DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Standards of Identity Modernization; Pasteurized Orange Juice; Final Rule

Docket No. FDA-2022-P-1668

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

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Executive Summary

This rule amends the U.S. standard of identity (SOI) for pasteurized orange juice (POJ) by reducing the minimum soluble solids content from 10.5° Brix to 10.0° Brix. The rule also increases the maximum allowable percentage by volume of juice from *Citrus reticulata* or *Citrus reticulata* hybrids in POJ from 10% to 15%. Non-quantified benefits include flexibility for manufacturers, flexibility of product choice for consumers, and potential sustainability for manufacturers in the face of disease or climate impacts. The rule does not impose any compliance costs to firms; however, it might result in costs associated with product reformulation or relabeling, should firms voluntarily choose to adjust their products given this new flexibility. We estimate potential cost savings to manufacturers due to the added flexibility that would allow substitution to cheaper inputs. The annualized costs would range from -$11.6 million to -$51.0 million, with a primary estimate of -$28.4 million, at a 7% discount rate, and from -$11.8 million to -$51.7 million, with a primary estimate of -$28.8 million, at a 3% discount rate.

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I. **Introduction and Summary**

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 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. Executive Order 14192 requires that any new incremental costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least ten prior regulations." The Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is a significant regulatory action under Executive Order 12866. This final rule is expected to be an Executive Order 14192 deregulatory action.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We conclude that this final rule would not generate compliance costs to industry, and we certify that the final 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 $193 million, using the most current (2025) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

The final rule does not require firms in the POJ industry to change their manufacturing practices or behavior in any way. As a result, we conclude that there would be no compliance costs associated with the rule. The final rule allows additional flexibility for, and the opportunity for innovation regarding, the manufacture of POJ, providing benefits to industry without harming consumers. Manufacturers may experience cost savings by avoiding or reducing blending single strength orange juice with higher Brix orange juice or orange juice concentrate, or by substituting cheaper inputs like local lower-Brix oranges that previously would not have been used to meet the SOI. Manufacturers may also experience cost savings by substituting a larger percentage of juice from unfermented *Citrus reticulata* or its hybrids in POJ. We note specifically that the final rule does not require any behavioral changes on the part of manufacturers, as it provides manufacturers with greater flexibility rather than imposing any restrictions. Manufacturers may continue to manufacture and sell POJ with a Brix of 10.5° if they choose, as the new Brix requirement of 10° is only a minimum requirement. No changes would be required for products that meet the existing POJ standard.

Our primary estimate of potential cost savings experienced by manufacturers due to the added flexibility that would allow substitution to cheaper inputs is -$28.4 million, annualized at 7% over 10 years; this primary estimate is -$28.8 million, annualized at 3% over 10 years. Our primary estimate of cost savings, annualized at 7% over a perpetual time horizon, is -$28.9 million. Therefore, we conclude that the final rule to amend the SOI for POJ is a deregulatory action under Executive Order 14192. Table 1 provides a summary of the benefits and costs associated with the final rule.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0	$0	$0	2024	7%	2026-2035	
		$0	$0	$0	2024	3%	2026-2035	
	Annualized Quantified					7%		
						3%		
	Qualitative						2026-2035	Benefits include additional flexibility for firms in production and innovation
Costs	Annualized Monetized $millions/year	-$28.4	-$11.6	-$51.0	2024	7%	2026-2035	
		-$28.8	-$11.8	-$51.7	2024	3%	2026-2035	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over an infinite time horizon, assuming 1% annual growth in cost savings corresponding to 1% annual growth of POJ market in perpetuity.

Table 2. EO 14192 Summary Table (millions of 2024 dollars, discounted over an infinite time horizon at a 7% discount rate)

	Primary Estimate
Present Value of Costs	$0
Present Value of Cost Savings	-$412.6
Present Value of Net Costs	-$412.6
Annualized Costs	$0
Annualized Cost Savings	-$28.9
Annualized Net Costs	-$28.9

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

FDA's proposed rule "Food Standards of Identity Modernization; Pasteurized Orange Juice," (90 FR 37817) (2025 POJ proposed rule) was published on August 6, 2025. The comment period for the 2025 POJ proposed rule closed on November 4, 2025.

In the paragraphs that follow, we describe and respond to the comments we received on the Preliminary Regulatory Impact Analysis (PRIA) for the 2025 POJ proposed rule that are within the scope of the rulemaking.

We have numbered each comment to help distinguish between different comment themes. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

Comment 1: Information about domestic production of POJ

One comment mentioned that domestic production of orange juice supplied nearly 75% of US consumption in 2005 but now meets only 16% and provided a source supporting that information (Ref. 1).

Response: We thank the commenter for the information and have incorporated this information into the quantified cost savings estimates in this final regulatory impact analysis.

Comment 2: Information used for cost savings estimates

One comment mentioned that the estimated cost savings in the PRIA were calculated based on figures "without factual support", including the fraction of imported oranges that could be replaced with domestic oranges, the percentage reduction in manufacturing costs, the fraction of the orange juice market that would experience cost reductions as a result of the rule, and the fraction of producers' revenues that are made up of costs. The comment did not provide any additional information about these inputs.

One comment questioned whether the cost savings estimated in the PRIA relied on tariff-inflated prices and posited that, if the cost savings did rely on the existence of tariffs, the cost savings may disappear if tariffs were struck down by a court decision. The comment also stated that if the estimated cost savings disappeared, FDA's justification of the rule may be unstable.

Response: We acknowledge the information gaps and limitations in our analysis of the rule's quantification of cost savings. While we attempted to provide quantified estimates rather than a qualitative discussion, we did not receive comments containing substantive data or information regarding the various inputs that would enable us to refine our quantified estimates. As such, we have not made changes to these estimates.

We note that the estimated cost savings in the analysis do not incorporate any assumed tariffs, either in the baseline state of the world or in the estimated impact of the rule. We also note that FDA's decision to publish this rule does not depend on the estimated cost savings in the analysis.

Comment 3: Changes made by manufacturers may not be voluntary

One comment suggested that stating "all changes made by manufacturers would be voluntary" is misleading.

Response: We note that the rule relaxes the minimum soluble solids requirement from a minimum of 10.5° Brix to a minimum of 10.0° Brix. The rule does not introduce any new requirements or restrictions for manufacturers. After the publication of the rule, any manufacturer may choose to continue producing POJ with a Brix of 10.5 or greater, in which case the manufacturer would make no changes at all. As such, we believe that any change in behavior on the part of manufacturers in response to the rule is entirely voluntary.

Comment 4: Firms would incur relabeling costs due to the rule

Several comments suggested that firms would incur relabeling costs due to the rule.

Response: Manufacturers of POJ generally do not include information on the minimum Brix level of the product on the label, and we do not anticipate that they would change labels to include such information. While we assume that most manufacturers choosing to make a change to the Brix of their POJ would update the Nutrition Facts label to reflect any changed sugar content in their next regularly scheduled, voluntary relabeling cycle, we recognize that under 21 CFR 101.9(g)(5) and (6) they would likely not be subject to enforcement if they did not make a timely change. As such, we do not believe firms will incur relabeling costs as a result of the rule.

Comment 5: Treat the rule as significant, quantify costs, and consider less burdensome alternatives to the rule

One comment requested that FDA treat the rule as "significant" under Executive Orders 12866 and 14094 and requested that FDA "provide a robust benefit-cost, alternatives, and distributional analysis consistent with OMB Circular A-4." The comment requested that, because the rule is significant, FDA provide quantified costs incurred due to labeling, reformulation, and

process change costs. The comment also requested we consider less burdensome alternatives to the rule.

Response: We note that Executive Order 14094 was revoked by Executive Order 14148, and that in the published Preliminary Regulatory Impact Analysis (p. 4), "The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action under Executive Order 12866." However, after including information accounting for the fraction of the US market supplied by domestic producers (see Summary of Changes in section I.D), our quantified estimate of the cost savings of the rule is now smaller than the monetary threshold ($100M) for significance. As we discuss in the following paragraph, we do not believe any firm will incur costs larger than its cost savings due to the rule. We also note that in the published PRIA document and in this Final Regulatory Impact Analysis, we have conducted benefit-cost analyses of the rule, which include alternatives sections and distributional effects sections.

We note specifically that the rule relaxes the minimum soluble solids requirement from a minimum of 10.5° Brix to a minimum of 10.0° Brix, and that no firms would be required to make any changes to meet this new requirement. Any firm producing POJ that meets the old requirement (minimum 10.5° Brix) could continue producing the exact same POJ after the rule is finalized while still meeting the new requirement (minimum 10.0° Brix). As such, we do not believe that firms will incur compliance costs as a result of the rule, and any production changes would be voluntary. Any firm that believed changes to its production process would be net costly could choose not to make changes. As such, we have not included quantified cost estimates, as any firm may choose not to incur any costs as a result of the rule. In the Regulatory Alternatives section of this document, we have considered alternatives that further relax requirements, including revoking

the minimum Brix level requirement for POJ and revoking the SOI for POJ. Additionally, the final rule is less burdensome than the proposed rule, as the final rule increases the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10% to 15% by volume.

Comment 6: Small entities would incur compliance costs due to the rule

One comment argued that FDA's Regulatory Flexibility Assessment/Small Business Regulatory Enforcement Fairness Act analysis is missing or insufficient. This comment posited that small entities in the POJ manufacturing industry would incur compliance costs from sources including labeling changes, reformulation, quality control and validation, inventory write-off, compliance training, and SOP revisions. The comment requested FDA assess small entity alternatives such as phased compliance dates, safe harbors and performance-based options for validations, and de minimis labeling accommodations. The comment requested that FDA withdraw the proposed certification that the rule will not have a significant economic impact on a substantial number of small entities.

Response: We infer from the text of the comment that the commenter is under the impression that the rule would impose some new restriction or make an existing regulation stricter, which would require manufacturers to make production changes by a specific date to meet a new or stricter requirement (as seen in the request for phased compliance dates). We note specifically that the rule relaxes the minimum soluble solids requirement from a minimum of 10.5° Brix to a minimum of 10.0° Brix, and that no firms would be required to make any changes to meet this new requirement. Any firm producing POJ that meets the old requirement (minimum 10.5° Brix) could continue producing the exact same POJ after the rule is finalized while still meeting the new requirement (minimum 10.0° Brix). As such, we do not believe that firms would incur compliance costs as a result of the rule, and any production changes on the part of the firms would be voluntary.

Any firm that believed changes to its production process would be costly could choose not to make changes. Because we do not believe firms will incur compliance costs, we do not believe small entities will incur compliance costs. As a result, we believe the rule will not have a significant economic impact on a substantial number of small entities. However, even though we do not believe the rule will have a significant economic impact on a substantial number of small entities, we developed and published an initial regulatory flexibility analysis (IRFA) that included additional alternatives to minimize the burden on small entities, including the alternatives to "Revoke the minimum Brix level requirement in the SOI" and "Revoke the SOI for POJ." After considering public comments, we are publishing a final regulatory flexibility analysis that similarly concludes that the final rule will not have a significant economic impact on a substantial number of small entities.

Comment 7: Costs would exceed Unfunded Mandates Reform Act threshold

One comment posited that costs generated by labeling, inventory write-offs, reformulation, testing, and process validation may cause expenditures caused by the rule to exceed the Unfunded Mandates Reform Act (UMRA) threshold of $187 million (2024 dollars) in a year. The comment requested FDA "provide a transparent cost aggregation and, if applicable, the required UMRA statements, including least-burdensome alternative analysis."

Response: We note specifically that the rule relaxes the minimum soluble solids requirement from a minimum of 10.5° Brix to a minimum of 10.0° Brix, and that no firms would be required to make any changes to meet this new requirement. Any firm producing POJ that meets the old requirement (minimum 10.5° Brix) could continue producing the exact same POJ after the rule is finalized while still meeting the new requirement (minimum 10.0° Brix). As such, we do not believe that firms will incur compliance costs as a result of the rule, and any production changes

on the part of the firms would be voluntary. Any firm that believed changes to its production process would be costly could choose not to make changes. As such, we do not believe the rule would generate costs that would exceed the UMRA threshold.

D. Summary of Changes

In this section, we detail changes made in this document from the published PRIA.

- We have updated several statistics about orange juice production and prices where more recent data became available.
- In the PRIA, our quantified cost savings estimates did not account for the fact that only 16% of the domestic orange juice market is supplied by domestic producers (Ref. 1), and this caused our cost savings estimate to attribute potential cost savings from all producers of orange juice sold in the US to domestic producers. As such, we have incorporated this information into our calculations in this document. We now separately estimate cost savings for domestic producers and foreign producers. We have applied a pass-through rate of 50% to estimated cost savings to foreign producers of orange juice.
- We have scaled estimated cost savings in 2026 by 50% to account for an estimated publication date of the final rule of May 31, 2026, which leads to an estimated compliance date of June 30, 2026.
- We have included discussion of non-quantified cost savings resulting from increasing the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10% to 15% by volume, which is a change in policy from the proposed rule.

II. **Final Economic Analysis of Impacts**

A. Background

FDA published a final order establishing SOIs for orange juice and orange juice products, including POJ, in 1963. The final order contained various findings of fact, first being that "[t]he food commonly and usually known as orange juice is the natural liquid that is squeezed from mature oranges" (28 FR 10900 at 10901). The order found that a new product had been developed that was heat-treated and that the name of this product is pasteurized orange juice (28 FR 10900 at 10901 through 10902).

In establishing minimum composition requirements for this product, the record supported a minimum orange juice soluble solids of not less than 10.5° Brix, and 10.5° was established as the minimum Brix requirement for POJ. The final order further stated that when fruit of low Brix is used in the manufacture of POJ, the Brix level may be adjusted by adding frozen single strength juice with higher Brix or orange juice concentrate, the latter being limited to one-fourth of the total orange juice solids. The label of POJ manufactured with concentrated orange juice ingredients was required to bear a declaration of "prepared in part from concentrated orange juice," "with added concentrated orange juice," or "concentrated orange juice added."

FDA received a citizen petition (Docket No. FDA-2022-P-1668) on July 25, 2022, asking us to amend the SOI for POJ to reduce the minimum soluble solids requirement for POJ from 10.5° to 10.0° Brix. According to the petition, the average Brix of Florida oranges has steadily dropped since 2010-2011 due to a bacterial disease called "citrus greening disease," also known as *Huanglongbing*; seasonal average Brix values (weighted by volume) are hovering below the minimum of 10.5° Brix (Petition at pages 3-4). Additional data from the Florida Department of Agriculture & Consumer Services submitted by the petitioners show that the average Brix level

continued to drop in 2022-2023 (average Brix of 9.7°) due to tree stress caused by weather and disease pressures (Citizen Petition Supplemental Materials at Appendix 2). Given these conditions impacting orange markets, the petitioners stated the current standards have become outdated.

We received another petition (Docket No. FDA-2023-p-5063) on November 15, 2023, for which most of the requests are outside the scope of this rulemaking. However, one request is relevant to the SOI for POJ. The POJ standard in 21 CFR 146.140 (currently provides for a maximum allowable percentage of unfermented juice from *Citrus reticulata* (i.e., mandarin or tangerine oranges) or *Citrus reticulata* hybrids of not more than 10% by volume. The request seeks to increase the maximum allowable percentage from 10% to 15%. The petition states that, "Increasing the permitted percentage of juices from tangelos and tangerines would contribute to a better balancing of juice from oranges in diminishing supply and juice from oranges where there is a surplus." FDA previously recognized that limited use of tangerine and tangelo juices may be used to achieve uniform color and flavor in orange juice without altering its essential characteristics (27 FR 10494).

B. Need for Federal Regulatory Action

Food standards are intended to promote honesty and fair dealing in the interest of consumers by protecting consumers' expectations about food and preventing economic adulteration.

In 1963, FDA published a SOI for POJ that mandated a minimum Brix level of 10.5°. However, Brix levels for Florida oranges have dropped in recent years, due in part to citrus greening disease (*Huanglongbing*). Manufacturers may face difficulty producing POJ that meets the SOI using oranges with lower Brix levels.

Lowering the minimum Brix level and increasing the maximum allowable percentage of juice from *Citrus reticulata* and *Citrus reticulata* hybrids in POJ from 10% to 15% in the SOI will provide additional flexibility to manufacturers of POJ, as well as additional sustainability of current and future production in the face of disease or climate disruption. For example, if disease or climate disruption limits the availability of oranges with higher Brix levels, manufacturers may be able to produce additional volume of POJ using more lower-Brix oranges when the minimum Brix of POJ is lowered to 10°. Also, FDA believes that permitting up to 15% expressed juice from *Citrus reticulata* and its hybrids in POJ is reasonable in light of current environmental conditions and is in the interest of consumers as it supports continued availability of a product that meets consumer expectations.

C. Purpose of the Final Rule

The final rule lowers the minimum Brix level for POJ from 10.5° to 10.0°. Lowering the minimum Brix level and increasing the maximum allowable percentage of juice from *Citrus reticulata* and *Citrus reticulata* hybrids in POJ from 10% to 15% will provide additional flexibility to manufacturers of POJ and promote honesty and fair dealing in the interest of consumers.

D. Baseline Conditions

In recent years, United States orange and orange juice producers have been affected by *Huanglongbing* and weather events, which have caused a decrease in production of domestic oranges and orange juice. Total US orange production declined from 146.6 million boxes in 2014-2015 (Ref. 2) to 103.0 million boxes in 2020-2021 (Ref. 3) and further declined to 58.3 million boxes in 2024-2025 (Ref. 4). Meanwhile, US imports of orange juice have risen from 280,000 metric tons (MT) in 2015-2016 to 400,000 MT in 2024-2025 (Ref. 5), as some manufacturers mix imported orange juice with domestic orange juice to meet the current minimum Brix requirement

(Citizen Petition, Docket No. FDA-2022-P-1668). Orange juice futures prices were relatively stable from 2015-2022 before spiking over 250% from January 2022 to a high in September 2024. As of February 2026, futures prices have fallen to a level approximately 50% higher than the January 2022 level (Ref. 6). Prices to consumers have followed a similar pattern; after relative price stability from 2015-2022, the US price index for a 12-ounce can of frozen orange juice concentrate increased by 86% from January 2022 to January 2026 (Ref. 7). Domestic consumption of orange juice declined from 631,000 MT in 2015-2016 to 542,000 MT in 2020-2021 and further declined to 486,000 MT in 2024-2025 (Ref. 5).

In this section, we present baselines of the US orange juice market. We use a baseline value of the US orange juice market of $10.37 billion (Ref. 8) and assume a uniform distribution of annual revenue growth from 0% to 2%. We use these parameters to simulate the growth of the US orange juice market; this method incorporates uncertainty about the annual growth rate of the industry. Table 3 presents the simulated baseline size of the market based on this assumption, including the low (5^{th} percentile) and high (95^{th} percentile) outcomes.

Table 3: Estimated Size of US Orange Juice Market By Year (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$10,380	$10,474	$10,567
2027	$10,436	$10,578	$10,723
2028	$10,508	$10,684	$10,862
2029	$10,588	$10,791	$10,997
2030	$10,669	$10,899	$11,128
2031	$10,754	$11,008	$11,262
2032	$10,841	$11,118	$11,396
2033	$10,930	$11,229	$11,528
2034	$11,025	$11,342	$11,664
2035	$11,115	$11,455	$11,797

We are uncertain what fraction of the orange juice industry's total revenues are profit and what fraction are costs. For the purposes of this analysis, we assume a uniform distribution from 70% to 90% of the fraction of revenue made up of costs. This assumed distribution includes a central estimate of 80%. We use these parameters to simulate the annual costs of the US orange juice market; this method incorporates uncertainty about the annual growth rate of the industry. Table 4 presents the simulated annual baseline costs of US orange juice production based on these assumptions, including low (5th percentile) and high (95th percentile) outcomes.

Table 4: Estimated Costs of US Orange Juice Market By Year (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$7,441	$8,379	$9,325
2027	$7,511	$8,463	$9,419
2028	$7,585	$8,547	$9,517
2029	$7,651	$8,633	$9,611
2030	$7,721	$8,719	$9,720
2031	$7,807	$8,806	$9,805
2032	$7,879	$8,894	$9,933
2033	$7,957	$8,983	$10,029
2034	$8,044	$9,073	$10,129
2035	$8,111	$9,164	$10,240
Annualized, 3%	$7,752	$8,745	$9,748
Annualized, 7%	$7,729	$8,718	$9,716

We are uncertain what proportion of orange juice manufacturers' input costs are made up of the oranges used to produce orange juice. For the purposes of this analysis, we assume oranges' fraction of costs follows a uniform distribution from 20% to 40%, which includes a central estimate of 30%. We use these parameters to simulate the annual input costs of oranges of the US orange juice market; this method incorporates uncertainty about oranges' fraction of input costs. Table 5 presents the simulated annual input costs of oranges, including low (5th percentile) and high (95th percentile) estimates.

Table 5: Estimated Input Costs of Oranges in US Orange Juice Market By Year (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$1,718	$2,514	$3,378
2027	$1,743	$2,539	$3,422
2028	$1,757	$2,564	$3,455
2029	$1,770	$2,590	$3,489
2030	$1,792	$2,616	$3,532
2031	$1,816	$2,642	$3,547
2032	$1,827	$2,668	$3,599
2033	$1,839	$2,695	$3,631
2034	$1,851	$2,722	$3,665
2035	$1,882	$2,749	$3,702
Annualized, 3%	$1,795	$2,624	$3,533
Annualized, 7%	$1,790	$2,615	$3,522

E. Benefits of the Final Rule

Benefits of the final rule may include additional sustainability of current and future POJ production in the face of threats like disease or climate disruption and additional flexibility of production for manufacturers of POJ.

Consumers may be negatively impacted if products no longer meet their expectations of POJ, either due to POJ having a lower Brix or due to an increased amount of *Citrus reticulata*. An additional consumer taste test submitted as a Supplemental appendix to the citizen petition (Supplemental Appendix 3, Docket No. FDA-2022-P-1668) found that fewer respondents correctly identified the difference between 10.5° Brix orange juice and 10.0° Brix orange juice than would be expected if respondents guessed randomly. Leschewski et al. find consumers pay no hedonic price premium for sugar in fruit juice (Ref. 9). We do not anticipate that POJ with a Brix of 10°-10.5° will fail to meet consumer expectations of POJ.

F. Costs of the Final Rule

The final rule lowers the minimum Brix requirement from 10.5° Brix to 10° Brix. Currently, some orange juice manufacturers mix juice from higher-cost higher-Brix imported oranges in the production process to meet the minimum Brix requirement (Docket No. FDA-2022-P-1668). The final rule may allow some manufacturers to substitute lower-cost domestic oranges for higher-cost imported oranges while meeting the new minimum Brix requirement.

We are uncertain how much cheaper orange juice production would become if manufacturers were able to substitute lower-cost domestic oranges as a result of the rule. The price per pound solids of Florida oranges for 2023-2024 crop year was $2.60 (Ref. 10); the futures price of orange juice fluctuated from $2.98 to $4.11 during that period (Ref. 11). Based on these statistics, domestic oranges as inputs may be approximately 13%-37% cheaper than buying imported orange juice on futures contracts. However, we are unsure what fraction of oranges used as inputs into domestic POJ is imported and what fraction is domestic. We are also unsure what fraction of the imported oranges used as inputs could be replaced by domestic oranges due to the reduction in minimum Brix level described in the rule. For example, if imported oranges were 20% cheaper than domestic oranges, imported oranges made up 10% of orange input costs, and half of the imported oranges could be replaced by domestic oranges due to the rule, the cost savings generated by input substitution allowed by the rule would be 1%.

For the purposes of this analysis, we assume a uniform distribution from 1% to 7% for the reduction in the input costs of oranges, which includes a central estimate of 4%. We use these parameters to simulate the annual cost savings of the rule if the entire orange juice industry were able to experience these cost reductions through input substitution; this method incorporates uncertainty about the reduction in input costs. Table 6 presents the simulated annual cost savings

due to the reduction in input costs, assuming the entire industry experiences these costs. The table also includes low (5th percentile) and high (95th percentile) outcomes.

Table 6: Estimated Reduction in Input Costs of Oranges By Year, Assuming Every Manufacturer Experiences Reductions (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$31.3	$100.5	$190.1
2027	$31.7	$101.6	$191.2
2028	$31.2	$102.6	$193.7
2029	$31.5	$103.6	$195.2
2030	$32.1	$104.6	$197.0
2031	$32.7	$105.7	$197.5
2032	$33.0	$106.7	$199.5
2033	$33.2	$107.8	$202.2
2034	$33.9	$108.9	$204.4
2035	$33.9	$110.0	$205.1
Annualized, 3%	$32.3	$104.9	$197.2
Annualized, 7%	$32.2	$104.6	$196.7

It is likely that not all manufacturers in the market would be able to substitute to cheaper orange inputs. We are uncertain about the fraction of the market that would be able to experience these input cost reductions as a result of the rule. For purposes of this analysis, we assume a uniform distribution from 30% to 70% for the fraction of the market that would experience these input cost reductions. We simulate the cost savings of the reduction in input costs using these parameters; this method incorporates uncertainty about the fraction of the market that would experience input cost reductions. For the purposes of this analysis, we multiply cost savings for 2026 by 0.5 to account for an assumed final rule effective date of May 31, 2026, which leads to an assumed compliance date of June 30, 2026. Table 7 presents the simulated annual cost savings of the rule, incorporating the uncertainty about the fraction of the market affected. The table includes low (5th percentile) and high (95th percentile) outcomes. Some manufacturers may also experience cost savings if substituting more *Citrus reticulata* juice or *Citrus reticulata* hybrid juices for non-

Citrus reticulata juice in POJ products reduces input costs. We do not quantify these cost savings due to lack of information about the relative prices of the inputs and lack of information about the percentage of the POJ market containing unfermented juice from *Citrus reticulata* or its hybrids.

Table 7: Estimated Reduction in Input Costs of Oranges By Year, Incorporating Uncertainty About Fraction of Market Affected (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$7.2	$25.1	$52.2
2027	$14.5	$50.8	$105.0
2028	$14.2	$51.3	$107.0
2029	$14.8	$51.8	$106.8
2030	$14.6	$52.3	$106.9
2031	$15.2	$52.8	$107.6
2032	$15.1	$53.4	$109.8
2033	$15.3	$53.9	$110.5
2034	$15.1	$54.4	$110.9
2035	$15.6	$55.0	$112.2
Annualized, 3%	$14.0	$49.6	$102.0
Annualized, 7%	$13.8	$49.0	$100.7

According to the American Farm Bureau Federation (Ref. 1), domestic production accounts for 16% of U.S. consumption of orange juice. We multiply the estimated cost savings in Table 7 by 0.16 to estimate the cost savings to domestic producers of orange juice, shown in Table 8; we multiply the estimated cost savings in Table 7 by 0.84 to estimate the cost savings to foreign producers of orange juice, shown in Table 9.

Table 8: Estimated Reduction in Input Costs of Oranges By Year, Incorporating Uncertainty About Fraction of Market Affected, Domestic Producers (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$1.1	$4.0	$8.3
2027	$2.3	$8.1	$16.8
2028	$2.3	$8.2	$16.8
2029	$2.4	$8.3	$16.9
2030	$2.4	$8.4	$17.3
2031	$2.4	$8.5	$17.4
2032	$2.4	$8.5	$17.4
2033	$2.4	$8.6	$17.7
2034	$2.5	$8.7	$18.0
2035	$2.5	$8.8	$18.2
Annualized, 3%	$2.2	$7.9	$16.3
Annualized, 7%	$2.2	$7.8	$16.1

Table 9: Estimated Reduction in Input Costs of Oranges By Year, Incorporating Uncertainty About Fraction of Market Affected, Foreign Producers (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$5.9	$21.1	$43.8
2027	$12.0	$42.7	$88.3
2028	$12.2	$43.1	$87.6
2029	$12.3	$43.5	$88.1
2030	$12.2	$43.9	$91.3
2031	$12.6	$44.4	$90.8
2032	$12.5	$44.8	$91.6
2033	$12.9	$45.3	$93.6
2034	$13.0	$45.7	$93.8
2035	$12.9	$46.2	$95.5
Annualized, 3%	$11.7	$41.7	$85.6
Annualized, 7%	$11.6	$41.1	$84.5

We assume a 50% pass-through rate of foreign cost savings to domestic consumers[1]; Table 10 presents the estimated cost savings of the rule, accounting for this pass-through rate. Based on

[1] We estimate cost pass-through from international firms to be between 0-100% with a midpoint of 50%, which is consistent with the broad scope of the literature on this topic. While there are many peer-reviewed papers that look at cost pass-through, the majority are not able to be extrapolated for general purposes, because they tend to be specific to the structure of a single industry and type of cost. We rely on a report called "Cost pass-through: theory, measurement, and potential policy implications" by RBB Economics (2014) for broad conclusions on this literature.

these assumptions, our primary estimate of the cost savings of the rule is $28.8 million, annualized at 3% over 10 years; annualized at 7% over 10 years, this primary estimate is $28.4 million.

Table 10: Estimated Cost Savings of Final Rule By Year, Incorporating 50% Pass-Through Rate For Foreign Producers (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$6.0	$14.6	$26.4
2027	$12.3	$29.5	$52.9
2028	$12.0	$29.7	$53.3
2029	$12.3	$30.0	$53.4
2030	$12.3	$30.3	$54.9
2031	$12.6	$30.6	$55.2
2032	$12.5	$31.0	$55.2
2033	$12.9	$31.3	$56.4
2034	$13.0	$31.6	$56.8
2035	$12.9	$31.9	$57.7
Annualized, 3%	$11.8	$28.8	$51.7
Annualized, 7%	$11.6	$28.4	$51.0

The final rule does not require manufacturers of POJ to change their manufacturing practices or behavior in any way. The recordkeeping requirements for manufacturers would be unchanged; as a result, we do not anticipate recordkeeping costs incurred due to the rule. Similarly, because the Brix level is not specified on product labels, manufacturers would not need to update their labeling due to the rule. We assume manufacturers choosing to make a change to the Brix of their POJ would update the Nutrition Facts label to reflect any changed sugar content in their next regularly scheduled, voluntary relabeling cycle. Because these manufacturers would not need to change their labeling sooner or more frequently than they would have otherwise, we do not

While this report is not peer reviewed, it summarizes the peer reviewed literature. The report concludes "In summary, the available evidence reveals a wide range of pass-through rates or elasticities. Absolute industry-wide pass-through can be as low as 20% but can also reach well over 100%. Pass-through elasticities may fall close to zero but in some cases they come close to one. However, there is not enough empirical evidence to tie these variations in pass-through to specific market features, as predicted by the theory described in the preceding chapters. In sum, we are able to draw little by way of solid conclusions in this respect."

anticipate relabeling costs due to the rule. We recognize that under 21 CFR 101.9(g)(5) and (6) they would likely not be subject to enforcement if they did not make a timely change.

Reducing the minimum required Brix level to 10.0° will likely result in some manufacturers producing POJ below the previous minimum required Brix level of 10.5°. We are uncertain if manufacturers will incur one-time reformulation costs. For example, manufacturers who previously used only domestic oranges as inputs and have recently begun mixing in higher-cost imported oranges may already have formulas and processes available for using only domestic oranges as inputs. We are also uncertain what fraction of firms, if any, may incur reformulation costs.

If firms incur reformulation costs, we assume that each firm would incur that cost only if its resultant cost savings from input substitution would be larger than the reformulation cost; otherwise, the firm would be better off continuing to produce its current product. Based on this assumption, we conclude that no firm would incur costs larger than its cost savings due to the rule.

G. Transfers Caused by the Final Rule

If manufacturers experience cost savings, some fraction of these savings may be passed on to consumers in the form of lower prices. However, we are uncertain about the magnitude of any transfer of surplus from producers to consumers. Additionally, there may be some transfer of surplus from foreign producers of oranges or POJ to domestic producers of oranges or orange juice if more domestic oranges can be used in POJ production due to the rule. There may also be some transfer of surplus from producers of non-*Citrus reticulata* oranges used in POJ to producers of *Citrus reticulata* or its hybrids if the increase in the maximum allowable percentage of unfermented juice of *Citrus reticulata* or its hybrids in POJ from 10% to 15% increases demand for *Citrus reticulata* or its hybrids.

H. Summary of Benefits, Costs, and Transfers

Table 11 presents the estimated cost savings of the rule over a 10-year time horizon. The table includes low (5th percentile) and high (95th percentile) outcomes. Based on these assumptions, our primary estimate of the cost savings of the rule is $28.8 million, annualized at 3% over 10 years; annualized at 7% over 10 years, this primary estimate is $28.4 million.

Table 11: Estimated Cost Savings of Final Rule By Year, Incorporating 50% Pass-Through Rate For Foreign Producers (millions 2024$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	$6.0	$14.6	$26.4
2027	$12.3	$29.5	$52.9
2028	$12.0	$29.7	$53.3
2029	$12.3	$30.0	$53.4
2030	$12.3	$30.3	$54.9
2031	$12.6	$30.6	$55.2
2032	$12.5	$31.0	$55.2
2033	$12.9	$31.3	$56.4
2034	$13.0	$31.6	$56.8
2035	$12.9	$31.9	$57.7
Annualized, 3%	$11.8	$28.8	$51.7
Annualized, 7%	$11.6	$28.4	$51.0

The rule does not generate compliance costs for firms, and firms would not need to change their recordkeeping or labeling. Some manufacturers may experience one-time reformulation costs if they choose to reformulate products using cheaper inputs. However, we are uncertain how many manufacturers, if any, would reformulate products. We assume any manufacturer that incurs reformulation costs would do so only if its cost savings from the reformulation were greater than the reformulation costs.

Benefits of the rule may include additional sustainability of current and future POJ production in the face of threats like disease or climate disruption and additional flexibility of production for manufacturers of POJ.

If manufacturers experience cost savings, some fraction of these savings may be passed on to consumers in the form of lower prices. However, we are uncertain about the magnitude of any transfer of surplus from producers to consumers.

I. Analysis of Regulatory Alternatives to the Final Rule

We consider the following regulatory alternatives for the POJ SOI:

1. Revoke the minimum Brix requirement in the SOI
2. Revoke the SOI for POJ
3. Provide temporary marketing permits for lower-Brix POJ products
4. Finalize the rule as proposed

Option 1: Revoke the minimum Brix requirement in the SOI

One regulatory alternative would be to no longer require a minimum Brix level in the manufacture of POJ. As such, POJ could be manufactured with any Brix level provided that the food meets the other requirements in the SOI. This regulatory alternative would also result in no compliance costs to industry, as well as increased sustainability for manufacturers and additional flexibility for manufacturers and consumers. Some manufacturers may experience larger cost savings relative to the rule if they are able to avoid blending single strength orange juice with higher Brix orange juice or orange juice concentrate or are able to substitute a larger fraction of cheaper inputs, such as using oranges with lower Brix level. We are unable to quantify the benefits of additional marginal flexibility of this alternative relative to the flexibility afforded by the action. While manufacturers may experience larger cost savings under this alternative if producing POJ with Brix level lower than 10.0° is cheaper than producing POJ with Brix level between 10.0° and 10.5°, we lack information about the relationship between the Brix level of POJ produced and the

cost savings experienced by manufacturers. We also lack information about the equilibrium Brix level of POJ that would be produced under this alternative of no minimum Brix level.

This regulatory alternative may negatively impact consumers of POJ if the revocation of the minimum Brix requirement results in products that are not consistent with consumer expectations of POJ. If removing the minimum Brix requirement from the SOI results in POJ with noticeably different taste or other attributes, consumers may no longer receive POJ consistent with their expectations.

Option 2: Revoke the SOI for POJ

Another potential regulatory alternative would be to revoke the SOI for POJ entirely. As in the other alternatives, this regulatory alternative would also result in no compliance costs to industry, as well as increased sustainability for manufacturers and additional flexibility for manufacturers and consumers. Some manufacturers may experience larger cost savings than in the rule or option 1 of the regulatory alternatives in section I if they are able to substitute even cheaper inputs or a greater fraction of cheaper inputs than in the rule or option 1 of the regulatory alternatives. Manufacturers may also experience additional cost savings if they are no longer required to comply with other provisions of the SOI.

Similar to removing only the minimum Brix requirement, we are unable to quantify the benefits of additional marginal flexibility of this alternative relative to the flexibility afforded by the proposal to amend the minimum Brix level to 10.0°. Revoking the SOI may negatively impact consumers of POJ if the revocation of the SOI results in products that are not consistent with consumer expectations of POJ and may negatively impact consumers more than in the final rule

scenario or first regulatory alternative if products become even less consistent with consumer expectations about POJ.

Option 3: Provide temporary marketing permits for lower-Brix POJ products

A third potential regulatory alternative would be to grant temporary marketing permits for POJ with a Brix between 10 and 10.5. FDA can issue temporary marketing permits (TMP) that enable food manufacturers to market test the advantages to and acceptance by consumers of a food that deviates from its definition and standard of identity (See 21 CFR 130.17). Manufacturers with a TMP may market test products that deviate from the relevant SOI for a period of time. If a TMP were granted in this case, manufacturers would be able to market test POJ with a Brix level as low as 10.0°. As in the other alternatives, this regulatory alternative would also result in increased sustainability for manufacturers and additional flexibility for manufacturers and consumers in terms of the types of products that could be produced. However, a TMP is meant to be temporary. If the average Brix levels of domestic oranges do not increase, this alternative may attempt to fix a permanent problem with a temporary solution.

In this alternative, manufacturers would incur labeling costs as a result of the requirement to label any products that are sold with a Brix level lower than 10.5°. FDA requires manufacturers to distinguish products under a TMP from products that do not deviate from the definition and standard of identity and bear different labeling (See 21 CFR 130.17(c)(9)). Manufacturers may also incur additional costs related to producing multiple variants (10.5° Brix vs. sub-10.5° Brix) of similar products. This alternative may also harm consumers if they are unaware of the difference between the variants available for purchase and prefer a specific variant.

Option 4: Finalize the rule as proposed

A fourth regulatory alternative would be to finalize the rule as proposed, without the additional provision that increases the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids in POJ from 10% to 15%. This final rule provides additional flexibility for producers of POJ relative to the regulatory alternative of the proposed rule. This final rule may also result in additional cost savings for producers of POJ if they are able to substitute cheaper inputs in the production process due to the additional *Citrus reticulata* provision. Due to the additional flexibility, this final rule is a less-burdensome alternative than the regulatory alternative of the proposed rule.

J. Distributional Effects

We do not anticipate any distributional effects as a result of the rule.

K. International Effects

United States imports of orange juice have risen from 280,000 metric tons (MT) in 2015-2016 to 400,000 MT in 2024-2025 (Ref. 5), as some manufacturers mix imported orange juice with domestic orange juice to meet the current minimum Brix standard (Docket No. FDA-2022-P-1668, Ref. 11). The rule may allow manufacturers to substitute domestic oranges for foreign oranges as inputs into the POJ production process, which may slow the trend of increasing US imports or cause US imports to decrease. Some international producers of POJ for the US market may experience cost savings if they are able to substitute cheaper inputs into production of POJ due to the lower minimum Brix requirement. As seen in Table 9, we estimate cost savings to foreign producers of POJ. Our primary estimate of the cost savings to foreign firms is $41.7 million, annualized at 3% over 10 years; annualized at 7% over 10 years, this primary estimate is $41.3 million.

L. Uncertainty and Sensitivity Analysis

Throughout the analysis, we incorporate assumptions about various parameters in the calculations of cost savings. For each of these parameters, we assume a distribution and simulate the outcomes, which allows us to present 5^{th}-percentile and 95^{th}-percentile outcomes for each estimate. We acknowledge uncertainty about the annual growth rate of the US orange juice market, the fraction of the market's revenue made up of costs, the fraction of manufacturers' costs made up of oranges as inputs, the percentage reduction in costs experienced due to the rule, and the fraction of the market that may experience cost savings due to input substitution.

III. **Final Small Entity Analysis**

The Regulatory Flexibility Act requires FDA to analyze regulatory options that would minimize any significant impact of a rule on small entities. HHS guidelines suggest the threshold for "significant impact" is 3% of annual revenue and the threshold for "substantial number" is 5% of small entities.

FDA's Food Facilities Registration database lists 1740 firms with valid registrations in the category of manufacturers of fruit or vegetable juice, pulp, or concentrate products. These firms fall into North American Industry Classification System (NAICS) categories 311411 (Frozen Fruit, Juice, and Vegetable Manufacturing) and 311421 (Fruit and Vegetable Canning). Based on Statistics of US Businesses firm size by NAICS code data, approximately 94% of firms in NAICS code 311411 are considered small (fewer than 1100 employees); using the same metric, approximately 95% of firms in NAICS code 311421 are considered small (fewer than 1000 employees). Using a weighted average of these percentages, we calculate that approximately 1660 of the firms with valid registrations in the FFR database would be considered small. We note that this estimate is an upper bound of the number of firms affected, as it is likely some firms in this category do not produce POJ and would not be affected by the rule.

The final rule provides flexibility to small firms, which may experience cost savings if they are able to substitute cheaper inputs for more expensive inputs in the production process or produce POJ more cheaply at the lower minimum Brix level allowed by the rule. Any firm may choose to continue to produce exactly as it did prior to the rule; as such, we do not believe any small entity will incur costs larger than its cost savings. We note also that firms are not required to change their behavior due to the rule, and any behavior change would be voluntary.

We certify that the final rule will not have a significant economic impact on a substantial number of small entities. In this analysis, our primary estimate of annualized cost savings for firms experiencing cost savings represents approximately 1.0% of annual revenue. Our high estimate (95^{th} percentile) of annualized cost savings represents approximately 1.8% of annual revenue. Given the input parameters, the maximum cost savings possible in the model would represent approximately 2.5% of annual revenue. As such, we do not expect at least 5% of small entities to experience cost savings of at least 3% of annual revenue. This analysis, as well as other sections in this document and the preamble of the rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. **References**

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