to such delinquent member advising such member that it is unlawful for the member under the provisions of such section of the Act to engage in business as a broker-dealer while in violation of such requirements of the Act and requesting an explanation in writing within ten days stating what he or she intends to do in order to cure such delinquency;

(2) To authorize formerly delinquent brokers or dealers, upon receipt of written confirmation from or on behalf of the Securities Investor Protection Corporation that the delinquencies referred to in paragraph (g)(1) of this section have been cured, and upon having been advised by the appropriate regional office of this Commission and the Division of Enforcement and Division of Trading and Markets that there is no objection to such member being authorized to resume business, and upon there appearing to be no unusual or novel circumstances which would warrant direct consideration of the matter by this Commission, to resume business as registered broker-dealers as provided in section 10(a) of this Act.

(h) With respect to the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*):

(1) Under section 15F(b) of the Act (15 U.S.C. 78o–10(b)):

(i) To authorize the issuance of orders granting on-going registration to security-based swap dealers and major security-based swap participants based on the security-based swap dealer's or major security-based swap participant's application, pursuant to § 240.15Fb2–1(e) of this chapter (Rule 15Fb2–1(e));

(ii) To authorize the issuance of orders canceling the registration of security-based swap dealers and major security-based swap participants registered pursuant to § 240.15Fb2–1 of this chapter (Rule 15Fb2–1) if such persons are no longer in existence or have ceased to do business as security-based swap dealers or major security-based swap participants, pursuant to § 240.15Fb3–3(a) of this chapter (Rule 15Fb3–3(a)); and

(iii) To determine by order, pursuant to § 240.15Fb3–2(b) of this chapter (Rule 15Fb3–2(b)), whether notices of withdrawal of registration filed by security-based swap dealers or major security-based swap participants pursuant to section 15F(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78o–10(b)) shall become effective sooner than the normal 60 day waiting period provided in Rule 15Fb3–2(b) (§ 240.15Fb3–2(b) of this chapter).

PART 201—RULES OF PRACTICE

■ 7. The authority citation for part 201 continues to read in part as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 78x, 80a–37, and 80b–11; 5 U.S.C. 504(c)(1).

* * * * *

■ 8. Section 201.430 is amended by revising paragraphs (a) and (c) to read as follows:

§ 201.430 Appeal of actions made pursuant to delegated authority.

(a) *Scope of rule.* Any person aggrieved by an action made by authority delegated in §§ 200.30–1 through 200.30–8 or §§ 200.30–11 through 200.30–19 of this chapter may seek review of the action pursuant to paragraph (b) of this section.

* * * * *

(c) *Prerequisite to judicial review.* Pursuant to Section 704 of the Administrative Procedure Act, 5 U.S.C. 704, a petition to the Commission for review of an action made by authority delegated in §§ 200.30–1 through 200.30–19 of this chapter is a prerequisite to the seeking of judicial review of a final order entered pursuant to such an action. Pursuant to 15 U.S.C. 7214(h)(2), any decision by the Commission pursuant to 200.30–11 shall not be reviewable under 15 U.S.C. 78y and shall not be deemed 'final agency action' for purposes of 5 U.S.C. 704.

■ 9. Section 201.431 is amended by revising paragraph (a) to read as follows:

§ 201.431 Commission consideration of actions made pursuant to delegated authority.

(a) *Scope of review.* The Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, any action made pursuant to authority delegated in §§ 200.30–1 through 200.30–19 of this chapter.

* * * * *

PART 203—RULES RELATED TO INVESTIGATIONS

■ 10. The authority citation for part 203 continues to read as follows:

Authority: 15 U.S.C. 77s, 77sss, 78w, 80a–37, and 80b–11, unless otherwise noted.

■ 11. Section 203.2 is revised to read as follows:

§ 203.2 Information obtained in investigations and examinations.

Information or documents obtained by the Commission in the course of any investigation or examination, unless made a matter of public record, shall be deemed non-public, but the Commission approves the practice whereby officials of the Divisions of Enforcement, Examinations, Corporation Finance, Trading and Markets, Investment Management, and the Office of International Affairs at the level of Assistant Director or higher, may engage in and may authorize members of the Commission's staff to engage in discussions with persons identified in § 240.24c–1(b) of this chapter concerning information obtained in individual investigations or examinations, including formal investigations conducted pursuant to Commission order.

By the Commission.

Dated: July 15, 2026.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2026–14540 Filed 7–17–26; 8:45 am]

BILLING CODE 8011–01–P

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to amend the standard of identity for pasteurized orange juice by lowering the minimum orange juice soluble solids content from 10.5° to 10° Brix and permitting up to 15 percent *Citrus reticulata* juice or *Citrus reticulata* hybrid juice, by volume. This final rule modernizes the pasteurized orange juice standard. This action responds to two citizen petitions: one submitted by the Florida Citrus Processors Association Inc. and the Florida Citrus Mutual Inc., and another submitted by the Florida Department of Citrus, the Florida Citrus Mutual, and the Juice Products Association.

DATES: This rule is effective August 19, 2026. This compliance date is August 19, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the

docket number found in brackets in the heading of this final rule 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, Human Food Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Keronica C. Richardson, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

We are lowering the minimum Brix requirement and increasing the maximum allowable percentage of *Citrus reticulata* juice or *Citrus reticulata* hybrid juice by volume for pasteurized orange juice (POJ). The purpose of this final rule is to reflect current agricultural conditions and to ensure that the standard of identity (SOI) for POJ promotes honesty and fair dealing in the interest of consumers.

B. Summary of the Major Provisions of the Final Rule

The final rule revises the minimum soluble solids content from 10.5° to 10° Brix and the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume for POJ in 21 CFR 146.140(a).

C. Legal Authority

We are finalizing this 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).

D. Costs and Benefits

Our primary estimates of annualized costs are approximately −$28.8 million at a 3 percent discount rate and approximately −$28.4 million at a 7 percent discount rate over 10 years. Non-quantified benefits include flexibility for manufacturers, flexibility of product choice for consumers, and potential sustainability for manufacturers in the face of disease or environmental impacts.

II. Background

A. Need for the Regulation/History of the Rulemaking

Under section 401 of the FD&C Act, FDA establishes SOIs to promote honesty and fair dealing in the interest of consumers. The SOI for POJ, first established in 1963, specifies compositional requirements for POJ, including a minimum soluble solids content of not less than 10.5° Brix and a maximum of 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (see ''Orange Juice and Orange Juice Products; Definitions and Standards of Identity; Findings of Fact and Final Order,'' 28 FR 10900, October 11, 1963). The percentage soluble solids by weight of an aqueous solution (*e.g.,* grams of sucrose in 100 grams of solution at 68 degrees Fahrenheit) can be expressed as Brix or degree of Brix (° Brix).

The Florida Citrus Processors Association Inc. and the 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 soluble solids content for POJ from 10.5° to 10° Brix, exclusive of the soluble solids from any added optional sweetening ingredients (see Citizen Petition from the Florida Citrus Processors Association Inc. and the Florida Citrus Mutual Inc., titled ''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)). Brix measures the sugar content in orange juice, and citrus greening disease is a bacterial infection that weakens orange trees, causing fruit to develop with lower Brix levels. Weather conditions, such as hurricanes, can also reduce the sugar content of the fruit. The petitioners stated that current agricultural conditions, including the effects of citrus greening disease, and substantial severe weather in recent years have caused damage to Florida's orange crop, have reduced the average soluble solids content of oranges, and that the SOI limits manufacturing flexibility without providing a benefit to consumers (Petition at pages 3–4).

We received another citizen petition, jointly submitted by the Florida Department of Citrus, the Florida Citrus Processors Association, the 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. Most of the requests in that petition were outside the scope of this rulemaking. However, one request was relevant to the SOI for POJ. The petition requested that we consider increasing the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume in POJ.

After reviewing these petitions and available information submitted to the docket, FDA published a proposed rule to amend the SOI for POJ on August 6, 2025 (90 FR 37817). We tentatively concluded that lowering the minimum soluble solids content to 10° Brix would promote honesty and fair dealing in the interest of consumers and better reflect current agricultural conditions. In addition to the proposed amendments, we requested comment on whether the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids should be increased from 10 percent to 15 percent by volume and whether such an increase would affect the essential characteristics or consumer acceptance of POJ.

In the proposed rule, FDA stated its intent to exercise enforcement discretion for POJ manufactured with a Brix level between 10° and 10.5°. FDA is continuing to exercise enforcement discretion for POJ with a Brix level between 10° and 10.5° until the effective date of this final rule. We are also exercising enforcement discretion for POJ manufactured with10 percent to 15 percent by volume of the unfermented juice obtained from mature oranges of

the species *Citrus reticulata* or *Citrus reticulata* hybrids until the effective date of this final rule.

B. Summary of Comments to the Proposed Rule

The proposed rule provided a 90-day comment period. We received fewer than 50 comments. The comments came from industry members, consumer advocacy groups, academia, healthcare professionals, and other interested persons. Among other things, the comments discussed:

- *Lowering the minimum Brix.* Many comments supported lowering the minimum Brix requirement, stating that the current minimum soluble solids content requirement of 10.5° Brix in POJ standard is outdated due to modern environmental and agricultural conditions and that lowering the minimum Brix requirement from 10.5° to 10° would not compromise the quality or consumer expectations of POJ.
- *Increasing the Citrus reticulata limit.* Some comments supported increasing the maximum allowable percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent. Supporters stated that this change would reflect modern citrus varieties, meet consumer expectations, maintain consumer transparency, preserve quality and nutrition, retain POJ's essential characteristics, and offer manufacturing flexibility.
- *Concerns regarding the proposed rule.* Comments opposing the proposed rule argued that lowering the minimum Brix standard of POJ from 10.5° to 10° could reduce sweetness, quality, and nutritional value, potentially misleading consumers about what qualifies as ''orange juice.''

III. Legal Authority

We are issuing this final 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 SOI to promote honesty and fair dealing in the interest of consumers. Section 701 of the FD&C Act grants us the authority to promulgate regulations for the efficient enforcement of the FD&C Act.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received fewer than 50 comments on the proposed rule by the close of the comment period, and each comment discussed one or more issues. We received comments from industry members, trade associations, academia, healthcare professionals, and other interested persons. The majority of the comments supported decreasing the minimum Brix requirement to 10° Brix. Numerous comments from industry stakeholders and citrus growers' associations strongly supported lowering the minimum Brix requirement to 10°. These comments cited longstanding agricultural challenges, including citrus greening (*Huanglongbing* or HLB) and severe weather events, which have contributed to declining Brix levels in domestic oranges. The comments also generally supported increasing the maximum percentage of unfermented juice from *Citrus reticulata or* its hybrids from 10 percent to 15 percent in POJ.

We describe and respond to the comments in sections B through G of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision.

(Comment 1) Many comments expressed general support for the proposed rule to lower the required minimum Brix level and to increase the allowable maximum percentage of unfermented juice from *Citrus reticulata* or its hybrids. A few comments stated that this rule is overdue and would have a positive impact for manufacturers and consumers.

(Response 1) We are amending the SOI for POJ to lower the required minimum soluble solids content from 10.5° to 10° Brix and to increase the allowable maximum percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume. FDA finds that a minimum 10° Brix and maximum 15 percent by volume of unfermented juice from *Citrus reticulata* or its hybrids in the SOI for POJ are reasonable and promote honesty and fair dealing in the interest of consumers.

C. Comments on Lowering the Minimum Brix Level and FDA Response

(Comment 2) Although numerous comments supported lowering the minimum Brix requirement to 10°, some comments asserted there would be no health benefit to consumers if FDA lowered the Brix requirement.

(Response 2) As explained in the proposed rule, lowering the minimum Brix requirement for POJ to 10° is reasonable given the decrease in the Brix of oranges that has occurred from citrus greening disease and the impacts of severe weather events (90 FR 37817, 37820). We acknowledged that until a treatment is found to prevent or cure citrus greening disease, it is unlikely that orange production will recover or that the Brix level of orange juice will return to previously observed levels. We also explained that we do not anticipate a negative impact on consumers because lowering the Brix has minimal impact on sugar and nutrient content and therefore is unlikely to significantly affect taste and nutritional value. We discussed that a lower Brix requirement may prevent the addition of concentrated orange juice ingredients to POJ and therefore provide consumers with ''not from concentrate'' POJ, which consumers tend to prefer (see Petition at page 5). As such, we maintain our conclusion that lowering the Brix to 10° is reasonable and promotes honesty and fair dealing in the interest of consumers.

(Comment 3) A few comments opposed the proposed rule, asserting that it would allow orange juice manufacturers to take advantage of the American public by producing lower-quality POJ.

(Response 3) We disagree. Lowering the minimum Brix requirement does not compromise quality; rather, it increases the likelihood that quality POJ products will be available to consumers. Most of these comments did not identify or describe factors related to quality that would be impacted by this rulemaking. The few comments that identified factors discussed potential changes in nutrition, taste, and flavor. We address these factors in the subsequent response as they relate to consumer expectations and whether the essential characteristics of POJ will be affected as a result of this final rule.

Also, it is important to note that the change in Brix does not require manufacturers to alter their practices. Manufacturers may continue to manufacture and sell POJ with a Brix of 10.5° if they would like, and if consumers prefer, since the Brix

requirement is only a minimum requirement.

(Comment 4) Several comments addressed consumer expectations and raised concerns that lowering the minimum Brix level could alter product flavor, taste, or nutritional value. Some comments expressed concern that a lower Brix requirement could diminish sweetness. Other comments stated that most consumers cannot reliably distinguish between 10° and 10.5° Brix and that a small reduction in natural sugars (about 1 gram per 8 ounce serving) would be minimal from both taste and nutritional perspectives.

One comment stated that nutrient content, other than sugar, would be compromised if the minimum Brix for POJ is lowered from 10.5° to 10°. The comment asserted that orange growers use Brix to assess the health, mineral content, and nutrient density of plants. The comment further stated that scientists do not use the Brix values of crops as a direct measure of the crops' nutritional value, but that Brix values can correlate with some accepted components of nutritive value. The comment concluded that lowering the required minimum Brix level for POJ presents a significant risk of reducing nutritional value.

(Response 4) FDA carefully considered these views and concludes that differences in soluble solids between 10.5° and 10° Brix range are unlikely to have any perceptible or significant impact on the flavor, taste, or nutritional value of POJ. We base this conclusion on our review of available data, including information submitted to the docket. For example, data submitted to the docket demonstrated that consumers' sensory evaluations did not reveal meaningful differences in taste or flavor between POJ with a 10.5° and 10° (See Petition, Supplemental Appendix 3 at page 2). The change in sugar content between POJ with a Brix of 10.5° and POJ with a Brix of 10° is modest, changing from 18 grams per serving to 17 grams per serving, as acknowledged in the proposed rule. The comments did not counter this information.

Regarding the comment about nutrient content other than sugar, we agree that Brix can correlate with some nutrients in oranges and therefore in POJ. However, lowering the minimum Brix requirement from 10.5° to 10° has minimal impact on the nutrient levels in orange juice: potassium decreased from 455 to 419 milligrams per serving (2 percent decrease in daily value), folate decreased from 96 to 89 micrograms of dietary folate equivalents per serving (5 percent decrease in daily value), and vitamin C increased from 74 to 85 milligrams per serving (10 percent increase in daily value) (see Petition, Appendix 4 at page 19). The comment did not identify any specific nutrients that would be reduced in POJ with a Brix of 10.5° compared to POJ with a Brix of 10° or whether such a reduction would be significant. We disagree with the comment's conclusion that lowering the minimum Brix to 10° presents a significant risk to the nutritional value of POJ.

(Comment 5) A comment stated that lowering the Brix level to 10° would allow more juice from oranges from trees affected with HLB to be used in the manufacture of POJ such that the ratio of such juice in POJ would increase. The comment further argued that we should impose a limit on the amount of juice from oranges from trees affected with HLB that may be used in the manufacture of POJ. The comment stated that the limit should be set at 25 percent maximum when juice from oranges from trees affected with HLB is blended or consumers will receive ''bitter, off-flavor juice, which will noticeably impact their taste buds.'' In support of this assertion, the comment pointed to studies that showed that independent of total soluble solids content (*i.e.,* Brix), the flavor of POJ is affected and certain components related to flavor (*i.e.,* limonin and nomilin) are impacted when made with fruit from trees with HLB.

(Response 5) Juice from oranges from trees with HLB in POJ has varying Brix and total sugar levels due to multiple factors (*i.e.,* disease progression, supplemental tree nutrition) (Refs. 1–2). Because of this, POJ producers would consider relative proportions as opposed to universally higher proportions. For example, a POJ producer with juice from trees with an early stage of HLB may need to use a higher proportion of this juice when blended in a final POJ product when compared to a producer with juice from trees with an advanced stage of HLB who may need to use a lower proportion of this juice in a final POJ product. Both POJ producers would be under the same market pressure to meet consumer expectations of flavor and taste profiles of POJ. Therefore, producers must consider the relative proportions, as opposed to making juice with overall higher proportions of juice.

We decline to impose a limit on the amount of juice from oranges from trees affected with HLB. The study on which the comment's 25 percent maximum recommendation appears to be based did not consider other scientific studies investigating such juice or other factors that impact growth and production (see Ref. 3). The study also failed to take other factors into consideration, including the stage of infection of a tree, research on supplemental nutrition for diseased trees, or differences in flavor profiles of different varieties infected with HLB (Refs. 3–5). Regarding the comment's assertion that the flavor of POJ made from oranges from trees with HLB is affected and certain flavor components (*i.e.,* limonin and nomilin) are impacted, the authors cited a study where limonin and nomilin were examined in juice from oranges of different cultivars of trees with HLB (Ref. 2). The study concluded that overall flavor differences are low between juice from oranges from trees with or without the causal agent of HLB, the alphaproteobacterium known as *Candidatus Liberibacter asiaticus* (Ref. 2). Further, the study authors stated that when juice is made and blended on a commercial scale, the flavor differences are ''likely to be not detectable'' (Ref. 2).

(Comment 6) One comment stated that FDA exceeded its authority by lowering the minimum Brix requirement without identifying a specific health risk.

(Response 6) We disagree that we are exceeding our authority or need to identify a health risk to amend the SOI for POJ. FDA is amending the SOI consistent with our authority in section 401 of the FD&C Act. Under section 401 of the FD&C Act, FDA is authorized to establish ''a reasonable definition and standard of identity . . . to promote honesty and fair dealing in the interest of consumers.'' In evaluating whether to revise the SOI, we considered the reasonableness of the minimum Brix requirement in light of current environmental and agricultural conditions and whether lowering the minimum Brix to 10° would impact the essential characteristics of POJ or result in products inconsistent with consumer expectations. This rule reflects our reasoned determination that amending the SOI promotes honesty and fair dealing in the interest of consumers, consistent with section 401 of the FD&C Act, because it does not impact the essential characteristics of POJ or result in products inconsistent with consumer expectations.

(Comment 7) Some comments asserted that lowering the minimum Brix requirement could mislead consumers into purchasing a product perceived as ''watered down.''

(Response 7) We disagree that POJ will become ''watered down'' with the Brix level set at 10° because § 146.140 does not permit added water or dilution. We reviewed available data, including

sensory information submitted to the docket, and we find that the differences in soluble solids between 10° and 10.5° are unlikely to materially affect the sensory experience for consumers. Furthermore, all compositional and production requirements other than the Brix value remain unchanged.

(Comment 8) One comment argued that by lowering the Brix, we fail to account for consumer preference.

(Response 8) FDA disagrees that we have not considered consumer preferences. In 2023, we issued a Request for Information (RFI) seeking comments, data, and other information regarding consumers' interest in, expectations of, and acceptance of POJ with a lower Brix level (FDA–2023–N–2632). Consumers who responded to the RFI stated that the change would have no detrimental effect on orange juice and that a 0.5° difference in Brix is not detectable in taste even by a trained sensory panel. The proposed rule invited comments from the public, including consumers, on lowering the minimum Brix requirement. We received comments from consumers and individuals that both supported and opposed lowering the minimum Brix requirement to 10°. We have considered all of these comments in developing this final rule.

D. Comments on Increasing the Citrus Reticulata Limit and FDA Response

(Comment 9) In the proposed rule, FDA invited additional public comment on the acceptability of increasing the maximum allowable amount of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume in POJ. All comments that responded to this issue supported this change. The comments discussed that the increase would improve blend flexibility, flavor balance, and color consistency and would maintain consumer expectations. Additionally, one comment stated that it would be more efficient for FDA to amend both the minimum Brix requirement and the maximum amount of unfermented juice from *Citrus reticulata* or its hybrids in the same rulemaking.

(Response 9) Since we received supportive comments and no adverse comments, we are amending the SOI for POJ to permit up to 15 percent unfermented juice from *Citrus reticulata* or its hybrids. Since FDA established the SOI for POJ in 1963, our regulations have been clear that *Citrus reticulata* or its hybrids may also be added to orange juice to achieve a uniform color and flavor without altering its essential characteristics (see 27 FR 10494, October 27, 1963). We anticipate that the amendment permitting up to 15 percent unfermented juice from *Citrus reticulata* or its hybrids will maintain the basic nature and essential characteristics of POJ. Increasing the amount of *Citrus reticulata* or its hybrids in POJ can help maintain a higher level of sweetness in products sold to consumers. We find this amendment to the SOI to be reasonable in light of current environmental and agricultural conditions.

Although the proposed codified text did not include this amendment, the preamble to the proposed rule requested comment on whether FDA should increase the maximum allowable amount of unfermented juice from *Citrus reticulata* or its hybrids to 15 percent. Interested parties had notice that FDA was considering this change and had an opportunity to comment. Therefore, FDA is amending both the minimum Brix requirement and the maximum amount of unfermented juice from *Citrus reticulata* or its hybrids in this rulemaking.

E. Comments on Additional Questions in the Proposed Rule and FDA Response

(Comment 10) In the proposed rule, FDA invited additional public comment on whether the minimum Brix requirement should be eliminated from the SOI. We also requested comments on whether the SOI for POJ is no longer necessary to promote honesty and fair dealing in the interest of consumers and therefore should be revoked to provide manufacturers with greater flexibility in POJ production. All comments in response to these questions opposed removing the Brix requirement and revoking the SOI. Comments that opposed revoking the SOI stated that FDA would not be able to fulfill its duty to protect and inform consumers. These comments expressed concerns that removing the minimum Brix requirement could negatively affect the quality and integrity of POJ. The comments further explained that consumers expect a certain quality in ''not from concentrate'' POJ, as guaranteed by the SOI, and removal of the SOI would undermine the consistency and quality of POJ. The comments also explained that without a Federal standard, states would impose differing or conflicting standards. Commenters also noted that it could disrupt the U.S. Department of Agriculture's (USDA's) Grade Standards, which serve as a foundation for marketing in the United States and quality assurance. Some comments stated that revocation would not be effective because manufacturers could face challenges in maintaining the consistency in POJ as consumers expect.

(Response 10) Since we did not receive any comments supportive of either option, we are not revoking the SOI for POJ or removing a minimum Brix requirement from the SOI for POJ. We are not aware of any evidence that the SOI for POJ or a minimum Brix requirement for POJ no longer promote honesty and fair dealing in the interest of consumers. The SOI ensures that POJ is consistent with the basic nature and essential characteristics of the food and meets consumer expectations about the food.

(Comment 11) One comment recommended that FDA lower the Brix to 9°. Another comment said that FDA should lower the levels of sugar in all foods, including orange juice, although it was not clear whether the comment deemed a Brix of 10° for POJ to be sufficiently low.

(Response 11) In the proposed rule, FDA invited public comments on whether the minimum Brix requirement should be further reduced. The recommendation in the comment to establish a minimum 9° Brix did not include any data, studies, or information to explain the rationale for this level and whether a Brix of 9° would maintain the essential characteristics of POJ. Reducing the Brix level too low could undermine POJ's essential characteristics, including consistency, taste, and flavor. No information was submitted in the comments to support a Brix lower than 10° or a lower sugar content for POJ.

(Comment 12) One comment asked how consumers would know that the POJ they are purchasing is naturally lower in sugar content.

(Response 12) The SOI for POJ allows for the addition of concentrated orange juice § 146.140(b) and optional sweetening ingredients under § 146.140(c). If concentrated orange juice is used to adjust the orange juice solids of POJ, it must be declared in the ingredients list, and the label must bear the statement ''prepared in part from concentrated orange juice'' or ''with added concentrated orange juice'' or ''concentrated orange juice added'' under § 146.140(e)(1). Similarly, if optional sweetening ingredients listed in § 146.140(c) are added to POJ, the sweetening ingredients must be declared in the ingredients list, and the product label must bear the appropriate statement in § 146.140(e)(1). Therefore, consumers can check the labeling and the ingredient list to determine whether the POJ contains added sugar. The sugar content of POJ is listed in the Nutrition Facts label. Consumers can consult the

Nutrition Facts label to determine the grams of sugar per serving and can compare the amount of sugar between POJ products.

F. Miscellaneous Comments and FDA Response

(Comment 13) Comments stated that FDA should require a ''category or grading system'' and ''a tiered labeling system'' to inform consumers of the Brix level or sweetness of POJ on product labeling. Comments advocated for labeling statements such as ''10.5° Orange Juice'' and ''10° Orange Juice''; and ''More Sweet'' for POJ with Brix 10.5° and ''Less Sweet'' for POJ with Brix 10°. Another comment assumed that POJ with a Brix of 10° would be labeled as ''10° Brix.'' Comments also stated that the labeling of POJ should include nutritional differences between products. One comment stated that we should offer ''an optional front-panel descriptor like 'Lower Sweetness Option' so that consumers who prefer a less-sweet juice can easily identify it.''

(Response 13) We do not agree that additional measures such as mandatory disclosure of Brix levels or relative sweetness would be helpful to consumers. Brix level does not have meaning to the average consumer. While consumers understand sweetness, we do not anticipate that the reduction in sugar between products with a Brix of 10° and 10.5° is significant from a taste perspective, especially considering other taste factors that may vary between brands of products. As previously explained, POJ with a Brix of 10.5° has approximately 18 grams of sugar per serving, whereas POJ with a Brix of 10° has approximately 17 grams of sugar per serving. There is a one gram decrease of sugar per serving from 18 grams to 17 grams. Moreover, the comments assume only two types of POJ are on the market: POJ with a Brix of 10° and POJ with a Brix of 10.5°. In reality, the Brix requirement is a minimum requirement, and products may vary in Brix across the market. POJ products could, for example, be sold with a Brix of 10°, 10.3°, 10.5°, 10.7°, and so on. Labeling these different Brix levels or associating them with labeling terms of relative sweetness may cause consumer confusion and fail to convey organoleptic differences between products. We believe that the best way to convey product differences to consumers in this case is through declaration of the sugar content on the Nutrition Facts label. With this information, consumers can compare labels and identify POJ products with slightly lower sugar content.

We disagree that labeling of nutritional differences between POJ products is necessary because of this rule. As explained, we evaluated the Nutrition Facts labels submitted by the petitioners, which showed minimal impact on key nutrient levels in orange juice, including potassium, folate, and vitamin C, when the Brix of POJ is lowered from 10.5° to 10°. The comments did not identify any other key nutrients that would be impacted by lowering the Brix requirement to 10°. The Nutrition Facts label will continue to disclose the amount of potassium, folate, and vitamin C on the labels of POJ, and consumers may compare the amount of these nutrients between products if they wish. The information on product labels, including any labeling regarding nutrition content claims, must be truthful, not misleading, and comply with regulations, including the regulations in 21 CFR 101.54 through 21 CFR 101.69.

(Comment 14) One comment stated that FDA cannot invoke consumer interest as a pretext to justify changing the long-standing SOI for purposes outside of our statutory authority, such as tariffs, economic hardship, or challenges facing the orange industry.

(Response 14) FDA issued the proposed rule consistent with our authority in section 401 of the FD&C Act. Under section 401, we can establish a reasonable definition and SOI to promote honesty and fair dealing in the interest of consumers. The amendments to the SOI for POJ are reasonable given the declining Brix levels of oranges largely driven by citrus greening disease and weather-related stress on orange crops. They are in the interest of consumers because they are unlikely to create a noticeable taste difference for consumers and will ensure that POJ products consistent with consumer expectations are available. This final rule is not based on tariff policy or economic hardship. Such considerations are irrelevant to the statutory standard and are not the basis for this rulemaking.

(Comment 15) Some comments proposed alternatives to lowering the minimum Brix requirement, such as establishing seasonal Brix or Brix grading systems, regional Brix standards, or a Brix range instead of a fixed minimum Brix requirement.

(Response 15) We reviewed these suggestions but determined that a single minimum Brix requirement in the SOI for POJ best maintains uniformity and prevents marketplace confusion. FDA concludes that the 10° Brix minimum requirement is clear and enforceable.

Also, FDA's SOIs generally do not provide for grading of commodities or products. Grading systems are typically within USDA's jurisdiction, as in the case of canned orange juice (see, *e.g., https://www.ams.usda.gov/grades-standards/canned-orange-juice-grades-and-standards*). One option to address seasonal variations could be for FDA to issue a temporary marketing permit (TMP). In our 2023 RFI, we asked whether orange juice producers would be interested in applying for a TMP under 21 CFR 130.17 that would permit manufacturers to deviate from SOI and market POJ with Brix levels between 10° and 10.5° (88 FR 55607 at 55610). Such TMPs would allow producers to collect data on consumer expectations and acceptance of POJ within this range (id.). We did not receive comments supporting the use of TMPs. Several comments in response to the RFI stated that TMPs are not appropriate because they are temporary and would not address a long-term solution. These comments also stated that the associated labeling requirements and additional stock-keeping units would create logistical burdens for manufacturers and could cause consumer confusion.

(Comment 16) Some comments urged FDA to make the final rule effective immediately upon publication. Another comment asked us to adopt a minimum 24-month compliance period for all entities and a 36-month compliance period for small entities.

(Response 16) We are maintaining an effective date of 30 days after publication of the final rule. Until the effective date, we are exercising enforcement discretion for POJ with a Brix between 10° and 10.5° and for POJ from unfermented juice obtained from mature oranges as specified in § 146.135 (21 CFR 146.135), to which is added 10–15 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids, provided that all other requirements in § 146.140 are met. Due to the voluntary nature of this rule and the fact that it does not introduce any new compositional or labeling requirements, FDA disagrees with a 24-month compliance period for all entities and a 36-month compliance period for small entities. Because the rule does not impose any 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, FDA will retain the 30-day compliance date from the proposed rule after publication of this final rule in the **Federal Register**. Therefore, the final rule will become

effective 30 days after publication with a concurrent 30-day compliance date after publication.

(Comment 17) A comment suggested that we should revise the Paperwork Reduction Act (PRA) analysis and submit an Information Collection Request to the Office of Management and Budget that quantifies incremental third-party disclosure (labeling) and recordkeeping burdens associated with the rule.

(Response 17) We disagree. This rulemaking does not change any labeling requirements for POJ. While the grams of sugar may vary based on the Brix level, the responsibility of labeling the grams of sugar in the Nutrition Facts label remains the same. As such, no additional PRA analysis is needed and Office of Management and Budget clearance under the PRA is not necessary.

G. Comments Outside of the Scope and FDA Response

(Comment 18) A few comments asked FDA to consider increasing the maximum percentage of *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume for three other orange juice standards (Canned orange juice, 21 CFR 146.141; Frozen concentrated orange juice, 21 CFR 146.146; and Orange juice for manufacturing, 21 CFR 146.151).

(Response 18) In the proposed rule, we invited public comment on the acceptability of increasing the maximum percentage of unfermented juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent by volume in POJ. In response to our question, some comments requested that we increase the maximum percentage of juice from *Citrus reticulata* or its hybrids from 10 percent to 15 percent in other orange juice-related regulations, such as Canned orange juice (§ 146.141), Frozen concentrated orange juice (§ 146.146), and Orange juice for manufacturing (§ 146.151). This request is outside the scope of this rulemaking. However, FDA may consider this request in the future through separate rulemaking.

(Comment 19) A comment suggested that FDA specify that Brix measurements must follow a named official method, such as Association of Official Analytical Collaboration (AOAC) 932.12 or an equivalent International Organization for Standardization protocol. The comment further suggested that FDA require digital refractometer calibration at 20° Celsius, with those details published in a guidance so that state inspectors and commercial laboratories can apply uniform protocols.

(Response 19) The proposed rule did not address this issue, so it is out of scope. We disagree that FDA should specify Brix measurements because Brix is a well-established analytical measurement with widely accepted standard practices already in use throughout the food industry and testing laboratories. Brix can be measured using specific gravity or density, as both have a linear relationship with sugar concentration. The most popular instruments for Brix measurement are either a refractometer or a hydrometer (see Sensors and Instruments for Brix Measurement: A Review *https://pmc.ncbi.nlm.nih.gov/articles/PMC8951823/pdf/sensors-22-02290.pdf*). Most industry personnel and inspectors use AOAC official method 932.12, which measures total soluble solids in fruits and fruit products using a refractometer and applies corrections for temperature and acidity (particularly citric acid in citrus) to determine sugar content (AOAC 932.12, *Official Methods of Analysis of AOAC International,* 20th edition, 2016). The data supports that the current approach provides adequate assurance of measurement reliability while allowing laboratories the flexibility to use validated methods appropriate for their operations.

(Comment 20) One comment stated that lowering the minimum Brix requirement is not a long-term solution for the issues plaguing Florida growers. Another comment suggested that we create a ''Florida Fresh'' designation for POJ made exclusively from Florida-grown oranges.

(Response 20) SOIs are established to promote honesty and fair dealing in the interest of consumers, rather than to address broader economic or agricultural policy challenges. This rulemaking does not preclude us from amending the SOI for POJ in the future should circumstances change that are relevant to section 401 of the FD&C Act. Furthermore, the creation of geographic marketing designations in the labeling of POJ, such as ''Florida Fresh,'' falls outside the scope of FDA's SOI authority. Manufacturers may include truthful statements in the labeling of their POJ about the origin of the oranges used in the manufacture of their POJ.

(Comment 21) A comment stated that ''FDA should amend the SOI for orange juice by changing the requirement that 90 percent of juice needs to be from *Citrus sinensis.*''

(Response 21) The SOI for orange juice under § 146.135 states that orange juice is the unfermented juice obtained from mature oranges of the species *Citrus sinensis* or of the citrus hybrid commonly called ''Ambersweet.'' The SOI for POJ states that POJ is prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids. Consequently, the starting point for orange juice manufactured into POJ is unfermented juice that is at least 90 percent *Citrus sinensis* and up to 10 percent *Citrus reticulata* or *Citrus reticulata* hybrids. This final rule amends the SOI for POJ to permit up to 15 percent *Citrus reticulata* or *Citrus reticulata* hybrids. Once this final rule is effective, the amount of unfermented juice from *Citrus sinensis* must be at least 85 percent.

It is unclear which SOI the comment thought we should amend or what percentage of orange juice the comment thought should be from *Citrus sinensis.* To the extent the comment was requesting amendment to § 146.135, the request is out of scope. To the extent the comment was requesting that the percentage of *Citrus sinensis* be changed in the SOI for POJ, this rulemaking changes the minimum percentage of *Citrus sinensis* as a consequence of the maximum percentage of *Citrus reticulata* being increased.

(Comment 22) Individual comments included requests to launch a plant sterol fortification campaign for POJ and to create a ''better and natural form of Vitamin C,'' a proposal to expand USDA's program to include pasteurized heart-healthy fortified juice in school nutrition programs, an authorization request, a comment about O.J. Simpson, and a submission purported to be in the form of a petition.

(Response 22) These comments were outside the scope of this rulemaking. However, the petition submitted to this docket was treated as a comment rather than as a citizen petition because it was not properly submitted under 21 CFR 10.30 as required by FDA for citizen petitions.

Finally, while not included in the proposed rule, we have identified a typographical error in § 146.140(a) that we correct in this final rule. We are changing the word ''that'' to ''than'' in the first sentence of § 146.140(a) so that the sentence reads, ''Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more than 15 percent by volume of the unfermented juice obtained from mature oranges of

the species *Citrus reticulata* or *Citrus reticulata* hybrids . . .''.

V. Effective/Compliance Date(s)

Effective date: This rule is effective August 19, 2026.

Compliance date: The compliance date of this final rule is August 19, 2026.

VI. Economic Analysis of Impacts

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 (also known as subtitle E of the 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 percent over 10 years; this primary estimate is −$28.8 million, annualized at 3 percent over 10 years. Our primary estimate of cost savings, annualized at 7 percent 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:			

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE—Continued
[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
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 percent annual growth in cost savings corresponding to 1 percent annual growth of POJ market in perpetuity.

TABLE 2—E.O. 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	−412.6
Present Value of Net Costs	−412.6
Annualized Costs	0
Annualized Cost Savings	−28.9
Annualized Net Costs	−28.9

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 6) and at *https://www.fda.gov/economics-staff/regulatory-impact-analyses-ria.*

VII. Analysis of Environmental Impact

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

VIII. Paperwork Reduction Act of 1995

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

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; however, except for the FDA Final Regulatory Impact Analysis (reference 6), these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

1. Bassanezi, R.B., L.H. Montesino, and E.S. Stuchi. ''Effects of Huanglongbing on Fruit Quality of Sweet Orange Cultivars in Brazil,'' *European Journal of Plant Pathology,* 125(4):565–572, 2009. Available at: *https://doi.org/10.1007/s10658-009-9506-3.*
2. Baldwin, E., A. Plotto, J. Manthey, G. McCollum, et al. ''Effect of Liberibacter Infection (Huanglongbing Disease) of Citrus on Orange Fruit Physiology and Fruit/Fruit Juice Quality: Chemical and Physical Analyses,'' *Journal of Agricultural and Food Chemistry,* 58(2):1247–1262, 2010. Available at: *https://doi.org/10.1021/jf9031958.*
3. Raithore, S., S. Dea, A. Plotto, et al. ''Effect of Blending Huanglongbing (HLB) Disease Affected Orange Juice with Juice from Healthy Orange on Flavor Quality,'' *LWT-Food Science and Technology,* 62(1):868–874, 2015. Available at *https://doi.org/10.1016/j.lwt.2014.06.020.*
4. Dala-Paula, B.M., A. Plotto, J. Bai, et al. ''Effect of Huanglongbing or Greening Disease on Orange Juice Quality, a Review.'' *Frontiers in Plant Science,* 9:1976, 2019. Available at: *https://doi.org/10.3389/fpls.2018.01976.*
5. Ikpechukwu, C. *A Sensory Evaluation of Citrus Greening-Affected Juice Blends.* Diss. University of Florida, 2012.
6. FDA, ''Food Standards of Identity Modernization; Pasteurized Orange Juice; Proposed Rule, Docket No. FDA–2022–P–1668, Final Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis.'' Available at: *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, 21 CFR part 146 is 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. 321, 341, 343, 348, 371, 379e.

■ 2. Amend § 146.140 by revising paragraph (a) to read as follows:

§ 146.140 Pasteurized orange juice.

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more than 15 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If the adjustment involves the addition of pulp, then such pulp shall not be of the washed or spent type. The solids may be adjusted by the addition of one or more of the optional concentrated orange juice ingredients specified in paragraph (b) of this section. One or more of the optional sweetening ingredients listed in paragraph (c) of this section may be added in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. Either before or after such heat treatment, all or a part of the product may be frozen. The finished pasteurized orange juice contains not less than 10 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–14573 Filed 7–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2026–0801]

Special Local Regulations; Marine Events Within the USCG East District—Atlantic City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Atlantic City Triathlon on August 9, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District identifies the regulated area for this event in Atlantic City, NJ. During enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.501 will be enforced for the special local regulation listed in Table 1 to Paragraph (i)(1) of § 100.501 for the event titled ''Triathlons in Atlantic City'' from 6 a.m. through 11 a.m. on August 9, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Petty Officer Dominick Dobridge, Waterways Management Division, Sector Delaware Bay, U.S. Coast Guard; telephone 206–815–6688, option 3, email *SecDelBayWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in Table 1 to Paragraph (i)(1) in 33 CFR 100.501, for the regulated area of the event titled ''Triathlons in Atlantic City'' from 6 a.m. to 11 a.m. on August 9, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the USCG East District, § 100.501, specifies the location of the regulated area for the ''Triathlons in Atlantic City'' which encompasses portions of the New Jersey Intracoastal Waterway in Atlantic City, NJ. During the enforcement period, as reflected in § 100.501(d)(2), a vessel operator may request permission to enter and transit through a regulated area by contacting the Event PATCOM or official patrol vessel on VHF–FM channel 16. When authorized to transit through the regulated area, the vessel must proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the event area.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Broadcast Notice to Mariners.

Roberto Rivera,

Captain, U.S. Coast Guard, Acting Captain of the Port, Sector Delaware Bay.

[FR Doc. 2026–14546 Filed 7–17–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[USCG–2026–0050]

2026 Quarterly Listings: First Quarter; Safety Zones, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notification of expired temporary rules issued.

SUMMARY: This document provides notification of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register**. This document lists temporary safety zones, security zones, and special local regulations, all of limited duration and for which timely publication in the **Federal Register** was not possible. This document also announces notifications of enforcement for existing reoccurring regulations that we issued but were unable to be published before the enforcement period ended.

DATES: This document lists temporary Coast Guard rules that became effective, primarily between January 2026 and March 2026, unless otherwise indicated, and were terminated before they could be published in the **Federal Register**.

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, using the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this document contact Ambar Ali, Office of Regulations and Administrative Law, email *HQS-SMB-CG-LRA-Admin@uscg.mil,* telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be