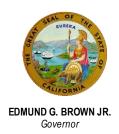


State of California—Health and Human Services Agency California Department of Public Health



May 5, 2017

REGULATORY ALERT 2017-01

NOTICE OF PROPOSED CHANGES TO THE CALIFORNIA WIC PROGRAM

Purpose

For the California Department of Public Health (CDPH) to inform stakeholders of the California Special Supplemental Nutrition Program for Women, Infants, and Children (WIC Program) of CDPH's plan to amend California WIC Authorized Food List WIC Bulletin Regulations Sections 82050 and 82300, pursuant to Health and Safety Code Section 123322.

Stakeholder Workgroup Information

In accordance with Health and Safety Code section 123322, CDPH will meet with stakeholders via webinar on May 24, 2017 to receive input on the amendments to the WIC Authorized Food List. If you are interested in participating in this stakeholder workgroup, please send an e-mail by close of business on May 12, 2017 with the subject line reading "Juice Stakeholder RSVP" to wICRegulations@cdph.ca.gov, with the following information included in the body of the e-mail:

Name:

Company Name (if applicable):

Address:

E-mail Address:

Stakeholder Group Represented: (Stakeholders can include, but are not limited to: currently authorized WIC vendors, owners or representatives of a non-WIC authorized store, manufacturers, WIC Local agency representatives, WIC participants, advocates, and consumer groups)

CDPH will contact you by May 18, 2017 with details on how and when to attend a webinar workgroup meeting. If multiple meetings are required, stakeholders will be assigned to the first available meeting.

Comment Period

CDPH will accept written comments from affected stakeholders regarding the adoption of the proposed action. The comment period will be open for 27 calendar days, from





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May 6, 2017 through June 1, 2017. Send your comments electronically to the following e-mail address: WICRegulations@cdph.ca.gov.

If this proposed action is not withdrawn, CDPH will publish its final action, including responses to the comments received, on its website no later than 120 days after the end of the comment period.

Proposed Regulation

The California Department of Public Health, which administers the California WIC Program, proposes to amend the following rules in California regulation via regulatory bulletin.

Article 5. WIC Authorized Food List

82050 WIC Authorized Food List: Bottled Juice

- (a) Bottled Juice Category
 - (1) Any brand of pasteurized juice is authorized in the Bottled Juice Category when the juice has all of the following characteristics:
 - (A) Is sold in sixty-four (64) ounce bottled (ready-to-drink) containers;
 - (B) Is one of the following kinds of juice:
 - 1. Grapefruit (white);
 - 2. Orange;
 - Apple;
 - 4. Cranberry;
 - 5. Grape (red, purple, or white);
 - 6. Grapefruit (ruby red or pink);
 - 7. Pineapple;
 - 8. Prune:
 - 9. Tomato (regular, low sodium, or spicy);
 - 10. Vegetable (regular, low sodium, or spicy); or
 - 11. Juice blends: juice that is named as two or more authorized types of juice on the front label, such as orange-white grapefruit or cranberry-grape.
 - (C) Juice and juice blends containing the kinds of juice listed in subsection (a)(1)(B)(3)-(10) above must have <u>both</u> "100% Juice" and <u>a Daily Value of</u> "12080% Vitamin C" (or more) printed on the front label:
 - (D) Is of regular calcium content or contains added calcium; and

- (E) Is of regular Vitamin D content or contains added Vitamin D.
- (2) The following products are never authorized for purchase as part of the Bottled Juice Category:
 - (A) Authorized kinds of juice other than orange juice and white grapefruit juice that are not labeled as specified in subsection (a)(1)(C);
 - (B) Cider;
 - (C) Diet, light, or "lite" juice;
 - (D) Juice with added ingredients or supplements, including but not limited to caffeine, carnitine, chromium, DHA, echinacea, gingko biloba, ginseng, guarana, St. John's wort, taurine, or wheatgrass;
 - (E) Organic juice; and
 - (F) Refrigerated juice.

82300 WIC Authorized Food List: Concentrate Juice

- (a) Concentrate Juice Category
 - (1) Any brand of pasteurized juice concentrate is authorized in the Concentrate Juice Category when the juice has all of the following characteristics:
 - (A) Is sold in eleven and a half (11.5), twelve (12), or sixteen (16) ounce containers;
 - (B) Is frozen or shelf-stable;
 - (C) Is one of the following kinds of juice:
 - 1. Grapefruit (white);
 - 2. Orange;
 - 3. Apple;
 - 4. Cranberry;
 - 5. Grape (red, purple, or white);
 - 6. Grapefruit (ruby red or pink);
 - 7. Pineapple;
 - 8. Prune;
 - 9. Tomato (regular, low sodium, or spicy);
 - 10. Vegetable (regular, low sodium, or spicy); or

- 11. Juice blends: juice that is named as two or more authorized types of juice on the front label, such as orange-white grapefruit or cranberry-grape.
- (D) Juice and juice blends containing the kinds of juice listed in subsection (a)(1)(C)(3)-(10) above must have <u>both</u> "100% Juice" and <u>a Daily Value of</u> "12080% Vitamin C" (or more) printed on the front label;
- (E) Is of regular calcium content or contains added calcium; and
- (F) Is of regular Vitamin D content or contains added Vitamin D.
- (2) The following products are never authorized for purchase as part of the Concentrate Juice Category:
 - (A) Authorized kinds of juice other than orange juice and white grapefruit juice that are not labeled as specified in subsection (a)(1)(D);
 - (B) Cider;
 - (C) Diet, light, or "lite" juice;
 - (D) Juice with added ingredients or supplements, including but not limited to caffeine, carnitine, chromium, DHA, echinacea, gingko biloba, ginseng, guarana, St. John's wort, taurine, or wheatgrass;
 - (E) Organic juice; and
 - (F) Refrigerated juice.

Nature of the Regulation

The Department proposes amendment of the WIC Authorized Food List Bulletin Regulations for Bottled Juice and Concentrate Juice as set forth in Attachment 1 of this notice. This proposed regulation would amend existing criteria for authorized Bottled Juice and Concentrate Juice.

Reason for the Regulation

The reasons for this amendment are included in Attachment 1 of this notice.

Authority

Federal:

The Child Nutrition Act of 1966, title 42 of the United States Code, section 1786 (Public law 89-645, Section 17), as amended, establishes the federal authority under which states may administer the Special Supplemental Nutrition Program for Women, Infants, and Children through local agencies. The WIC Program was established as a result of a Congressional finding that substantial numbers of pregnant, postpartum and breastfeeding women, infants and young children up to the age of 5 from families with

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eligible income are at special risk with respect to their physical and mental health by reason of inadequate nutrition or health care, or both. The purpose of the WIC Program is to provide supplemental foods and nutrition education.

In fulfilling this objective, the WIC Program is funded and administered by the United States Department of Agriculture (USDA), Food and Nutrition Service, pursuant 7 Code of Federal Regulations, part 246.

The WIC Program is also subject to federal memoranda and directives from USDA.

State:

The WIC Program was established under the authority of Health and Safety Code section 123275 et seq. The regulations for CDPH's administration of the WIC Program are contained in the California Code of Regulations, title 22, sections 40601 through 40815, and in the WIC Regulatory Bulletins posted at:

http://www.cdph.ca.gov/programs/cfh/dwicsn/pages/lawsandregulations.aspx.

Questions and Additional Information:

If you have any questions, please contact CDPH at WICRegulations@cdph.ca.gov.

Catherine Lopez, M.Ed.

Policy and Planning Branch Chief Women, Infants and Children Division California Department of Public Health

Attachment 1 WIC Authorized Food List Juice Amendments and Statement of Reasons

California Special Supplemental Nutrition Program for Women, Infants, and Children

May 5, 2017

Health & Safety Code § 123322 authorizes the California Department of Public Health to establish regulations regarding the authorized foods for the California Special Supplemental Nutrition Program for Women, Infants, and Children using a regulatory bulletin process. The Department is utilizing this process to adopt these regulations. This document is intended to provide reasons why the Department proposes to amend WIC Authorized Food List Bulletin Regulations for Bottled Juice and Concentrate Juice as specified in Regulatory Alert 2017-01.

Attachment 1
WIC Authorized Food List
Juice Amendments and
Statement of Reasons

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82050 WIC Authorized Food List: Bottled Juice

PROPOSED REGULATION

82050 WIC Authorized Food List: Bottled Juice

- (a) Bottled Juice Category
 - (1) Any brand of pasteurized juice is authorized in the Bottled Juice Category when the juice has all of the following characteristics:
 - (A) Is sold in sixty-four (64) ounce bottled (ready-to-drink) containers;
 - (B) Is one of the following kinds of juice:
 - Grapefruit (white);
 - 2. Orange;
 - Apple;
 - 4. Cranberry;
 - 5. Grape (red, purple, or white);
 - Grapefruit (ruby red or pink);
 - 7. Pineapple;
 - 8. Prune:
 - 9. Tomato (regular, low sodium, or spicy);
 - 10. Vegetable (regular, low sodium, or spicy); or
 - 11. Juice blends: juice that is named as two or more authorized types of juice on the front label, such as orange-white grapefruit or cranberry-grape.
 - (C) Juice and juice blends containing the kinds of juice listed in subsection (a)(1)(B)(3)-(10) above must have <u>both</u> "100% Juice" and <u>a Daily Value of</u> "12080% Vitamin C" (or more) printed on the front label;
 - (D) Is of regular calcium content or contains added calcium; and
 - (E) Is of regular Vitamin D content or contains added Vitamin D.
 - (2) The following products are never authorized for purchase as part of the Bottled Juice Category:
 - (A) Authorized kinds of juice other than orange juice and white grapefruit juice that are not labeled as specified in subsection (a)(1)(C);
 - (B) Cider;

- (C) Diet, light, or "lite" juice;
- (D) Juice with added ingredients or supplements, including but not limited to caffeine, carnitine, chromium, DHA, echinacea, gingko biloba, ginseng, guarana, St. John's wort, taurine, or wheatgrass;
- (E) Organic juice; and
- (F) Refrigerated juice.

AUTHORITY

Federal:

7 Code of Federal Regulations part 246.10(b)(1)(i) (2017): State agency responsibilities State agencies may: Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section for the supplemental foods in their States . . . These State agency criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal.

7 Code of Federal Regulations part 246.10(b)(2)(i) (2017): State agency responsibilities State agencies must identify the brands of foods and package sizes that are acceptable for use in their States in accordance with the requirements of this section.

7 Code of Federal Regulations part 246.10(e)(12), table 4 (2017): *Minimum requirements and specifications for supplemental foods*The minimum requirements and specifications for bottled juice in all applicable food packages are as follows:

Must be pasteurized 100% unsweetened fruit juice. Must contain at least 30 mg of vitamin C per 100 mL of juice. Must conform to FDA standard of identity as appropriate (21 CFR part 146) or vegetable juice must conform to FDA standard of identity as appropriate (21 CFR part 156). With the exception of 100% citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf-stable. Blends of authorized juices are allowed.

21 Code of Federal Regulations part 101.9(c)(8)(iv) (2017): *Nutrition Labeling of Food* The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

		RDI				
Nutrient	Unit of measure	Adults and children ≥4 years	Infants ¹ through 12 months	Children 1 through 3 years	Pregnant women and lactating women	
Vitamin C	Milligrams (mg)	90	50	15	120	

¹RDIs are based on dietary reference intake recommendations for infants through 12 months of age.

21 Code of Federal Regulations part 101.9(c)(8)(i) (2017): *Nutrition Labeling of Food* For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years, pregnant women, and lactating women shall use the RDIs that are specified for the intended group. For foods represented or purported to be specifically for both infants through 12 months of age and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants through 12 months of age and children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. All other foods shall use the RDI for adults and children 4 or more years of age.

State:

Health and Safety Code section 123290: The Department . . . shall . . . designate specific supplemental foods to meet the minimum nutritional requirements for recipients.

Health and Safety Code section 123322, subdivisions (a)(3) and (b): (a) In order to effectively manage and administer the federal and state requirements for the vendors in the WIC Program, and remain in compliance with the conditions of federal funding, the department shall establish requirements for all of the following: . . . (3) The WIC Program authorized foods. (b) Notwithstanding any other provisions of law, including the requirement in Section 123315 for enacting regulations to implement that section and Section 123310, the department may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement, interpret, or make specific this section by means of an action by bulletin or similar instruction.

California Code of Regulations, title 22, section 40715, subdivisions (c)(1)-(4): The specific foods authorized shall be determined by the department based upon federal minimum nutrient requirements specified for the particular food group, programmatic

needs, financial constraints, and space limitations on the face of the food instruments . . The following criteria shall be used by the Department to designate the specific foods authorized:

- (1) Cost of the foods:
- (2) Appropriateness of foods to the participant's category;
- (3) Statewide availability of the foods for a period of at least one year; and
- (4) Nutrient content of the food, its relationship to the nutritional needs of participants, and its consistency with the nutrition education goals of the Program.

STATEMENT OF REASONS

82050 WIC Authorized Food List: Bottled Juice

(a)(1)(C) The Department proposes to change the specified labeling requirement from "100% Juice" and '120% Vitamin C' or more" to "Both '100% Juice' and a Daily Value of '80% Vitamin C' or more."

7 Code of Federal Regulations part 246.10(e)(12), table 4, requires the Department to ensure that all authorized juice contains 30 mg of Vitamin C for each 100 mL of juice. The Department has ensured this requirement is met by adopting labeling requirements for non-100%-citrus juice products in lieu of another method. The labeling requirement makes it easy for participants and vendors to identify authorized products, with the qualifying criteria appearing right on the front of the product.

The current labeling requirements provide that all authorized non-100%-citrus juice products must have front labels reflecting that their contents contain 120% Daily Value (DV) of vitamin C per 8 ounce (236.588 mL) serving of juice. The 120% DV used for this requirement was based on a 60 mg per day RDI. This percentage is equivalent to a minimum of 72 mg of vitamin C in each 236.588 mL of juice or 30.433 mg in each 100 mL of juice.

The Food and Drug Administration (FDA) revised the RDI for vitamin C in July 2016, raising the RDI for adults and children 4 or more years of age from 60 mg per day to 90 mg per day. (21 C.F.R. §101.9(c)(8)(iv).) The DV requirement is based on the RDI as set forth in 21 Code of Federal Regulations part 101.9(c)(8)(i), with the DV representing the percentage of the RDI mg requirement. As a result, the Department is proposing to revise the labeling requirement to maintain the current levels of vitamin C in juice while reflecting the change in the RDI regulations.

The Department is proposing to require that all authorized non-100%-citrus juice products must have front labels reflecting that their contents contain 80% of the DV of vitamin C per 8 ounce (236.588 mL) serving, which is equivalent to 72 mg of vitamin C in each 236.588 mL of juice or 30.433 mg in each 100 mL of juice. This requirement ensures that the 30 mg of vitamin C

in 100 mL of juice requirement for authorized foods in 7 Code of Federal Regulations part 246.10(e)(12), table 4 is met.

If the Department does not revise the current labeling requirement, in order for their products to remain authorized, juice manufacturers would be forced to reformulate their products to contain a higher level of vitamin C. This reformulation could represent a burden on manufacturers, since requiring an increased amount vitamin C could affect products' stability and palatability, potentially leading to additional reformulations. Changing the Department's DV labeling requirement to reflect the FDA's change in RDI ensures that the original intent of the Department's requirement is still intact while minimizing the burden on manufacturers.

82300 WIC Authorized Food List: Concentrate Juice

PROPOSED REGULATION

82300 WIC Authorized Food List: Concentrate Juice

- (a) Concentrate Juice Category
 - (1) Any brand of pasteurized juice concentrate is authorized in the Concentrate Juice Category when the juice has all of the following characteristics:
 - (A) Is sold in eleven and a half (11.5), twelve (12), or sixteen (16) ounce containers;
 - (B) Is frozen or shelf-stable;
 - (C) Is one of the following kinds of juice:
 - 1. Grapefruit (white);
 - 2. Orange;
 - Apple;
 - 4. Cranberry;
 - 5. Grape (red, purple, or white);
 - 6. Grapefruit (ruby red or pink);
 - 7. Pineapple;
 - 8. Prune:
 - 9. Tomato (regular, low sodium, or spicy);
 - 10. Vegetable (regular, low sodium, or spicy); or
 - 11. Juice blends: juice that is named as two or more authorized types of juice on the front label, such as orange-white grapefruit or cranberry-grape.
 - (D) Juice and juice blends containing the kinds of juice listed in subsection (a)(1)(C)(3)-(10) above must have <u>both</u> "100% Juice" and <u>a Daily Value of</u> "12080% Vitamin C" (or more) printed on the front label:
 - (E) Is of regular calcium content or contains added calcium; and
 - (F) Is of regular Vitamin D content or contains added Vitamin D.
 - (2) The following products are never authorized for purchase as part of the Concentrate Juice Category:

- (A) Authorized kinds of juice other than orange juice and white grapefruit juice that are not labeled as specified in subsection (a)(1)(D);
- (B) Cider;
- (C) Diet, light, or "lite" juice;
- (D) Juice with added ingredients or supplements, including but not limited to caffeine, carnitine, chromium, DHA, echinacea, gingko biloba, ginseng, guarana, St. John's wort, taurine, or wheatgrass;
- (E) Organic juice; and
- (F) Refrigerated juice.

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7 Code of Federal Regulations part 246.10(b)(1)(i) (2017): State agency responsibilities State agencies may: Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section for the supplemental foods in their States . . . These State agency criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal.

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7 Code of Federal Regulations part 246.10(e)(12), table 4 (2017): *Minimum requirements and specifications for supplemental foods*The minimum requirements and specifications for concentrate juice in all applicable food packages are as follows:

Must be pasteurized 100% unsweetened fruit juice. Must contain at least 30 mg of vitamin C per 100 mL of juice. Must conform to FDA standard of identity as appropriate (21 CFR part 146) or vegetable juice must conform to FDA standard of identity as appropriate (21 CFR part 156). With the exception of 100% citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf-stable. Blends of authorized juices are allowed.

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¹RDIs are based on dietary reference intake recommendations for infants through 12 months of age.

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- .. The following criteria shall be used by the Department to designate the specific foods authorized:
- (1) Cost of the foods;
- (2) Appropriateness of foods to the participant's category;
- (3) Statewide availability of the foods for a period of at least one year; and
- (4) Nutrient content of the food, its relationship to the nutritional needs of participants, and its consistency with the nutrition education goals of the Program.

STATEMENT OF REASONS

82300 WIC Authorized Food List: Concentrate Juice

(a)(1)(C) The Department proposes to change the specified labeling requirement from "100% Juice" and '120% Vitamin C' or more" to "Both '100% Juice' and a Daily Value of '80% Vitamin C' or more."

7 Code of Federal Regulations part 246.10(e)(12), table 4, requires the Department to ensure that all authorized juice contains 30 mg of Vitamin C for each 100 mL of juice. The Department has ensured this requirement is met by adopting labeling requirements for non-100%-citrus juice products in lieu of another method. The labeling requirement makes it easy for participants and vendors to identify authorized products, with the qualifying criteria appearing right on the front of the product.

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The Food and Drug Administration (FDA) revised the RDI for vitamin C in July 2016, raising the RDI for adults and children 4 or more years of age from 60 mg per day to 90 mg per day. (21 C.F.R. §101.9(c)(8)(iv).) The DV requirement is based on the RDI as set forth in 21 Code of Federal Regulations part 101.9(c)(8)(i), with the DV representing the percentage of the RDI mg requirement. As a result, the Department is proposing to revise the labeling requirement to maintain the current levels of vitamin C in juice while reflecting the change in the RDI regulations.

The Department is proposing to require that all authorized non-100%-citrus juice products must have front labels reflecting that their contents contain 80% of the DV of vitamin C per 8 ounce (236.588 mL) serving, which is equivalent to 72 mg of vitamin C in each 236.588 mL of juice or 30.433 mg in

each 100 mL of juice. This requirement ensures that the 30 mg of vitamin C in 100 mL of juice requirement for authorized foods in 7 Code of Federal Regulations part 246.10(e)(12), table 4 is met.

If the Department does not revise the current labeling requirement, in order for their products to remain authorized, juice manufacturers would be forced to reformulate their products to contain a higher level of vitamin C. This reformulation could represent a burden on manufacturers, since requiring an increased amount vitamin C could affect products' stability and palatability, potentially leading to additional reformulations. Changing the Department's DV labeling requirement to reflect the FDA's change in RDI ensures that the original intent of the Department's requirement is still intact while minimizing the burden on manufacturers.