

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Docket No. FDA-2022-P-1668

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

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Executive Summary

This proposed rule would, if finalized, amend 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° Brix. 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 proposed rule, if finalized, would not impose any compliance costs to firms; however, it might result in costs associated with product reformulation, relabeling, and recordkeeping, which we do not quantify in this analysis. We estimate cost savings to manufacturers due to substitution to cheaper inputs. The annualized costs would range from -\$14.7 million to -\$106.7 million, with a primary estimate of -\$52.3 million, at a 7 percent discount rate, and from -\$14.8 million to -\$107.0 million, with a primary estimate of -\$52.5 million, at a 3 percent discount rate.

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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 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all 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 proposed rule is a significant regulatory action under Executive Order 12866. This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we tentatively conclude that this proposed rule, if finalized, would not generate compliance costs to industry, 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

\$187 million, using the most current (2024) 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 proposed rule, if finalized, would not require firms in the POJ industry to change their manufacturing practices or behavior in any way. As a result, we tentatively conclude that there would be no compliance costs associated with the proposed rule. The proposed rule would allow additional flexibility for, and the opportunity for innovation regarding, POJ, providing benefits to industry without harming consumers. Manufacturers may experience cost savings if they are able to avoid blending single strength orange juice with higher Brix or orange juice concentrate, or if they are able to substitute cheaper inputs into the manufacturing process, such as using cheaper local lower-Brix oranges that previously would not have been used to meet the SOI. We note specifically that the proposed rule does not require any behavioral changes on the part of manufacturers, as it provides manufacturers with greater flexibility rather than imposing any restrictions. The proposed changes would provide for a wider range of products to be marketed as POJ. No changes would be required for products that already meet the existing POJ standard. Therefore, any changes made by manufacturers of POJ would be voluntary.

Our primary estimate of cost savings experienced by manufacturers is -\$52.3 million, annualized at 7% over 10 years; this primary estimate is -\$52.5 million, annualized at 3% over 10 years. Therefore, we tentatively conclude that the proposed rule to amend the SOI for POJ, if finalized, is a deregulatory action under Executive Order 14192. Table 1 provides a summary of the benefits and costs associated with the proposed rule. We request comment on our described benefits and costs of the proposed rule.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed 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%	10 years	
		\$0	\$0	\$0	2024	3%	10 years	
	Annualized Quantified					7%		
						3%		
Qualitative						10 years	Benefits include additional flexibility for firms in production and innovation	
Costs	Annualized Monetized \$millions/year	-\$52.3	-\$14.7	-\$106.7	2024	7%	10 years	
		-\$52.5	-\$14.8	-\$107.0	2024	3%	10 years	
	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 percent discount rate)

	Primary Estimate
Present Value of Costs	\$0
Present Value of Cost Savings	-\$732.0
Present Value of Net Costs	-\$732.0
Annualized Costs	\$0
Annualized Cost Savings	-\$51.2
Annualized Net Costs	-\$51.2

II. Preliminary 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 10901-10902).

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° 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 continued to fall 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.

B. Potential 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 acceptable Brix level 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 limit the availability of oranges with Brix levels that can be used in the manufacture of POJ to meet the current minimum of 10.5°, manufacturers may be able to produce additional volume of POJ using oranges that meet the proposed minimum Brix level of 10°.

C. Purpose of the Proposed Rule

The proposed rule, if finalized, would lower the minimum Brix level for POJ from 10.5° to 10°. Lowering the minimum Brix level in the SOI 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. 1) to 103.0 million boxes in 2020-2021 (Ref. 2) and further declined to 64.6 million boxes in 2023-2024 (Ref. 3). 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. 4), 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 June 2025, futures prices have fallen to a level approximately 100% higher than the January 2022 level (Ref. 5). 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 69% from January 2022 to April 2025 (Ref. 6). 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. 4).

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. 7) 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. We request comment on the assumption of the annual growth rate of revenue of the US orange juice market. Table 3 presents the simulated baseline size of the market based on this assumption, including the low (5th percentile) and high (95th percentile) outcomes.

Table 3: Estimated Size of United States 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 United States orange juice market; this method incorporates uncertainty about the annual growth rate of the industry. We request comment on the fraction of orange juice producers’ revenues made up of costs or orange juice producers’ profit margins. Table 4 presents the simulated annual baseline costs of United States orange juice production based on these assumptions, including low (5th percentile) and high (95th percentile) outcomes.

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

Year	Low Estimate	Primary Estimate	High Estimate
2026	\$7,437	\$8,379	\$9,321
2027	\$7,509	\$8,463	\$9,414
2028	\$7,582	\$8,547	\$9,515
2029	\$7,659	\$8,633	\$9,613
2030	\$7,728	\$8,719	\$9,716
2031	\$7,805	\$8,806	\$9,825
2032	\$7,879	\$8,894	\$9,918
2033	\$7,955	\$8,983	\$10,023
2034	\$8,031	\$9,073	\$10,126
2035	\$8,100	\$9,164	\$10,235
Annualized, 3%	\$7,750	\$8,745	\$9,746
Annualized, 7%	\$7,727	\$8,718	\$9,714

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 United States orange juice market; this method incorporates uncertainty about oranges’ fraction of input costs. We request comment on the fraction of orange juice producers’ input costs made up of oranges. 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	\$1,734	\$2,539	\$3,413
2028	\$1,754	\$2,564	\$3,435
2029	\$1,771	\$2,590	\$3,479
2030	\$1,799	\$2,616	\$3,514
2031	\$1,811	\$2,642	\$3,554
2032	\$1,827	\$2,668	\$3,587
2033	\$1,838	\$2,695	\$3,622
2034	\$1,874	\$2,722	\$3,663
2035	\$1,877	\$2,749	\$3,714
Annualized, 3%	\$1,796	\$2,624	\$3,527
Annualized, 7%	\$1,790	\$2,615	\$3,516

E. Benefits of the Proposed Rule

Benefits of the proposed rule, if finalized, 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. However, a survey submitted by the Florida Citrus Packers Association and Florida Citrus Mutual (Docket No. FDA-2023-N-2632) found that 95 percent of respondents agreed that orange juice with less sugar should still be called orange juice. An additional taste test submitted as an appendix to the citizen petition (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. 8). We do not anticipate that the reduced minimum-Brix product will fail to meet consumer expectations of POJ; we request comment on whether consumer expectations will be met.

F. Costs of the Proposed Rule

The proposed rule, if finalized, would lower the minimum Brix value 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 standard (Docket No. FDA-2022-P-1668). The proposed rule may allow some manufacturers to substitute lower-cost domestic oranges for higher-cost imported oranges while still meeting the minimum Brix standard.

We are uncertain how much cheaper orange juice production would become if manufacturers were able to substitute to 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. 9); the futures price of orange juice fluctuated from \$2.98 to \$4.11 during that period and sits at \$3.27 as of July 22, 2025 (Ref. 10). 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 are imported and what fraction are 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 proposed 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 proposed rule, the cost savings generated by input substitution allowed by the proposed rule would be 1%. We request comment on the fraction of imported oranges used in domestic POJ production and the fraction of imported oranges used in domestic POJ production that could be replaced by domestic oranges due to the proposed rule.

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. We request comment on the percentage reduction in the input costs of oranges that manufacturers may experience as a result of the proposed rule. 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	\$30.4	\$100.5	\$188.6
2027	\$31.6	\$101.6	\$192.0
2028	\$31.5	\$102.6	\$192.3
2029	\$32.2	\$103.6	\$193.1
2030	\$32.1	\$104.6	\$196.4
2031	\$32.4	\$105.7	\$199.6
2032	\$33.2	\$106.7	\$199.5
2033	\$33.3	\$107.8	\$202.2
2034	\$33.2	\$108.9	\$206.3
2035	\$34.0	\$110.0	\$206.9
Annualized, 3%	\$32.3	\$104.9	\$197.2
Annualized, 7%	\$32.2	\$104.6	\$196.6

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 proposed 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. We request comment on the fraction of the orange juice market that would experience input cost reductions as a result of the proposed rule. Table 7 presents the simulated annual cost savings of the proposed rule, incorporating the uncertainty about the fraction of the market affected. The table includes low (5th percentile) and high (95th percentile) outcomes. Based on these assumptions, our primary estimate of the cost savings of the proposed rule is \$52.5 million, annualized at 3% over 10 years; annualized at 7% over 10 years, this primary estimate is \$52.3 million.

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	\$14.2	\$50.3	\$102.8
2027	\$14.5	\$50.8	\$104.4
2028	\$14.3	\$51.3	\$104.5
2029	\$14.7	\$51.8	\$104.8
2030	\$14.5	\$52.3	\$106.5
2031	\$14.9	\$52.8	\$107.2
2032	\$15.0	\$53.4	\$109.3
2033	\$15.1	\$53.9	\$109.8
2034	\$15.3	\$54.4	\$111.6
2035	\$15.5	\$55.0	\$111.6
Annualized, 3%	\$14.8	\$52.5	\$107.0
Annualized, 7%	\$14.7	\$52.3	\$106.7

The proposed rule, if finalized, would 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 proposed rule. Similarly, because the minimum Brix level is not specified on product labels, manufacturers would not need to update their labeling due to the proposed rule. As such, we do not anticipate relabeling costs due to the proposed rule.

Reducing the minimum required Brix level to 10° will likely cause some manufacturers to produce 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. We request comment on potential reformulation costs of the rule, as well as the percentage of firms that may incur them.

If firms would 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 as a result of the proposed rule.

G. Transfers Caused by the Proposed 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 proposed rule.

H. Summary of Benefits, Costs, and Transfers

Table 8 presents the estimated cost savings of the proposed 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 proposed rule is \$52.5 million,

annualized at 3% over 10 years; annualized at 7% over 10 years, this primary estimate is \$52.3 million.

Table 8: Estimated Cost Savings By Year (millions 2025\$)

Year	Low Estimate	Primary Estimate	High Estimate
2026	\$14.2	\$50.3	\$102.8
2027	\$14.5	\$50.8	\$104.4
2028	\$14.3	\$51.3	\$104.5
2029	\$14.7	\$51.8	\$104.8
2030	\$14.5	\$52.3	\$106.5
2031	\$14.9	\$52.8	\$107.2
2032	\$15.0	\$53.4	\$109.3
2033	\$15.1	\$53.9	\$109.8
2034	\$15.3	\$54.4	\$111.6
2035	\$15.5	\$55.0	\$111.6
Annualized, 3%	\$14.8	\$52.5	\$107.0
Annualized, 7%	\$14.7	\$52.3	\$106.7

The proposed 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 proposed rule, if finalized, 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 Proposed Rule

We consider the following regulatory alternatives for the POJ SOI:

1. Revoke the minimum Brix level requirement in the SOI
2. Revoke the SOI for POJ
3. Provide temporary marketing permits for lower-Brix POJ products

Option 1: Revoke the minimum Brix level 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 proposed rule if they are able to avoid blending single strength orange juice with higher Brix 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 proposed 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 level results in products that are not consistent with consumer expectations of POJ. If removing the minimum Brix level requirement from the SOI results in POJ with noticeably different taste or other attributes, consumers may be worse off than before. FDA is seeking more information about this alternative in the proposed rule (see section *VI. Questions About POJ SOI* in the NPRM).

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 proposed rule or the first regulatory alternative if they are able to substitute even cheaper inputs or a greater fraction of cheaper inputs than in the other two scenarios. Manufacturers may also experience additional cost savings if they are no longer required to comply with other provisions of the SOI.

As in the case of removing only the Brix level 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°. This regulatory alternative 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 proposed rule scenario or first regulatory alternative if products become even less consistent with

consumer expectations about POJ. FDA is seeking more information about this alternative in the proposed rule (see section *VI. Questions About POJ SOI* in the NPRM).

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

A third potential regulatory alternative would be to allow temporary marketing permits for lower-Brix products. FDA can issue temporary marketing permits (TMP) that enable food manufacturers to market test the advantages to and consumer acceptance of a food that deviates from applicable definitions and standards 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. In this case, if there were a TMP for products with a lower Brix level, 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, if lowered Brix levels in domestic oranges do not increase, this may be a temporary solution to a permanent problem.

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 TMP products from the standardized product 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.

J. Distributional Effects

We do not anticipate any distributional effects as a result of the proposed 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. 4), 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 proposed 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.

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 5th-percentile and 95th-percentile outcomes for each estimate. We acknowledge uncertainty about the annual growth rate of the United States 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 proposed rule, and the fraction of the market that may experience cost savings due to input substitution. We request comment on each of these parameters.

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.

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 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.

Because this rule does not generate compliance costs, we propose to certify that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. We do not believe firms will incur reformulation costs due to the proposed rule; as such, we do not believe small entities will incur costs. We note also that firms are not required to change their behavior due to the rule, and any behavior change would be voluntary. Small entities may experience cost savings if they are able to produce POJ more cheaply at the lower minimum Brix level allowed by the proposed rule. 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.

The proposed rule, if finalized, would provide flexibility to small firms. Small firms may experience cost savings if they are able to substitute cheaper inputs for more expensive inputs in the production process.

IV. References

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