

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that this is not classified as a "significant energy action" under that order because it is a "significant regulatory action" under Executive Order 12866 and it would not have a significant adverse effect on the supply, distribution, or use of energy.

Environment

The proposed rule would have no significant impact on the environment.

PART 256—[REMOVED AND RESERVED]

1. Accordingly the Department proposes to remove 14 CFR art 256 and reserve art 256.

Issued in Washington, DC, on March 27, 2005.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 05-6650 Filed 4-1-05; 8:45 am]

BILLING CODE 4910-62-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2001N-0548] (formerly Docket No. 01N-0548)

Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 3, 2005, the comment period for a proposed rule published in the **Federal Register** of March 20, 2002. In that document, FDA proposed to amend its voluntary nutrition labeling regulations by updating the names and nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States. Since publication of the proposed rule, the agency has received new data in comments that it intends to use to further update the nutrition labeling

values. The agency also intends to use additional data from the U.S. Department of Agriculture (USDA) for certain nutrients in raw produce. Those data became available after the close of the comment period. FDA is reopening the comment period to allow all interested parties the opportunity to review its tentative nutrition labeling values based upon data FDA received within and after the comment period, and to comment on the additional nutrient data for some of the 20 most frequently consumed raw fruits, vegetables, and fish. FDA will evaluate any new data submissions during this reopened comment period and will consider use of those data in a final rule.

DATES: Submit written or electronic comments by June 3, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2001N-0548, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2001N-0548 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/hand delivery/courier [for paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number or regulatory information number for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the relevant docket number, 01N-0548, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Brandt, Center for Food Safety and Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint Branch

Pkwy., College Park, MD 20740, 301-436-1788.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 2002 (67 FR 12918) (the proposed rule), FDA proposed to amend its voluntary nutrition labeling regulations by updating the names and nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States based upon new data submitted or made available to the agency. In that document, we requested comments on the proposal by June 3, 2002. In the **Federal Register** of June 6, 2002 (67 FR 38913), we corrected the proposed rule that published with an incorrect docket number (i.e., Docket No. 01N-0458) and provided additional time to submit comments, until August 20, 2002.

In a comment to the proposed rule, USDA submitted nutrient data from its 2001-2002 nationwide sampling of fruits and vegetables (see <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/01n-0548-c000006-vol1.pdf>). USDA provided data for 16 of the 20 most frequently consumed fruits: Apple, avocado (California), banana, cantaloupe, grapefruit, honeydew melon, kiwifruit, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, and watermelon; and 12 of the top 20 vegetables: Bell pepper, broccoli, carrot, celery, cucumber, iceberg lettuce, leaf lettuce, onion, potato, radish, sweet potato, and tomato. At the time USDA submitted the comment, the data results for vitamin C, sodium, and potassium were not yet available, and the analysis of carotenoids for carrots, sweet potatoes, cucumbers, onions, and sweet peppers had not been completed. In June and July of 2003, after the close of the comment period, USDA provided sodium, potassium, and some carotenoid values that it did not submit earlier (Ref. 1). It also submitted vitamin C values for pineapple.

In other comments to the proposed rule, the Citrus Research Board and Food Research, Inc., provided nutrient data from 1998 for oranges, grapefruit, tangerines (Mandarin oranges), and lemons (see <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/081602/8001f4e1.pdf>, <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082902/01N-0548-cr00001-01-vol1.htm>, and <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082902/8002574a.doc>).

Two comments recommended that Chinook salmon be included with the revised species of fish (see <http://>

www.fda.gov/ohrms/dockets/dailys/02/Aug02/082102/800222f0.pdf and <http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082202/8002239d.pdf>. One comment noted that according to nutrient data from the USDA Nutrient Database for Standard Reference, the nutrient profile of Chinook salmon is most similar to the proposed category and values for Atlantic, Coho, and Sockeye salmon (Ref. 2).

Based upon data received during the comment period and USDA data received after the comment period, we have calculated updated nutrition labeling values for some of the 20 most frequently consumed raw fruits, vegetables, and fish. FDA is now reopening the comment period to allow the raw produce and fish industries and other interested parties the opportunity to review and react to updated nutrition labeling values based upon data FDA received within and after the comment period. Reopening the comment period may also provide an impetus for completion of additional nutrient analyses. We will evaluate any new data submissions received during this reopened comment period and will consider use of those data in a final rule.

II. Updating the Nutrition Labeling Values

We are reopening the comment period to revise the nutrition labeling values of the 20 most frequently consumed raw fruits, vegetables, and fish, which are included in appendices C and D to part 101. The proposed appendices C and D that we are publishing in this document include the updated values described in tables 1 and 2 of this document. As noted in the proposed rule, the agency

believes that the values in proposed appendices C and D could be used on an interim basis prior to completion of the rulemaking, provided that the nutrition information is presented in a manner consistent with this document. However, firms should be aware that values included in a final rule may differ and would need to be changed.

Reference 3 provides complete documentation of the derivation of each nutrition labeling value for the 20 most frequently consumed raw fruits, vegetables, and fish.

A. FDA Analysis of the Data

1. Outlier Screening

Originally, for the proposed rule, we completed outlier screening of the data using the Grubbs outlier screening method to determine influential observations in the distributions of data for each nutrient and food. However, based upon comments received in response to the proposed rule and discussion of outliers in the statistical literature, we have determined not to conduct Grubbs outlier screening on the nutrient data for raw produce and fish.

In developing the nutrient values in the proposed rule, we took a conservative approach to outliers and deleted those data points identified through outlier screening.

There were several comments in response to the proposed rule that addressed outlier screening. Comments questioned the validity of using Grubbs outlier screening for fruits and recommended the use of visual scattergrams and bar graphs. Another comment questioned the removal of outliers.

The National Institute of Standards and Technology (NIST) *e-Handbook of Statistical Methods* states that the Grubbs test is based on the assumption of normality and should only be used with data that are normally distributed (Ref. 4). NIST also recommends that the test should not be used for sample sizes of six or less since it frequently tags most of the points as outliers. Many of the nutrient levels in the voluntary nutrition labeling program are based on small sample sizes because that is all the data that are available to FDA. Small sample sizes simply do not contain enough information to make inferences about the shape of the distribution in the entire population (Ref. 5).

Therefore, based on the information in the previous paragraphs, we have decided not to conduct Grubbs outlier screening on the nutrient data.

B. Changes in Nutrition Labeling Values for Raw Fruits and Vegetables

The following is a summary of tentative changes from the nutrition labeling values in the proposed rule for some of the 20 most frequently consumed raw fruits and vegetables. FDA derived the updated values from the raw data provided by USDA and the Citrus Research Board during the comment period, as well as existing data. We also considered data for sodium, potassium, carotenoids, and vitamin C that USDA submitted after the comment period. Other changes were related to discontinuance of outlier screening. As explained in the proposed rule, when possible, FDA used compliance calculations based on 95 percent intervals to derive nutrition labeling values.

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|------------------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Apple (154 grams (g)) | | | | |
| Potassium | 170 milligrams (mg) | 5% | 160 mg | 5% |
| Total carbohydrate | 22 g | 7% | 21 g | 7% |
| Dietary fiber | 5 g | 20% | 3 g | 12% |
| Iron | | 2% | | 0% |
| Avocado (30 g) | | | | |
| Total fat | 6 g | 9% | 5 g | 8% |
| Saturated fat | 0.5 g | 3% | 1 g | 5% |
| Potassium | 160 mg | 5% | 140 mg | 4% |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|------------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Banana (126 g) | | | | |
| Sodium | 0 mg | 0% | 5 mg | 0% |
| Potassium | 400 mg | 11% | 450 mg | 13% |
| Total carbohydrate | 29 g | 10% | 30 g | 10% |
| Dietary fiber | 4 g | 16% | 2 g | 8% |
| Sugars | 21 g | | 19 g | |
| Cantaloupe (134 g) | | | | |
| Sodium | 25 mg | 1% | 20 mg | 1% |
| Potassium | 280 mg | 8% | 240 mg | 7% |
| Total carbohydrate | 13 g | 4% | 12 g | 4% |
| Sugars | 12 g | | 11 g | |
| Vitamin A | | 100% | | 120% |
| Calcium | | 2% | | 0% |
| Grapefruit (154 g) | | | | |
| Potassium | 230 mg | 7% | 160 mg | 5% |
| Total carbohydrate | 16 g | 5% | 15 g | 5% |
| Dietary fiber | 6 g | 24% | 2 g | 8% |
| Sugars | 10 g | | 11 g | |
| Vitamin A | | 15% | | 35% |
| Vitamin C | | 110% | | 100% |
| Calcium | | 2% | | 4% |
| Honeydew melon (134 g) | | | | |
| Sodium | 35 mg | 1% | 30 mg | 1% |
| Potassium | 310 mg | 9% | 210 mg | 6% |
| Total carbohydrate | 13 g | 4% | 12 g | 4% |
| Sugars | 12 g | | 11 g | |
| Kiwifruit (148 g) | | | | |
| Calories | 100 | | 90 | |
| Total fat | 1 g | 2% | 1.5 g | 2% |
| Potassium | 480 mg | 14% | 450 mg | 13% |
| Total carbohydrate | 24 g | 8% | 20 g | 7% |
| Sugars | 16 g | | 13 g | |
| Protein | 2 g | | 1 g | |
| Calcium | | 6% | | 4% |
| Iron | | 4% | | 2% |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|--------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Lemon (58 g) | | | | |
| Sodium | 5 mg | 0% | 0 mg | 0% |
| Potassium | 90 mg | 3% | 75 mg | 2% |
| Sugars | 1 g | | 2 g | |
| Nectarine (140 g) | | | | |
| Calories | 70 | | 60 | |
| Calories from fat | 0 | | 5 | |
| Total fat | 0 g | 0% | 0.5 g | 1% |
| Potassium | 290 mg | 8% | 250 mg | 7% |
| Total carbohydrate | 17 g | 6% | 15 g | 5% |
| Sugars | 13 g | | 11 g | |
| Orange (154 g) | | | | |
| Potassium | 260 mg | 7% | 250 mg | 7% |
| Total carbohydrate | 21 g | 7% | 19 g | 6% |
| Dietary fiber | 7 g | 28% | 3 g | 12% |
| Vitamin A | | 2% | | 0% |
| Iron | | 2% | | 0% |
| Peach (147 g) | | | | |
| Calories | 70 | | 60 | |
| Total fat | 0 g | 0% | 0.5 g | 1% |
| Potassium | 260 mg | 7% | 230 mg | 7% |
| Total carbohydrate | 18 g | 6% | 15 g | 5% |
| Sugars | 14 g | | 13 g | |
| Vitamin A | | 8% | | 6% |
| Pear (166 g) | | | | |
| Calories from fat | 10 | | 0 | |
| Total fat | 1 g | 2% | 0 g | 0% |
| Potassium | 210 mg | 6% | 180 mg | 5% |
| Sugars | 17 g | | 16 g | |
| Protein | 1 g | | 0 g | |
| Calcium | | 2% | | 0% |
| Pineapple (112 g) | | | | |
| Calories | 60 | | 50 | |
| Potassium | 115 mg | 3% | 120 mg | 3% |
| Total carbohydrate | 16 g | 5% | 13 g | 4% |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|------------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Sugars | 13 g | | 10 g | |
| Vitamin A | | 0% | | 2% |
| Vitamin C | | 25% | | 50% |
| Iron | | 2% | | 0% |
| Plums (151 g) | | | | |
| Calories | 80 | | 70 | |
| Potassium | 250 mg | 7% | 230 g | 7% |
| Total carbohydrate | 21 g | 7% | 19 g | 6% |
| Dietary fiber | 2 g | 8% | 1 g | 4% |
| Sugars | 13 g | | 16 g | |
| Iron | | 2% | | 0% |
| Strawberries (147 g) | | | | |
| Potassium | 270 mg | 8% | 170 mg | 5% |
| Total carbohydrate | 12 g | 4% | 11 g | 4% |
| Dietary fiber | 4 g | 16% | 2 g | 8% |
| Sugars | 8 g | | 6 g | |
| Calcium | | 2% | | 0% |
| Iron | | 4% | | 0% |
| Sweet cherries (140 g) | | | | |
| Calories | 90 | | 100 | |
| Potassium | 300 mg | 9% | 350 mg | 10% |
| Total carbohydrate | 23 g | 8% | 26 g | 9% |
| Dietary fiber | 3 g | 12% | 1 g | 4% |
| Sugars | 20 g | | 16 g | |
| Protein | 2 g | | 1 g | |
| Tangerine (109 g) | | | | |
| Calories from fat | 5 | | 0 | |
| Total fat | 0.5 g | 1% | 0 g | 0% |
| Sodium | 0 g | 0% | 5 mg | 0% |
| Potassium | 180 mg | 5% | 160 mg | 5% |
| Dietary fiber | 3 g | 12% | 2 g | 8% |
| Sugars | 8 g | | 9 g | |
| Vitamin A | | 0% | | 6% |
| Vitamin C | | 50% | | 45% |
| Watermelon (280 g) | | | | |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|---------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Calories | 100 | | 80 | |
| Sodium | 10 mg | 0% | 0 mg | 0% |
| Potassium | 230 mg | 7% | 270 mg | 8% |
| Total carbohydrate | 27 g | 9% | 21 g | 7% |
| Dietary fiber | 2 g | 8% | 1 g | 4% |
| Sugars | 25 g | | 20 g | |
| Vitamin A | | 20% | | 30% |
| Bell pepper (148 g) | | | | |
| Calories | 30 | | 25 | |
| Sodium | 0 mg | 0% | 40 mg | 2% |
| Potassium | 270 mg | 8% | 220 mg | 6% |
| Total carbohydrate | 7 g | 2% | 6 g | 2% |
| Vitamin A | | 8% | | 4% |
| Iron | | 2% | | 4% |
| Broccoli (148 g) | | | | |
| Sodium | 55 mg | 2% | 80 mg | 3% |
| Potassium | 540 mg | 15% | 460 mg | 13% |
| Total carbohydrate | 8 g | 3% | 10 g | 3% |
| Dietary fiber | 5 g | 20% | 3 g | 12% |
| Sugars | 3 g | | 2 g | |
| Protein | 5 g | | 2 g | |
| Vitamin A | | 15% | | 6% |
| Iron | | 6% | | 4% |
| Carrot (78 g) | | | | |
| Calories | 35 | | 30 | |
| Sodium | 40 mg | 2% | 60 mg | 3% |
| Potassium | 280 mg | 8% | 250 mg | 7% |
| Total carbohydrate | 8 g | 3% | 7 g | 2% |
| Vitamin A | | 270% | | 110% |
| Celery (110 g) | | | | |
| Calories | 20 | | 15 | |
| Sodium | 100 mg | 4% | 115 mg | 5% |
| Potassium | 350 mg | 10% | 260 mg | 7% |
| Total carbohydrate | 5 g | 2% | 4 g | 1% |
| Dietary fiber | 2 g | 8% | 1 g | 4% |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|------------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Sugars | 1 g | | 2 g | |
| Protein | 1 g | | 0 g | |
| Vitamin A | | 2% | | 10% |
| Cucumber (99 g) | | | | |
| Potassium | 170 mg | 5% | 140 mg | 4% |
| Protein | 1 g | | 0 g | |
| Iceberg lettuce (89 g) | | | | |
| Calories | 15 | | 10 | |
| Potassium | 120 mg | 3% | 125 mg | 4% |
| Total carbohydrate | 3 g | 1% | 2 g | 1% |
| Vitamin A | | 4% | | 6% |
| Leaf lettuce (85 g) | | | | |
| Sodium | 30 mg | 1% | 35 mg | 1% |
| Potassium | 230 mg | 7% | 170 mg | 5% |
| Total carbohydrate | 4 g | 1% | 2 g | 1% |
| Dietary fiber | 2 g | 8% | 1 g | 4% |
| Sugars | 2 g | | 1 g | |
| Vitamin A | | 40% | | 130% |
| Iron | | 0% | | 4% |
| Onion (148 g) | | | | |
| Calories | 60 | | 45 | |
| Potassium | 240 mg | 7% | 160 mg | 5% |
| Total carbohydrate | 14 g | 5% | 11 g | 4% |
| Protein | 2 g | | 1 g | |
| Calcium | | 4% | | 2% |
| Iron | | 2% | | 4% |
| Potato (148 g) | | | | |
| Calories | 40 | | 110 | |
| Sodium | 10 mg | 0% | 0 mg | 0% |
| Potassium | 650 mg | 19% | 620 mg | 18% |
| Total carbohydrate | 7 g | 2% | 26 g | 9% |
| Dietary fiber | 4 g | 16% | 2 g | 8% |
| Sugars | 2 g | | 1 g | |
| Vitamin C | | 40% | | 45% |
| Iron | | 8% | | 6% |

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—
Continued

| Food and Nutrient | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|----------------------|----------------------|------|--|------|
| | | % DV | | % DV |
| Radishes (85 g) | | | | |
| Calories | 15 | | 10 | |
| Sodium | 25 mg | 1% | 55 mg | 2% |
| Potassium | 230 mg | 7% | 160 mg | 5% |
| Dietary fiber | 0 g | 0% | 1 g | 4% |
| Protein | 1 g | | 0 g | |
| Iron | | 0% | | 2% |
| Sweet potato (130 g) | | | | |
| Calories | 140 | | 100 | |
| Sodium | 45 mg | 2% | 70 mg | 3% |
| Potassium | 340 mg | 10% | 440 mg | 13% |
| Total carbohydrate | 32 g | 11% | 23 g | 8% |
| Vitamin A | | 440% | | 120% |
| Calcium | | 2% | | 4% |
| Tomato (148 g) | | | | |
| Calories | 35 | | 25 | |
| Calories from fat | 5 | | 0 | |
| Total fat | 0.5 g | 1% | 0 g | 0% |
| Sodium | 5 mg | 0% | 35 mg | 1% |
| Potassium | 360 mg | 10% | 340 mg | 10% |
| Total carbohydrate | 7 g | 2% | 5 g | 2% |
| Sugars | 4 g | | 3 g | |
| Iron | | 2% | | 4% |

C. Changes in Nutrition Labeling Values for Raw Fish

The following is a summary of tentative changes from the nutrition labeling values in the proposed rule for some of the 20 most frequently consumed raw fish. Changes were

related to discontinuance of outlier screening and to inclusion of raw Chinook salmon with Atlantic, Coho, and Sockeye salmon. FDA derived values for fish using data from the USDA National Nutrient Databank (Ref. 6). When possible, FDA used

compliance calculations based on 95 percent intervals to derive nutrition labeling values. When raw data were unavailable, FDA used data from the newest version of USDA Nutrient Database for Standard Reference, Release 17 (Ref. 2).

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING FOR COOKED FISH

| Food and Nutrient (per 84 grams (g)/3 ounces) | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|---|----------------------|------|--|------|
| | | % DV | | % DV |
| Cod | | | | |
| Sodium | 55 milligrams (mg) | 2% | 65 mg | 3% |
| Flounder/sole | | | | |

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING FOR COOKED FISH—Continued

| Food and Nutrient (per 84 grams (g)/3 ounces) | 2002 Proposed Values | | Reopening Comment Period Proposed Values | |
|---|----------------------|------|--|------|
| | | % DV | | % DV |
| Potassium | 400 mg | 11% | 390 mg | 11% |
| Calcium | | 0% | | 2% |
| Haddock | | | | |
| Sodium | 75 mg | 3% | 85 mg | 4% |
| Halibut | | | | |
| Cholesterol | 35 mg | 12% | 40 mg | 13% |
| Calcium | | 4% | | 2% |
| Ocean perch | | | | |
| Cholesterol | 50 mg | 17% | 45 mg | 15% |
| Iron | | 6% | | 4% |
| Pollock | | | | |
| Calories | 100 | | 90 | |
| Rockfish | | | | |
| Calories | 100 | | 110 | |
| Total fat | 1.5 g | 2% | 2 g | 3% |
| Salmon, Atlantic/Coho/Sockeye—Chinook added in update | | | | |
| Calories | 190 | | 200 | |
| Cholesterol | 65 mg | 22% | 70 mg | 23% |
| Sodium | 65 mg | 3% | 55 mg | 2% |
| Potassium | 320 mg | 9% | 430 mg | 12% |
| Vitamin A | | 2% | | 4% |
| Vitamin C | | 2% | | 4% |
| Salmon, chum/pink | | | | |
| Calories from fat | 35 | | 40 | |
| Scallops | | | | |
| Cholesterol | 60 mg | 20% | 65 mg | 22% |
| Vitamin C | | 6% | | 0% |
| Iron | | 2% | | 14% |
| Shrimp | | | | |
| Sodium | 250 mg | 10% | 240 mg | 10% |
| Iron | | 6% | | 10% |

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic

comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Brandt, M.M., memo to the file: Nutrient data from U.S. Department of Agriculture received after close of comment period, Center for Food Safety and Applied Nutrition, FDA, February 2005.
2. U.S. Department of Agriculture, Agricultural Research Service, USDA Nutrient Database for Standard Reference, Release 17, 2004. Available on the Internet at USDA's Nutrient Data Laboratory home page, <http://www.nal.usda.gov/fnic/foodcomp/>.
3. LeGault, L.A. and M.M. Brandt, "Documentation for the Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish," Center for Food Safety and Applied Nutrition, FDA, November 2004.
4. NIST/SEMATECH *e-Handbook of Statistical Methods*, <http://www.itl.nist.gov/div898/handbook/index.htm> and <http://www.itl.nist.gov/div898/handbook/eda/section3/eda35h.htm>. Accessed January 3, 2005.
5. The Prism Guide to Interpreting Statistical Results, excerpted from *Analyzing Data With GraphPad Prism*, http://www.graphpad.com/articles/interpret/Analyzing_two_groups/choos_anal_comp_two.htm. Accessed March 21, 2005.
6. U.S. Department of Agriculture, National Nutrient Data Bank, maintained at the Nutrient Data Laboratory, Agricultural Research Service, Beltsville Human Nutrition Research Center, Beltsville, MD.

BILLING CODE 4160-01-S

Appendix C to Part 101.—Nutrition Facts for Raw Fruits and Vegetables

| Nutrition facts ¹ for raw fruits and vegetables edible portion | Cal- ories | Cal- ories from fat | Total Fat (g) | Saturated Fat (g) | Trans Fat (g) | Cholesterol (mg) | Sodium (mg) | Potassium (mg) | Total Carbo- hydrate (g) | Dietary Fiber (g) | Sug- ars (g) | Pro- tein (g) | Vita- min A (%) | Vita- min C (%) | Cal- cium (%) | Iron (%) | | | | | |
|--|---------------|------------------------------|------------------|-------------------------|---------------------|---------------------|----------------|-------------------|-----------------------------------|-------------------------|--------------------|---------------------|-----------------------|-----------------------|---------------------|-------------|---|-----|-----|---|---|
| Apple, 1 medium (154 g/5.5 oz) | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 160 | 5 | 21 | 7 | 3 | 12 | 16 | 0 | 2 | 8 | 0 | 0 | | |
| Avocado, California, 1/5 medium (30g/ 1.1 oz) | 50 | 45 | 5 | 8 | 1 | 5 | 0 | 0 | 0 | 140 | 4 | 2 | 1 | 4 | 0 | 1 | 0 | 4 | 0 | 0 | |
| Banana, 1 medium (126 g/4.5 oz) | 110 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 450 | 13 | 30 | 10 | 2 | 8 | 19 | 1 | 0 | 15 | 0 | 2 |
| Cantaloupe, 1/4 medium (134g/4.8 oz) | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 1 | 240 | 7 | 12 | 4 | 1 | 4 | 11 | 1 | 120 | 80 | 0 | 2 |
| Grapefruit, 1/2 medium (154g/5.5 oz) | 60 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 160 | 5 | 15 | 5 | 2 | 8 | 11 | 1 | 35 | 100 | 4 | 0 |
| Grapes, 3/4 cup (126 g/4.5 oz) | 90 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 1 | 240 | 7 | 23 | 8 | 1 | 4 | 20 | 0 | 0 | 2 | 2 | 0 |
| Honeydew Melon, 1/10 medium melon (134 g/4.8 oz) | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 30 | 1 | 210 | 6 | 12 | 4 | 1 | 4 | 11 | 1 | 2 | 45 | 0 | 2 |
| Kiwi fruit, 2 medium (148 g/5.3oz) | 90 | 10 | 1.5 | 2 | 0 | 0 | 0 | 0 | 0 | 450 | 13 | 20 | 7 | 4 | 16 | 13 | 1 | 2 | 240 | 4 | 2 |
| Lemon, 1 medium (58 g/2.1 oz) | 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 75 | 2 | 5 | 2 | 1 | 4 | 2 | 0 | 0 | 40 | 2 | 0 |
| Lime, 1 medium (67 g/2.4 oz) | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 75 | 2 | 7 | 2 | 2 | 8 | 0 | 0 | 0 | 35 | 0 | 0 |
| Nectarine, 1 medium (140 g/5.0 oz) | 60 | 5 | 0.5 | 1 | 0 | 0 | 0 | 0 | 0 | 250 | 7 | 15 | 5 | 1 | 4 | 11 | 1 | 8 | 15 | 0 | 2 |
| Orange, 1 medium (154 g/5.5 oz) | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 250 | 7 | 19 | 6 | 3 | 12 | 14 | 1 | 0 | 130 | 6 | 0 |
| Peach, 1 medium (147 g/5.3 oz) | 60 | 0 | 0.5 | 1 | 0 | 0 | 0 | 0 | 0 | 230 | 7 | 15 | 5 | 2 | 8 | 13 | 1 | 6 | 15 | 0 | 2 |
| Pear, 1 medium (166 g/5.9 oz) | 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 180 | 5 | 25 | 8 | 4 | 16 | 16 | 0 | 0 | 10 | 0 | 0 |
| Pineapple, 2 slices, 3" diameter, 3/4" thick (112 g/4 oz) | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 120 | 3 | 13 | 4 | 1 | 4 | 10 | 1 | 2 | 50 | 2 | 0 |
| Plums, 2 medium (151 g/5.4 oz) | 70 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 230 | 7 | 19 | 6 | 1 | 4 | 16 | 1 | 8 | 10 | 0 | 0 |
| Strawberries, 8 medium (147g/5.3 oz) | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 170 | 5 | 11 | 4 | 2 | 8 | 6 | 1 | 0 | 160 | 0 | 0 |
| Sweet cherries, 21 cherries; 1 cup (140 g/5.0 oz) | 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 350 | 10 | 26 | 9 | 1 | 4 | 16 | 1 | 2 | 15 | 2 | 2 |
| Tangerine, 1 medium (109 g/3.9 oz) | 50 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 160 | 5 | 13 | 4 | 2 | 8 | 9 | 1 | 6 | 45 | 4 | 0 |
| Watermelon, 1/18 medium melon; 2 cups diced pieces (280 g/10.0 oz) | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 270 | 8 | 21 | 7 | 1 | 4 | 20 | 1 | 30 | 25 | 2 | 4 |

Appendix C to Part 101.—Nutrition Facts for Raw Fruits and Vegetables-Continued

| Nutrition facts ¹ for raw fruits and vegetables edible portion | Cal- ories | Cal- ories from fat | Total Fat (g) (%) | Saturated Fat (g) (%) | Trans Fat (g) | Cholesterol (mg) (%) | Sodium (mg) (%) | Potassium (mg) (%) | Total Carbo- hydrate (g) (%) | Dietary Fiber (g) (%) | Sug- ars (g) | Pro- tein (g) | Vita- min A (%) | Vita- min C (%) | Cal- cium (%) | Iron (%) |
|---|---------------|------------------------------|----------------------|-----------------------------|---------------------|-------------------------|--------------------|-----------------------|---------------------------------------|-----------------------------|--------------------|---------------------|-----------------------|-----------------------|---------------------|-------------|
| Asparagus, 5 spears (93 g/3.3 oz) | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 230 | 7 | 4 | 1 | 2 | 8 | 2 | 2 | 2 |
| Bell pepper, 1 medium (148 g/5.3 oz) | 25 | 0 | 0 | 0 | 0 | 0 | 40 | 220 | 6 | 2 | 2 | 8 | 4 | 1 | 4 | 4 |
| Broccoli, 1 medium stalk (148 g/5.3 oz) | 45 | 0 | 0.5 | 1 | 0 | 0 | 80 | 3 | 460 | 13 | 10 | 3 | 12 | 2 | 2 | 6 |
| Carrot, 1 carrot, 7" long, 1 1/4" diameter (78 g/2.8 oz) | 30 | 0 | 0 | 0 | 0 | 0 | 60 | 3 | 250 | 7 | 7 | 2 | 8 | 5 | 1 | 110 |
| Cauliflower, 1/6 medium head (99 g/3.5 oz) | 25 | 0 | 0 | 0 | 0 | 0 | 30 | 1 | 270 | 8 | 5 | 2 | 8 | 2 | 2 | 2 |
| Celery, 2 medium stalks (110 g/3.9 oz) | 15 | 0 | 0 | 0 | 0 | 0 | 115 | 5 | 260 | 7 | 4 | 1 | 4 | 2 | 0 | 15 |
| Cucumber, 1/3 medium (99 g/3.5 oz) | 15 | 0 | 0 | 0 | 0 | 0 | 0 | 140 | 4 | 3 | 1 | 1 | 4 | 2 | 0 | 2 |
| Green (snap) beans, 3/4 cup cut (83 g/3.0 oz) | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 200 | 6 | 5 | 2 | 3 | 12 | 2 | 1 | 4 |
| Green cabbage, 1/12 medium head (84 g/3.0 oz) | 25 | 0 | 0 | 0 | 0 | 0 | 20 | 1 | 190 | 5 | 5 | 2 | 8 | 3 | 1 | 70 |
| Green onion, 1/4 cup chopped (25 g/0.9 oz) | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 70 | 2 | 2 | 1 | 1 | 4 | 1 | 0 |
| Iceberg lettuce, 1/6 medium head (89 g/3.2 oz) | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 125 | 4 | 2 | 1 | 1 | 4 | 2 | 6 |
| Leaf lettuce, 1 1/2 cups shredded (85 g/3.0 oz) | 15 | 0 | 0 | 0 | 0 | 0 | 35 | 1 | 170 | 5 | 2 | 1 | 1 | 4 | 1 | 130 |
| Mushrooms, 5 medium (84 g/3.0 oz) | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 300 | 9 | 3 | 1 | 1 | 4 | 0 | 3 | 0 |
| Onion, 1 medium (148 g/5.3 oz) | 45 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 160 | 5 | 11 | 4 | 3 | 12 | 9 | 1 |
| Potato, 1 medium (148 g/5.3 oz) | 110 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 620 | 18 | 26 | 9 | 2 | 8 | 1 | 3 |
| Radishes, 7 radishes (85 g/3.0 oz) | 10 | 0 | 0 | 0 | 0 | 0 | 55 | 2 | 160 | 5 | 3 | 1 | 1 | 4 | 2 | 0 |
| Summer squash, 1/2 medium (98 g/3.5 oz) | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 260 | 7 | 4 | 1 | 2 | 8 | 2 | 1 |
| Sweet corn, kernels from 1 medium ear (90 g/3.2 oz) | 90 | 20 | 2.5 | 4 | 0 | 0 | 0 | 0 | 250 | 7 | 18 | 6 | 2 | 8 | 5 | 4 |
| Sweet Potato, 1 medium, 5" long, 2" diameter (130 g/4.6 oz) | 100 | 0 | 0 | 0 | 0 | 0 | 70 | 3 | 440 | 13 | 23 | 8 | 4 | 16 | 7 | 2 |
| Tomato, 1 medium (148 g/5.3 oz) | 25 | 0 | 0 | 0 | 0 | 0 | 35 | 1 | 340 | 10 | 5 | 2 | 1 | 4 | 3 | 1 |

¹ Raw, edible weight portion. Percent Daily Values (%DV) are based on a 2,000 calorie diet.

Appendix D to Part 101.—Nutrition Facts for Cooked Fish

| Nutrition facts ¹ fish (84 g/3 oz) | | Cal- ories | Cal- ories from fat | Total Fat (g) %DV | Saturated Fat (g) %DV | Trans Fat (g) | Cholesterol (mg) % | Sodium (mg) % | Potassium (mg) % | Total Carbo- hydrate (g) % | Dietary Fiber (g) % | Sug- ars (g) | Pro- tein (g) | Vita- min A % | Vita- min C % | Cal- cium % | Iron % |
|---|---------------------------------------|---------------|------------------------------|----------------------|-----------------------------|---------------------|-----------------------|------------------|---------------------|-------------------------------------|---------------------------|--------------------|---------------------|---------------------|---------------------|-------------------|-----------|
| | Blue crab | 100 | 10 | 1 2 | 0 0 | 0 | 95 32 | 330 14 | 300 9 | 0 0 | 0 0 | 0 0 | 20 0 | 0 4 | 10 4 | | |
| | Catfish | 130 | 60 | 6 9 | 2 10 | 0 | 50 17 | 40 2 | 230 7 | 0 0 | 0 0 | 0 0 | 17 0 | 0 0 | 0 0 | | |
| | Clams, about 12 small | 110 | 15 | 1.5 2 | 0 0 | 0 | 80 27 | 95 4 | 470 13 | 6 2 | 0 0 | 0 0 | 17 10 | 0 8 | 30 30 | | |
| | Cod | 90 | 5 | 1 2 | 0 0 | 0 | 50 17 | 65 3 | 460 13 | 0 0 | 0 0 | 0 0 | 20 0 | 0 2 | 2 2 | | |
| | Flounder/sole | 100 | 15 | 1.5 2 | 0 0 | 0 | 55 18 | 100 4 | 390 11 | 0 0 | 0 0 | 0 0 | 19 0 | 0 0 | 2 0 | | |
| | Haddock | 100 | 10 | 1 2 | 0 0 | 0 | 70 23 | 85 4 | 340 10 | 0 0 | 0 0 | 0 0 | 21 2 | 0 2 | 6 6 | | |
| | Halibut | 120 | 15 | 2 3 | 0 0 | 0 | 40 13 | 60 3 | 500 14 | 0 0 | 0 0 | 0 0 | 23 4 | 0 2 | 6 6 | | |
| | Lobster | 80 | 0 | 0.5 1 | 0 0 | 0 | 60 20 | 320 13 | 300 9 | 1 0 | 0 0 | 0 0 | 17 2 | 0 6 | 2 2 | | |
| | Ocean perch | 110 | 20 | 2 3 | 0.5 3 | 0 | 45 15 | 95 4 | 290 8 | 0 0 | 0 0 | 0 0 | 21 0 | 0 2 | 10 4 | | |
| | Orange roughy | 80 | 5 | 1 2 | 0 0 | 0 | 20 7 | 70 3 | 340 10 | 0 0 | 0 0 | 0 0 | 16 2 | 0 0 | 4 2 | | |
| | Oysters, about 12 medium | 100 | 35 | 4 6 | 1 5 | 0 | 80 27 | 300 13 | 220 6 | 6 2 | 0 0 | 0 0 | 10 0 | 0 6 | 6 45 | | |
| | Pollock | 90 | 10 | 1 2 | 0 0 | 0 | 80 27 | 110 5 | 370 11 | 0 0 | 0 0 | 0 0 | 20 2 | 0 0 | 2 2 | | |
| | Rainbow trout | 140 | 50 | 6 9 | 2 10 | 0 | 55 18 | 35 1 | 370 11 | 0 0 | 0 0 | 0 0 | 20 4 | 0 4 | 8 2 | | |
| | Rockfish | 110 | 15 | 2 3 | 0 0 | 0 | 40 13 | 70 3 | 440 13 | 0 0 | 0 0 | 0 0 | 21 4 | 0 0 | 2 2 | | |
| | Salmon, Atlantic/Coho/Sockeye/Chinook | 200 | 90 | 10 15 | 2 10 | 0 | 70 23 | 55 2 | 430 12 | 0 0 | 0 0 | 0 0 | 24 4 | 0 4 | 2 2 | | |
| | Salmon, Chum/Pink | 130 | 40 | 4 6 | 1 5 | 0 | 70 23 | 65 3 | 420 12 | 0 0 | 0 0 | 0 0 | 22 2 | 0 2 | 4 4 | | |
| | Scallops, about 6 large or 14 small | 140 | 10 | 1 2 | 0 0 | 0 | 65 22 | 310 13 | 430 12 | 5 2 | 0 0 | 0 0 | 27 2 | 0 0 | 4 14 | | |
| | Shrimp | 100 | 10 | 1.5 2 | 0 0 | 0 | 170 57 | 240 10 | 220 6 | 0 0 | 0 0 | 0 0 | 21 4 | 0 4 | 6 10 | | |
| | Swordfish | 120 | 50 | 6 9 | 1.5 8 | 0 | 40 13 | 100 4 | 310 9 | 0 0 | 0 0 | 0 0 | 16 2 | 0 2 | 0 6 | | |
| | Tilapia | 110 | 20 | 2.5 4 | 1 5 | 0 | 75 25 | 30 1 | 360 10 | 0 0 | 0 0 | 0 0 | 22 0 | 0 2 | 0 2 | | |
| | Tuna | 130 | 15 | 1.5 2 | 0 0 | 0 | 50 17 | 40 2 | 480 14 | 0 0 | 0 0 | 0 0 | 26 2 | 0 2 | 4 4 | | |

¹ Cooked, edible weight portion. Percent Daily Values (%) are based on a 2,000 calorie diet.

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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