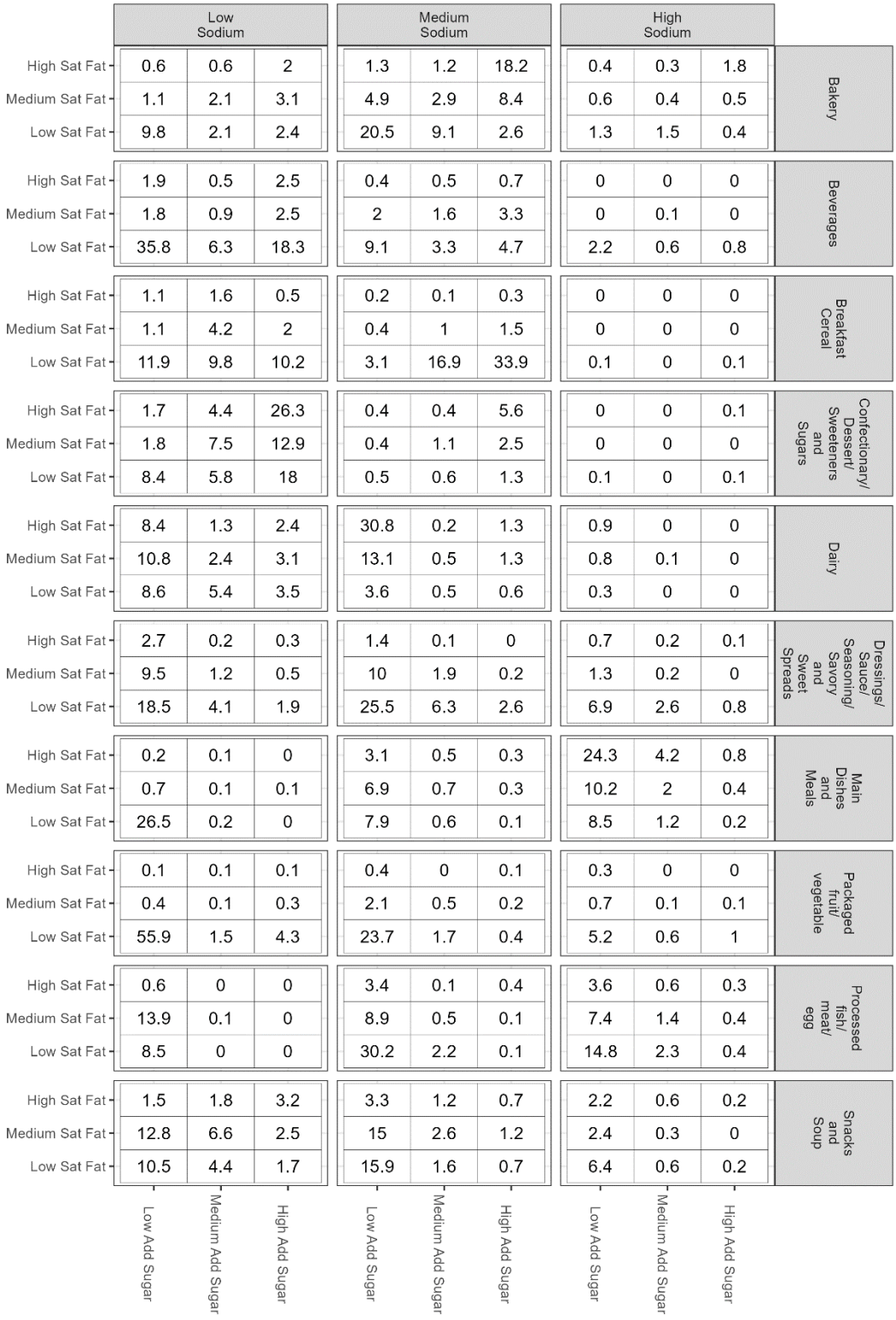
We note that the percentages presented in Table 2 do not include other FOP voluntary claims adopted by the food industry, such as Facts Up Front, Guiding Stars, and other voluntary industry-led labeling initiatives.[9] We are not able to identify the share and type of products that display voluntary FOP nutrition schemes within the Nielsen IQ Label Insight data or other data sources.[10] We invite comment on how voluntary industry-led FOP nutrition labels may impact consumers' current awareness of the nutrient content of foods in the marketplace. We also invite data on the share and type of products that currently display voluntary industry-led FOP nutrition labels.

The proposed rule, if finalized, would require interpretive descriptions and percent DV on most products required to bear the Nutrition Facts label. Figure 1 illustrates that current products across food categories contain myriad combinations of "Low", "Med", and "High" levels of saturated fat, sodium, and added sugars, based on the percent DV thresholds included in the proposed rule. The number in each cell represents the percent of products that contain a particular combination of "Low," "Med," or "High" saturated fat, sodium, or added sugars levels for the given food category. This information is based on the mandatory declarations of these nutrients in the Nutrition Facts label.

[9] For details, see Appendix A of FDA's 2023 Front of Package Labeling Literature Review, https://downloads.regulations.gov/FDA-2023-N-0155-0031/content.pdf.

[10] The Nielsen IQ Label Insight data concatenates all text on a product except for brand, product name, ingredients, and nutrient information into a single variable. While it is possible to identify a certain string of letters such as "low sodium," Facts Up Front or other voluntary industry-led FOP labeling claims have no consistent starting or ending characters, making it more complex to identify. The inconsistency of the way Nielsen IQ Label Insight text data is structured means that identifying these claims would be unreliable for analysis.

Figure 1. Percent of Products in Each Nutrient Level Combination Per Food Category



Notes:
Each number represents the percent of products that are in a particular nutrient combination for the given food category.

The percentages vary in predictable ways. For instance, almost none of the 9,096 breakfast cereals contain "High" sodium. Within the breakfast cereals that contain "Medium" levels of sodium, the majority are "Low" in saturated fat (53.9%=3.1% + 16.9% + 33.9%) and more than one third (33.9%) contain "High" amounts of added sugar. On the other hand, 56 percent of packaged fruits and vegetables have "Low" levels of saturated fat, sodium, and added sugars. While some food categories, such as snacks/soups and bakery, contain products evenly distributed across nutrient levels, each food category tends to have a high concentration of items in one or two nutrient level combinations.

2. Consumer Label Use

Results from FDA's 2019 Food Safety and Nutrition Survey (FSANS), the most recent FSANS data available, suggest that consumers are aware of many nutrient content claims, such as "low sugar," "no added sugar," "low sodium," and "low saturated fat," and purchase products with these nutrient content claims. For instance, the 2019 FSANS found that approximately 90 percent of respondents had seen food products "labeled 'low sodium' or 'low fat' or 'no added sugar'" and 22 percent of respondents purchased these foods regularly [Ref. 1].

The FSANS found that 87 percent of adults living in the U.S. look at the Nutrition Facts label on food packages, and at least 76 percent use the Nutrition Facts label when buying a food for the first time [Ref. 1]. The FSANS also found that, of those that ever use the Nutrition Facts label, 56.5 percent of respondents looked for sodium, 39 percent looked for added sugars, and 34 percent looked for saturated fat.

FSANS results found that 57 percent of all consumers correctly interpret the percent DV [Ref. 10]. Similarly, using the 2017-2020 National Health and Nutrition Examination Survey (NHANES), we find that 60 percent of respondents understood the meaning of the percent DV. However, of the 87 percent of respondents who looked at the Nutrition Facts label in the FSANS, only 49 percent reported looking at the percent DV. Earlier consumer research data also found that some consumers have difficulty understanding the concept of percent DV, suggesting that providing interpretive information such as "Low," "Med," and "High" could provide consumers with more context about nutritional information at the point of purchase [Ref. 11].

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. 12].[11] The study found households with low nutrition information use scored lower on the Healthy Eating Index (HEI), a measure of diet quality measuring a consumer's conformity to the Dietary Guidelines. Households with low nutrition use had a Healthy Eating Index score of 48.1, compared to 53.8 for households with medium nutrition information use. There is also evidence that label use varies across

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

subgroups: consumers with higher education levels and more nutrition knowledge use nutrition labels more often [Ref. 13, 14], while adolescents and older adults who are obese use nutrition labels less frequently [Ref. 15].

Additionally, use of nutrient information may be associated with consumers' health status. For example, studies found that individuals with chronic diseases such as diabetes, hypertension, and/or hyperlipidemia were more likely to use the Nutrition Facts label, compared to those without any of these diseases [Ref. 16, 17]. A 2015 study found that individuals with hypertension compared to those with no hypertension were more likely to use the Nutrition Facts label for sodium information [Ref. 18].

E. Benefits of the Proposed Rule

The proposed rule, if finalized, would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. The proposed rule may result in industry reformulating products to maintain nutrient content claims and reformulating products based on interpretive label information that would be required by this FOP labeling rule, if some manufacturers choose to do so. We discuss the benefits to consumers of this proposed rule below.

1. Informational Effects

FDA conducted a systematic review of the scientific literature on FOP labeling schemes.[12] The literature suggested that familiarity with such schemes may make them more useful as time passes, and that these schemes can be useful across all demographics and levels of nutrition knowledge, can help consumers understand the nutrition quality of food, and can positively impact consumers' intention to purchase healthful foods.

FDA also conducted an experimental study to explore consumer responses to various FOP labeling schemes.[13] The study tested three FOP scheme categories with various features (e.g., one scheme category shown both with and without nutrient percent DV), for a total of eight FOP schemes. Each scheme displayed information about saturated fat, sodium, and added sugars in the three scheme categories: (1) Guideline Daily Amount (GDA); (2) Nutrition Info; and (3) High In. The Nutrition Info schemes mimicked the design of the Nutrition Facts label and provided interpretive nutrition information by identifying the level of the three nutrients per serving as "Low," "Med," and "High."

The Nutrition Info schemes produced more correct answers and higher scores than the other schemes tested, and participants were generally able to correctly identify the level of saturated fat, sodium, and added sugars in products. Participants viewing the Nutrition

[12] See *Front of Package Labeling Literature Review*, Available from: https://www.fda.gov/media/175617/download?attachment.
[13] See *Front of Pack (FOP) Schemes to Test.* Available from: https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=253321

Info schemes also spent significantly less time evaluating the nutrient profile of a product than those viewing the other schemes tested (i.e., they felt confident enough to answer questions in a shorter amount of time). See section III.D of the proposed rule for more information about the other schemes tested.

The "Low," "Med," and "High" interpretive descriptions included in the experimental study for the three nutrients to limit were based on established FDA criteria for determining the percent DV of a nutrient, and we are proposing to use those same criteria for the rule. These descriptions would interpret the percent DV of saturated fat, sodium, and added sugars per product serving. The findings of the experimental study suggest that the "Low," "Med," and "High" interpretive descriptions, which would be new information not contained in the Nutrition Facts label, could be particularly useful for consumers who had challenges understanding the numerical information.

Some research indicates that use of the Nutrition Facts label differs by sex, race/ethnicity, education level, and household income; specifically, regular use of the Nutrition Facts label is lower among men, those with lower education levels, and those with lower income [Ref. 2, 19, 20]. Therefore, nutrition labeling that is interpretive and prominently displayed on the front of food packaging could help improve consumer awareness of nutrients to limit by providing a more accessible description of certain information contained in the Nutrition Facts label.

2. Reformulation Effects

Although reformulation is not a requirement or goal of the proposed rule, the proposed rule may result in some food manufacturers reformulating their products in response to this policy. We discuss the cost of reformulation to food manufacturers in section II.F.2 below. A 2023 systematic review of the effect of various front of package labels concluded that mandatory labels with interpretive information, such as the FOP label proposed in this rule, incentivize manufacturers to reformulate products [Ref. 21]. We anticipate some manufacturers could voluntarily choose to reduce saturated fat, sodium, or added sugars in a food to display "Low" or "Med" instead of "Med" or "High" in the Nutrition Info box. We expect approximately 2,000 UPCs (0.5 percent of all covered UPCs) would be reformulated as a result of the proposed FOP labeling rule, resulting in reduced saturated fats, sodium, and added sugars in the packaged food marketplace.

Further, manufacturers may reformulate in order to continue making nutrient content claims. This rule, if finalized, would update the definition of the low sodium nutrient content claim to be consistent with current nutrition science, which the 2016 Nutrition Facts label already reflects. The updated definition for the low sodium nutrient content claim may result in some manufacturers who are currently using the low sodium claim on products that have 116-140 mg sodium, which would no longer qualify for the low sodium nutrient content claim, lowering sodium levels in their products to 115 mg or less per RACC (or 115 mg per 100 grams for meals and main dishes). We estimate that 232 UPCs (0.07

percent of all covered UPCs) would be reformulated exclusively to keep the low sodium claim.

Limited data are available on the magnitude of the reformulation due to introduction of FOP labeling. Systematic literature reviews suggest that after introducing "High In" warning labels in Chile, the share of products required to bear a high-in added sugar label went from 80 percent to 60 percent and the share of products required to bear a high-in sodium label went from 74 percent to 27 percent. However, these food products were reformulated to just below the nutrient cutoffs [Ref. 22]. Studies suggest that voluntary FOP schemes lead to less reformulation because packaged food manufacturers can choose not to use the schemes on their products [Ref. 22].

Consumers would benefit from potential nutritional improvements by the shift in the composition of reformulated products, and reformulation would increase the number of options for "Low" or "Med" products on the market. We are not aware of any research looking at reformulation of foods to reduce saturated fats, sodium, and added sugars at the same time, although some studies have estimated the cost effectiveness of industry reformulation to reduce the amount of sodium and added sugars in packaged foods separately [Ref. 23, 24, 25]. We are not aware of any studies focusing on reformulation to reduce saturated fat in packaged foods; studies showed that, in general, reductions and reformulations were related to sodium, added sugars, and calories, but not saturated fat.

We expect that even minor reductions in the three nutrients to limit could result in a healthier food supply for consumers, particularly when considered across a person's total daily diet. Research shows that even small reductions in sodium are associated with a reduced risk of hypertension and cardiovascular disease [Ref. 21, 23, 24].

We are not sure whether the impact of reformulation as a result of this proposed rule, if finalized, would be smaller or larger than the impact of a hypothetical sugar reformulation policy described above. While the proposed rule may result in some reformulation regarding the three nutrients to limit, we are unsure how manufacturers might change the full recipes to reformulate, including whether they would choose to reformulate to adjust the levels of one, two, or three of the nutrients to limit.

Limited data are available on the magnitude of the potential reformulation, the market share of such reformulated products, and the distribution of sales across consumers. Thus, we do not quantify the potential beneficial effects of voluntary reformulation to reduce saturated fat, sodium, or added sugars on health outcomes.

F. Costs of the Proposed Rule

Food manufacturers affected by the proposed rule will incur costs of re-labeling all food products and potentially voluntarily reformulating some foods. Labeling costs are the

costs associated with printing the proposed label on the front of food packages. Because of the proposed changes to the nutrient content claim definitions, some members of industry may choose to remove the claims from their product that no longer qualify for the claims rather than reformulate. However, these products will have to establish front of pack labels, so we assume the costs associated with removing nutrient content claims are subsumed into the costs of establishing the front of pack label, since these activities would happen simultaneously and would be coordinated. Reformulation costs are the costs associated with altering the composition of foods in order to change the nutrient levels that would need to be declared on, among other things, the FOP label. We estimate the cost of reformulation because it may be a result of the proposed rule, even if it is not a requirement of the rule.

1. Labeling Costs

In order to comply with the rule as proposed, manufacturers of covered products would need to print the FOP label on food packages, which may include a redesign of the package to accommodate the label in the designated area. We estimate the labeling costs associated with the proposed rule by multiplying the number of expected covered UPCs by per-UPC costs estimated using the FDA Labeling Cost Model [Ref. 26].

a. Number of Covered UPCs

We estimate the number of UPCs that would need to establish an FOP label using Nielsen IQ Label Insight data. See Section II.D.1 for details on how we use the Nielsen IQ Label Insight data to count the number of food product UPCs that would need to establish an FOP label. See Table 3 for a summary of the number of covered UPCs by food category. We anticipate approximately 322,000 products would undergo a relabeling process to establish an FOP label. We observe that the confectionary/dessert/sweeteners and sugars category has the largest number of UPCs, while breakfast cereal and processed fish/meat/egg have relatively few covered UPCs.

Table 3. Number of UPCs Expected to Relabel

Food Category	No. UPCs Relabel
Bakery	37,268
Beverages	19,302
Breakfast Cereal	9,096
Confectionary/Dessert/Sweeteners and Sugars	69,680
Dairy	33,974
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	31,823
Main Dishes and Meals	28,538

Food Category	No. UPCs Relabel
Packaged fruit/vegetable	27,057
Processed fish/meat/egg	10,287
Snacks and Soup	55,301
Total	322,326

b. Per-UPC Labeling Costs

Per-UPC labeling costs were estimated using FDA's Labeling Cost Model 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. 26]. 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. 26]. Labeling costs include labor, materials, inventory (discarded inventory and disposal costs), and recordkeeping. They are first calculated on a per-UPC basis and then aggregated across each product category, and are calculated separately as low, mean, and high-cost estimates.

The labeling cost model includes administrative and recordkeeping costs associated with understanding the regulation, determining manufacturer responses, tracking required changes throughout the labeling change process, and reviewing and updating records of product labels. We do not expect food manufacturers will incur additional recordkeeping costs beyond these because the current Nutrition Facts label already provides the percent DV information needed to determine which interpretive information will be displayed on the FOP informational graphic (i.e., "Low," "Med," or "High").

Most products that voluntarily relabel do so in a two- to five-year cycle, with private-label products[14] less likely to be relabeled in any given year than branded products [Ref. 26]. Manufacturers can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) and would incur lower costs than they would otherwise. Longer compliance periods increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling changes. If a manufacturer cannot coordinate required label changes with planned label changes, we classify those costs as uncoordinated costs.

Regardless of coordination, the FDA Labeling Cost Model includes costs of administrative and recordkeeping activities associated with labeling changes. Other types of costs, though, such as prepress, graphic design, and engraving plates or cylinders, are not

[14] A private-label product is typically manufactured and distributed by the retailer selling the product, while a branded product is manufactured and distributed by a brand that is not a food retailer.

attributed to the regulation if the required labeling change is coordinated with a planned voluntary label change.

See Table 4 for a summary of costs for uncoordinated and coordinated relabeling costs by food category. Although the per-UPC costs vary across food categories, uncoordinated costs are approximately six times higher than coordinated costs.

Table 4. Estimated Per-UPC Relabeling Costs, 2023 USD, by Food Category

	Uncoordinated			Coordinated		
Food Category	**Primary**	**Low**	**High**	**Primary**	**Low**	**High**
Bakery	**$12,939**	$6,465	$23,072	**$1,909**	$567	$4,290
Beverages	**$13,307**	$6,748	$23,657	**$2,177**	$646	$4,892
Breakfast Cereal	**$11,173**	$5,714	$19,770	**$1,713**	$508	$3,849
Confectionary/Dessert/Sweeteners and Sugars	**$13,591**	$7,266	$23,571	**$1,912**	$568	$4,297
Dairy	**$11,692**	$5,999	$20,553	**$1,701**	$505	$3,821
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	**$11,143**	$5,729	$19,661	**$1,691**	$502	$3,800
Main Dishes and Meals	**$10,060**	$5,014	$18,107	**$1,669**	$495	$3,750
Packaged fruit/vegetable	**$12,108**	$6,207	$21,315	**$1,815**	$539	$4,079
Processed fish/meat/egg	**$11,322**	$5,659	$20,147	**$1,669**	$495	$3,750
Snacks and Soup	**$12,197**	$6,214	$21,552	**$1,750**	$519	$3,933

c. Total Labeling Costs

As described above, per-UPC labeling costs differ based on whether a manufacturer is able to coordinate a required label change with a scheduled voluntary change. The prevalence of coordination is different for branded versus private label goods, and the rate at which coordination is possible is different over compliance periods for branded versus private label goods [Ref. 26]. For example, for a compliance period of one year,

89 percent of branded products and 95 percent of private label products would face uncoordinated costs. For a three-year compliance period, all branded products would be able to coordinate label changes, while 43 percent of private label products would still face uncoordinated costs.

The FDA Labeling Cost Model has data on the number of branded versus private-label products within each food category. The data we use from Nielsen IQ Label Insight does not contain any indicator for whether or not an individual UPC is branded or private-label. We therefore use the percent of branded and private-label goods from the FDA Labeling Cost Model and apply those percentages to the total count of products by food category to arrive at a number of branded and private-label UPCs in our data. We invite comment on the prevalence of branded and private-label products on the market.

See Table 5 for a summary of labeling costs for a three-year compliance period. We calculate the labeling costs by performing a Monte Carlo simulation where we take 1,000 draws from a triangular distribution defined by the primary, low, and high per-UPC cost estimates provided by the FDA Labeling Cost Model and multiplying that distribution by the number of expected UPCs in each food category. We summarize the median (primary), 5th (low), and 95th (high) percentiles of the final distribution of costs per food category in Table 5. For completeness, we estimate label costs in the same way for compliance periods of one, two, three, and four or more years. As described above, these costs differ depending on the number of branded or private-label goods there are in each food category, and what percent of each type of product can coordinate given a certain compliance period.

Table 5. Estimated Relabeling Costs for a Three-Year Compliance Period, 2023 USD, Millions

Food Category	Primary	Low	High
Bakery	**$175**	$120	$243
Beverages	**$89**	$61	$121
Breakfast Cereal	**$42**	$29	$56
Confectionary/Dessert/Sweeteners and Sugars	**$351**	$240	$468
Dairy	**$140**	$99	$186
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	**$108**	$74	$149
Main Dishes and Meals	**$87**	$58	$120
Packaged fruit/vegetable	**$117**	$83	$157
Processed fish/meat/egg	**$34**	$23	$46

Food Category	Primary	Low	High
Snacks and Soup	**$191**	$126	$262
Total	**$1,333**	$911	$1,807

The proposed rule sets a compliance date of three years for large manufacturers and four years for small manufacturers. Because our Nielsen IQ Label Insight data does not contain a variable for the manufacturer of an individual product,[15] we cannot be certain if an individual UPC is manufactured by a large or small manufacturer. We therefore assume that 48 percent of UPCs are made by small manufacturers, and the remaining 52 percent of UPCs are made by large manufacturers.[16] We invite comment on this assumption.

See Table 11 for the stream of labeling costs over the ten-year time horizon of the rule. We attribute 52 percent of the estimated costs shown above in year 3 of the rule, and 48 percent of the estimated costs in year 4 to reflect the staggered large and small manufacturer compliance dates.

Across the ten-year time horizon, our primary estimate of undiscounted labeling costs is approximately $1 billion 2023 USD. Annualized labeling costs over 10 years would range from $66 million to $154 million at a 2 percent discount rate, with a primary estimate of $105 million. See Section II.F.4 for a summary of total costs. We invite comment on these estimates and our underlying assumptions.

2. Reformulation Costs

The proposed rule does not require reformulation, but manufacturers may voluntarily choose to do so if they want to avoid “High” or “Med” descriptions of sodium, added sugars, or saturated fat. We estimate the cost because it may be a result of the proposed rule, even if it is not a requirement of the rule. Since some UPCs may share a single formula, we assess reformulation costs on a per-formula basis. The unit of observation in our data is UPC, so we make a simplifying assumption throughout that there are 0.8 formulas per UPC.

[15] The Nielsen IQ Label Insight data may contain information on individual manufacturers, but it is not in any standard format and we can therefore not use any data manipulation to reliably tease out manufacturers.

[16] This assumption is based on 2016 analysis using Nielsen scanner data in support of the Nutrition Facts label Final Regulatory Impact Analysis and is consistent with prior analysis of the food marketplace. See 81 FR 33742.

a. Number of UPCs Expected to Reformulate

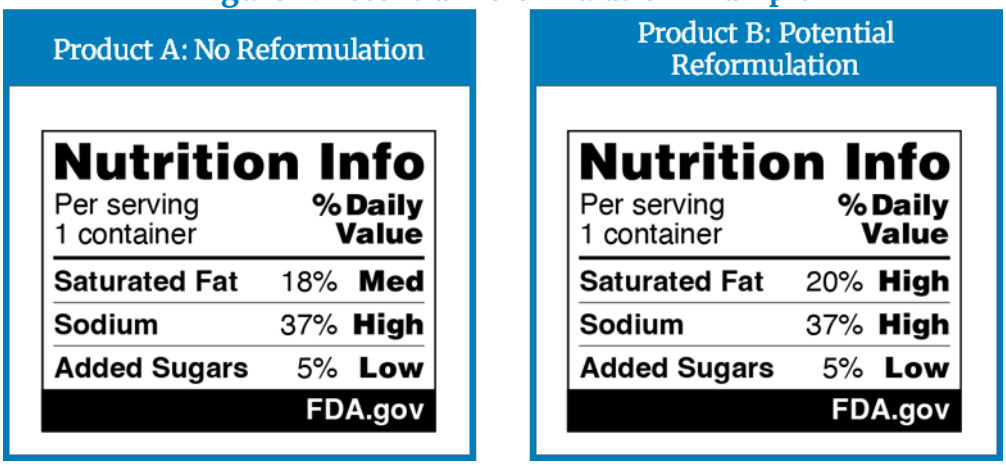
It is difficult to predict how the proposed rule would influence manufacturers' decisions to reformulate. We expect that some manufacturers would reformulate their food products so that the nutrient levels may move from "High" to "Med" or "Med" to "Low," while others would not reformulate and would keep their baseline nutrient levels. Other manufacturers of products with nutrient content claims may choose to reformulate so that the product can keep the claim after the proposed changes. For some products, reformulation may allow a product to both keep a nutrient content claim and move from a "Med" to "Low" level on the FOP label. Because the decision to reformulate is internal to each manufacturer, factors that lead to either the decision or magnitude with which to reformulate, as used in the quantification below, are subject to uncertainty.

We therefore count the number of UPCs that may reformulate in two steps. First, we identify 1) products that have nutrient levels that are within one percentage point of the DV thresholds for the "Med" or "Low" levels across any of the three nutrients; and 2) products that have a low sodium or low saturated fat nutrient content claim, would be ineligible for the nutrient content claim under the proposed changes, but are within one percentage point of the daily value threshold for "Low" levels of sodium or saturated fat. In the case of sodium, we also identify products that currently have a low sodium nutrient content claim but that would not be eligible for the nutrient content claim under the proposed changes (because they have between 116 mg and 140 mg sodium per RACC) despite having 5% DV or less sodium per serving.

Second, conditional on being within the one percentage point threshold, we assume the likelihood of a product reformulating is about 5 percent (see below for more details on this assumption), unless the product has a nutrient content claim but would be ineligible for the claim under the proposed changes to the nutrient content claim regulations. In this case, conditional on being identified as part of the groups above, we assume the likelihood of a product reformulating is about 85 percent. See below for an explanation of these assumptions.

See Figure 2 for an example of the first step in our process: selecting products that are within one percentage point of the percent DV thresholds for the nutrient levels. We assume Product A will not reformulate because it would either have to reduce saturated fat from 18% DV to 5% DV (a 13-percentage point reduction in the percent DV) to move from "Med" to "Low" or reduce sodium from 37% DV to 19% DV (an 18-percentage point reduction) to move from "High" to "Med." Notice, however, that the saturated fat in Product B is 20% DV. Product B could reduce the saturated fat by one percentage point to move from "High" to "Med" saturated fat on the FOP label. Product A is flagged for no reformulation and thus faces no reformulation costs, while Product B is considered in the second step in our process.

Figure 2. Potential Reformulation Example



See Table 6 for a summary of characteristics for each group flagged for an estimate regarding reformulation. Products in the first group have no nutrient content claims and are within one percentage point of the "Med" or "Low" thresholds for any nutrient, as described above and shown in Figure 2. Products in the second group are within one percentage point of the "Low" FOP threshold and have a nutrient content claim. These products are separated out because they may choose to reformulate in order to keep the nutrient content claim. However, these products would need to reformulate such that their product has 5% or less DV per serving, which would accomplish both being required to declare a "Low" FOP designation *and* allowing them to keep their nutrient content claim. Products in the third group, however, would reformulate only to keep their nutrient content claim. These are products that already have a "Low" FOP description but would need to reformulate the amount of sodium per RACC to keep their nutrient content claim. We separate these groups to better understand the contribution of parts of the rule to the total estimated costs of the rule, and because we assume that groups 2 and 3 are more likely to reformulate.

Table 6: Description of Groups Flagged for Reformulation by Cause of Reformulation

Group Number	Cause of Reformulation	Range of %DV	Range of nutrients per RACC	Nutrient Content Claim
1	FOP	One percentage point away from "Med" or "Low" thresholds	Any	No

Group Number	Cause of Reformulation	Range of %DV	Range of nutrients per RACC	Nutrient Content Claim
2	Both FOP and Nutrient Content Claim	One percentage point away from "Low" threshold	Any	Yes
3	Change in Nutrient Content Claim	At or Below 5%	115mg/RACC to 140mg/RACC	Sodium

After counting the number of products that fall into the categories above, the second step in our process involves Monte Carlo simulation. Specifically, we aggregate the number of UPCs by food category that are within each group, and then multiply that aggregate number by a statistically uncertain percentage that reflects the probability of reformulation. The group with no nutrient content claims is multiplied by a uniform distribution that ranges from 3 to 7.5 percent. The groups with nutrient content claims are multiplied by a uniform distribution that ranges from 80 to 90 percent. The range for the group with no nutrient content claims 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. 27]. Second, the high bound is borrowed from the Final Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Final Rule;[17] the analysis estimated that 7.5 to 9 percent of formulas that significantly contribute added sugars to diets would be reformulated once added sugars were required on the NFL. The range for the group with nutrient content claims is based on our best estimate of the probability of reformulation given the presence of a nutrient content claim at baseline. We invite comment on our assumptions.

We note that for the confectionary/dessert/sweeteners and sugars food category, we expect no products to reformulate. We set this number to zero because we expect that even if a product is within a percentage point of the DV threshold, the product will likely not reformulate because foods in this category do not compete on nutrients to limit; in other words, consumers likely expect these products will contain higher levels of saturated fat, sodium, and added sugars. We also note that for dairy, we only consider reformulation for sodium and added sugars. The dairy market is already segmented along saturated fat levels: dairy products are already labeled as "non-fat," "low-fat," or "whole," so it is unlikely products will reformulate along that nutrient dimension, regardless of proximity to the percent DV thresholds. We note that this assumption is particularly relevant for fluid dairy and to a lesser extent other dairy such as cheese, yogurts, etc. We invite comment on this and other reformulation assumptions.

[17] See https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-nutrition-facts-label-and-serving-size-final-rules.

See Table 7 for the number of products we expect to reformulate by the reasons for reformulation. These are post-simulation estimates that reflect both the count of products in the distinct categories *and* the fact that reformulation is uncertain. Only primary estimates are presented for brevity, but the full range of estimates is used in our analysis. We present Table 7 to illustrate that the majority of products that we expect might reformulate do so because of the FOP labeling scheme. We expect only 232 products may reformulate specifically because of the changes to the nutrient content claim regulations.

The remainder of the analysis aggregates estimated reformulation costs across these identified groups. After simulating which products may reformulate as a result of the proposed rule, we multiply those products by unit costs that do not explicitly vary over cause of reformulation.

See Table 8 for the primary, low, and high estimates of the total number of UPCs we expect may reformulate by food category. For completeness, we also present the number of covered UPCs that would relabel as a result of the rule. In total, we expect approximately 2,000 out of 322,000 UPCs to reformulate (0.5 percent of all covered UPCs).

Figure 6 in the Appendix illustrates the nutrient combinations that we expect would be reformulated. For instance, within the Packaged Fruits/Vegetables food category, 13 products are identified as containing “Low” saturated fat and sodium but contain added sugar levels within one percentage point above the “High” percent DV threshold of 20%. Thus, we expect these products would remove some amount of added sugars in order to be able to use the “Med” added sugars interpretive description in the Nutrition Info box.

Table 7: Number of UPCs Expected to Reformulate by Reason for the Choice to Reformulate

	Reason for Reformulation		
Food Category	**Front-of-Pack**	**Change in Nutrient Content Claim**	**Both Front-of-Pack and NCC**
Bakery	355	15	5
Beverages	84	5	13
Breakfast Cereal	73	16	9
Confectionary/Dessert/Sweeteners and Sugars	0	0	0
Dairy	185	0	4

	Reason for Reformulation		
Food Category	**Front-of-Pack**	**Change in Nutrient Content Claim**	**Both Front-of-Pack and NCC**
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	250	49	13
Main Dishes and Meals	180	2	11
Packaged fruit/vegetable	101	58	76
Processed fish/meat/egg	56	0	7
Snacks and Soup	452	87	83
Total	1,735	232	221

Table 8. Estimated Number of UPCs Expected to Reformulate, by Food Category

		No. UPCs Reformulated		
Food Category	**No. UPCs Relabeled**	**Primary**	**Low**	**High**
Bakery	37,268	**375**	238	513
Beverages	19,302	**102**	69	135
Breakfast Cereal	9,096	**98**	70	125
Confectionary/Dessert/Sweeteners and Sugars	69,680	**0**	0	0
Dairy	33,974	**189**	120	263
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	31,823	**312**	218	408
Main Dishes and Meals	28,538	**192**	122	261

		No. UPCs Reformulated		
Food Category	**No. UPCs Relabeled**	**Primary**	**Low**	**High**
Packaged fruit/vegetable	27,057	**235**	196	273
Processed fish/meat/egg	10,287	**63**	41	84
Snacks and Soup	55,301	**621**	448	788
Total	322,326	**2,187**	1,521	2,850

b. Per-Formula Reformulation Costs

Per-formula reformulation costs were estimated using FDA's Reformulation Cost Model [Ref. 28]. The FDA Reformulation Cost Model was developed in 2015 using an expert panel of individuals who previously oversaw product reformulation at major food manufacturing companies or who provided formulation consulting services to small and large food manufacturers. The model 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), (iv) 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 (v) compliance period (costs are higher for shorter compliance periods because if the compliance period is short, manufacturers would incur increased costs for overtime labor, additional staffing, and rush charges with vendors and suppliers). 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 may be overestimated. We invite comment on our reformulation model assumptions, including food product complexity, company size, reformulation type, and activities.

See Table 9 for a summary of per-formula reformulation costs by food category. Although the per-formula costs vary across food categories, the primary estimate for the cost of reformulation for a single formula is approximately $1 million.

Table 9. Estimated Per-Formula Reformulation Costs, 2023 USD, by Food Category

Food Category	Primary	Low	High
Bakery	**$1,226,336**	$584,278	$2,210,720
Beverages	**$1,030,544**	$499,207	$1,840,838
Breakfast Cereal	**$1,507,614**	$721,608	$2,709,476
Confectionary/Dessert/Sweeteners and Sugars	**$1,370,071**	$654,083	$2,466,553
Dairy	**$1,163,294**	$562,088	$2,080,911
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	**$927,424**	$445,404	$1,665,346
Main Dishes and Meals	**$1,236,525**	$591,806	$2,223,688
Packaged fruit/vegetable	**$1,039,841**	$496,614	$1,872,248
Processed fish/meat/egg	**$1,118,925**	$535,015	$2,013,313
Snacks and Soup	**$1,316,904**	$631,420	$2,365,321

c. Total Reformulation Costs

As described above, we make the simplifying assumption that there are 0.8 formulas per UPC to convert our counts of UPCs to formulas and multiply that count by the per-formula unit costs described above. Specifically, we multiply the full distribution of formula counts estimated using a Monte Carlo simulation with a uniform distribution described in Section II.F.2.a by the full distribution of per-formula costs using a triangular distribution. We perform this simulation for each food category. See Table 10 for a summary of total costs of reformulation by food category. Our primary estimate is the median of the final distribution, while the low and high estimates are the 5th and 95th percentiles respectively.

Recall that per-formula reformulation costs are relatively similar across food categories, so the high reformulation costs for bakery goods and snacks/soups are primarily a function of the large number of UPCs we predict will reformulate in those categories. In total, we expect reformulation costs to range from $1.2 billion to $3.6 billion, with a primary estimate of $2.2 billion. Annualized reformulation costs over 10 years would range from $125 million to $377 million at a 2 percent discount rate, with a primary estimate of $227 million. See Section II.F.4 for a summary of costs. We invite comment and data on these estimates and our underlying assumptions.

Table 10. Estimated Costs of Reformulation, 2023 USD Millions, by Food Category

Food Category	Primary	Low	High
Bakery	**$383**	$194	$667
Beverages	**$87**	$47	$153
Breakfast Cereal	**$125**	$72	$203
Confectionary/Dessert/Sweeteners and Sugars	**$0**	$0	$0
Dairy	**$183**	$97	$310
Dressings/Sauce/Seasoning/Savory and Sweet Spreads	**$243**	$137	$402
Main Dishes and Meals	**$201**	$102	$340
Packaged fruit/vegetable	**$209**	$123	$314
Processed fish/meat/egg	**$59**	$33	$102
Snacks and Soup	**$698**	$399	$1,130
Total	**$2,188**	$1,204	$3,623

3. Qualitative Discussion of Cost Incidence and Non-Quantified Costs

Manufacturers can use the front of food packages to entice consumers at the point of sale to purchase their products. To the extent that mandatory FOP labels limit the space available to manufacturers to market their product at the point of sale, mandatory FOP labels may reduce manufacturers' marketing capacity. Thus, there may be an opportunity cost associated with the proposed rule in that the rule would require manufacturers to devote space on the principal display panel to the Nutrition Info box that could otherwise be used for branding or marketing content which may, in turn, potentially negatively impact revenue. The University of Connecticut Rudd Center for Food Policy and Health estimates that food, beverage, and restaurant companies spend almost $17 billion per year (2023$) on food advertisements in the United States.[18] However, we are unaware of any data or other information that would allow us to refine this estimate to, in turn, estimate the value of advertising that might be impacted as a result of the requirements of the proposed rule. Hence, we invite comment on any such data and other information, which might include information about the distribution of front of package sizes as well as information about the percentage of UPCs that currently use their front of packaging for branding, which we estimate to be 100 percent, and the percentage of UPCs that currently use their front of packaging for marketing content.

[18] See https://uconnruddcenter.org/research/food-marketing/#:~:text=Food%2C%20beverage%20and%20restaurant%20companies,advertisements%20in%20the%20United%20States.

While we do not necessarily expect the proposed rule, if finalized, to impact food prices overall, it is possible there could be certain price effects once a final rule is implemented. Using standard supply and demand analysis, the costs associated with the rule's requirements could put upward pressure on the price of foods affected by the rule via an upward shift in the supply curve for these foods. On the demand side, foods that are mostly "Low" in saturated fat, sodium, and added sugars might experience an increase in demand, which could put added upward pressure on the prices of these foods. Foods that are mostly "High" in saturated fat, sodium, and added sugars could experience a decrease in demand, which alone could put downward pressure on the prices of these foods but when combined with the supply curve shift described above could have an indeterminate effect on the prices of these foods.

If it occurs, we expect the upward shift in the supply curve and subsequent price effects would be small in magnitude across the total food market. As shown in the analysis, mandatory labeling is only 34 percent of the estimated costs of the rule. While reformulation accounts for 63 percent of total costs, we estimate that less than one percent of all food products would reformulate. Thus, some food products may experience an increase in the price, but consumers could select a product that has not been recently reformulated.

There is a recent study that looks at the impact of nutrition warning labels in Chile, whereby products containing an above-threshold amount of calories, sugar, saturated fat, or sodium must display warning labels on the front of their packages, that finds that the nutrition warning labels lead to higher prices of labeled cereals [Ref. 29]. However, Chile's warning labels differ from the proposed FOP labels in that the former take the form of warnings only on foods determined to be "high in" select nutrients while the latter provide interpretive information of the same three nutrients on all food products. The study also focuses on a single food category (breakfast cereals). Therefore, the study has limited applicability in evaluating the potential impact of this proposed rule on food prices.

We are unaware of any data or other information that would allow us to estimate the potential impact of the proposed rule on food prices and, thus, invite comment on any such data and other information.

One additional potential cost includes consumer and producer surplus losses associated with any aesthetic value provided to consumers and producers by existing labeling. We are unaware, though, of any data or other information that would allow us to estimate this cost and, thus, invite comment on any data or other information that might allow us to do so, such as data or information on the size of the proposed FOP label as a percentage of total front of package size.

4. Summary of Costs of the Proposed Rule

In Table 11, we present the stream of undiscounted, monetized costs of the proposed rule over 10 years. Recall that the compliance date for the proposed rule is staggered by manufacturer size: three years for large manufacturers, four years for small

manufacturers. We make the simplifying assumption that 52 percent of UPCs are manufactured by large manufacturers[19] and thus 52 percent of the total costs occur in year three, while the remaining costs occur in year four. We have been able to quantify no other costs of compliance in any other year. In total, our primary estimate of the total undiscounted costs of the proposed rule is $3.2 billion 2023 USD.

Table 11. Stream of Primary Estimates of Undiscounted Costs of Proposed Rule over 10 Years (millions of 2023 USD)

Year	Relabeling Costs	Reformulation Costs	Total Costs
1	$0	$0	$0
2	$0	$0	$0
3	$693	$1,138	$1,831
4	$318	$1,050	$1,368
5	$0	$0	$0
6	$0	$0	$0
7	$0	$0	$0
8	$0	$0	$0
9	$0	$0	$0
10	$0	$0	$0
Total Undiscounted Costs	$1,011	$2,188	$3,199

In Table 12, we present the present and annualized values of monetized costs over 10 years. Using a 2 percent discount rate, the present value of costs over 10 years would range from $1.7 billion to $4.9 billion, with a primary estimate of $3.1 billion. Annualized costs over 10 years would range from $191 million to $530 million at a 2 percent discount rate, with a primary estimate of $333 million.

[19] This assumption is based on a 2016 analysis using Nielsen scanner data in support of the Nutrition Facts Label Final Regulatory Impact Analysis and is consistent with prior analysis of the food marketplace. See 81 FR 33742.

Table 12. Present and Annualized Costs Over Ten Years, Millions 2023 USD

	Primary	Low	High
Total Undiscounted Costs	$3,199	$1,834	$5,097
Present Value, 2%	$3,049	$1,749	$4,856
Annualized Value, 2%	$333	$191	$530

G. Break-Even Calculation

This proposed rule would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. As described above, consumers would gain access to the information provided in the FOP labels.

We undertake a break-even calculation to describe the magnitude of non-quantified benefits required for the benefits to equal or exceed the costs of the regulation.
Under the requirements of this proposed rule, if finalized, most foods that must display a Nutrition Facts label (packaged foods, typically) would bear the proposed FOP label. The benefits of this proposed rule would come from the value consumers receive from the information provided by the proposed FOP label. The proposed FOP label would give consumers additional standardized context about certain nutrients that appear in the Nutrition Facts label and allow them to compare this nutrition information across foods.

Using proprietary Circana Unify Liquid Data from market research firm Circana[20], we estimate that about 184.6 billion packaged food units were sold in the United States in 2023, which we use as our primary estimate of the annual expected number of consumer encounters with the proposed FOP label. However, consumer encounters with non-purchased items are relevant, as those encounters potentially inform the consumer's ultimate purchase. Thus, we estimate that for every N number of units sold, 2*N number of units are encountered by the consumer (we invite comment on this estimate, specifically on data that might assist us in refining this estimate). Based on this, our upper bound estimate of the annual expected number of consumer encounters with the proposed FOP label is 369.2 billion (= 184.6 billion x 2). On the other hand, it might be that beneficial FOP label encounters are limited to less frequent users of the Nutrition Facts label. Data from the 2017-2018 wave of the National Health and Nutrition Examination Survey (NHANES) reveal that 60 percent of people use the Nutrition Facts label sometimes, rarely, or never. Based on this, our lower bound estimate of the annual expected number of consumer encounters with the proposed FOP label is 110.8 billion (= 184.6 billion x 0.6).

[20] https://www.circana.com/company/history/

The cost of this proposed rule, if finalized, annualized over 10 years and using a 2 percent discount rate, ranges from $191 million to $530 million, with a mean estimate of $333 million. If the information provided by the proposed FOP label was valued between around $0.0005 per encounter (= $191 million / 369.2 billion) and approximately $0.0048 per encounter (= $530 million / 110.8 billion) with a mean estimate of about $0.0018 per encounter (= $333 million / 184.6 billion), or one fifth of a cent, then the annual benefits generated by the rule would equal the estimated annual costs of the rule.[21]

The United States faces a growing prevalence of preventable diet-related chronic diseases and conditions (we use the term "diseases" to cover both diseases and conditions), which can include hypertension, cardiovascular disease, type 2 diabetes, and certain forms of cancer. These diseases are leading causes of death and disability in the United States [Ref. 30]. Data show that about one in 10 Americans has diabetes, and 90 to 95 percent of those have type 2 diabetes;[22] at least one in three people will have cancer in their lifetime;[23] and nearly half of American adults have high blood pressure, which is linked to leading causes of death for Americans: heart disease and stroke.[24] While these diseases can result from a mix of risk factors, such as genetic, biological, behavioral, socioeconomic, and environmental factors, unhealthy dietary patterns increase the risk of developing these chronic diseases.[25]

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC) displays estimates of the annual cost associated with various diet-related chronic diseases described above, as well as the sources of these estimates in case greater granularity is desired.[26] Using these sources, Table 13 lists estimates of the annual cost of hypertension, cardiovascular disease, diabetes, and cancer. The hypertension and cardiovascular disease estimates are based on direct costs, such as hospital inpatient stays, hospital emergency department visits, hospital outpatient or office-based provider visits, home health care, and prescribed medicines, as well as indirect costs in the form of lost productivity/mortality. The diabetes estimate comprises direct medical costs as well as indirect costs such as workdays absent, reduced performance at work, reduced

[21] The break-even calculations are based on the total cost of the proposed rule, of which about 15 percent relate to changes in the sodium and saturated fat nutrient content claim requirements. Including these costs in the break-even calculations yields larger break-even values per encounter.
[22] See "Type 2 Diabetes," at the Centers for Disease Control and Prevention (CDC), available at https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/basics/type2.html.
[23] See "Cancer Characteristics, Definitions, and Recent Investigations," at the CDC, available at https://www.cdc.gov/cancer-environment/php/guidelines/characteristics.html?CDC_AAref_Val=https://www.cdc.gov/nceh/cancer-environment/guidelines/cancer-characteristics.html.
[24] See "High Blood Pressure Facts," at the CDC, available at https://www.cdc.gov/high-blood-pressure/data-research/facts-stats/?CDC_AAref_Val=https://www.cdc.gov/bloodpressure/facts.htm and "Multiple Causes of Death 2018-2021" on the CDC WONDER Database, available at https://wonder.cdc.gov/mcd.html.
[25] See *Dietary Guidelines for Americans 2020-2025*, downloaded here https://www.dietaryguidelines.gov/
[26] These estimates and their sources are available at https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html.

productivity days for those not in the labor force, reduced labor force participation due to disability, and mortality. Finally, the cancer estimate is based on direct medical care costs.

This proposed rule is intended to provide consumers with interpretive nutrition information that can help them to quickly and easily identify how foods can be part of a healthy diet. If the proposed rule is finalized and if, through the information provided in the interpretive label on food packages (the proposed FOP label), it also has the indirect effect of reducing the annual cost of hypertension, cardiovascular disease, diabetes, and cancer by about 0.03 percent (= $333 million / $1.09 trillion), then the annual cost savings that would be generated by the rule would equal the $333 million mean estimated annual cost of the rule. We invite comment, including data and information, that might inform analysis of consumers' willingness to pay for the information on the proposed FOP nutrition label.

Table 13. Estimates of the Annual Cost of Certain Diseases that Can be Diet-Related (2023 USD)

Disease	Annual Cost Estimate
Hypertension[a]	$68 billion
Cardiovascular Disease[b]	$356 billion
Diabetes[c]	$426 billion
Cancer[d]	$236 billion
TOTAL	**$1,086 billion**

[a] Source: Table 25-1, "Hypertensive Disease" column of the Benjamin et al. (2018) *Circulation* paper cited by the CDC (see Footnote 23).
[b] Source: Table 25-1, "Heart Disease", "Stroke", and "Other Circulatory Conditions" columns of the Benjamin et al. (2018) *Circulation* paper cited by the CDC (see Footnote 23).
[c] Source: Abstract of the American Diabetes Association (2024) *Diabetes Care* paper cited by the CDC (see Footnote 23)
[d] Source: Abstract of the Mariotto et al. (2020) *Cancer Epidemiology, Biomarkers & Prevention* paper cited by the CDC (see Footnote 23).

H. Transfers Caused by the Proposed Rule

We do not anticipate any transfers caused by the proposed rule.

I. Analysis of Regulatory Alternatives to the Proposed Rule

1. Shorten Compliance Date One Year

Shortening the compliance date for the proposed rule would increase both relabeling and reformulation costs. Labeling costs would increase because fewer manufacturers would be able to coordinate required label changes with voluntary changes. Reformulation costs would increase because for compliance dates of two years or less, costs are multiplied by 1.5 to reflect the increased costs manufacturers would bear to speed up the

reformulation process, shown in Table 14. This multiplier is applied to large manufacturers in year 2, but not to small manufacturers in year 3.

Table 14. Alternative 1: Shorten Compliance Date By One Year, Stream of Discounted Costs (millions 2023 USD, discounted at 2%)

Year	Relabeling Costs	Reformulation Costs	Total Costs
1	$0	$0	$0
2	$917	$1,673	$2,590
3	$615	$1,009	$1,624
4	$0	$0	$0
5	$0	$0	$0
6	$0	$0	$0
7	$0	$0	$0
8	$0	$0	$0
9	$0	$0	$0
10	$0	$0	$0
Total Discounted Costs	$1,532	$2,683	$4,214
Annualized Costs, 2%	$167	$293	$460

Under this regulatory alternative, if the information provided by the proposed FOP label was valued between around $0.0007 per encounter (= $276 million / 369.2 billion) and approximately $0.0064 per encounter (= $711 million / 110.8 billion) with a mean estimate of about $0.0025 per encounter (= $460 million / 184.6 billion), or about one fifth of a cent, then under this regulatory option the annual benefits generated by the rule would equal the estimated annual costs of the rule.

2. Extend Compliance Date One Year

Extending the compliance date for the proposed rule would reduce costs to industry as they would have more time to coordinate label changes, and all costs would be faced further in the future, which, when discounted, results in a lower present value, as shown in Table 15. On the other hand, a longer compliance date may result in an extended period of time when consumers see FOP labels on some products and not others.

Table 15. Alternative 2: Extend Compliance Date, Stream of Discounted Costs (millions 2023 USD, discounted at 2%)

Year	Relabeling Costs	Reformulation Costs	Total Costs
1	$0	$0	$0
2	$0	$0	$0
3	$0	$0	$0
4	$325	$1,072	$1,397
5	$294	$970	$1,264
6	$0	$0	$0
7	$0	$0	$0
8	$0	$0	$0
9	$0	$0	$0
10	$0	$0	$0
Total Discounted Costs	$619	$2,042	$2,661
Annualized Costs, 2%	$68	$223	$290

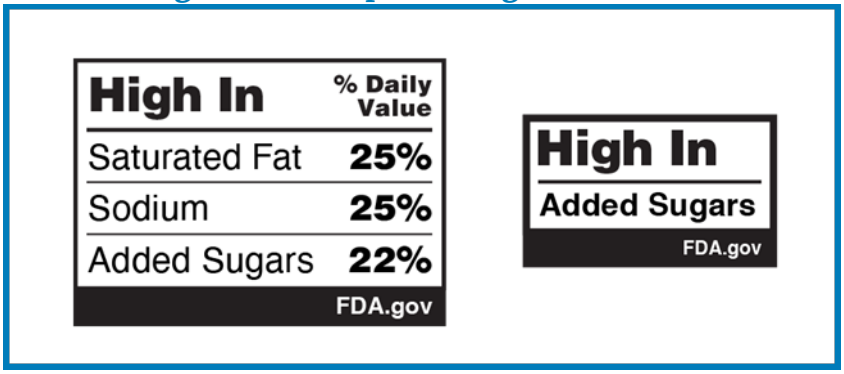
Under this regulatory alternative, if the information provided by the proposed FOP label was valued between around $0.0004 per encounter (= $156 million / 369.2 billion) and approximately $0.0044 per encounter (= $483 million / 110.8 billion) with a mean estimate of about $0.0016 per encounter (= $290 million / 184.6 billion), or about one fifth of a cent, then under this regulatory option the annual benefits generated by the rule would equal the estimated annual costs of the rule.

3. High In Scheme

One scheme tested in FDA's focus groups (OMB control number 0910-0497, "Front-of-Pack Focus Groups") was the "High In" scheme, which only displays nutrients and their relative amounts if they are "high" (e.g. 20% DV or more of a nutrient per serving). See Figure 3 for an example. A variety of "High In" schemes were tested. We note that, in FDA's experimental study, the "High In" scheme performed the worst among the schemes tested when participants were asked to identify a product's healthfulness. Participants were also significantly less likely to identify the "least healthy" and "healthiest" foods when

presented with the "High In" scheme versus with other schemes. Participants viewing the "High In" schemes also spent significantly more time evaluating the information provided before answering questions about the healthiest and least healthy nutrient profiles (i.e., they were not as confident in providing an answer in the same amount of time as compared to their responses when using other schemes). This is evidence of a less-effective FOP scheme, but we nonetheless estimate the costs of the rule if we were to propose and finalize a "High In" FOP scheme while also changing the nutrient content claim regulations.

Figure 3: Examples of High In Scheme



We estimate the costs of a "High In" scheme using each step in the main analysis, with some notable differences. First, labeling costs are not applicable to all products. Only products with nutrient levels of "High" in one or more key nutrients would need to generate a label for the FOP. Second, fewer products would potentially reformulate. Products without nutrient content claims would be considered for reformulation (prior to simulation) only if they were within one percentage point of the "Med" level for any nutrient that is "High" at baseline. We estimate that products with nutrient content claims would reformulate only to keep their nutrient levels within the "Low" FOP level, since we assume that the nutrient content claim regulations would still change as proposed even if we proposed a "High In" scheme for the FOP. Finally, if a product is reformulated in its nutrient level to move from "High" to "Med," the manufacturer would not face any relabeling costs associated with that nutrient, since they would no longer have to print the "High In" label. All other input assumptions remain the same in our analysis of the costs of a "High In" scheme.

See Table 16 for primary, low, and high estimates of the total and annualized costs of the rule under a "High In" scheme. We expect the annualized costs of the rule under a 2% discount rate range from $72 million to $173 million, with a primary estimate of $117 million. Recall that the primary estimate for annualized costs of the proposed rule is $333 million.

Table 16: Summary of Costs Associated with "High In" Regulatory Alternative, Millions 2023 USD

	Primary	Low	High
Total Undiscounted Costs	**$1,125**	$687	$1,666
Total Discounted Costs	**$1,073**	$656	$1,588
Annualized Costs, 2%	**$117**	$72	$173

Using Circana Unify Liquid Data, we estimate that about 46 percent of UPCs and 84.9 billion packaged food units would bear a "High In" FOP label. Consistent with the break-even discussion in Section G, we use 84.9 billion as our primary estimate of the annual expected number of consumer encounters with the high-in FOP label with 169.8 billion as our upper bound estimate and 50.9 billion as our lower bound estimate. Thus, under this regulatory alternative, if the information provided by the "High In" FOP label was valued between about $0.0004 per encounter (= $72 million / 169.8 billion) and $0.0034 per encounter (= $173 million / 50.9 billion) with a mean estimate of roughly $0.0014 per encounter (= $117 million / 84.9 billion), or one tenth of a cent, then the annual benefits generated by the rule would equal the estimated annual costs of the rule.

4. Addition of Calorie Information on Front-of-Pack Label

We also consider an alternative where calorie information is added to the proposed FOP label.[27] This policy alternative aligns with the requests in a 2022 citizen petition asking FDA to require FOP nutrition labeling that is "1) mandatory, 2) nutrient-specific, 3) includes calories, and is 4) interpretative with respect to the levels of added sugars, sodium, and saturated fat per serving."[28] As discussed in the proposed rule, there is no daily recommended value, and thus no percent DV, for calories. In the 2016 Nutrition Facts final rule, FDA noted that quantitative intake recommendations for calories are called estimated energy requirements (EERs), and they are based on healthy individuals of defined age, sex, weight, height, and level of physical activity (81 FR 33742 at 33782). We explained that it would be difficult to combine the EERs into a single reference calorie level applicable to the general population because calorie needs vary based on many factors (id.). We are aware of no new data or other information published after the 2016 Nutrition Facts label final rule that changes our determination. Therefore, we tentatively conclude that do not currently have a basis on which to provide consumers with an interpretation of the quantitative calorie information required on the Nutrition Facts label.

[27] We acknowledge that some food manufacturers are voluntarily providing calorie information on the front of food labels, including to help vending machine operators comply with FDA's calorie labeling requirements for articles of food sold from certain vending machines (see § 101.8(c)(2)(ii)), and have an interest in continuing this practice. Our existing regulations allow manufacturers to voluntarily include such a statement on the principal display panel.

[28] See docket FDA-2022-P-1832 at https://www.regulations.gov/docket/FDA-2022-P-1832.

Additionally, a restatement of the level of calories is not included in the proposed rule and requiring such a restatement would not provide new interpretive information to consumers.

If the proposed rule added a mandatory calorie labeling requirement to the proposed FOP label, estimated costs (and by extension, break-even calculations) would remain the same. Our per-unit labeling costs are based on a "major" label change for the proposed rule, and the inclusion of calories would not affect that level of label change. In other words, we assume the addition of calorie information could be achieved at zero marginal cost conditional on already creating the proposed FOP scheme.

5. Summary of Regulatory Alternatives

See Table 17 for a summary of the annualized cost estimates (using a 2 percent discount rate) by regulatory alternative.

Table 17. Primary Estimates of Annualized Cost and Break-Even Value per FOP Encounter by Regulatory Alternative

	Annualized Cost (millions of 2023 USD)	Break-Even Value per FOP Encounter (actual 2023 USD)
Proposed Rule, Primary Compliance Period	**$333**	$0.0018
Proposed Rule, Shorten Compliance Period by One Year	**$460**	$0.0025
Proposed Rule, Extend Compliance Period by One Year	**$290**	$0.0016
"High In" Scheme	**$117**	$0.0014
Addition of Calorie Information in Front of Pack Label	**$333**	$0.0018

J. Distributional Effects

Diet-related chronic diseases are experienced at disproportionally higher rates by certain racial and ethnic populations. For example, more than four in ten American adults experience hypertension and that number increases to almost six in ten for non-Hispanic Black adults [Ref. 31]. Additionally, rates of diagnosed diabetes and heart disease are

higher among American Indians and Alaskan Native populations in comparison to other racial and ethnic populations.[29]

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 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

	Saturated Fat (g)		Sodium (mg)		Total Sugar (g)	
Non-Hispanic White	13.7	(0.1)	1,619	(18.2)	51	(0.9)
Non-Hispanic Black	12.6	(0.1)	1,657	(39.6)	54	(0.7)
Non-Hispanic Asian	11.3	(0.3)	1,817	(34.0)	46	(0.9)
Hispanic	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/.

As described in Section II.D.2, in FDA's FSANS survey, 87 percent of respondents stated that they look at the Nutrition Facts label on food packages and 57 percent of all respondents correctly interpreted the percent DV. This varied across demographic variables, seen in Table 19. For instance, relative to non-SNAP recipients, SNAP recipients were less likely to use the Nutrition Facts label as well as the declarations of all three nutrients to limit and less likely to correctly interpret the percent DV. This suggests that SNAP recipients may benefit more than non-SNAP recipients from additional interpretive context regarding the levels of saturated fat, sodium, and added sugars in a serving of a food to help them quickly and easily identify how foods can be part of a healthy diet. Similarly, non-Hispanic Black and Hispanic respondents were less likely to correctly interpret the percent DV.

Respondents with lower education attainment and lower income were less likely to use the Nutrition Facts label and correctly interpret the percent DV, which is consistent with previous studies [Ref. 2, 3, 32]. Respondents living in rural areas were less likely to use the Nutrition Facts label as well as information about saturated fat, sodium, and added sugars. If these populations use the Nutrition Info box on the FOP label to better identify how foods can be part of a healthy diet, it is possible that underlying diet-related health

[29] 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

inequities as well as the risk of developing diet-related chronic diseases could be reduced. We do not have the data to estimate the magnitude of this potential shift. We invite comment on the distributional effects of this proposed rule.

Table 19. Nutrition Facts Label: Percentage Use by Select Demographic Variables

	NFL[a]	Saturated Fat[b]	Sodium[b]	Added Sugars[b]	Correctly Interpret Percent DV[c]
Sex					
Male	84.5	38.3	57.0	37.4	58.2
Female	90.2	30.7	55.6	39.4	56.7
Race					
Non-Hispanic White	88.1	32.7	52.6	58.5	60.3
Non-Hispanic Black	85.0	30.1	62.7	52.5	51.6
Non-Hispanic Other	84.2	40.8	66.6	56.2	59.8
Hispanic	87.3	40.8	61.4	45.2	49.8
Age					
18-30	86.5	26.1	48.3	62.3	60.4
31-50	88.1	37.1	55.8	54.6	61.8
51-60	87.1	36.1	53.4	52.6	55.8
61-70	87.6	31.9	58.3	57.0	53.4
71+	86.6	36.2	70.9	51.7	49.2
SNAP Recipients					
Yes	77.5	26.8	49.8	45.5	43.7
No	88.6	35.5	56.7	56.5	59.4
Location					
Rural	77.0	27.1	53.6	55.0	58.5
Urban	89.3	35.7	57.1	55.4	50.5
Educational Attainment					
Less than high school degree	82.2	41.8	54.9	36.7	36.0
High school graduate or GED	79.8	25.6	54.9	34.1	42.4
Some college	90.0	37.2	56.9	38.2	64.0
College graduate	93.4	35.8	58.1	43.0	68.8
Postgraduate degree	94.2	43.2	56.6	45.3	74.3
Income					
Less than $25,000	79.9	33.3	58.5	41.7	44.3
$25,000 to 34,999	89.1	36.4	58.5	40.4	52.0
$35,000 to $49,999	86.3	28.5	60.9	40.7	53.1
$50,000 to $74,999	86.9	33.0	53.6	34.3	54.2
$75,000 to $99,999	82.6	32.9	56.4	45.5	63.0
$100,000 or more	94.3	40.2	52.2	62.0	74.4
All respondents	**87.3**	**34.4**	**56.5**	**55.2**	**57.1**

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.

[a] Respondents were asked, "Do you ever look at the Nutrition Facts label on food packages?"

[b] Respondents were asked, "Which of the following do you usually look for when looking at a Nutrition Facts label?"
[c] Percentage of respondents that correctly identified a food with the Nutrition Facts label showing that one serving of the food contains 25% of the Daily Value (DV) of Sodium.

K. International Effects

Foreign entities are currently required to use the Nutrition Facts label on all foods sold in the United States and would be subject to this rulemaking. This rule would affect foreign entities that currently or in the future would sell packaged food products in the United States. This proposed rule does not include regulatory requirements for foreign entities beyond what would also be required of domestic manufacturers. We invite comment on the effects that this rule may have on foreign entities.

L. Uncertainty and Sensitivity Analysis

1. Uncertainty Analysis

We incorporate uncertainty throughout our analysis. Our estimates of relabeling and voluntary reformulation costs are calculated using Monte Carlo simulations of uncertain input, namely: per-unit costs derived from the cost models and the proportion of food products captured in the Label Insight database. See Section II.F for a thorough discussion of where and how we use simulation to incorporate the uncertainty endemic to our data.

While we present our primary, low, and high estimates of costs throughout this document, those estimates are summary statistics of a full distribution of estimated costs. Figure 4 and Figure 5 below illustrate the full distribution of cost estimates from our Monte Carlo simulation.

Figure 4. Distribution of Labeling Costs (3-Year Compliance) by Food Category, 2023 USD, Millions

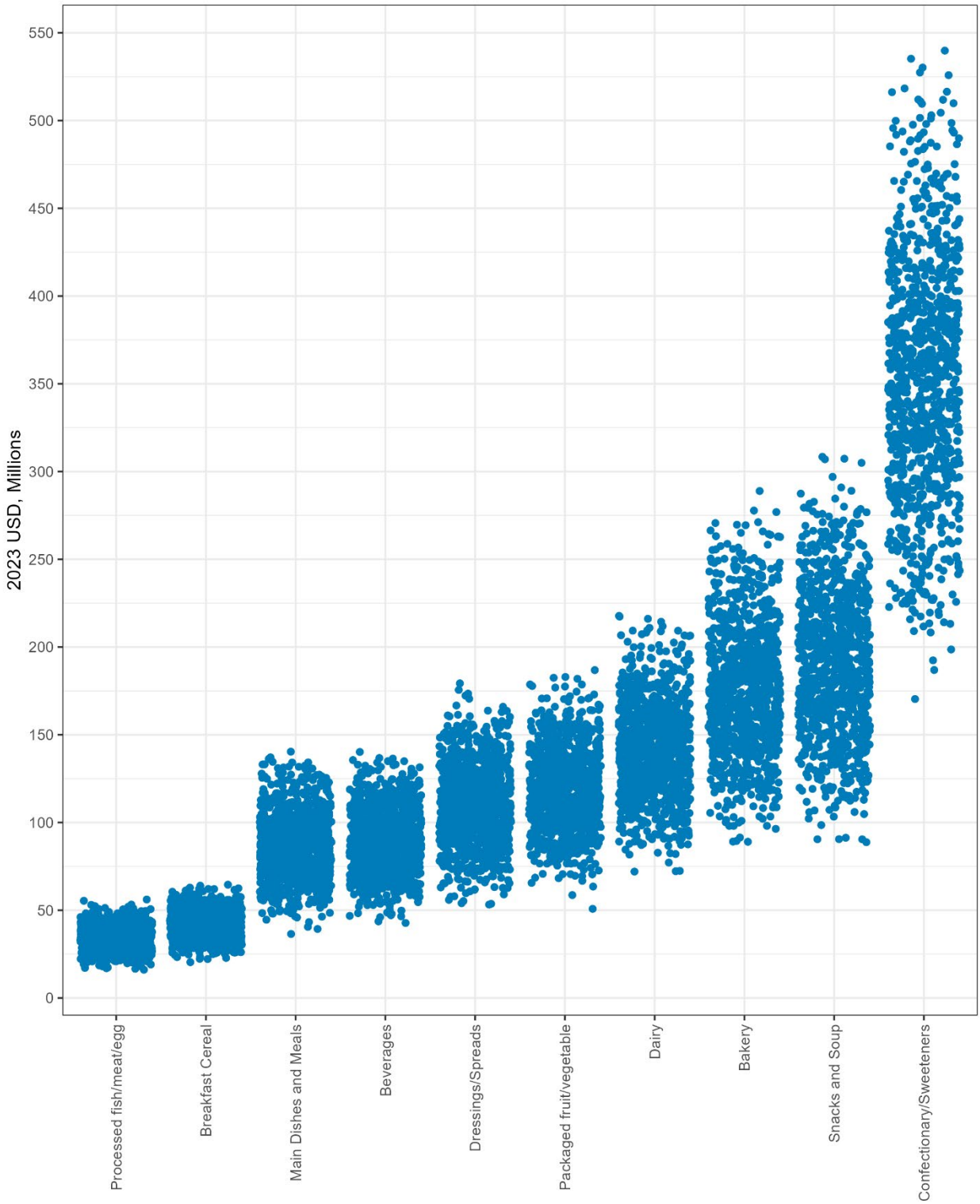
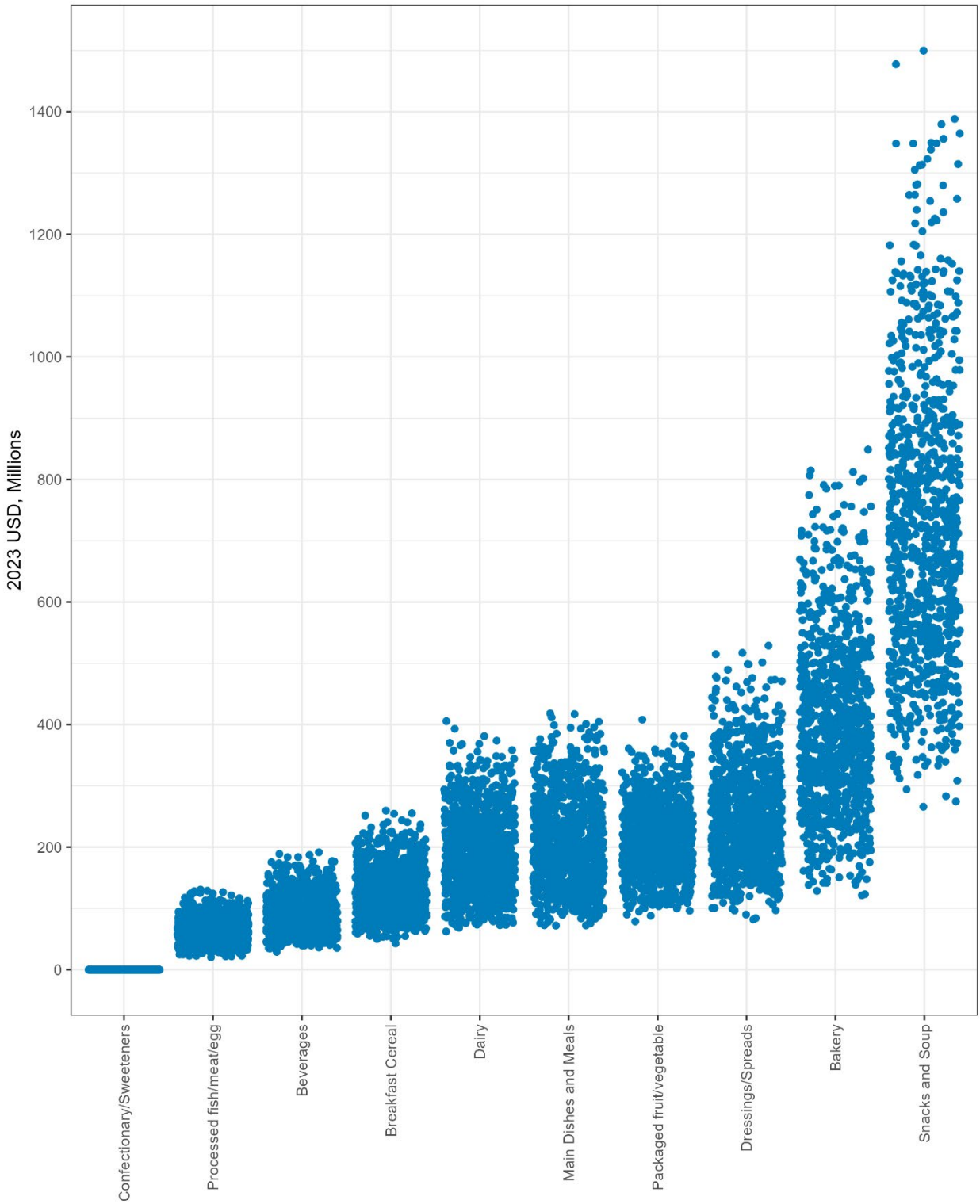


Figure 5. Distribution of Reformulation Costs (3-Year Compliance) by Food Category, 2023 USD, Millions



2. Sensitivity Analysis: Impact of Updating the Definition of "Healthy"

If the proposed FOP label is finalized, manufacturers impacted by both that and the updated requirements for the "healthy" nutrient content claim might be able to coordinate their relabeling and any reformulation activities so that they only need to relabel once and voluntarily reformulate once instead of relabeling twice and voluntarily reformulating twice (once for each rule). If the timing of the two rules allows for this kind of coordination, and if manufacturers in turn engage in this kind of coordination, then our estimate of the cost of the proposed rule could be overestimated. However, because the estimated number of food products to be affected by the "Healthy" rule (21,328 UPCs) is just a fraction of the number of food products affected by this proposed rule (322,326 UPCs), the magnitude of the potential overestimate of costs is likely small.

The recently updated "Healthy" nutrient content claim definition and the FOP proposed rule provide distinct nutrition information to consumers and are intended to accomplish separate but interrelated policy goals. We note the potential for limited scenarios in which a food product bears a "healthy" claim but would display a "High" or "Med" level of saturated fat, sodium, or added sugars in the Nutrition Info box. We invite comment on the anticipated prevalence of this situation and how consumers may use such information.

III. Initial 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. Because we estimate that the annual economic impact of this proposed rule is less than 3 percent of annual revenue, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.[30] This analysis, as well as other sections in this document and the Preamble of the proposed rule, serve as the Initial 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 United States Small Business Administration's (SBA) definition of a small business as it applies to the relevant economic sectors, in this case, North American Industry Classification System (NAICS) 311 (food manufacturing), 312111 (soft drink manufacturing) and 312112 (bottled water manufacturing). SBA 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.[31] 2021 U.S. Census Bureau Statistics of U.S. Businesses (SUSB) data indicate that there are a total of 30,413 establishments within these manufacturing sectors; food manufacturing (as defined by NAICS 311) comprises 97 percent of these establishments.[32]

Table 20 shows the breakdown of the sectors by number of employees. Of these establishments, we estimate that at least 86 percent of these establishments qualify as a small business.

Table 20. NAICS 311, 312111, and 312112 by Number of Employees

Size by Number of Employees	NAICS 311	NAICS 312111	NAICS 312112	Total
Less than 20 employees	18,858	233	168	19,259

[30] The United States Department of Health and Human Services has adopted default numerical thresholds for "significant economic impact" and "substantial number." More specifically, "significant economic impact" is defined as an economic impact exceeding 3 percent of annual revenue (receipts) and "substantial number" is defined as 5 percent or more of the affected small entities within an identified industry.
[31] 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.
[32] See "U.S. & States, 6-digit NAICS", downloaded at https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.

20 - 99 employees	4,622	62	35	4,719
100 - 499 employees	2,068	36	21	2,125
500 + employees	3,964	266	80	4,310
All Establishments	29,512	597	304	30,413

Table 21 shows that the average annual receipts per establishment varies substantially by size category.[33] For food manufacturers in NAICS 311, average annual receipts for establishments with less than 20 employees is $1.5 million and $199 million for establishments with more than 500 employees. The average annual receipts per small business establishment in NAICS 311 is estimated to be $9.1 million.

Table 21. Average Estimated Annual Receipts per Establishment by Number of Employees, in Millions $2023

Size by number of employees	NAICS 311	NAICS 312111	NAICS 312112
Less than 20 employees	$1.5	$3.3	$1.6
20 - 99 employees	$12.7	$21.4	$12.1
100 - 499 employees	$62.3	$78.9	$29.3
500 + employees	$198.5	$160.0	$75.2
All Establishments	$35.1	$84.6	$23.9
Limited to Small Businesses [a]	$9.1	$19.3	$6.9

[a] The U.S. Census SUSB data provide limited enterprise size options. Hence, we use the < 500 employees threshold for the purposes of this calculation.

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

The total discounted cost of the proposed rule per entity (including large firms) is approximately $100,253 ($3,049 million/30,413 establishments). We cannot estimate the exact cost per small entity because we do not know how many UPCs on average are owned by small entities as defined using the SBA definition. This number likely significantly overstates the cost per small entity, because the share of firms that are small businesses is typically large, and the share of sales controlled by small firms is typically small. This is evident from the above tables. On the other hand, brands owned by small entities may have relatively low sales and thus are not represented fully in our data. We invite public comment on the cost of this proposed rule on small entities.

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

We estimate that the mandatory labeling and voluntary reformulation costs incurred due to the proposed rule would cost roughly $1,030 annually per UPC, or less than a percent of estimated annual receipts. For instance, a food manufacturing establishment with less than 20 employees owning 10 UPCs would incur a cost of $10,300, or 0.7 percent of annual receipts. This estimated cost includes reformulation, which is not a requirement of the rule, but is a cost some manufacturers may voluntarily choose to incur, for instance, to avoid selling products labeled “High” or “Med” sources of saturated fat, sodium, or added sugars. If firms choose not to reformulate, total costs annually per UPC are just $326 because voluntary reformulation makes up about 68 percent of total costs.

C. Alternatives to Minimize the Burden on Small Entities

In the proposed rule, firms earning less than $10 million in annual food sales, which covers approximately 95 percent of all food manufacturers and 48 percent of all food UPCs, have a 4-year compliance period, while firms with $10 million in sales or more per year have a 3-year compliance period. We estimate that the extended compliance period for small firms reduces cost per establishment from $111,288 to $100,253 and cost per UPC from $10,501 to $9,459.

An alternative to the proposed rule that would further minimize the burden on small entities is to provide a 5-year compliance period for firms earning less than $10 million in annual food sales and a 4-year compliance period for firms with $10 million in sales or more per year. This would reduce the cost per establishment from $100,253 to $87,495 and the total cost per UPC from $9,459 to $8,256.

In conclusion, and as stated above, because we estimate that the annual economic impact of this proposed rule is less than 3 percent of annual revenue, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

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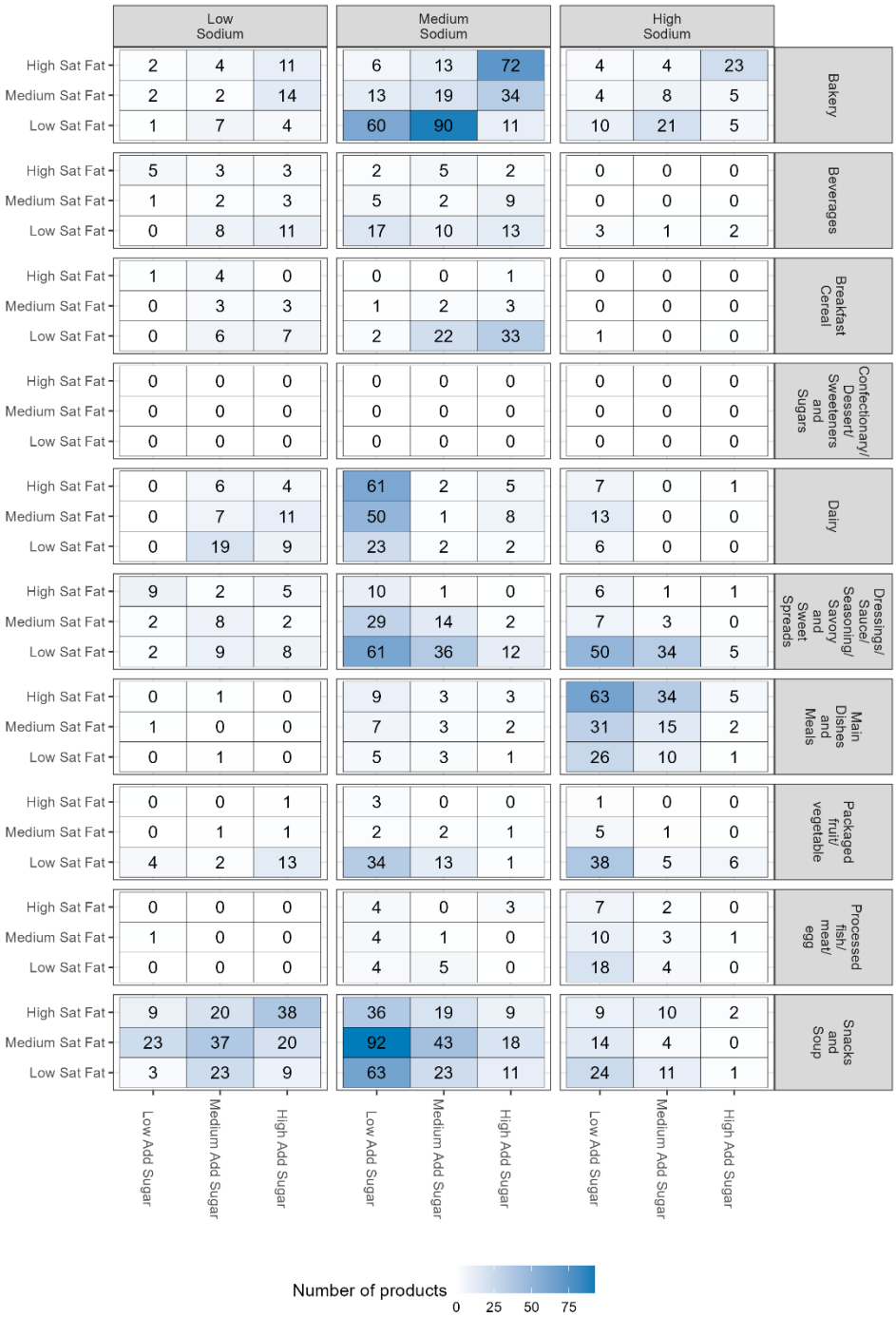
V. Appendix

Figure 6. Estimated Number of Products Expected to Reformulate by Nutrient Combination and Food Category



Notes:
Each number represents the percent of products that are in a particular nutrient combination for the given food category.
Sum of products per category may not match primary estimate from analysis due to rounding.