DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Proposed Rule to Revoke Authorization of Use of Brominated Vegetable Oil in Food

Docket No. FDA-FDA-2023-N-0937

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

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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 not a significant regulatory action under 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 this proposed rule will impact at most 2.5 percent of small businesses within the beverage manufacturing industry, and this falls below the threshold of 5 percent that constitutes a substantial number of small entities (Ref. 1), and because we believe that costly disruptions to small entities are likely to be small due to replacement formulas for

BVO having been in place and widely used for decades, we propose to certify that the 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 $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

The costs of this proposed rule come from reformulating products currently manufactured with BVO, re-labeling products currently manufactured with BVO, ingredient substitutes for BVO, and possible changes to sensory product properties (which could lead to decreased consumption). The benefits of this proposed rule come in the form of public health gains from reduced exposure to BVO. The annualized costs (with a discount rate of 7 percent) of this rule, minus the costs of the baseline of gradual voluntary reduction, are $0.09 million to $0.23 million. The first-year costs of the proposed rule are $6.4 million to $15.9 million. We estimate the annualized reduction in BVO exposure under the proposed rule relative to the baseline of gradual voluntary reduction to be roughly 0.02 million ounces (oz). For the proposed rule to be cost effective, it would have to prevent $0.15 million worth of illness (with a discount rate of

7 percent) on an annual basis to cover the domestic costs to industry. This means that in order for the proposed rule to be cost effective, there would have to be almost $9 worth of public health benefits per oz of reduced BVO exposure. The costs of this rule will likely be split between beverage producers and beverage consumers in the form of higher beverage prices. We do not know what percentage of the costs will be passed on to consumers.

Table 1 Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified	0.02 million oz	0.01 million oz	0.03 million oz			2026 - 2045	The benefits of the proposed rule come in the form of reduction in exposure to BVO
	Qualitative	For the rule to be cost effective, it would have to prevent almost $9 worth of illness annually per oz of reduced BVO exposure.						
Costs	Annualized Monetized $millions/year	$0.15	$0.09	$0.23	2022	7%	2026 - 2045	The first-year costs are roughly $6.4 million to $15.9 million
		$0.06	$0.03	$0.08	2022	3%	2026 - 2045	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From: Producers			To: Consumers			We do not know what percentage of producer costs will be passed on to consumers.
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

II. Preliminary Economic Analysis of Impacts

A. Background

Brominated vegetable oil (BVO) is a complex mixture of plant-derived triglycerides that have been reacted to contain atoms of the element bromine bonded to the molecules. BVO is used primarily to help emulsify citrus-flavored soft drinks, preventing them from separating during distribution. It is permitted for use in the U.S. under an interim food additive regulation at 21 CFR 180.30. BVO was originally listed by FDA as Generally Recognized as Safe (GRAS). In 1966, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) voiced concerns that bioaccumulation and long-

term health effects of dietary exposure to BVO were understudied. Safety studies published in 1969 and 1970 led FDA to conclude that the use of BVO in food was not GRAS, but not an immediate threat to health. This led to authorization of BVO as a food additive on an interim basis. Initial reports of BVO toxicity involved bromine bioaccumulation and histopathological changes in the hearts of animals fed BVO. Later, reports of reproductive toxicity, thyroid toxicity, and neurotoxicity were published.

In our review of new data, we have concluded that there is no longer a reasonable certainty of no harm from the continued use of BVO in food. Results from new NCTR studies demonstrate bioaccumulation of lipid-bound bromine at all exposure levels tested, which was the original concern expressed by JECFA in 1966 regarding use of BVO in food. Bioaccumulation of BVO reduces confidence in the results of BVO subchronic safety studies. This new study also reported evidence of thyroid toxicity at all exposure levels in male rats and at high exposure levels in female rats. Therefore, we are proposing to revoke the interim food additive regulation for BVO.

B. Potential Need for Federal Regulatory Action

The proposed rule would remove the authorization of the use of Brominated Vegetable Oil (BVO) as an ingredient in food. Although many beverage manufacturers have already removed BVO from their products, and others will likely remove BVO without agency action, manufacturers are still producing, and consumers are still buying, products with BVO (accounting for at least $163,417,288 in sales and 83,094,061 in unit sales in the latest 52 weeks ending in 10-31-2021[1]). In addition, news about manufacturers committing to removing BVO has been prevalent in the past decade (Ref.

1 See https://advantage.iriworldwide.com/unify-client/index.html (accessed Dec 15, 2021)

2), which may lead to consumers spending less time reading food product labels to determine whether food contains BVO. This would potentially create an information asymmetry where consumers incorrectly believe that their food no longer contains BVO. Thus, intervention is needed to avoid potential adverse health impacts in the shorter term.

C. Purpose of the Proposed Rule

The proposed rule would remove the authorization of the use of Brominated Vegetable Oil (BVO) as a food ingredient intended to stabilize flavoring oils in fruit-flavored beverages. It is currently authorized for this use in the U.S. under an interim food additive regulation. We are taking this action in light of our determination that there is no longer a reasonable certainty of no harm from the continued use of BVO in food.

D. Baseline Conditions

To determine the current usage of BVO, we first identify all products with BVO listed as an ingredient in the Label Insight database.[2] Because the Label Insight database does not remove products once they are no longer on the market, we match the identified products to the IRi sales database[3] by UPC code. We keep only products with sales in the latest 52 weeks ending in 10-31-2021. To determine how many of the remaining products were still being manufactured using BVO in 2021, we refer to ingredient listings on manufacturer websites. Of the 1705 products identified in the Label Insight database, only 480 (or about 28%) were listed in the IRi database as having sales in the latest 52 weeks ending in 10-31-2021. Of those 480 products, we confirmed that 51 (about 10.6%) were still being manufactured using BVO in 2021. We were unable to confirm

2 See https://app.labelinsight.com/login (accessed Dec 15, 2021)
3 See https://advantage.iriworldwide.com/unify-client/index.html (accessed Dec 15, 2021)

ingredients for 167 (about 34.8%) of the products, and the rest (about 54.6%) were confirmed to no longer be manufactured using BVO. The table below shows the breakdown of these products by beverage category. These categorizations are determined based on the final report for FDA's Reformulation Cost Model (Ref. 3). Four of these products[4] are unable to be categorized by the Reformulation Cost Model and are omitted from this analysis. These products account for 0% of products with confirmed BVO usage in 2021, and 2.4% of the products with unknown BVO usage in 2021. We acknowledge that this could lead to an underestimate of the number of products with BVO usage in 2021.

Table 2 Products with BVO listed as ingredient with sales in the latest 52 weeks ending in 10-31-2021

Category/Subcategory	BVO Usage Unknown in 2021	BVO Usage Confirmed in 2021
Low Calorie Soft Drinks	12	14
Regular Soft Drinks	117	25
Cocktail Mixes	11	0
Shelf Stable Drink	16	0
Refrigerated Drink	7	11
Fruit Punch Bases/Syrups	0	1
Total	163	51

Label Insight and IRi do not provide a comprehensive list of all products on the market, which means that the numbers above are likely underestimates. However, assuming that these databases capture products that are representative of the beverage industry (Ref. 4, Ref. 5), they can provide accurate estimates of the percentage of the beverage industry accounted for by products manufactured using BVO in 2021. To estimate these percentages, we match all products that fall under a beverage category in the Label Insight database to the IRi sales database by UPC code. We once again keep

[4] One product is a cake, two are meat sauces, and one is an aseptic energy drink.

only products with sales in the latest 52 weeks ending in 10-31-2021. We estimate the minimum percentages of beverage industry categories accounted for by products with BVO by assuming that only the products with confirmed BVO usage still used BVO in 2021. We estimate the maximum percentage of beverage industry categories accounted for by products with BVO by assuming that products with confirmed and unknown BVO usage still used BVO in 2021. We assume the midpoint between the minimum and maximum percentages constitutes the most likely percentage of products being manufactured using BVO in 2021.

Table 3 Percentage of Beverage Industry Using BVO in 2021

	Beverage products with sales in the latest 52 weeks ending in 10-31-2021	**Products with BVO Usage in 2021**		**Percentage of Beverage Industry Category Accounted for by Products with BVO Usage in 2021**		
Category/ Subcategory	**Number of Products**	**Unknown**	**Confirmed**	**Primary Estimate**	**Low Estimate**	**High Estimate**
Low Calorie Soft Drinks	948	12	14	2.11%	1.48%	2.74%
Regular Soft Drinks	2719	117	25	3.07%	0.92%	5.22%
Cocktail Mixes	543	11	0	1.01%	0.00%	2.03%
Shelf Stable Drink	2259	16	0	0.35%	0.00%	0.71%
Refrigerated Drink	821	7	11	1.77%	1.34%	2.19%
Fruit Punch Bases/ Syrups	98	0	1	1.02%	1.02%	1.02%
Total	7388	163	51	1.79%	0.69%	2.90%

The above table shows that products manufactured with BVO in 2021 are estimated to account for between 1.48% and 2.74% of Low-Calorie Soft Drinks, between 0.92% and 5.22% of Regular Soft Drinks, between 0% and 2.03% of Cocktail Mixes, between 0% and 0.71% of Shelf Stable Drinks, between 1.34% and 2.19% of

Refrigerated Drinks, and1.02% of Fruit Punch Bases/Syrups. To translate these percentages to number of formulas, we use FDA's Reformulation Cost Model (Ref. 3).

Table 4 Number of Formulas Manufactured with BVO in 2021

	Primary Estimate		Low Estimate		High Estimate	
Product Subcategory	**UPCs**	**Formulas**	**UPCs**	**Formulas**	**UPCs**	**Formulas**
Carbonated beverages - low calorie Total	91	36	64	25	118	47
Carbonated beverages - regular Total	460	229	138	68	781	388
Cocktail mixes Total	14	11	0	0	28	22
Fruit drinks - refrigerated Total	29	21	22	16	36	26
Fruit drinks - shelf stable Total	38	27	0	0	77	55
Fruit punch bases/syrups Total	4	3	4	3	4	3
Total	636	327	228	113	1045	542

The table above shows that an estimated 327 unique formulas contain BVO as of 2021, with a lower bound of 113 and an upper bound of 542. The table also shows that an estimated 636 products contain BVO as of 2021, with a lower bound of 228 and an upper bound of 1,045.

In order to estimate the total dietary exposure to BVO, we use the combined 2015-2018 National Health and Nutrition Examination Survey (NHANES) to estimate food consumption. We then apply an initial assumption that BVO is used at the maximum level of 15 mg/kg permitted under 21 CFR 180.30 in all foods in NHANES categories found to have beverages containing BVO[5] to those estimates to arrive at an estimated mean dietary exposure of 5 milligram (mg) BVO/person (p)/day (d) for the U.S. population aged 2 years and older (Ref. 6). Using 2021 population data from the

[5] The NHANES categories include Iced Tea / Lemonade juice drink; Soft drink, cream soda; Soft drink, fruit flavored, caffeine free; Soft drink, fruit flavored, diet, caffeine free; Soft drink, fruit flavored, caffeine containing; Soft drink, fruit flavored, caffeine containing, diet; Soft drink, ginger ale; Fruit juice drink; Lemonade, fruit juice drink; Fruit flavored drink; Margarita mix, nonalcoholic; Slush frozen drink; and Energy Drink.

U.S. Census Bureau[6], we estimate that the U.S. population aged 2 years and older is almost 324.5 million. Multiplying the exposure estimates by this population and by 365 days, and converting to ounces (oz), we estimate the total annual dietary exposure to be about 20.7 million oz.

This is an overestimate, as the NHANES categories found to still have beverages containing BVO do not comprise exclusively or primarily products containing BVO, and it is unlikely that all products containing BVO contain the maximum allowable level (Ref. 2). In Table 3 above, we estimate that products containing BVO in 2021 account for between about 0.69 and 2.9 percent of industry categories found to have beverages containing BVO. Multiplying these estimates by 20.7 million oz, we get an estimate of the annual consumption of BVO in 2021, shown in the table below. While the categories used in Table 3 are defined differently from the NHANES categories, we assume for the purposes of this analysis that they encompass the same subset of the beverage industry.

Table 5 Annual Consumption of BVO in millions of oz in 2021

	Consumption of BVO in millions oz
Primary Estimate	0.37
Low Estimate	0.14
High Estimate	0.60

Table 5 above shows that the estimated annual consumption of BVO in 2021 falls between 0.1 and 0.6 million oz. This is still likely an overestimate as it is based on the assumption that products containing BVO contain the maximum currently allowable amount.

6 See U.S. Census Bureau at https://www2.census.gov/programs-surveys/popest/datasets/2020-2021/national/asrh/ (accessed March 16, 2022)

Media coverage surrounding BVO has been prevalent in the past decade, covering consumer petitions and manufacturer plans to remove the ingredient (Ref. 2). At the time of this rulemaking, many manufacturers have already reformulated their products to exclude BVO, although many continue to use BVO. Given the consumer push for the removal of BVO, and the fact that BVO is already banned in other countries (Ref. 2), we do not believe that manufacturers would back track on their reformulations or that any manufacturers not using BVO in their reformulations would start using BVO. We expect that some consumers will continue to put pressure on producers to remove BVO through things such as petitions. It is, however, difficult to determine how quickly BVOs would be phased out solely due to consumer pressure, without FDA intervention.

If we assume products manufactured with BVO continue to follow the trend found in the IRi data for the latest 52 weeks ending in 10-31-2021 (i.e., between 10.5% and 45% of products with BVO sold in a year continue to be manufactured using BVO), we expect that, without regulation, products with BVO would take between three and seven years to fully stop being produced. Because much of the decrease in products with BVO in the latest 52 weeks ending in 10-31-2021 reflected reformulations by large brands, the remaining products with BVO likely reflect smaller brands. We believe that it will take longer for smaller brands to be phased out, and that three to seven years is an underestimation. For simplicity, we assume that, without regulation, BVO would take roughly 20 years to phase out, with the number of products dropping by 25 percent every year. We acknowledge that this could be an over- or under-estimate of the amount of time it would take for BVO to be phased out.

Table 6 below shows the baseline projections of BVO products and exposure. For the purposes of this analysis, we assume that the impacts of the proposed rule, if it is finalized, would begin in 2026. This timeline accounts for the effective date of the proposed rule, and a compliance date that we propose will be one year after the effective date, to provide the opportunity for companies to reformulate and deplete the inventory of BVO-containing products prior to enforcing the requirements of the final rule. We acknowledge that there is uncertainty surrounding the assumption that impacts would begin in 2026.

Table 6 Baseline Projections of BVO Products and Dietary Exposure to BVO Assuming a Voluntary Reduction of 25% Each Year

Period	Year	Dietary Exposure (million oz.)	UPCs	Formulas
Before impacts begin	2021	0.37	636	327
	2022	0.28	477	245
	2023	0.21	358	184
	2024	0.16	268	138
	2025	0.12	201	104
Year 1	2026	0.09	151	78
Year 2	2027	0.07	113	58
Year 3	2028	0.05	85	44
Year 4	2029	0.04	64	33
Year 5	2030	0.03	48	25
Year 6	2031	0.02	36	18
Year 7	2032	0.02	27	14
Year 8	2033	0.01	20	10
Year 9	2034	0.01	15	8
Year 10	2035	0.01	11	6
Year 11	2036	0	8	4
Year 12	2037	0	6	3
Year 13	2038	0	5	2
Year 14	2039	0	4	2
Year 15	2040	0	3	1
Year 16	2041	0	2	1
Year 17	2042	0	2	1
Year 18	2043	0	1	1

Year 19	2044	0	0	0
Year 20	2045	0	0	0

E. Benefits of the Proposed Rule

The benefits of this proposed rule primarily come in the form of public health gains from reduced exposure to BVO. We use the estimates of current BVO consumption presented in Table 5 and assume that the proposed rule would reduce BVO consumption by 100 percent (resulting in no consumption) in the first year. We then compare this to the baseline of gradual voluntary reduction, in which products using BVO drop by 25% every year (and assume that this translates into BVO exposure also dropping by 25% every year). Table 7 below presents estimates of the annualized reduction in BVO exposure as a result of this proposed rule relative to the baseline (see Table 13 for the annual breakdown). The annualized benefits of this proposed rule, relative to a baseline of gradual voluntary reduction, are a reduction in BVO exposure of between 0.01 and 0.03 million oz.

Table 7 Annual Reduction in BVO Exposure (millions oz) due to this Proposed Regulation, over 20 years (2026 to 2045)

	Primary Estimate	**Low Estimate**	**High Estimate**
millions oz of BVO	0.02	0.01	0.03

Studies suggest that excessive consumption of BVO may cause adverse events such endocrine and central nervous systems disruptions, and that bromine also accumulates easily in the body. Case studies, such as the 1997 case study describing a patient who developed Bromism after excessive consumption of beverages containing

BVO, mention specific adverse events such as loss of coordination, inability to walk, and severe headaches, as well as invasive medical interventions such as hemodialysis (Ref. 8). Clinical data on adverse events in humans from consuming BVO, however, are limited. There is also a lack of published independent studies that estimate the change in health outcomes from removing BVO from the food industry. Because of the data limitations and absence of independent studies that quantify health benefits, we do not estimate the monetary value of the public health benefits of this proposed rule. We seek comment and data that would inform a more robust analysis of the potential public health benefits.

F. Costs of the Proposed Rule

Costs of removing BVO from beverages will come from reformulating products currently manufactured with BVO, re-labeling products currently manufactured with BVO, substituting ingredients, and changes to sensory product properties. The costs in this section refer to differences between the estimated costs required by this proposed rule and the estimated baseline costs.

We use FDA's Reformulation Cost Model (Ref. 3) to estimate the average cost of reformulation as a result of this proposed rule. Because BVO is found in beverage flavoring, we look at model estimates for the Flavoring Syrup and Concentrate Manufacturing sector (NAICS 311930). Assuming a compliance period of 12 months, a price adjustment factor (relative to the base year of 2014) of 1.24, a need for turbidity tests and consumer focus groups, and that the reformulation will not require manufacturers to engage in any additional recordkeeping, we estimate that the per

formula reformulation costs associated with the substitution of a minor nonfunctional ingredient are as follows. Values in columns may not add up due to rounding.

Table 8 Per Formula Reformulation Costs ($ thousands) Associated with The Substitution of a Minor Nonfunctional Ingredient for the Flavoring Syrup and Concentrate Manufacturing Sector

Reformulation Activity	Primary Estimate	Low Estimate	High Estimate
Determine response to regulation	$9.87	$4.09	$19.03
Project management	$26.48	$11.20	$50.56
Product reformulation/process modification	$25.31	$11.59	$46.41
Packaging assessment[7]	$4.43	$1.95	$8.39
Packaging development[8]	$0.00	$0.00	$0.00
Product and package performance testing[9]	$0.00	$0.00	$0.00
Production scale-up testing	$19.26	$8.99	$35.13
Recordkeeping	$0.00	$0.00	$0.00
Analytical tests	$0.02	$0.02	$0.02
Consumer tests[10]	$17.15	$16.25	$18.06
Total	**$102.52**	**$54.10**	**$177.60**

The table above shows that the reformulation cost per formula is approximately $102.5 thousand, with a minimum cost of about $54 thousand and a maximum cost of about $177.6 thousand. To obtain total reformulation costs, we multiply the reformulation cost per formula by the number of projected formulas in 2026 (see Table 6). To account for the uncertainty in reformulation cost per formula and number of formulas, we use a Monte Carlo simulation.

Table 9 Estimated Total Cost of Reformulation ($ millions)

	Total Reformulation Cost
Primary Estimate	$8.31

[7] This involves assessing (1) compatibility of product and packaging and shelf stability with new formulation and (2) conformance of package and label to regulations.
[8] Based on model assumptions, the development of new packaging will not be needed for reformulations associated with the substitution of a minor nonfunctional ingredient.
[9] Based on model assumptions, this testing, which is done to determine how a product or packaging will respond to temperatures and other conditions, is unnecessary for reformulations associated with the substitution of a minor nonfunctional ingredient.
[10] This refers to consumer acceptance research, which is done to determine how consumers react to potential sensory differences.

Low Estimate	$4.29
High Estimate	$13.29

Table 9 above shows that the total cost of reformulation is approximately $8.3 million with a lower bound of $4.3 million and an upper bound of $13.3 million. It is important to note, however, that most beverages that once contained BVO have already been reformulated to replace it. It is therefore likely that many of the companies supplying flavoring syrup and concentrate to beverage manufacturers have already gone through the process of reformulating products to substitute BVO. While we do not have estimates of how many of these already reformulated products could be used in beverages currently containing BVO, we assume that there may be some overlap and that these estimates likely reflect an overestimation of costs.

To determine the cost of re-labeling, we use FDA's Labeling Cost Model (Ref. 7). Assuming a 12-month compliance period and no need for analytical or market tests, we find that the per-UPC re-labeling cost for a minor labeling change is as follows. Values in columns may not add up due to rounding.

Table 10 Per UPC Re-Labeling Cost Estimates ($ thousands)

Cost Type	5th Percentile	Mean	95th Percentile
Labor	$2.10	$4.94	$9.56
Materials	$1.05	$1.58	$2.10
Analytical	$0.00	$0.00	$0.00
Market	$0.00	$0.00	$0.00
Inventory	$0.53	$0.63	$0.63
Recordkeeping	$0.00	$0.00	$0.00
Total	**$3.68**	**$7.15**	**$12.40**

The above table shows that the per-UPC cost of re-labeling as a result of this proposed rule is roughly $7.15 thousand, with a lower bound of $3.68 thousand and an upper bound of $12.40 thousand.

To determine total labeling costs, we multiply the per-UPC re-labeling costs by the number of UPCs in 2026 (see Table 6). Because our estimated number of UPCs only captures products that are purchased by consumers, we need to also account for the fact that the companies supplying flavoring syrup and concentrate to beverage manufacturers will also need to change their labels. Because we do not have an estimate of the number of flavoring-syrup UPCs impacted by this proposed rule, we double the number of UPCs. This likely reflects an overestimate of the number of UPCs requiring re-labeling as a result of this proposed rule. To account for the uncertainty in reformulation cost per formula and number of formulas, we once again use a Monte Carlo simulation.

Table 11 Total Re-Labeling Cost Estimates ($ millions)

	Re-Labeling Costs
Primary Estimate	$2.24
Low Estimate	$1.17
High Estimate	$3.58

The total costs to industry for re-labeling as a result of this rule are approximately $2.2 million, with an upper bound of $3.6 million and a lower bound of $1.2 million. As discussed, these estimates likely reflect an overestimate of the costs of re-labeling.

The viable alternatives to BVO are sucrose acetate isobutyrate (aka SAIB), glycerol ester of (wood) rosin (aka ester gum), and locust/carob (bean) gum, which are

approved food additives or GRAS.[11,12,13] We do not have estimates for how the cost of manufacturing a flavoring syrup or concentrate is expected to differ when using these alternatives and assume that the costs are comparable. We request public comment on the per-weight or per-volume price of BVO and the price of the viable alternatives identified.

Because established alternatives to BVO already exist, and many manufacturers have already reformulated their products to replace BVO, we assume that there will be a minimal change to product properties. We request comment on this assumption.

Summing the costs of reformulation and the costs of re-labeling, we calculate the total costs of this proposed regulation. As noted in the Baseline section, we assume that, absent regulation, BVO would be phased out over 20 years, with products dropping by 25% every year. We use a Monte Carlo simulation to account for uncertainties and calculate low and high estimates for the net costs. The estimated rule and baseline reformulation costs for each year, and their Net Present Values (NPV) and annualizations (Ann) are as follows.

Table 12 Total Costs ($ millions) of this Proposed Regulation, annualized over 20 years (2026 – 2045)

	Primary Estimate	**Low Estimate**	**High Estimate**
NPV 3%	$0.84	$0.51	$1.26
NPV 7%	$1.62	$0.98	$2.44
Ann 3%	$0.06	$0.03	$0.08
Ann 7%	$0.15	$0.09	$0.23

The annualized costs of this rule (at 7 percent), relative to a baseline of gradual voluntary reduction, are $0.09 million to $0.23 million for the years 2026 to 2045.

11 See 21CFR172.833
12 See 21CFR172.735
13 See GRAS Substances (SCOGS) Database. https://www.fda.gov/food/generally-recognized-safe-gras/gras-substances-scogs-database (accessed May 18, 2023)

F. Transfers Caused by the Proposed Rule

It is possible that the cost of reformulation and re-labeling could be passed on to consumers in the form of higher prices. We do not know what percentage of the costs will be passed on to consumers. We seek comment and data that would inform a more robust analysis of these potential impacts at the final rule stage.

G. Summary of Benefits, Costs, and Transfers

Table 13 presents the summary of the primary undiscounted stream of costs and benefits for this proposed rule. We evaluate the proposed rule over a 20-year time horizon from the effective date of the proposed rule, if finalized.

Table 13 Stream of Total Costs ($ million) and Benefits (millions oz) of this Proposed Regulation

	Cost Under Proposed Rule	Baseline Cost	Net Cost Primary Estimate	BVO Consumption Under Baseline	BVO Consumption Under Proposed Rule	Impact of Proposed Rule on BVO Consumption
2026	$10.55	$2.64	$7.91	0.09	0.00	-0.09
2027	$0.00	$1.98	-$1.98	0.07	0.00	-0.07
2028	$0.00	$1.48	-$1.48	0.05	0.00	-0.05
2029	$0.00	$1.11	-$1.11	0.04	0.00	-0.04
2030	$0.00	$0.83	-$0.83	0.03	0.00	-0.03
2031	$0.00	$0.63	-$0.63	0.02	0.00	-0.02
2032	$0.00	$0.47	-$0.47	0.02	0.00	-0.02
2033	$0.00	$0.35	-$0.35	0.01	0.00	-0.01
2034	$0.00	$0.26	-$0.26	0.01	0.00	-0.01
2035	$0.00	$0.20	-$0.20	0.01	0.00	-0.01
2036	$0.00	$0.15	-$0.15	0.00	0.00	0.00
2037	$0.00	$0.11	-$0.11	0.00	0.00	0.00
2038	$0.00	$0.08	-$0.08	0.00	0.00	0.00
2039	$0.00	$0.06	-$0.06	0.00	0.00	0.00
2040	$0.00	$0.05	-$0.05	0.00	0.00	0.00
2041	$0.00	$0.04	-$0.04	0.00	0.00	0.00
2042	$0.00	$0.03	-$0.03	0.00	0.00	0.00
2043	$0.00	$0.02	-$0.02	0.00	0.00	0.00
2044	$0.00	$0.01	-$0.01	0.00	0.00	0.00
2045	$0.00	$0.01	-$0.01	0.00	0.00	0.00

The annualized costs of this rule (at 7 percent), relative to a baseline of gradual voluntary reduction, are $0.09 million to $0.23 million for the years 2026 to 2045. The costs of this rule will likely be split between beverage producers and beverage consumers in the form of higher beverage prices. The annualized benefits of this rule, relative to a baseline of gradual voluntary reduction, are a reduction in BVO exposure of between 0.01 and 0.03 million oz. For the proposed rule to be cost effective, it would have to prevent $0.15 million worth of illness (with a discount rate of 7 percent) on an annual basis to cover the domestic costs to industry. This amounts to almost $9 worth of public health benefits per oz of reduced BVO exposure.

H. Analysis of Regulatory Alternatives to the Proposed Rule

1. Take no action

Taking no action would lead to minimal cost savings at the cost of public health benefits.

2. Delayed Compliance

A compliance date three years after publication rather than one year after publication would lower reformulation and re-labeling costs and save two years of rule costs. It would also slightly lower avoided BVO exposure. This is shown in the table below.

Table 14 Costs and Benefits if impacts begin in 2028

	Costs
NPV 3%	$0.47
NPV 7%	$0.91

Ann 3%	$0.03
Ann 7%	$0.09
	Benefits
millions oz of BVO exposure avoided	0.01

I. Distributional Effects

This proposed rule, if finalized, may have a positive impact for multiple specific populations, including persons of color, persons who live in rural areas, LGBTQI+ persons, and persons otherwise adversely affected by persistent poverty. BVO-containing beverages are often also sugar-sweetened beverages (SSB). Below we present recent statistics and studies showing differential consumption of SSB across race, ethnicity, geographical region, and economic status. Each of these populations will benefit from the improved health risk reduction from eliminating dietary exposure to BVO.

- Data from the National Health and Nutrition Examination Survey (NHANES) indicates that non-Hispanic Black girls and Hispanic and non-Hispanic Black men and women consume more calories per day from SSB and the largest fraction of their daily calories from SSB (Ref. 9).
- Ismoisili, *et al*. reported in 2020 that there was a higher prevalence of daily SSB intake by adults in non-metropolitan areas compared to metropolitan areas (Ref. 10).
- Zoellner, *et al*. reported in 2022 that younger, single parents with lower income and their preschoolers consumed more sugary drinks per day (Ref. 11).

- Dunford, *et al*. reported in 2022 that non-Hispanic Black adults consumed more SSB than Mexican American or non-Hispanic white adults (Ref. 12). They also reported that SSB intake was inversely proportional to income.
- Lundeen, *et al*. reported in 2017 that Hispanic and non-Hispanic Black respondents as well as respondents living in non-metropolitan areas consumed SSB more frequently (Ref. 13).
- Minnis, *et al*. reported in 2016 that gay men and gay and bisexual women were more likely than heterosexual men and women to consume SSB (Ref. 14).

J. International Effects

Because there are few domestic beverage manufacturers that still use BVO, and because BVO is already banned in many countries, we do not expect there to be significant international effects. Potential effects could come in the form of small increases in imports of BVO substitutes.

K. Uncertainty and Sensitivity Analysis

One of our main sources of uncertainty is our estimate of how quickly products containing BVO would take to stop being produced absent regulation. If products containing BVO do not decline at all absent regulation, then the number of products containing BVO (as well as BVO exposure) in 2026 will be the same as in 2021. Further, absent regulation, the number of products containing BVO (as well as BVO exposure) will not change over time. To calculate the costs under this scenario, we use the number of formulas and UPCs in 2021 (see Table 6) and the per-formula and per-UPC cost estimates (see Table 8, Table 10).

Table 15 Stream of Total Costs ($ million) and Benefits (millions oz), assuming no change in BVO usage absent regulation

	Cost Under Proposed Rule	Baseline Cost	Net Cost Primary Estimate	BVO Consumption Under Baseline	BVO Consumption Under Proposed Rule	Impact of Proposed Rule on BVO Consumption
2026	$44.44	$0.00	$44.44	0.37	0	-0.37
2027	$0.00	$0.00	$0.00	0.37	0	-0.37
2028	$0.00	$0.00	$0.00	0.37	0	-0.37
2029	$0.00	$0.00	$0.00	0.37	0	-0.37
2030	$0.00	$0.00	$0.00	0.37	0	-0.37
2031	$0.00	$0.00	$0.00	0.37	0	-0.37
2032	$0.00	$0.00	$0.00	0.37	0	-0.37
2033	$0.00	$0.00	$0.00	0.37	0	-0.37
2034	$0.00	$0.00	$0.00	0.37	0	-0.37
2035	$0.00	$0.00	$0.00	0.37	0	-0.37
2036	$0.00	$0.00	$0.00	0.37	0	-0.37
2037	$0.00	$0.00	$0.00	0.37	0	-0.37
2038	$0.00	$0.00	$0.00	0.37	0	-0.37
2039	$0.00	$0.00	$0.00	0.37	0	-0.37
2040	$0.00	$0.00	$0.00	0.37	0	-0.37
2041	$0.00	$0.00	$0.00	0.37	0	-0.37
2042	$0.00	$0.00	$0.00	0.37	0	-0.37
2043	$0.00	$0.00	$0.00	0.37	0	-0.37
2044	$0.00	$0.00	$0.00	0.37	0	-0.37
2045	$0.00	$0.00	$0.00	0.37	0	-0.37
NPV 3%			$43.15		Annual reduction	-0.37
NPV 7%			$41.54			
Ann 3%			$2.90			
Ann 7%			$3.92			

As shown in Table 15 above, under this scenario, the annualized costs of this rule (at 7 percent), relative to a baseline, would be roughly $3.92 million for the years 2026 to 2045. The annual benefits of this rule, relative to the baseline, would be a reduction in BVO exposure of roughly 0.37 million oz. For the proposed rule to be cost effective,

there would have to be over $10.5 worth of public health benefits per oz of reduced BVO exposure.

If products containing BVO decline at a much faster rate than estimated absent regulation (for example, as a result of a state regulation limiting BVO usage), then the costs of this proposed rule would decrease. The table below shows the costs of this proposed rule under the assumption that products containing BVO would decrease by 50 percent, as opposed to 25 percent, each year absent regulation.

Table 16 Stream of Total Costs ($ million) and Benefits (millions oz), assuming BVO decline of 50 percent per year

	Cost Under Proposed Rule	Baseline Cost	Net Cost Primary Estimate	BVO Consumption Under Baseline	BVO Consumption Under Proposed Rule	Impact of Proposed Rule on BVO Consumption
2026	$1.39	$0.69	$0.69	0.01	0	-0.01
2027	$0.00	$0.35	-$0.35	0.01	0	-0.01
2028	$0.00	$0.17	-$0.17	0.00	0	0.00
2029	$0.00	$0.09	-$0.09	0.00	0	0.00
2030	$0.00	$0.04	-$0.04	0.00	0	0.00
2031	$0.00	$0.02	-$0.02	0.00	0	0.00
2032	$0.00	$0.01	-$0.01	0.00	0	0.00
2033	$0.00	$0.01	-$0.01	0.00	0	0.00
2034	$0.00	$0.00	$0.00	0.00	0	0.00
2035	$0.00	$0.00	$0.00	0.00	0	0.00
2036	$0.00	$0.00	$0.00	0.00	0	0.00
2037	$0.00	$0.00	$0.00	0.00	0	0.00
2038	$0.00	$0.00	$0.00	0.00	0	0.00
2039	$0.00	$0.00	$0.00	0.00	0	0.00
2040	$0.00	$0.00	$0.00	0.00	0	0.00
2041	$0.00	$0.00	$0.00	0.00	0	0.00
2042	$0.00	$0.00	$0.00	0.00	0	0.00
2043	$0.00	$0.00	$0.00	0.00	0	0.00
2044	$0.00	$0.00	$0.00	0.00	0	0.00
2045	$0.00	$0.00	$0.00	0.00	0	0.00
NPV 3%			$0.04		Annual reduction	0.00012
NPV 7%			$0.08			

Ann 3%			$0.00			
Ann 7%			$0.01			

As shown in Table 16 above, under this scenario, the annualized costs of this rule (at 7 percent), relative to a baseline, would be roughly $0.01 million for the years 2026 to 2045. The annual benefits of this rule, relative to the baseline, would be a reduction in BVO exposure of roughly 0.0012 million oz. For the proposed rule to be cost effective, there would have to be almost $6.5 worth of public health benefits per oz of reduced BVO exposure.

Another source of uncertainty is our assumption that manufacturers will not incur additional costs to buy BVO substitutes. The table below shows what the costs of this proposed rule would be if continuing costs doubled our estimates of the cost per formula.

Table 17 Stream of Total Costs ($ million) and Benefits (millions oz), assuming ongoing additional costs of BVO substitutes

	Cost Under Proposed Rule	Baseline Cost	Net Cost Primary Estimate	BVO Consumption Under Baseline	BVO Consumption Under Proposed Rule	Impact of Proposed Rule on BVO Consumption
2026	$21.09	$5.27	$15.82	0.09	0	-0.09
2027	$10.55	$6.59	$3.96	0.07	0	-0.07
2028	$10.55	$6.26	$4.28	0.05	0	-0.05
2029	$10.55	$5.36	$5.19	0.04	0	-0.04
2030	$10.55	$4.35	$6.20	0.03	0	-0.03
2031	$10.55	$3.42	$7.12	0.02	0	-0.02
2032	$10.55	$2.65	$7.90	0.02	0	-0.02
2033	$10.55	$2.03	$8.52	0.01	0	-0.01
2034	$10.55	$1.54	$9.00	0.01	0	-0.01
2035	$10.55	$1.17	$9.38	0.01	0	-0.01
2036	$10.55	$0.88	$9.67	0.00	0	0.00
2037	$10.55	$0.66	$9.88	0.00	0	0.00
2038	$10.55	$0.50	$10.05	0.00	0	0.00
2039	$10.55	$0.37	$10.17	0.00	0	0.00
2040	$10.55	$0.28	$10.27	0.00	0	0.00
2041	$10.55	$0.21	$10.34	0.00	0	0.00
2042	$10.55	$0.16	$10.39	0.00	0	0.00

2043	$10.55	$0.12	$10.43	0.00	0	0.00
2044	$10.55	$0.09	$10.46	0.00	0	0.00
2045	$10.55	$0.07	$10.48	0.00	0	0.00
NPV 3%			$130.65		Annual reduction	-0.02
NPV 7%			$90.70			
Ann 3%			$8.78			
Ann 7%			$8.56			

As shown in Table 17 above, under this scenario, the annualized costs of this rule (at 7 percent), relative to a baseline, would be roughly $8.56 million for the years 2026 to 2045. The annual benefits of this rule, relative to the baseline, would be a reduction in BVO exposure of roughly 0.02 million oz. For the proposed rule to be cost effective, there would have to be over $487 worth of public health benefits per oz of reduced BVO exposure.

When the impacts of this proposed rule are expected to begin is another source of uncertainty. The table below shows the costs and benefits of this rule under the assumption of impacts beginning in different years. In all cases, for the proposed rule to be cost effective, there would have to be almost $9 worth of public health benefits per oz of reduced BVO exposure.

Table 18 Costs ($ million) and Benefits (millions oz) under assumption of impacts beginning in different years

	Year that impacts of proposed rule begin			
	2024	**2025**	**2027**	**2028**
Costs				
NPV 3%	$1.49	$1.12	$0.63	$0.47
NPV 7%	$2.89	$2.17	$1.22	$0.91
Ann 3%	$0.10	$0.08	$0.04	$0.03
Ann 7%	$0.27	$0.20	$0.11	$0.09
Benefits				

millions oz of BVO exposure avoided	0.03	0.02	0.01	0.01

Our estimates of how many products are manufactured using BVO in 2021 and BVO exposure in 2021 are also sources of uncertainty. The table below shows the costs and benefits of this rule under the assumption that we underestimated the number of products manufactured using BVO in 2021 and overestimated BVO exposure in 2021. We present a scenario in which there are twice as many products manufactured using BVO in 2021 as estimated and BVO exposure in 2021 is only half the amount estimated.

Table 19 Costs ($ million) and Benefits (millions oz), doubling number of products manufactured with BVO and halving exposure to BVO

	Costs
NPV 3%	$1.68
NPV 7%	$3.25
Ann 3%	$0.11
Ann 7%	$0.31
	Benefits
millions oz of BVO exposure avoided	0.01

As shown in Table 19 above, under this scenario, the annualized costs of this rule (at 7 percent), relative to a baseline, would be roughly $0.31 million for the years 2026 to 2045. The annual benefits of this rule, relative to the baseline, would be a reduction in BVO exposure of roughly 0.01 million oz. For the proposed rule to be cost effective, there would have to be almost $35 worth of public health benefits per oz of reduced BVO exposure.

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 this proposed rule will impact at most 2.5 percent of small businesses within the beverage manufacturing industry which falls below the threshold of 5 percent that constitutes a substantial number of small entities (Ref. 1), and because we believe that costly disruptions to small entities are likely to be small due to replacement formulas for BVO having been in place and widely used for decades, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

To determine how many businesses are impacted by this proposed rule, we identify the number of unique parent companies of the products captured in Table 2.

Table 20 Number of Unique Parent Companies in 2021

		Current BVO Usage		Percentage of Industry Category		
Number of Unique Parent Companies for All Beverages	**Number of Unique Parent Companies for Beverages with confirmed or unknown BVO usage in 2021**	**Unknown**	**Confirmed**	**Max**	**Min**	**Most Likely**
1860	47*	41	8	2.53%	0.43%	1.48%

* Some companies have known and unknown BVO usage, which is why this is not the sum of 41 and 8

As shown in Table 20 above, we estimate that between 0.43 and 2.53 percent of beverage companies manufacture products with BVO as of 2021.

According to the Small Business Administration (SBA), businesses within the beverage manufacturing industry (NAICS 3121) are considered small if they have under 500 employees.[14] Data from the U.S. Census Bureau[15] shows the following breakdown of firm size for the beverage manufacturing industry.

Table 21 Breakdown of Firm Size for Beverage Manufacturing Industry

4-DIGIT NAICS INDUSTRY	FIRM SIZE (By Num. Emp.)	FIRMS
Beverage Manufacturing (3121)	Size 1 to 19	7,416
Beverage Manufacturing (3121)	Size 20 to 499	1,740
Beverage Manufacturing (3121)	Size 500 or More	102

According to Table 21 above, 9,156 of 9,258 (or about 98.9 percent of) firms in the beverage manufacturing industry are small businesses as defined by SBA. If we assume that the companies in our data (see Table 20) are representative of the beverage manufacturing industry, then we can estimate that about 1,840 (1,860 multiplied by 98.9 percent) of them are small businesses. If we further assume that all the parent companies with BVO usage in 2021 are small businesses, we estimate that between 0.43 and 2.5 percent of small businesses within the beverage manufacturing industry manufacture products using BVO in 2021. This percentage is an overestimate and will likely be even smaller in 2026, when the impacts of this proposed rule will begin. This falls below the threshold of 5 percent that constitutes a substantial number of small entities (Ref. 1).

14 See U. S. Small Business Administration. Table of Small Business Size Standards Matched to North American Industry Classification System Codes at https://www.sba.gov/sites/default/files/Size_Standards_Table.pdf (accessed Jan 5, 2023)
15 See U.S. Census Bureau Business Dynamics Statistics at https://www.census.gov/programs-surveys/bds.html (accessed July 10, 2023)

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

We do not estimate revenues for small businesses impacted by this proposed rule but believe that costly disruptions to small entities are likely to be small. First, replacement formulas for BVO have been in place for decades and are widely used in beverage products throughout the U.S. and the world. In addition, the time between the publication of our proposal and any subsequent final rule as well as that rule's compliance period should minimize costly disruptions to manufacturers, including small entities, still using BVO.

C. Alternatives to Minimize the Burden on Small Entities

In the section on Regulatory Alternatives, we show that a compliance date three years after publication rather than one year after publication would lower reformulation and re-labeling costs and save two years of rule costs. Because small entities as defined by SBA make up almost the entirety of the beverage manufacturing industry, we present this as an alternative to minimize the burden on small entities.

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