



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 146

[Docket No. FDA-2022-P-1668]

RIN 0910-AI98

Food Standards of Identity Modernization; Pasteurized Orange Juice

AGENCY: Food and Drug Administration, Health and Human Services.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend the standard of identity for pasteurized orange juice (POJ) by lowering the minimum orange juice soluble solids content from 10.5° to 10° Brix. We tentatively conclude that this proposed amendment will promote honesty and fair dealing in the interest of consumers and provide industry greater flexibility in the manufacture of pasteurized orange juice. This action, if finalized, will respond to a citizen petition submitted by the Florida Citrus Processors Association Inc. and Florida Citrus Mutual Inc.

DATES: Either electronic or written comments on the proposed rule must be submitted by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-P-1668 for "Food Standards of Identity Modernization; Pasteurized Orange Juice; Proposed Rule."

Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the "Providing Accountability Through Transparency Act," or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Vivien Yan Peng, Office of Nutrition and Food Labeling, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Keronica C. Richardson, Office of Policy, Regulations, and Information, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to revise the standard of identity (SOI) for POJ established at 21 CFR 146.140 (§ 146.140). The SOI currently requires that finished POJ contain not less than 10.5 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients (§ 146.140(a)). The percentage soluble solids by weight of an aqueous solution (e.g., grams of sucrose in 100 grams of solution at 68 degrees F) can be expressed as Brix or degree of Brix (° Brix). The current SOI for POJ therefore requires a minimum orange juice soluble solids of 10.5° Brix. The proposed rule, if finalized, will amend the POJ standard by lowering the minimum orange juice soluble solids from 10.5° to 10° Brix for finished POJ. We tentatively conclude that this proposed amendment will promote honesty and fair dealing in the interest of consumers and provide greater flexibility in the manufacture of POJ (see section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341)).

B. Legal Authority

We are issuing this proposed rule consistent with our authority in sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341, 371).

C. Costs and Benefits

The proposed rule, if finalized, would not require firms in the POJ industry to change their manufacturing processes or behavior in any way. Qualitative benefits include flexibility for manufacturers, flexibility of product choice for consumers, and potential sustainability for manufacturers in the face of disease or climate impacts. 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. The proposed rule, if finalized, would not

impose any compliance costs to firms. 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.

II. Background

A. Citizen Petition and FDA's Request for Information

The Florida Citrus Processors Association Inc. and Florida Citrus Mutual Inc. (“petitioners”) jointly submitted a citizen petition (Docket No. FDA-2022-P-1668) on July 22, 2022, asking us to amend the SOI for POJ to reduce the minimum orange juice soluble solids content for POJ from 10.5° to 10° Brix, exclusive of the solids from any added optional sweetening ingredients. See Citizen Petition from the Florida Citrus Processors Association Inc. and Florida Citrus Mutual Inc., entitled “Request to Amend Pasteurized Orange Juice Standard of Identity,” sent to the Division of Dockets Management (now the Dockets Management Staff), Food and Drug Administration, dated July 22, 2022 (“Petition”).

The petitioners stated that when FDA issued the SOI for POJ in 1963 (see “Orange Juice and Orange Juice Products; Definitions and Standards of Identity; Findings of Fact and Final Order,” 28 FR 10900, October 11, 1963), FDA recognized that Florida was the dominant supplier of juice oranges with an average Brix level of 11.8°. The petitioners asserted that, based on the fruits used in preparing POJ at that time, FDA set a minimum Brix level of 10.5° for the POJ standard (Petition at page 3). However, the petitioners stated that 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 (Petition at pages 3-4). According to information on the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service’s (APHIS) website, symptoms of trees infected with citrus greening include blotchy mottled leaves, stunted growth, reduced fruit production, reduced fruit size, bitter fruit, and

premature fruit drop. See USDA APHIS, “Citrus Greening and Asian Citrus Psyllid,” at <https://www.aphis.usda.gov/plant-pests-diseases/citrus-diseases/citrus-greening-and-asian-citrus-psyllid>. Currently, there is no cure or mitigating treatment for citrus greening disease and most trees die within a few years of being infected (*id.*). The U.S. production forecast for oranges is down to the lowest level in 88 years due to diseases like citrus greening and unfavorable weather (see USDA Foreign Agricultural service Global Market Analysis, “Citrus: World Markets and Trade,” at <https://www.fas.usda.gov/data/citrus-world-markets-and-trade-01302025>). The petitioners also stated that severe weather, particularly Hurricane Irma in 2017, has resulted in the reduced production of oranges and lower average fruit sugar content (Petition at pages 3-4). The soluble solids in orange juice consist mainly of sugars. The petitioners explained that, due to these factors, seasonal average Brix levels (weighted by volume) are hovering below the minimum of 10.5° Brix (Petition at page 4). The petitioners stated that the SOI for POJ was carefully constructed to reflect the qualities of U.S. oranges at the time the SOI was established, however they asserted that the SOI should now be updated to align with the modern U.S. crop (Petition at page 5). Hence, while still under review, the current USDA standard for Grades of POJ is based on the current POJ SOI (Ref. 1).

The POJ SOI allows for the addition of optional concentrated orange juice ingredients to increase the POJ solids to meet the minimum 10.5° Brix (§ 146.140(a)) with the label declaration of “prepared in part from concentrated orange juice,” “with added concentrated orange juice,” or “concentrated orange juice added” (§ 146.140(e)(1)). This label declaration enables consumers to identify POJ made from only expressed orange juice and POJ that has been made with concentrated orange juice ingredients. The petitioners asserted that “not from concentrate” orange juice is the most popular form of orange juice, indicating that consumers have a preference for POJ that is made from expressed juice rather than from concentrated juice (Petition at page 5). The petitioners explained that almost the entire Florida orange crop is used for the production of “not from concentrate” POJ (Petition at pages 4-5), thereby emphasizing

the importance of Florida oranges in meeting consumer demand for “not from concentrate” POJ. Florida plays a vital role in the orange juice industry, although other states like California, Arizona, and Texas also contribute to the overall citrus production in the United States. Some states, such as California, primarily produce orange crops for the fresh market. However, in Florida, almost the entire orange crop is used to make POJ that is “not from concentrate” (Petition at page 4). The petitioners further explained that while “not from concentrate” orange juice may have a lower Brix value, the reduction in sugar content would be minimal and would unlikely impact consumer acceptance with respect to characteristics like taste and flavor (Petition at pages 5-6). The petitioners stated that most fruit juices, albeit many of which have a relatively lower volume of sales, have no SOI and that “this regulatory discrepancy further emphasizes the need to amend the SOI for POJ to keep pace with modern scientific understanding and naturally occurring dynamics impacting product production (Petition at page 7)”. The petitioners also stated that the 10° minimum Brix level they requested for POJ is consistent with the minimum Brix level of 10° in the SOI for canned orange juice (*See* 21 CFR 146.141) (Petition at page 6).

In the *Federal Register* of August 16, 2023, we published a request for information (RFI) (Docket No. FDA-2023-N-2632) seeking comments on several topics, including if amending the POJ SOI could result in products that are inconsistent with consumer expectations and if consumers would accept changes in the nutritional value of POJ with a lower minimum soluble solids content (88 FR 55607, August 16, 2023). We requested this information to determine whether the SOI for POJ should be amended. Many comments supported lowering the Brix level. The comments stated that the Brix level is an intrinsic variable for oranges based on year, origin, and crops. The comments also asserted that most consumers would not notice the difference in taste and flavor of POJ with Brix levels between 10° and 10.5° and that any nutritional differences are minimal. A few comments opposed the petition, stating that there was no benefit to consumers if FDA lowered the Brix level. However, these comments did not indicate or provide evidence suggesting that consumers would be disadvantaged by lowering the

Brix level.

The petitioners provided supplemental materials to their petition with new information on the decreasing average Brix level from the 2022-2023 orange season) and findings from a recent study demonstrating consumers' acceptance of POJ with a lower Brix level of 10°. See Citizen Petition Supplemental Materials from the Florida Citrus Processors Association Inc. and Florida Citrus Mutual Inc., entitled "Citizen Petition Supplemental Materials," sent to the Division of Dockets Management (now the Dockets Management Staff), Food and Drug Administration, dated May 23, 2024 ("Supplemental Materials"). The petitioners also noted that the average Brix level continued to fall in 2022-2023 with an average Brix level of 9.7° due to tree stress caused by weather and disease pressures (Supplemental Materials at Appendix 2). The petitioners urged FDA to take swift action to amend the SOI for POJ by lowering the minimum Brix level from 10.5° to 10° (Supplemental Materials at page 1).

We received another citizen petition, jointly submitted from Florida Department of Citrus, Florida Citrus Processors Association, Florida Citrus Mutual and the Juice Products Association, regarding SOIs for orange juice and orange juice products (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 POJ SOI. The POJ standard in § 146.140(a) currently provides for a maximum allowable percentage of *Citrus reticulata* (i.e., mandarin or tangerine oranges) or *Citrus reticulata* hybrids juice of not more than 10 percent by volume. The request seeks to increase the maximum allowable percentage from 10 percent to 15 percent. 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." The petition cited a 2021 study conducted by University of Florida Institute of Food and Agricultural Sciences Citrus Research and Education Center that found orange juice and Sugar Belle® blends at 50-50% levels performed better in sensory evaluation than pure orange juice. The study further noted that "consumer acceptance of the OJ

label revealed that adding up to 30% tangerine juice to OJ might still be considered OJ by most consumers, providing an initial guide for citrus legislation to loosen the regulation on the content of tangerine juice blended with OJ." While the proposed rule does not propose increasing the maximum allowable percentage of *Citrus reticulata* or *Citrus reticulata* hybrids juice because we do not know the potential impacts of such a change on POJ, in section VI. of this proposed rule, we invite comments about increasing the maximum allowable percentage of *Citrus reticulata* or *Citrus reticulata* hybrids in § 146.140(a).

B. History of the Rulemaking

FDA published a final order establishing SOIs for orange juice and orange juice products, including POJ, in 1963 (28 FR 10900, October 11, 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. Specifically, Florida was the dominant supplier of orange juice at the time, so we looked to the characteristics of Florida oranges (See 28 FR 10900 at 10905). 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 or orange juice concentrate, the latter being limited to one-fourth of the total orange juice solids (28 FR 10900 at 10902). The standard of identity permitted frozen concentrated orange juice (as specified in § 146.146) and concentrated orange juice for manufacturing (as specified in § 146.153) when made from mature oranges as optional concentrated orange juice ingredients (28 FR 10900 at 10906).

C. Need for the Regulation

Section 401 of the FD&C Act permits us to establish a reasonable definition and

standard of identity when such action will promote honesty and fair dealing in the interest of consumers. The Brix level of expressed juice, in contrast to concentrated juice, is subject to the vagaries of nature and therefore has a naturally occurring range beyond the manufacturer's control (see 58 FR 2897 at 2906). As such, a reasonable definition and standard of identity for POJ should take this circumstance into consideration. We recognize that citrus greening disease has caused damage to Florida's orange crop and to much of the orange crop of the United States. See USDA APHIS, "Citrus Greening and Asian Citrus Psyllid," at <https://www.aphis.usda.gov/plant-pests-diseases/citrus-diseases/citrus-greening-and-asian-citrus-psyllid>. We also acknowledge that until a treatment is found to prevent or cure citrus greening disease, it is unlikely that the orange crop will recover and that the Brix level of juice from oranges will return to levels previously seen. The data submitted by the petitioners demonstrates that the Brix value of Florida oranges has been decreasing since 2010-2011, and a minimum Brix of 10.0° for POJ appears to be a reasonable level based on information submitted by the petitioners showing the historical seasonal Brix levels decreasing by year (Supplemental Materials at Appendix 2).

We have also considered whether amending the SOI for POJ would promote honesty and fair dealing in the interest of consumers. Although the SOI for POJ permits the addition of concentrated orange juice to raise the Brix level, some modern-day consumers may prefer POJ that is made from only expressed juice rather than from added concentrated juice. The petitioners assert that "not from concentrate" orange juice has become the most popular orange juice form. Since the SOI for POJ was established, consumers have come to prefer 100% juice, and labeling requirements have been established to inform consumers whether juice products are from concentrate (see 21 CFR 101.30(b)(3), (i), and 102.33(g)). Lowering the minimum Brix to 10.0° may prevent the addition of concentrated orange juice ingredients because they would not be needed to meet this minimum.

We further note that, as asserted by the petitioners and in comments submitted to the

RFI we reviewed, lowering the minimum Brix from 10.5° to 10.0° is unlikely to affect the taste of POJ. Nutrition labels for POJ provided by the petitioners show that a serving (8oz) of orange juice with a Brix of 10.5° has 18 grams of sugar, whereas a serving of orange juice with a Brix of 10.0° has 17 grams of sugar. Thus, lowering the minimum Brix of POJ, as proposed in this rule, would result in one gram difference in sugar content per serving. Moreover, data submitted by the petitioners indicates that a change in Brix from 10.5° to 10.0° has a minimal impact on the nutrient levels in orange juice.

Based on this information, we tentatively conclude that amending the SOI for POJ to permit a minimum Brix of 10.0° is reasonable and will promote honesty and fair dealing in the interest of consumers. Because the Brix value is a minimum value, orange juice processors may produce POJ with higher Brix. The proposed rule would lower the minimum Brix, thereby permitting more flexibility in the range of orange juice that can be used in the manufacture of POJ.

Pending issuance of a final rule amending the SOI for POJ or a response to the 2022 citizen petition in accordance with 21 CFR 10.30(e)(2), FDA intends to consider the exercise of enforcement discretion when POJ is manufactured with a Brix from 10.0° to 10.5° and is otherwise in compliance with § 146.140.

III. Legal Authority

We are issuing this proposed rule consistent with our authority in sections 401 and 701 of the FD&C Act (21 U.S.C. 341, 371). Section 401 of the FD&C Act permits us to promulgate regulations establishing for foods a reasonable definition and standard of identity to promote honesty and fair dealing in the interest of consumers.

IV. Description of the Proposed Rule

A. Scope/Applicability

The proposed rule, if finalized, would amend the SOI for POJ in § 146.140. Our

regulation, at § 146.140(a), requires a minimum orange juice soluble solids content of 10.5° Brix for POJ. The proposed rule would lower the minimum orange juice soluble solids content from 10.5° to 10° Brix.

B. Amending the Standard of Identity Regulation to reduce the minimum Brix level

The proposed rule, if finalized, would amend § 146.140(a) to allow the manufacture of POJ with a lower soluble solids content, which in turn impacts sugar content. The sugar content is reduced by 1 gram per serving (8 oz) when the Brix level of POJ decreases from 10.5° to 10°. This change is expected to have insignificant impact on taste and flavor and may facilitate the manufacture of POJ without added concentrated orange juice ingredients. The proposed rule reflects FDA's efforts to update and modernize food standards by aligning the standard with current crop properties and providing greater production flexibility, while maintaining the basic nature and essential characteristics of standardized foods. We tentatively conclude that this action would promote honesty and fair dealing in the interest of consumers.

This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action.

V. Proposed Effective and/or Compliance Date(s)

We propose that any final rule that may result from this rulemaking become effective 30 days after its publication in the *Federal Register*. The final rule would apply to POJ products produced or delivered for introduction into interstate commerce on or after the effective date. We propose that the compliance date for any final rule that may result from this rulemaking be 30 days after its publication in the *Federal Register*.

VI. Questions About POJ SOI

The petitioners requested that we amend the SOI for POJ to lower the minimum Brix level to 10° (Petition at page 2). The proposed standard was published when Florida oranges,

the dominant supplier, had an average Brix level of 11.8° and FDA published the SOI with a minimum Brix level of 10.5° (28 FR 10905). Currently, we understand that Brix level has been declining over the past few decades, making it challenging for manufacturers to meet the current minimum Brix level of 10.5° (Petition at pages 3-4).

Thus, in addition, we invite comment on whether the minimum Brix level requirement should be further reduced or removed entirely from the SOI for POJ due to the steadily declining Brix levels. Would removal of a minimum Brix requirement better promote honesty and fair dealing in the interest of consumers while supporting innovation? Specifically, would it result in products that continue to meet consumers expectations about POJ? Please explain your answers and provide references and data that support your explanation, if possible.

We also invite comment on whether the SOI for POJ should be revoked so that manufacturers have more flexibility in POJ production. This would result in POJ being a nonstandardized food, similar to other juices such as apple, grape, and cranberry juices. Is the SOI for POJ no longer necessary to promote honesty and fair dealing in the interest of consumers such that it should be revoked? Please explain your answers and provide references and data that supports your explanation, if possible.

As mentioned in section II.A, we received a citizen petition requesting that we increase the maximum allowable amount of unfermented juice that can be obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids from 10 percent by volume to 15 percent by volume of the unfermented juice (see § 146.140(a)). We understand from industry that *Citrus reticulata* is sweeter than *Citrus sinensis* and thus has a higher Brix value. Increasing the maximum allowable amount of juice from *Citrus reticulata* to 15 percent by volume could help increase the overall Brix value of POJ. We invite comment on the acceptability of increasing the maximum allowable amount of unfermented juice from *Citrus reticulata* or *Citrus reticulata* hybrids from 10% to 15% by volume in § 146.140(a). If such change were made, would the essential characteristics of POJ be preserved? Please

explain and provide any data or factual information.

VII. Preliminary Economic Analysis of Impacts

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.

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

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. 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	\$0	\$0	\$0	2024	7%	10 years	
	Monetized \$millions/year	\$0	\$0	\$0	2024	3%	10 years	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	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 2 we estimate present and annualized values of costs, cost savings, and net costs over an infinite time horizon.

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

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	\$0	\$0	\$0
Present Value of Cost Savings	-\$320.9	-\$90.3	-\$654.0
Present Value of Net Costs	-\$320.9	-\$90.3	-\$654.0
Annualized Costs	\$0	\$0	\$0
Annualized Cost Savings	-\$22.5	-\$6.3	-\$45.8
Annualized Net Costs	-\$22.5	-\$6.3	-\$45.8

We request comment on our described benefits and costs of the proposed rule. We have developed a full Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 2) and at <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains no new or revised collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain

policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov> and at the website address provided below. FDA has verified the website addresses as of the date this document publishes in the Federal Register, but websites are subject to change over time.

1. U.S. Department of Agriculture. “United States Standards for Grades of Orange Juice, January 10, 1983”.
https://www.ams.usda.gov/sites/default/files/media/Canned_Orange_Juice_Standard%5B1%5D.pdf
2. 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.
<https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>.

List of Subjects in 21 CFR Part 146

Food grades and standards, Fruit juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 146 be amended as follows:

PART 146 – CANNED FRUIT JUICES.

1. The authority citation for part 146 continues to read as follows:

Authority: 21 U.S.C. 341, 371.

2. In § 146.140, revise paragraph (a) by replacing “10.5 percent by weight” to read as
“10 percent by weight.”

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services

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